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Pharmacy Curriculum & Beyond
Pharmaceutical Spray Freeze Drying Process as Quantum Leap

Swiss Journal of the Pharmaceutical Industry

Schweizerische Zeitschrift für die pharmazeutische Industrie

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Pharmaceutical Spray Freeze Drying Process as Quantum Leap

Special issue
SWISS PHARMA
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Editorial – Pharmaceutical Developments

The pharmaceutical industry plays a key role in Switzerland and is one of its largest employers. Research and innovation assure the future welfare of the industry and its continuing benefit to society. This journal will give an insight into expected future developments from new, emerging, and revolutionary technologies.

Pharmacy plays an increasingly important role in health-care: the last year has shown us how vaccines and medication will become more complex, with increasingly ingenious routes to their development and fabrication. But, pharmacy as a profession has many aspects, all of which are changing rapidly. The research pharmacist is confronted with the need to deploy skills from many different disciplines in the formulation of novel medicines. The industrial pharmacist will need skills in precision engineering alongside medicine processes and technologies. The role and the responsibility of the community-based pharmacist will acquire new dimensions of diagnosis and the supply of generic therapies.

This edition of the fully independent journal SWISS PHARMA 43 (2021) No. 4 will give an appreciation of the changing pharmacy world, emphasizing the roles of emerging technologies such as artificial intelligence, nano-pharmacy, and robotics. The changes in the pharmaceutical industry go beyond the research implications: they include the impact of Industry and the Internet of Things, and the new requirements in the education of the younger generation. The influence of society, economics, and politics will become ever more visible and ethical aspects will gain importance and require more attention from the points of view of bioethics, ethics of science, ethics of technology, and business ethics.

This edition will focus on a few important and selected topics:

The first chapter deals with the changes, needs, benefits, and constraints that the new, emerging technology of nano-science, technology and engineering will bring in the pharma world. Pharmaceutical nanotechnology will produce new and innovative medicines for improved and more efficient medical treatments, but delivering this innovative nano-pharma will impact on university education, pharma research, the process industry, economy, and society.

A second chapter highlights the impact of new trends in the processing and production of complex, targeted, and precision medicines and vaccines, as demonstrated in «Spray Freeze-Drying»: a key innovation in producing lyophilized, instant soluble pellets for the formulation of precision medicines and with the potential to manufacture nanocomposite vaccine formulations, which can be stored at room temperature.

A third chapter deals with Business Ethics in the Pharmaceutical Industry and Beyond: the understanding of the ethical dilemmas nanotechnology presents in the industry. Scientific integrity and integrity of data are necessary that these technologies are approved by health authorities. In addition, they need to be respected in all areas including business and all other human interactions. As a result, a global harmonization of the legal framework and

the ethical conduct need to be adopted. This measure is a prerequisite for a healthy society leading to a peaceful and sustainable world. For this purpose, it is important that all agree to replace any kind of the «Law of the Jungle» by a scientific method to find a «win-win» solution for all parties involved, leading to the survival of mankind.

The 4th chapter examines the requirements of the Swiss pharmacy curriculum [Ausbildung zum Apotheker (pharmasuisse.org); Formation de pharmacien (pharmasuisse.org)] at the Federal Institute of Technology in Zurich, at the Universities of Basel, Bern, and Geneva with the goal to satisfy the needs of Swiss society and industry. The degrees offer a large spectrum of job opportunities in the various pharmaceutical sectors of society: retail (community), hospital pharmacies, cantonal regulatory authorities and the federal Swiss regulatory Office (https://www.swissmedic.ch/swissmedic/en/home.html), international organizations such as WHO in Geneva and in various areas of the large pharmaceutical industry in Switzerland such as in Analytical Pharmacy, Biopharmacy, Clinical Pharmacy, Drug Discovery, Formulation Research & Development, Production, Quality Assurance, Registration, etc. International companies such as Novartis and Roche also offer positions abroad.

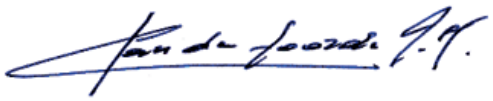
The 5th chapter is devoted to Life Science Studies at Universities of Applied Sciences offering specialization from environmental technology, to bioanalysis, biomedical engineering, chemistry and pharma technology being in the focus of this issue, information technology, and medical opportunities.

The 6th chapter is devoted to the topic of «Negotiation Engineering and Conflict Management» that is of primary importance in the field of international diplomacy. Artificial Intelligence, computational science, all emerging new technologies such as CIRSP, etc., require a transdisciplinary approach between the natural sciences – mathematics, physics, chemistry, biology, engineering – and the humanities – philosophy, law, sociology, and ethics – to reach optimal solutions for complex problems that span technology, science, ethics, politics, and society. In this context, Quantitative Negotiation Engineering is an innovative approach which could be most useful and valuable in contributing to solving a wide variety of problems in different fields and contexts in business and company negotiations. However, a sustainable «win-win» solution for all partners involved can be achieved *on the basis of scientific integrity and on the integrity of data. Indeed, scientific integrity and integrity of data are the common denominator of all contributions in this issue of SWISS PHARMA 43 (2021) No. 4.*

The final, 7th, chapter is devoted to the necessary restructuring of University studies to accommodate solutions for future problems in the modern society. Universities are often still strongly discipline-oriented although the society is mostly confronted with problems of a «multidisciplinary» character such as climate change, virus technology, treatments in medicine, and industrial advances. Solutions and inventions often originate in the interfaces between different disciplines. The modern approach to University education and research recognizes the need to cut across traditional boundaries. Universities are well placed to take on the challenges and create new Faculties and Departments that embody combinations of teaching and research that could never have been envisaged before. The EPFL (Ecole Polytechnique Fédérale de Lausanne) is already introducing the principle of «Trans disciplinarity» *(https://www.epfl.ch/research/services/fund-research/funding-opportunities/research-funding/interdisciplinary-seed-fund/)* with the recruitment of a Faculty Professor in interdisciplinary cancer research *(https://www.epfl.ch/about/working/faculty-position-in-interdisciplinary-cancer-research/).* A phenomenon that will become very popular in European universities in the future.

SWISS PHARMA is a specialist journal designed for experts working in the pharmaceutical sector. However, the present issue is also intended for a broader readership, including the wider healthcare profession, University students in sciences and engineering, University academics in all disciplines, and education and science policymakers.

Geneva, Switzerland, 21 March 2021



Marcel Van de Voorde

The Future of Pharmaceutical Nanotechnology

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COVID-19, climate change, population movements in the world, are all causing drastic changes in global politics and society. Complemented with the revolutionary developments in technologies such as the internet, artificial intelligence, and nanotechnology, the future can no longer be extrapolated on the basis of past experiences but will be completely different. In this transition, what will be the outlook and role for nano-pharma?

1. The Emerging Innovative Pharmaceutical Nanotechnology

Given the importance of the pharmaceutical industry in Switzerland and its role and impact worldwide, the opportunities and changes arising from the nanotechnology revolution are of immediate relevance and concern.

1.1. Introduction in Nanotechnology

Nanotechnology is defined as an exciting technology at a scale of one billionth of a meter: 1/80.000 the width of a human hair. Many molecules, including some proteins, range between one and a few nanometers. Powerful microscopes allow observations at the nanometer scale. At the nanometer scale, the physical, chemical, biological properties of materials differ in fundamental and valuable ways from the properties of the base material: for example, yellow gold is colored dark red at the nanoscale, and nano-silver kills bacteria.

The goal of nanotechnology research is to be able to artificially design and construct materials and devices that exploit nanoscale mechanisms in the same way as natural processes have evolved to do. The dynamic, multidisciplinary field of nanotechnology involves scientists and engineers from different disciplines: physics, chemistry, engineering and biology.

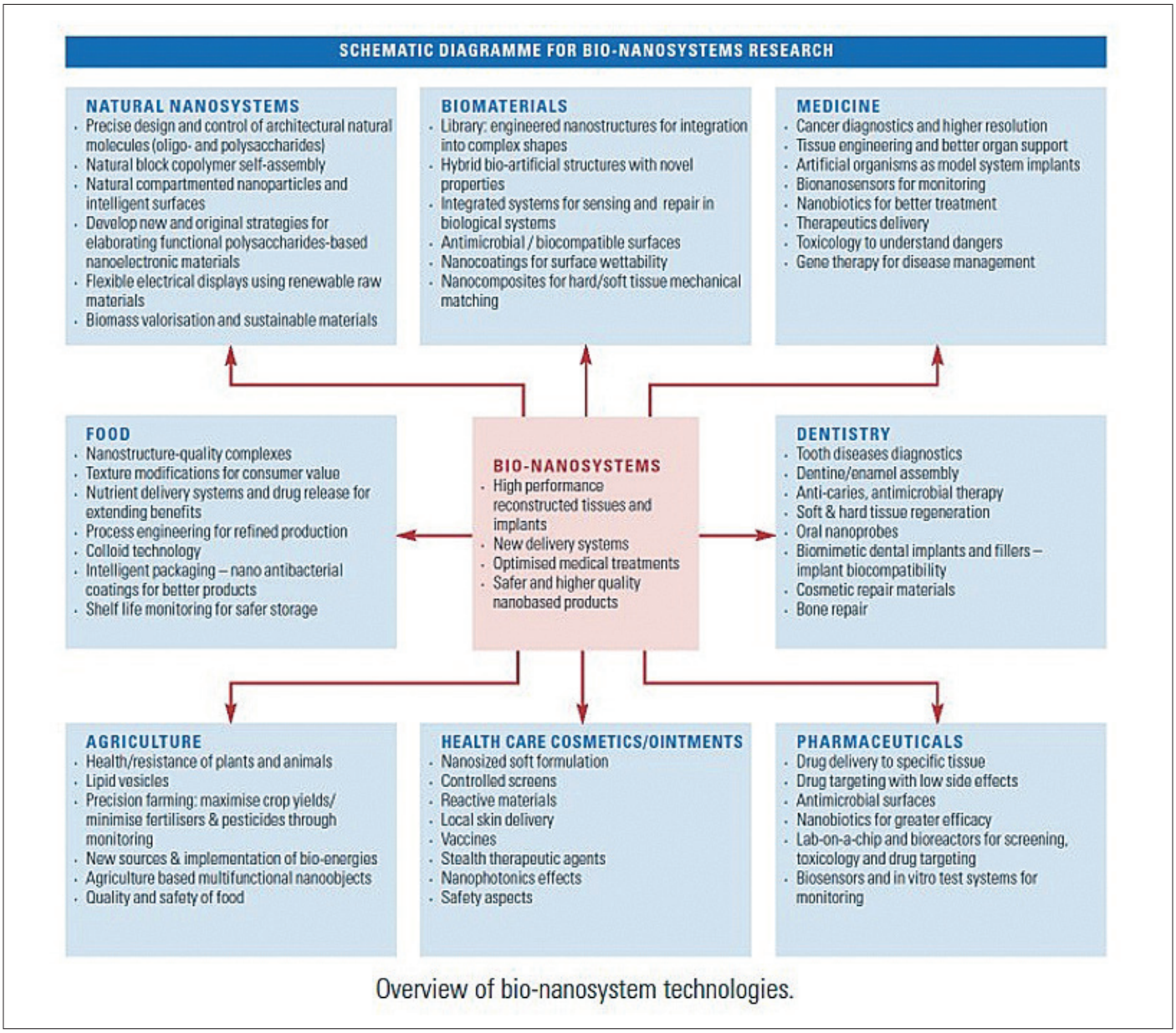
The applications are continually extending to various areas, and their implementations are impressive over the last 20 years, heralding the industrial revolution of the 21st century and promising to change every aspect of human life. Examples are: clean drinking water due to nano filters that can entrap organisms and toxins; clean environments by removal of pollutants through remediation; new smart self-cleaning and dirt-repellent textiles; anti-ageing cosmetics; nano-catalysts in the chemical industry; a new world of nano-informatics; and improved healthcare systems by fabrication of devices and drug delivery systems for diagnosis, monitoring and treatment of diseases through smart delivery of chemotherapy drugs to specific cells, such as cancer cells.

The research and development of nanotechnology in the field of biotechnology are summarized in the figure «Overview of bio-nanosystems technologies».

1.2. Pharmaceutical Nanotechnology [3), 4), 5)]

Some special attention is now given to the inter-relation between «nanotechnology» and «biotechnology» since recently many advances in nanotechnology are increasingly being utilized in combination with pharmacy. The unique properties of materials at the nanoscale, the capacity to synthesise, to visualise and the ability to manipulate and tailor their physiochemistry at the nanometre scale where biomolecular interactions happen, opens up a myriad of opportunities in the pharma arena: it gives the unprecedented possibility to directly target at the scale of biomolecular interactions. Hence, nano-pharmaceuticals offer a huge platform to directly combat disease in a more targeted way than is possible with conventional therapies. Nano-pharmaceutics can improve solubility and dissolution, modulate interactions with biological surfaces, and also control drug release. The implementation of nanotechnology thus allows to increase therapeutic efficiency and decrease side effects. For example: drugs with high toxic potentials like cancer chemotherapeutic drugs can be given with better safety with the utility of nanotechnology.

Pharmaceutical Nanotechnology aims at applying nanotechnology to drug therapy for diseases and medical diagnostics. More precisely, it involves the preparation and delivery of therapeutic substances in the molecular and nanometer size range to the expected site of action in the human body, reaching maximum efficiency while alleviating undesirable side effects in healthy organs and tissues. Pharmaceutical nanotechnology requires very specific knowledge of many topics such as drug formulation, drug delivery, route of administration, specific targeting, imaging, and diagnoses. Research in this field requires a multidisciplinary approach, involving pharmacists, materials and chemical engineers, cellular biologists, and biophysicists as well as ICT specialists and medical specialists.



Overview of bio-nanosystems technologies [1), 2)]

Our society is growing older. The desire to stay healthy and mobile until later in life, together with amplified occurrence of diseases, such as cancer, diabetes, atherosclerosis, cardiovascular diseases, or Alzheimer's disease, is an increasing challenge for medicine today. Therefore, nano-pharmacy opens new horizons for diagnosis, imaging, and therapy. Although several applications are developed, or even on market, nano-pharmacy is still a young and emerging technology.

1.3. Nano-Safety

Alongside the benefits of nanotechnologies, attention must be given to possible risks to human health and the environment, along with social and ethical issues. When a technology relies on nanoparticles, we have to understand the risks and consequences in the body and of release into the environment, so that the hazards are fully understood and can be controlled.

Nano-particles can enter the body through inhalation, ingestion, and by direct contact with the skin, and may lead to toxicity or disease. The figure «Diseases associated to nanoparticles exposures» shows the diseases probably associated to the effect of nanoparticles.

At present, there is limited understanding of the human health and safety risks associated with nanotechnology. For all these reasons, it is advocated that nanotechnology be closely regulated by governments during the initial stages of its introduction into the marketplace.

1.4. Social and Ethical implications of nanotechnology [6)]

Nanotechnology has the potential to change society, positively or adversely. Despite many benefits there are also potential hazards and risks issues involved in its use as toxic nanoparticles which could easily cross the blood-brain barrier.

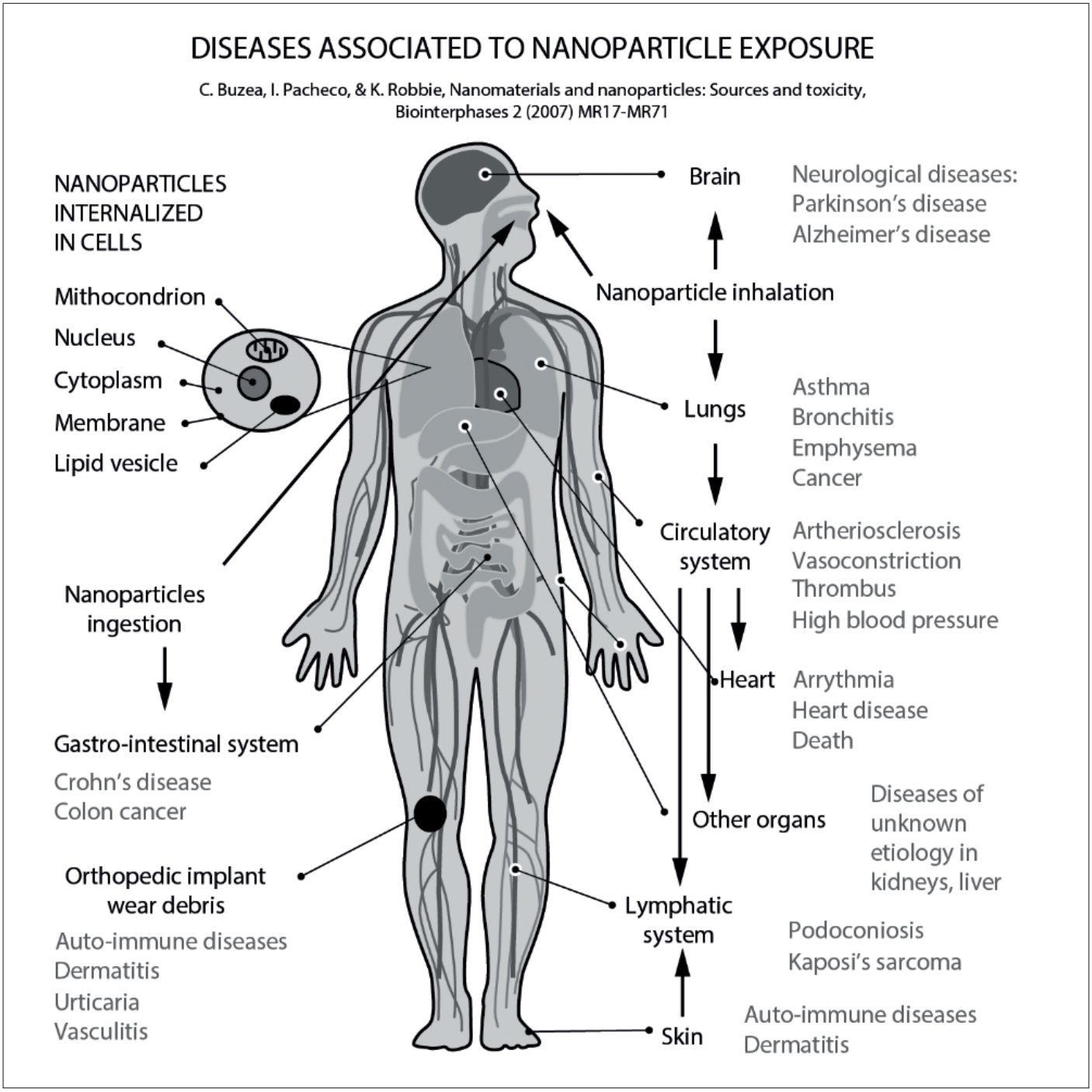
The social implementations of nanotechnology encompass so many fundamental areas such as environmental pollution, hazards, moral risks, economic abuse, push in commercialization, doubts in government regulation and controls, security and the global justice issues between developed and developing countries. As Nanotech-

nology will affect everyone; all citizens should have a voice in its development and commercialization phases.

2. Nanotechnologies for the discovery of new medicines [7), 4), 8)]

In the past 30 years, the explosive growth of nanotechnology innovations in pharmacology are in the process of revolutionising the delivery of biologically active compounds. The main input of today nanotechnology in pharmacology is that it allows real progresses to achieve temporal and special site-specific delivery. Thus, the concept of the «magic bullet» proposed a century ago by the immunologist Nobel laureate Paul Ehrlich is today becoming reality with the appearance of several approved forms of drug targeting systems for the treatment of certain cancers and serious infectious diseases. This breakthrough was made possible by the development of various types of nano systems resulting from cutting edge researches based on multidisciplinary approaches. From the first liposomes proposed in 1874 by Greogoriadis, today there is an explosion in the number of nanodevices suitable for drug delivery which are either made of lipids or composed of polymers.

These systems are exploited for therapeutic purposes to carry the drug in the body in a controlled manner from the site of administration to the therapeutic target. This implies the passage of the drug molecules and drug delivery system across numerous physiological barriers which represent the most challenging goal in drug targeting. Nano systems were also found useful to improve the performance of imaging techniques applied for the in vivo diagnosis of tumors. In this case, colloidal metals are often incorporated in the nanodevice.



Diseases associated to nanoparticles exposures [2)]

In general, nanocarriers may i) protect a drug from degradation, ii) enhance drug absorption by facilitating diffusion through the epithelium, iii) modify pharmacokinetic and drug tissue distribution profile and/or iv) improve intracellular penetration and distribution.

Applications of nanotechnology in pharmacology are now undeniably linked to the potential of drug targeting. Although we are still far from the ideal «magic bullet», nanotechnology has already completed several key achievements to reach this goal. The most straightforward application is in cancer therapy with several marketed compounds (Caelyx, Doxil, Abraxane and Livatag).

Another very demanding field includes infectious diseases [Human Immunodefficiency Virus (HIV), Leishmaniosis, malaria, nocosonial infections, all kind of infections in immunocompromised patients] with already approved drugs for clinical uses (Ambisome).

Treatment of these severe diseases generally involved highly toxic compounds for healthy tissues and their use in therapy is considerably limited by occurrence of dramatic side effects using the traditional pharmaceutical formulations. Nanotechnology also appears as a promising alternative to overcome the problems of the administration of peptides and proteins, and of the new drug molecules coming out of the discovery pipeline. Many of them are, indeed poorly soluble in both aqueous and organic media, which results in poor bio-availability with low and/or erratic absorption when using traditional formulations. Nucleic acids are other potential candidates for which nanotechnology represents a unique opportunity to be used in therapy. They are rapidly degraded in biological media and they hardly cross biological barriers. Indeed, these molecules are sometimes considered as «undeliverable» compounds to reach the intracellular target to achieve their therapeutic effect. Therefore, the tremendous therapeutic potential of nucleic acids depends on the success to find suitable carriers that will bring them to their target site.

Recently the possibility to design «multidrug» nanoparticles has been proposed either by combining in the same nanodevice chemotherapy and imaging (i.e., «nano-theranostics») or by loading into nanoparticles various drugs with complementary biological targets. Smart nanomedicines sensitive to endogenous (i.e., pH, ionic strength, enzymes etc) or exogenous (i.e., magnetic or electric field, light, ultrasounds etc.) stimuli allow a still better spatio-temporal controlled delivery of drugs and overcome resistance to current treatments. Finally, the development of strategies aiming to develop entities existing in Mother Nature and based on bio-mimetism should also participate to major progresses in the next few years.

3. Nanotechnology: a valuable aid for vaccines in the world of virology

The innovation of the nanovaccine in the fight against COVID-19 control is a good example of the need for trans-disciplinary study programmes on the one hand and the importance of pharmaceutical nanotechnology on the other.

Since the end of 2019, the SARS-CoV-2 outbreak has highlighted the importance of new technologies as a means of containing and stopping the spread of the disease. The lack of antiviral drugs or approved vaccines, as well as their low efficacy with side effects, requires the use of new treatment strategies against COVID-19. Classical therapeutic approaches are based on antiviral drugs and adjuvant molecules already used in other viral diseases, which can inhibit the absorption of the virus into tissues and block the activity of proteases in infected cells. However, this strategy only decreases the replication of the virus and relieves any symptoms to a certain degree.

3.1. Nanomedicine [2), 3), 8)]

Nanomedicine and nanopharmacy are now important tools in the fight against the novel coronavirus, although their use in clinical practice still presents great challenges, mainly with regard to in vivo behavior, the toxicity of nano transporters, and production on an industrial scale. Although these elements have not yet been fully explored, understanding them is essential for the safe and effective implementation of nanotechnologies against SARS-CoV-2 infection. The relative failure of conventional antiviral therapies against COVID-19 presents in many ways an opportunity to boost the use of nanotechnology tools in virology.

3.2. Nanotechnology and Vaccines that fight COVID [9), 10), 11), 12)]

The new COVID-19 vaccines combine nanotechnology and biology by providing the ability to bypass the immune system to deliver treatment to target cells. On November 18, 2020, BioNtech and Pfizer announced the final results of their Phase 3 clinical trial of the COVID-19 vaccine on BNT162b2. This followed an announcement by Moderna of preliminary results from another Phase 3 study of an alternative mRNA-1273 vaccine. A recurring problem in the development of drugs and vaccines is therefore to bypass the body's natural defense mechanisms and reach target cells without being degraded, and this also concerns COVID-19. This «direct distribution» approach would also reduce harmful side effects. The answer to this problem, it seems, lies in understanding the methods that nature has already developed.

BNT162b2 and mRNA-1273 both use the same method to bypass the body's natural defense mechanism, allowing them to deliver a medical payload to target cells without being degraded or destroyed. The vaccines mentioned above follow in the footsteps of Onpattro, a drug that Alnylam Pharmaceuticals developed in 2018 when they created the first siRNA drug. Onpattro – originally designed to help patients with inherited neurological disease – packs small molecules of interfering RNA into lipid nanoparticles, i.e., fat. It is these fatty envelopes that help mRNA get past the biological «gatekeepers», and that inspired the mechanism being used to fight COVID-19. These two new vaccines use nanocarriers against COVID-19 by delivering mRNA to cells, triggering the production of antigens so that they begin to create antibodies. This results in a reaction of the immune system which fights the virus and thus prevents the development of the disease. They would thus have an infection prevention efficiency of about 95%. This technique differs considerably from those used by more «traditional» vaccines. It is clear that the BNT162b2 and mRNA-1273 vaccines represent a huge breakthrough in molecular medicine and biotechnology. But more than that, the three drugs show that the delivery of nanoparticle drugs is not only a basic research avenue, but can translate into life-saving and successful medical interventions. For me, one of the heroes of this story is the RNA nanoparticle, because it was the siRNA that led to mRNA vaccines.

4. University Education in Nano-Pharma Studies [1]

The interface between nano systems and biosystems is emerging as one of the broadest and most dynamic areas of science and technology. There will be very many applications that at present we cannot conceive, and a new interdisciplinary education model will be required to bring together the knowledge to best take forward

[1] For more information see author's article «Our Universities: Knowledge Foundries for New Global Challenge». Closing the Gap Between Our Education and Our Future Through Transdisiplinarity Across the Arts, Humanities and Sciences, in: SWISS PHARMA 43 (2021) No. 4.

these new ideas. One will have to bring together biology, chemistry, physics, and many areas of engineering, with biotechnology.

While a typical pharmaceutical already requires input from a broad range of specialisms during its evolution from a new molecular entity to an applicable formulation, developing nano pharmaceuticals requires even more disciplines to work together.

The modern approach to University education and research recognizes the need to cut across traditional boundaries. Universities need to adapt their approaches to the management and organization of research and teaching for transdisciplinary working. This has become an urgent consideration given that we now face unprecedented global threats which demand a new kind of skilled individual who is literate across multiple fields: an intellectual multi-tasker and polymath. We have already secured in Europe a standardization of degree awards, and promote cross-European student mobility. This will need to extend globally and to reach out across continents and language barriers. Only in this way can there be the advancement of global inclusiveness, and the opportunity for all to add their talents to global challenges that affect us all. Universities are well placed to take on the challenges and create new Faculties and Departments that span traditional disciplines.

In view of the revolutionary developments, one may promote the creation of Nano- Pharma Departments and Nano-Pharma Professorial positions to provide teaching and research that spans all aspects of:

- Drug delivery and targeting
- Characterization methods
- Computational molecular modeling
- Nanotoxicity/nanosafety, immunological and biological compatibility
- Pharmaceutical applications including medical imaging
- Drug development, especially cancer drugs and vaccines, and dermo-cosmetics
- Production/manufacturing technologies
- Occupational safety & health
- Translation to the clinic, regulatory issues, clinical trials
- Use of nanoscience in the design and development of medical devices, medical textiles, etc.
- Marketing and commercialization aspects
- Ethical, legal and social implications
- Soft skills including staff management
- Business-relevant skills (accounting, marketing, etc.)

Transdisciplinary Faculty Positions in nano-pharmacy would be most welcome. New teaching in pharmacy needs to broaden the trans-disciplinarity agenda. New staff recruited to pharmacy schools will have molecular modelling, bioengineering, nanotechnology and information technology expertise.

In the best Universities of the world, the principle of «transdisciplinary» Professorial Chairs is established. Prof. P. AEBISCHER, former president of EPFL (Ecole Polytechnique Fédérale de Lausanne), one of the better Universities in Europe and Switzerland, introduced the principle of Trans-disciplinarity already a few years ago[13].

This resulted recently in the announcement of a Professor Position[14] in the field of **Interdisciplinary Cancer Research** for undergraduate and graduate teaching, interdisciplinary cancer research, and its potential therapeutic applications. Cancer-related studies at a University and/or hospital are multiple: cancer genetics, functional genomics and genome instability, epigenetic regulation of cancer genotypes, cancer metabolism, computational cancer genetics, bioengineering of cell-based therapies and oncolytic viruses, and synthetic biology, systems biology, chemical biology of cancer.

Prof. Dr. Dr. h.c. mult. Marcel Van De Voorde

Marcel Van De Voorde studied natural and applied sciences in Belgian and European universities which resulted in various academic degrees. He started his academic career as Professor at the Catholic University Leuven and the State University Ghent in Belgium. In the eighties, he was nominated professor at the Technical University Delft (NL) and visiting professor at various known universities in Europe, US, Japan and China, including the reputed Tsinghua University in Beijing in 1992. In his research career, he had direction and senior scientist functions at CERN (European Organization for Nuclear Research), Geneva, European Commission Research in Belgium, Max Planck Institutes in Germany. He also held important research mandates at the ESA (European Space Agency), Paris and NATO R&D&T in Brussels.

He was/is chairman/member of Research Councils and Governing Boards, worldwide e.a. CNRS (FR), CSIC (ES), (CNR (IT), NIMS (JP), etc; senator at the European and is trustee at the World academies of sciences and arts; honorary professor and doctor honoris causa of multiple universities.

He had/is advisor to Ministers, Directors of research centres, rectors of Universities in Europe and worldwide and at the Science Council of the French Senate and National Assembly in Paris, etc. He received many honors e.g. from the Belgian King, the Luxemburg State, European Commission etc. He is caritative also very engaged: Promotion of the Catholic universities in Bethlehem and Madaba (Jordan), creation of a research institute in the Balkans, a research center in the Middle-East containing eight countries including Israel.

Related to this conference: Important achievements are in University Education in Europe with pioneering work in the BOLOGNA Ministers Declaration with BSc, MSc, PhD degrees all over Europe and the popular EC-ERASMUS mobility programme. In the eighties, he was Co-founder of the IMEC's «Inter-University Nano-Micro Electronics Centre»: a spin-off of the Catholic University Leuven which hosts today 4.000 scientists, engineers, etc from 100 different nations worldwide. The research initiatives on Proton-Therapy for Cancer (PTC) treatments at CERN had, during the last decade, an explosive development in PTC-hospital clinics in Europe.

P.S. My pharmacy experience relates to the Dr Paul Janssen Laboratories, founder of the successful «Janssen Pharma Belgium» now the Janssen/Johnson & Johnson US. At the European Commission I was in close contacts with the European Pharma.

This trend will certainly accelerate in the future in all Faculties of Universities in Europe and will span «natural» and «human» sciences. Pharmacy education and research will not escape this evolution; for details see the author's article «Our Universities: Knowledge Foundries for New Global Challenges. Closing the Gap Between Our Education and Our Future Through Transdisciplinarity Across the Arts, Humanities and Sciences», in: SWISS PHARMA 43 (2021) No. 4. The European Commission will also introduce this system in the EC-2021-2027 research programme.

4. CONCLUSIONS

The world of Artificial Intelligence and nano-Pharma will impact on all elements of industry and society. Many jobs will disappear and new ones will be created. There will be very many applications that at present we cannot conceive, and a new interdisciplinary education model will be required to bring together the knowledge to best take forward these new ideas. Revolutionary developments are expected in human health with illnesses like cancer and Alzheimer's being detected earlier and treated more effectively. The issue that needs urgently to be addressed is to understand the safety aspects so that industrialists and the consumer can utilise nanotechnologies without any danger.

With the increasingly likely prospect of ending the COVID-19 pandemic with the aid of a nano-pharma-based vaccine (both the Moderna and BioNTech/Pfizer vaccines are based on lipid nanoparticle formulations), we are witnessing the coming of the age of nano-pharmacy. In collaboration with nanotoxicology and safety regulations, nano-pharmacy will herald a pharma revolution.

Switzerland plays an important role in the Pharmaceutical industry and it is greatly welcomed that the Swiss Pharma Journal SWISS PHARMA devotes its issue 43 (2021) No. 4 to the topic «Pharmaceutical Nanotechnology» and therefore is a forerunner in highlighting these important aspects.

Acknowledgements

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I am respectful to the former EPFL President P. Aebischer, specially for the contacts and the exchanges of information. I also profit from this occasion to mention that Switzerland, United Kingdom, and Israel will take part in the execution on the EC-2021 – 2027 research programme in which the promotion of the pharma research and development will play an active role.

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Spray freeze-drying for Formulations of Precision Medicine & Vaccines

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Key words: Nanoparticles and Nano composites, Innovation in Bulk Freeze-drying, Precision Medicine & Vaccine Formulation, Phage & Viral Cancer Therapy

The majority of the novel highly potent drugs, developed on the basis of modern molecular medicine, taking into account cell surface recognition techniques for precision medicine, are often thermo-sensitive and have poor water-solubility. A substantial increase of drug solubility can be obtained by the formulation of nanocomposite pellets using a spray freeze-drying process, which was originally developed at the University of Basel. This process was successfully commercialized by the company Meridion (meridion.de) of Dr B. Luy. This platform, among others, can be used for manufacturing vaccines, biosimilars, biologics, monoclonal antibodies, antibody-drug conjugates for precision medicine. In this context, it is important to keep in mind that in case of a vaccine formulation the double chamber syringes can be kept at room temperature and do not need to be stored at –77°C. In addition, this platform can be used for medications based on the phage therapy to treat antibiotic resistant (MRSA) bacterial infections. In this context, a specific phage having the property of a virus only infects the bacterial cells. Thus, the infected bacteria cell loses its negative function and starts to serve as a host cell for the replication of more «friendly» viruses. Such an approach is also used for a viral therapy of cancer cells which will lead to cancer therapy without the side effects of traditional chemotherapy and radiation treatment. This type of highly specific targeted medication is the future of precision medicine. At the same time, it can be predicted that this innovative spray freeze-drying technology will be the future of manufacturing lyophilized products.

1. Spray – Freeze-drying as a Method of Choice for a safe Manufacturing and Handling of Nanoparticles and Nano Composites

1.1. Rationale of this Approach

The classical freeze-drying process (Freeze-drying – Wikipedia) in a traditional vial has a lot of limitations due to the fact that the liquid is directly frozen and dried in the vial, leading to heat transfer problems as shown in Fig. 1.1. This energy transfer depends on the local temperature of the vials on the shelf, which explains that the cake may show cracks **(Patel et al 2017)** and is not perfect as in Fig. 1.2. Therefore, the company Seidenader (https://www.seidenader.de/en/inspection/our-technologies/) offers automated inspection, to test each sample and to discard vials with defective cakes. Besides product sterility, the most critical parameter is the residual moisture content of the lyophilized product. For this reason, the company Roche uses an in-line residual moisture determination for a complete batch inspection of lyophilized end products **(Sukowski L 2017,** Fig 1.1). From an ethical point of view, a 100 % inspection of all vials means that the company really takes care of the patients.

On the other hand, the necessity of a 100 % inspection shows that the classical freeze-drying process is not an optimal method. Fig. 1.3 shows a vial containing mono-sized pellets obtained by the spray freeze-drying process, the future method of choice.

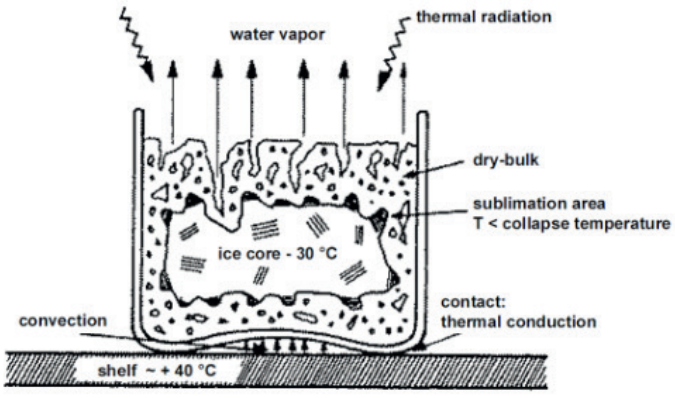


Fig.1.1: Heat transfer and vapor transport in the vial. (Courtesy Sukowski L 2003)

Fig.1.2: Vial with intact cake. (Courtesy Meridion)

Fig.1.3: Vial with mono-sized pellets obtained by Spray Freeze-drying. (Courtesy Meridion)

In the context of Fig. 1.1 it is important to realize that the control of the primary freezing step is most essential regarding the final quality of the lyophilized product. In the case of classical freeze-drying of the vials on shelves (Fig.1.1) this step is very critical since the pharmacological activity of the biological product is a function of the speed of this initial freezing step and of the formulation. Thus, the ultra-fast freezing step of the MERIDION technology has decisive advantages for obtaining the targeted optimal activity of the biological being close to 100 %. This fact impressed specialists in classical freeze-drying attending the 2019 AIChE Annual Meeting in Orlando listening to the MERIDION presentation «Advances in Spray-Freeze Drying for Uniform Bulk Intermediates and Lyo Products» **(Leuenberger H 2019b).**

2. Implementation of the Spray Freeze-drying concept by Meridion.

2.1. Technology Development Background

Started in 1980's in cooperation with Glatt AG (Switzerland) the PhD candidates Alain Kahn **(Kahn – Wyler A H 1987)**, Marco Mumenthaler **(Mumenthaler M 1990)**, Hans-Peter Mennet **(Mennet HP 1994)** and Mathias Plitzko **(Plitzko M 2006**) evaluated the conditions, which should allow the manufacture of drug formulations which show as solid dosage forms a high stability and an instant solubility to be used in case of low water-soluble drugs for sterile injections, for capsule formulations and for instant-drink solutions. Thus, this novel technology has the potential to replace the classical freeze-drying process. Alain Kahn was the first to show the feasibility using this process, Marco Mumenthaler was the first who showed that it is possible to manufacture instant soluble coffee powder without losing the original flavor, i.e., there was no need first to collect the aromatic flavors in the classical freeze-drying process and to add the flavor subsequently to the product. Matthias Plitzko was the first who was able to manufacture mono-sized pellets with this novel process. The work of the PhD students led among others to the US patent 6, 584, 782 B2, July 1, 2003 as part of the 12 patent families of the Glatt Group with the name Hans Leuenberger as inventor **(Leuenberger H, Prasch AKT, Luy B 2003).** However, the patent based on a quasi-continous process separating the spray-freezing step from the subsequent drying processes was not implemented by the Glatt group despite the fact that the US patent already proposed to separate the freezing and the drying process. Ergo, the process line consisted of three towers taking care of the instant freezing step at $T_{AIR} < -60°C$ in the fluidized bed (FB) tower Nr. 1, of the primary drying phase at $T_p < -10°$ C in the subsequent FB tower Nr. 2 and of the secondary drying phase at T_s = ambient temp. in the FB tower Nr. 3. As already shown by Alain Kahn, Marco Mumenthaler and Hans-Peter Mennet, a single pot process is not the solution. Thus, Meridion Technologies succeeded in commercializing the spray freeze-drying technology using two steps, a) the instant freezing process for the formation of nano composite pellets in a separate tower and b) as a second innovative step a dynamic bulk drying process using a rotary drum based on the patent US 20140230266 A1, 2014 for the production of freeze-dried particles. Thus, the company Meridion could avoid the use of fluidized bed processes for commercializing the spray freeze-drying process.

Prof. Hans Leuenberger

Hans Leuenberger studied experimental physics resulting in a PhD in nuclear physics at the University of Basel. He worked for twelve years at Sandoz (today Novartis) before he was elected as a full time professor in Pharmaceutical Technology at the University of Basel. He served as Dean of the Science Faculty, as President of the Scientific Council of the Swiss Academy of Engineering Sciences SATW and as Vice President of SATW. He received numerous awards (www.ifiip.ch/awards gallery), and was Visiting Professor of the Grand Ecole des Mines, Albi, France (https://www.imt-mines-albi.fr/en/imt-mines-albi) being Member of its Advisory Board 2001–2006. He is Honorary Member of SATW (www.satw.ch), of the Society of the Swiss Industrial Pharmacists (SSIP) (www.gsia.ch), Corresponding Member of the Royal Academy of Pharmacy of Spain, Foreign Member of the Russian Academy of Engineering; Fellow of the Swiss Academy of Pharmaceutical Sciences and Fellow of the American Association of Pharmaceutical Scientists (AAPS). After moving to Florida he is Member of the Adjunct Faculty of the College of Pharmacy of the University of Florida. Lake Nona Campus, Orlando.

2.2. Spray Freezing: The Generation of homogeneous frozen bulk

At an ambient-pressure, frozen microspheres are generated by dispersing the substrate liquid, using frequency nozzles, into single droplets, which by gravity pass through a cooling zone, congealing to frozen spheres.

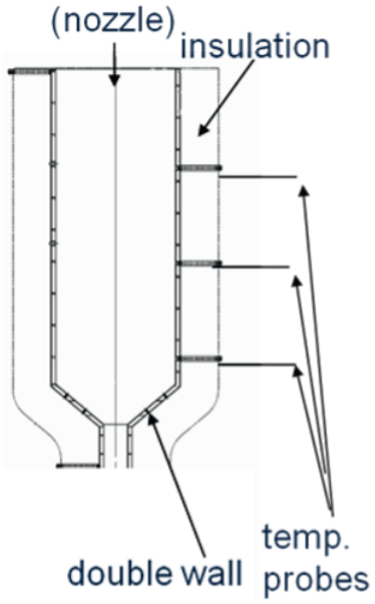


Fig. 2.2.1: Scheme of Spray-freeze Chamber. (Courtesy Meridion)

Fig. 2.2.2: Spray-freeze Lab Unit. (Courtesy Meridion)

The mono-sized droplets are sprayed into the processing gas, which is cooled by the double wall with liquid or gaseous nitrogen in the temperature range of –77°C to –140°C. Thus, the droplets are immediately frozen, which is important for the stability of biologicals. This is an important asset compared to the classical freeze-drying process as confirmed by other speakers at the AIChE 2019 meeting in Orlando **(Leuenberger H, 2019b).**

2.2.1 Droplet generation by controlled laminar jet break

Matthias Plitzko **(Plitzko M, 2006)** used first, in his PhD thesis, a special prilling nozzle, which allowed him to generate mono-sized droplets as an example with a diameter d_d of 270 µm. The diameter is a function of the nozzle diameter D_n, throughput SR (ml/min), and the frequency f of the unit (Fig. 2.2.1 Table 2.2.1), which is needed to create a controlled laminar jet break.

D_n (nozzle) [µm]	d_d (droplet) [µm]	SR (spray rate) [ml/min]	f (frequency) [Hz]
150	270	2.8	3072
200	330	7.0	2720
300	480	10.5	2030
400	610	10.5	860

Table 2.2.1: The correct choice of the operating parameters (D_n, SR, f) is crucial to avoid the coalescence of the droplets of the diameter d_d **(Plitzko M, 2006).**

Fig.2.2.3: Stream of droplets. (Courtesy Meridion)

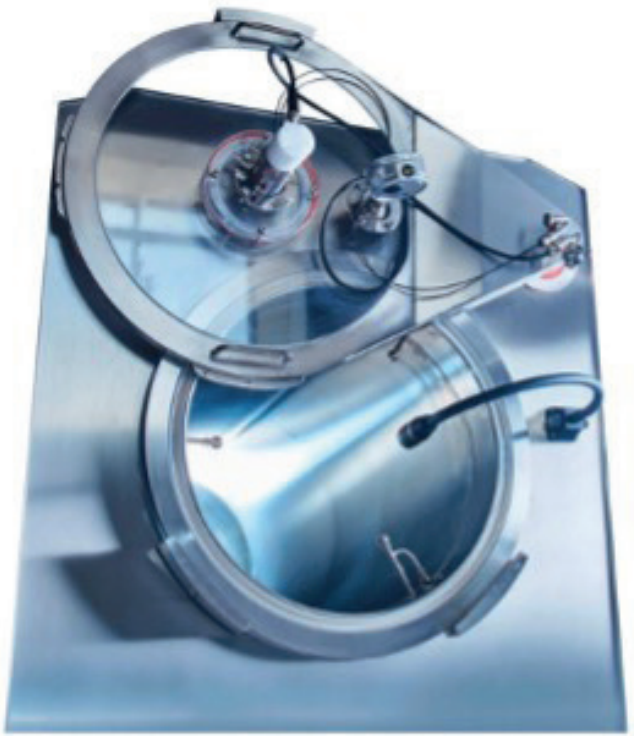


Fig.2.2.4: Top Lid with Spray Nozzle of the Spray-Freeze Chamber. (Courtesy Meridion)

Fig.2.2.3 shows the separation of the droplets in the spray freeze chamber and Fig. 2.2.4 is the photo showing the top lid with the spray nozzle. For the separation of the droplets and for avoiding the subsequent coalescence the droplets need to be charged with the same polarity. This is the function of the high voltage cathode of Fig. 2.2.5.

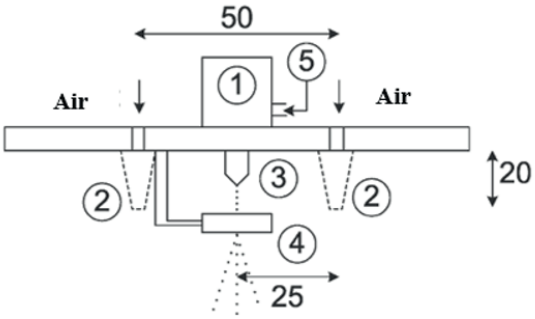


Fig. 2.2.5: Scheme of the Prilling Spray Nozzle: ① prilling control device for the separation of the droplets; ② Air flow; ③ Nozzle with the diameter D_n; ④ Cathode (1.1-1.8 kV) ⑤ Spray rate SR (material flow, ml/min). (Courtesy Plitzko M, 2006)

As an alternative of using an electrode, MERIDION has developed a gas-based deflection technology to avoid electrostatic charges which could interfere with product handling requirements. In addition, it has to be kept in mind that a minimum amount of the solid content of the spray solution is needed that the freeze-dried droplet is stable and keeps its shape. Thus, if the final porosity of the product is too high, the pellets will not be mechanically stable and will disintegrate into smaller particles. This statement is related to the fact that the amount of solid content dissolved needs to percolate the droplet. On the other hand, a high porosity is desirable of such nanocomposite particles since the high internal surface of the pellets is an important quality attribute for the instant solubility of the formulations in case of drink solutions or for parenterals. Needless to say that an aseptic process is a prerequisite for manufacturing sterile parenterals.

2.3. Dynamic Bulk Freeze-drying: The Lyophilization of frozen bulk

The frozen bulk ware is lyophilized in a rotational vacuum freeze-dryer under constant gentle mixing and at low pressure such as 20 µbar which is used in a classical freeze-dryer. Sublimation energy is transferred by radiation and temperature-controlled surfaces. In this context this process only differs from the well-known classical principle by the rotational movement of the material to be lyophilized. This is, however an important innovation since the movement of the material leads to a homogenization of the freeze-drying conditions. Thus, this innovation resolves the problem of the classical freeze-drying dishes which are cooled to –55°C for the freezing of the solution in the vial and which are subsequently used, e.g., at a temperature of +55°C, for supplying enough energy (heat) to the frozen solution to induce and sustain the sublimation process. Unfortunately, this energy transfer may depend on the location of the vials (Fig. 1.1) on the table/shelf. A similar problem exists in case a microwave oven. Uneven heating in microwaved food can be partly due to the uneven distribution of microwave energy inside the oven. Thus, this problem can be reduced by by a turntable or carousel that turns the food in the **microwave oven** (Wikipedia). In case of the dynamic bulk freeze-drying process the material is gently mixed in the rotating drum with a controlled surface temperature. The heat transfer from the surface of the drum to the pellets results from silicon oil circulating in a double wall of the drum. The silicon oil can be adjusted in the range from –55°C to +55°C . To be on the safe side, the dynamic bulk freeze-drying process uses infrared radiation for the optimization of the heat transfer needed for the removal of water by sublimation. It is evident that the mechanical stability of the dried pellets depends on the concentration of dissolved solid formulation. The solid material in the solution needs to percolate the 3D volume of the pellet **(Holman LE. Leuenberger H, 1990).** Thus, at very low concentrations the final porosity of the pellets would be too high and the nanocomposite pellets would mechanically disintegrate into finer components. This is not the goal of nanocomposite pellets since nanocomposite material has a reduced surface activity and as a result a better storage stability as nanoparticles. In the optimal case the pharmaceutical nanocomposite pellets disintegrate into nanoparticles in the stomach after oral administration, which is an important advantage in case of low water-soluble drugs **(Leuenberger H, 2002).**

Fig. 2.3.1: Laboratory dynamic bulk freeze-drying unit. (Courtesy Meridion).

2.4. From laboratory to manufacturing scale

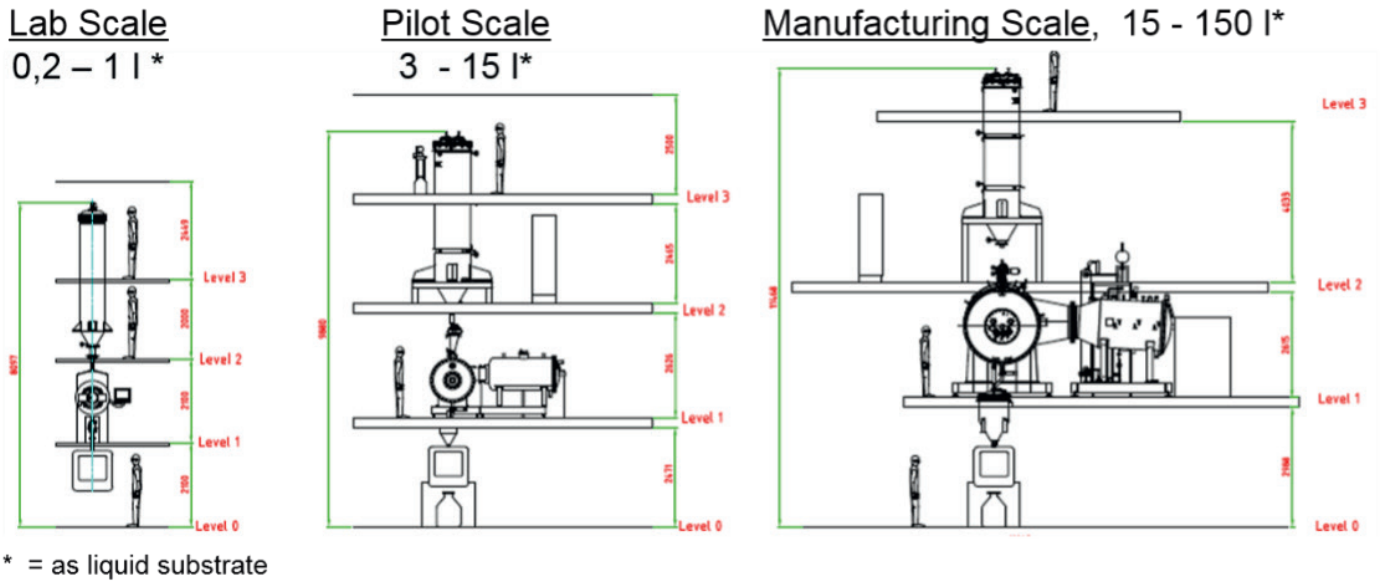


Fig. 2.4.1: Process lines from laboratory to manufacturing scale. (Courtesy Meridion)

In conclusion, the innovative spray freeze-drying technology leads to dust-free nanocomposite pellets, which can be safely handled. The resulting pellets show a high homogeneity and quality. Thus, there is no need for a 100 % control of each vial of a batch. Due to the fact that during the initial freezing process the (non-sterile) liquid nitrogen is not in direct contact with the sprayed pharmaceutical formulation, the manufactured nanocomposite pellets can be used as an instant water-soluble product for sterile injections.

In this context, the containment technology used for the whole process in a laboratory and in an industrial environment (see Fig. 2.4.1 and Fig.2.4.2) is of primary importance to being approved by FDA. Thus, nanocomposite medical pellets can serve as a societal blessing in contrast to the harmful diesel exhaust. Unfortunately, diesel exhaust does not only contain micro particles of the diesel exhaust scandal, but also a substantial amount of nanoparticles, which is not subject to existing regulations.

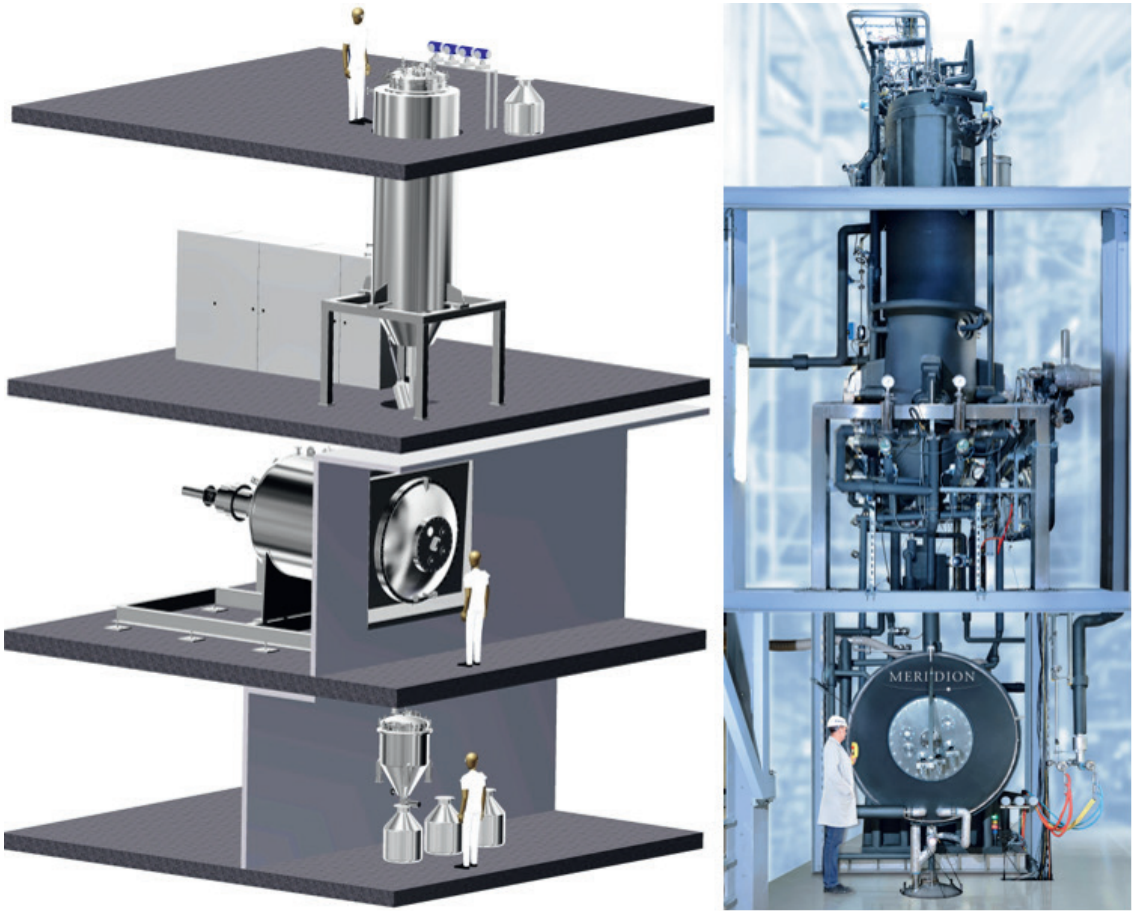


Fig.2.4.2: Industrial Spray Freeze-drying Concept for Aseptic (full containment) Processing. (Courtesy Meridion).

3. Spray freeze-drying as a safe Technology Platform for the Production of Nanoparticles

3.1. Range of Applications in the Pharmaceutical Industry and beyond

Most of the novel highly potent drugs developed on the basis of modern molecular medicine, taking into account cell surface recognition techniques for precision medicine, show poor water-solubility. A chemical modification of the drug substance enhancing the solubility often decreases the pharmacological activity. Hence, as an alternative, increase of the solubility can be obtained by the formulation of micro or nano sized drug particles. Unfortunately, nanosized particles are often not physically stable and need to be stabilized in an appropriate matrix. Thus, it is important to manufacture nanostructured, composite systems which can be efficiently realized by the innovative spray freeze-drying process with a broad range of applications.
This platform allows the manufacturing of stable formulations of vaccines, which need not to be kept at –77°C for long term storage as in case of Pfizer/BioNTech or at –20°C for the Moderna vaccine manufactured by Lonza. Both vaccines are manufactured based on mRNA technology, respectively, using mRNA encapsulated in lipid nanoparticles (Fig. 3.1).

Fig. 3.1 shows that the messenger RNA is picked up by the cell, staying in the cytosol of the cell, without entering the nucleus of the cell. Thus, the mRNA vaccine is not able to alter the DNA of the nucleus, a widespread disinformation in social media *(RNA vaccine – Wikipedia)*. It is important to notice that the RNA vaccines offer advantages for the following reasons: a) the manufacturing process is cheaper; b) is faster; c) is better standardized, and, last but not least, is not based on attenuated (weakened) or killed forms of the pathogenic virus. Thus, the manufacturing process of the traditional vaccine needs to be safe to avoid inacceptable side effects.

New research findings show that the health condition of the human being depends, among other factors, on the quality and composition of the intestinal microbiome **(Leuenberger H, 2019 a).** Indeed, the positive role of **friendly** microorganisms **(bacteria)** in

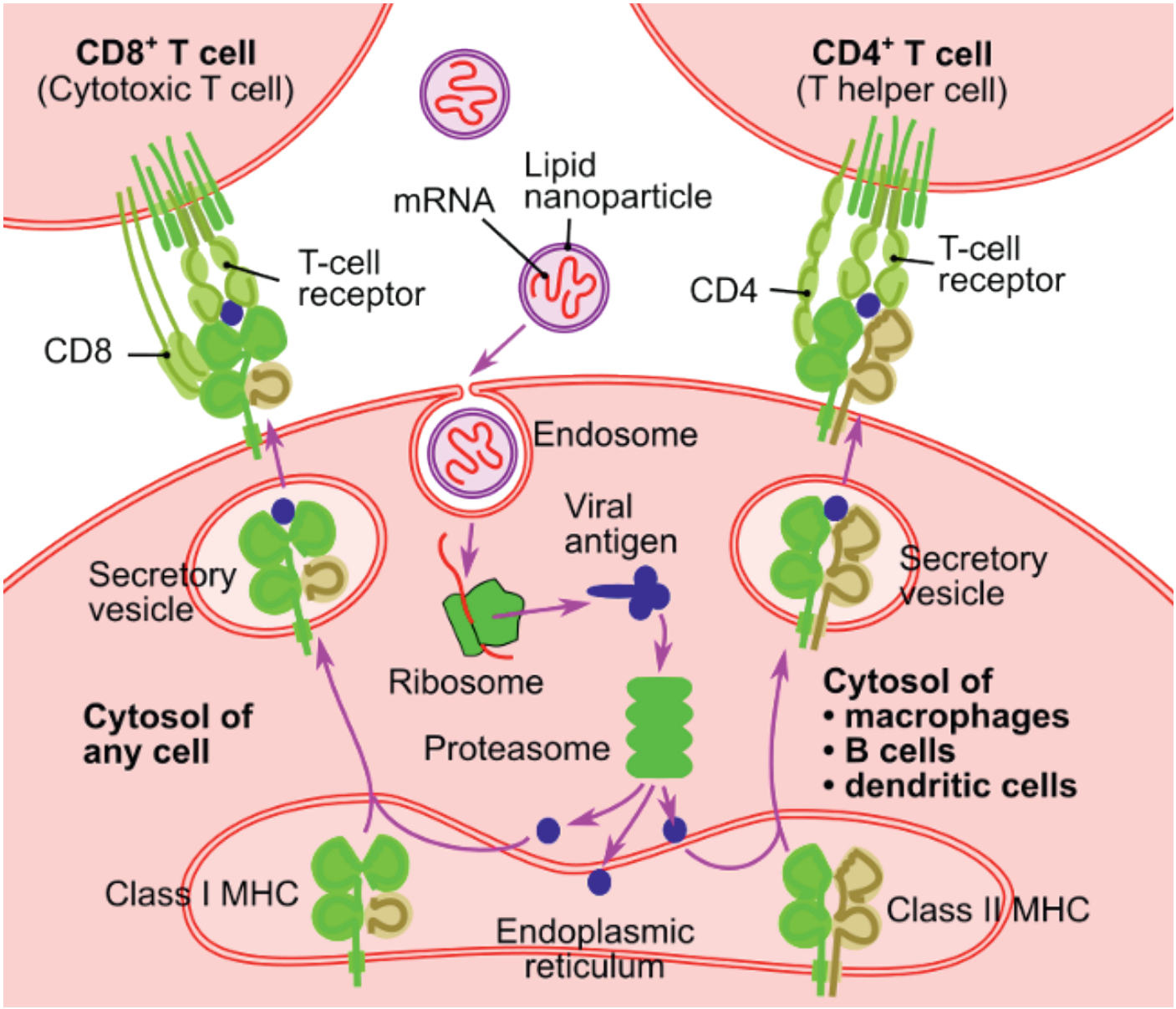
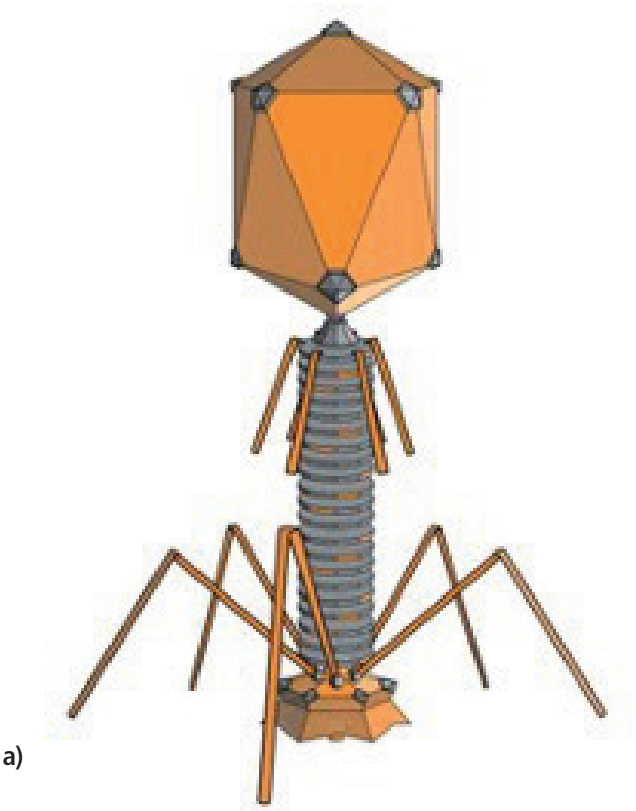


Fig. 3.1: The mRNA (messenger RNA) technology uses lipid nanoparticles as delivery vector for manufacturing the vaccine, inducing the immune response. According to Bernhard Luy (MERIDION), both mRNA molecules (Qiu et al, 2019) and lipid nanoparticles have been described in the literature to have successfully undergone lyophilization; therefore spray freeze drying can be considered as a promising option for appropriate mRNA formulations. (Courtesy RNA vaccine, Wikimedia Commons).

our intestine is now in the focus. In this context, **the contemporary research needs, also, to embrace the friendly types of viruses!**

This **is an urgent request** since we can take advantage of **Bacteriophages (= viruses)** to clean up our waste water **(Withey S et al, 2005)** and we can use **phage therapy** (Wikipedia) for an effective and optimal treatment of antibiotic resistant bacteria. In addition, as mentioned in the ppt presentation at the Nano Science & Technology symposium at Fukuoka (Japan) in 2017, **the phage therapy could in principle also be used** for **curing cancer patients (Leuenberger H, 2017).** It has to be emphasized that the patients **are cured** and not simply treated based on classical chemotherapy with side effects and with the uncertainty that the cancer therapy is successful. The phage therapy or therapy **of cancer patients with a friendly** virus is based on the following concept: The phage (virus) is looking for the human specific cancer cell as a host for its replication. It is important to realize that **only the malign cancer cells serve as host cells,** which explains that **this treatment is a cure without side effects.** The other very positive point is the following: The **MERIDION spray freeze technology is the process of choice for a safe, efficient and aseptic production of such a high-precision medicine.** The active ingredients, the phages, have the size of nanoparticles (Fig. 3.2) which need to be delivered to the cancer cell or to the pathogenic bacteria being resistant to antibiotics (Fig. 3.3).
It remains the hope that enough funds will be available, like in the case of finding a COVID vaccine, to explore new research avenues for the advancement of nano science and technology in the area of phage therapy. In addition to these advanced therapies for treating patients, the MERIDION technology can be successfully used for the aseptic production of formulations of classical high potent, thermo-sensitive, poor water-soluble drugs, of vaccines, biosimilars, biologics, monoclonal antibodies, and antibody-drug conjugates for precision-medicine.



a)

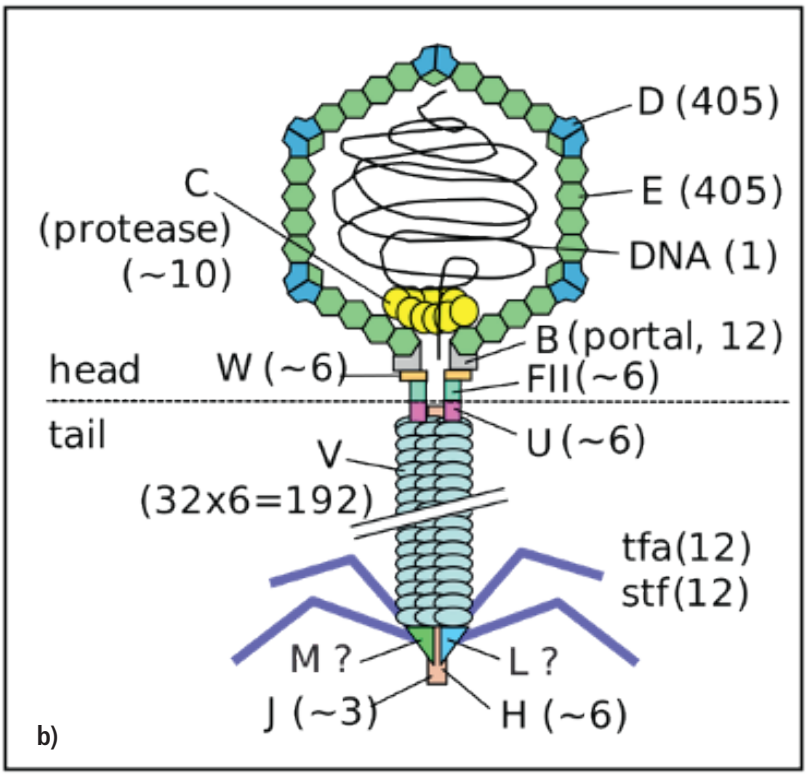


Fig. 3.2 a/b: Scheme of the Lambda phage [a] with the capsid (typical diameter 20 nm) on the top. The DNA [b] is used to replicate the virus in the host cell, such as a pathogen bacteria or a cancer cell. (Courtesy Wikimedia Commons).

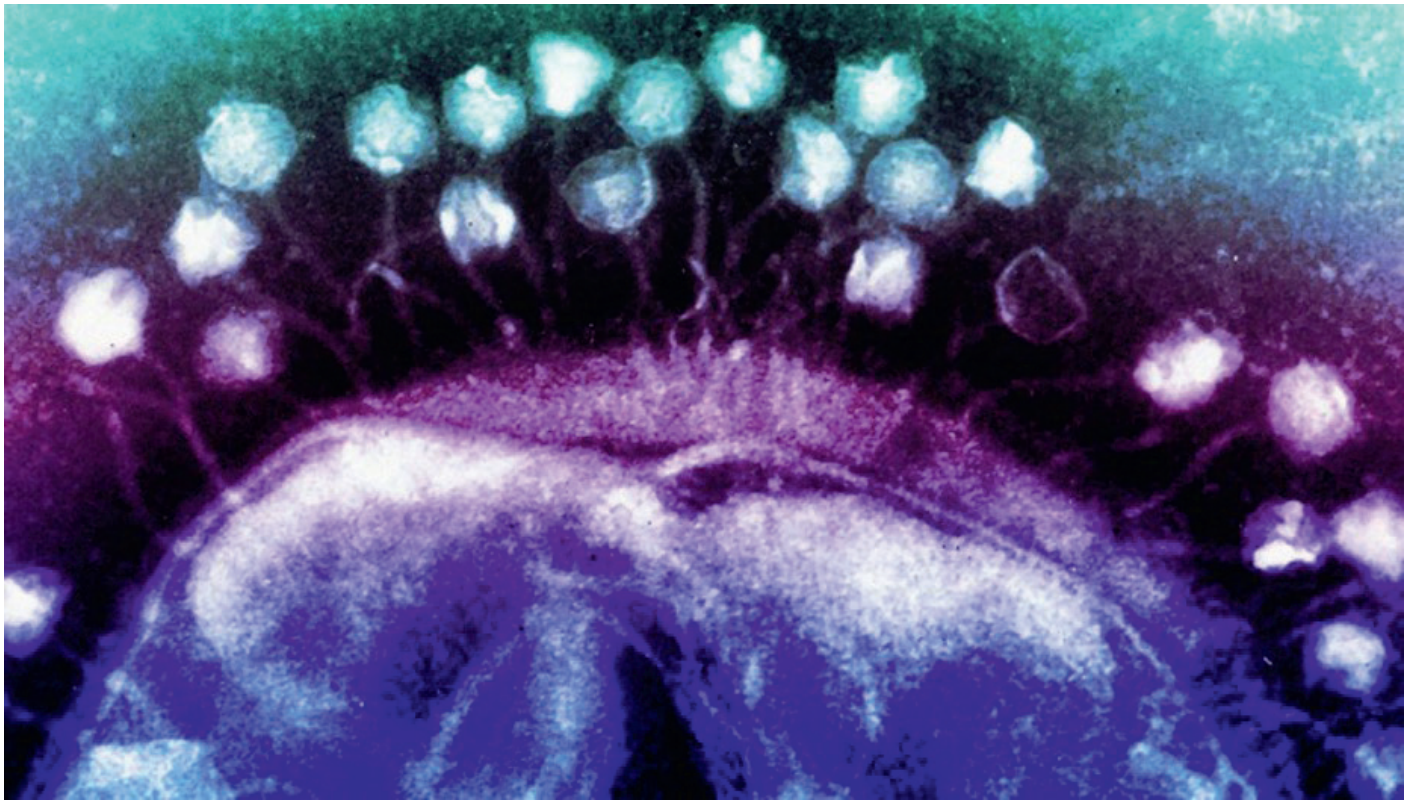


Fig.3.3: Cell (resistant to antibiotic treatment, or a cancer cell) being attacked by «friendly» phages using the cells as «food» and as hosts for replication of the viruses, respectively. The «friendly» virus in the human body is only active as long as there is «food» for its replication.

Due to the problem that natural phages cannot be patented, the incentive to do research by the pharmaceutical industry slowed down, but there is an opportunity that engineered and optimized phages can **(Glasgow J & Tulllman-Ercec D, 2014)** be patented. The latter point is not discussed in the following article «Business Ethics in the Pharmaceutical Industry and Beyond» in this issue SWISS PHARMA issue 43 (2021) No. 4.

Due to the fact that the spray freeze-drying of poor water-soluble, high potency drugs is approved as a **standard operation procedure** by the FDA **(Guidance for industry, 2006),** this platform technology should be used for manufacturing clinical samples for clinical phase I studies for all types of drugs.
Thanks to this platform the FDA concept of «Right, First Time» could be rigorously interpreted **(Leuenberger H, Leuenberger MN. Puchkov M, 2010)** already, in an early phase of the development of novel drugs **(Leuenberger H, Puchkov M, Schneider B, 2013).**

This concept is a prerequisite that an optimal quality of the final marketed drug dosage form used in clinical phase III can be achieved **(Leuenberger H and Leuenberger M N, 2016).** Accordingly, failures as a result of poor drug water-solubility can be avoided for clinical phase I studies. The rigorous implementation of the concept «Right, First Time» in combination with this innovative platform and the implementation of the in-silico design of solid dosage forms will allow the pharmaceutical industry to adopt the successful workflow of the automotive and aircraft industry **(Maneerojpakdee, D et al, 2017).**

This workflow was successfully introduced by Go Kimura at the company Shionogi in Japan. In addition, the current failure rates of the clinical phase I-III studies can be substantially reduced by using the above concepts. Johannes von Orelli **(Von Orelli J, 2005)** demonstrated with his PhD thesis the problem of capsule formulations with a poor wettability, if a higher strength of drug dosage is needed without compromising the bioavailability of the capsule formulation for clinical phase I studies.

It is important to notice that the MERIDION spray freeze-drying technology for manufacturing tailor made nanoparticles is used in high-tech 3D sound devices of the consumer electronics industry **(Leuenberger H, 2017, 2019b).** In this case multiple drying units allow a continuous 24h/7d manufacturing process.

4. Conclusions

The spray freeze-drying process is used for the safe manufacturing and handling of nanocomposite pharmaceutical products. The technological prerequisites can be summarized as follows:

- The manufacturing process of this platform follows in detail the same technological prerequisites as other pharmaceutical products to grant safety.
- As a result, the manufacturing process follows the needs of the regulations of the health authorities such as FDA and EMA.
- In this context, the containment concept and the concept of aseptic processing play an important role.

The results of this conclusion prompt the following important questions:

- Do we agree that the same regulations should be applied for all manufacturing processes regarding nanoparticles beyond the pharmaceutical industry?
- Is it necessary to adopt a broader view to protect the interests of the patient and the consumer?

Both points are discussed in the following contribution: Business ethics and Nanoparticles in this SWISS PHARMA 21/4 issue.

5. Acknowledgements

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Business Ethics in the Pharmaceutical Industry and Beyond

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Key words: Nature's evolutionary principle securing survival, nanomedicine, scientific integrity, integrity of data, religion and ethics, business ethics, legal framework and science diplomacy, negotiations engineering & conflict management, transdisciplinary research & teaching.

This contribution is partly based on the author's chapter «Debate: Nanoparticles – A Blessing or A Curse?» of the book «Ethics in Nanotechnology» (in press) by G. Jesmani & M. Van De Voorde. Six axioms derived in the publication «What is Life?» available at www.ifiip.ch/downloads (SWISS PHARMA 41, 2019/1, 20-36) allow to define the life of a human being and to describe the concept of a virtual patient. Six additional axioms lead to the definition of the «Life of a Society». In other words, the society can be compared to a human being. Thus, thanks to computational science and the emerging field of artificial intelligence, it is not only possible to describe a virtual human being but also a virtual society. In this context, it is also possible to define a healthy society having no problems accepting Nano and Precision Medicine, if these new technologies are based on scientific integrity and the integrity of data. Scientific integrity and integrity of data are necessary that these technologies are approved by health authorities. In this context, the International Council of Harmonization (ICH Official web site: ICH) worldwide promotes public health by globally harmonizing laws. Accordingly, these officially authorized medical nanoparticles are a blessing in contrast to the harmful micro- and nanoparticles in the air, known since the rigged measurement of microparticles that triggered the diesel exhaust scandal. Diesel exhaust also contains nanoparticles that are a curse and need to be regulated. In this context, scientific integrity and integrity of data play a key role. This result can be generalized by taking into account other factors defining a healthy or a sick society beyond new technologies such as business ethics in general. Thus, scientific integrity and integrity of data need to be respected in all areas including business and all other human interactions. First of all, a rigorous interpretation of laws as well as a global harmonization of the legal framework and the ethical conduct need to be adopted. This measure is a prerequisite for a healthy society leading to a peaceful and sustainable world. For this purpose, it is important that all agree to replace any kind of the «Law of the Jungle» by a scientific method to find a «win-win» solution for all parties involved, leading to the survival of mankind. For this purpose, postgraduate courses such as «Negotiations Engineering & Conflict Management» based on scientific integrity and the integrity of data need to be boosted. Computational science and artificial intelligence will lead to convergence of all sciences and will trigger a new university educational reform promoting transdisciplinary research and teaching. Thus, university graduates will become more flexible, following nature's principle that flexibility is the key factor in a fast-changing environment.

1. Introduction

1.1. What is Life of a Human Being?

The author earlier published six axioms leading to the creation of human life and to the concept of a virtual patient **(Leuenberger H 2019).** The definition of the six axioms were inspired by the work of Ilya Prigogine (Nobel laureate 1977) and embrace:

Axiom 1 (Prigogine) Far from equilibrium, conditions exist favoring transformations from disorder into order, leading to the creation of life:
Chaos ➡ Order.

In this context, the treasure of organic compounds offers incredible opportunities such as the creation of DNA double helix (Fig.1.1).

Axiom 2 (Leuenberger) The same process is responsible for the formation of beautiful highly ordered crystals in nature (Fig.1.2): Chaos ➡ Order. This fact prompted the author to coin the crystallization process as **inorganic life** since the same laws are responsible for the creation of a higher order in the organic and inorganic world far from thermodynamic equilibrium conditions! In this context, however, according to our present knowledge, compounds of inorganic chemistry are not able to store the incredible amount of information as in the case of the DNA helix of Fig.1.1.

It is important to realize the direction of the arrows of axiom 1 & axiom 2 from a chaotic system to a system of higher order: Chaos ➡ Order! This direction is the result of an **open system** with the influx of energy **far from thermodynamic equilibrium.** This result is the opposite of a **closed system in a thermodynamic equilibrium,** which is subject to an **aging process** according to the **second law**

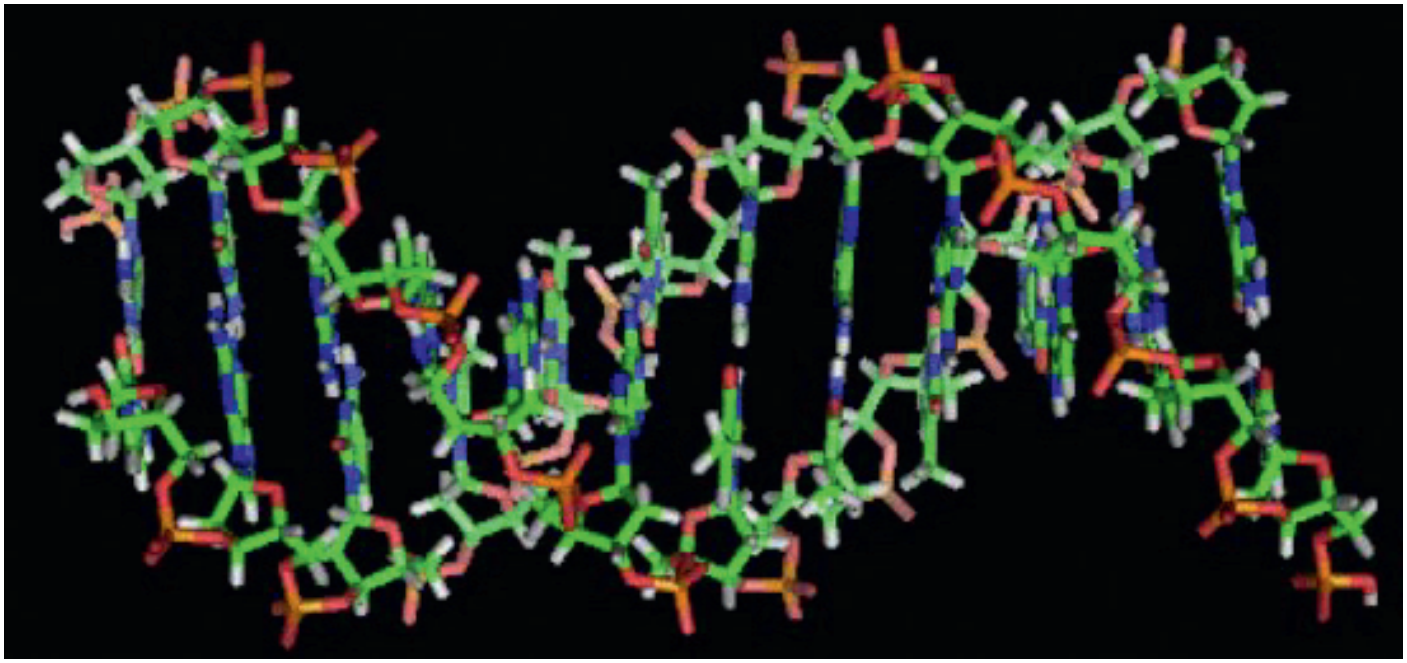

Fig.1.1: DNA double helix containing the code of life = software = axiom 3. (Nucleic acid double helix – Wikipedia Courtesy: Wikimedia Commons)

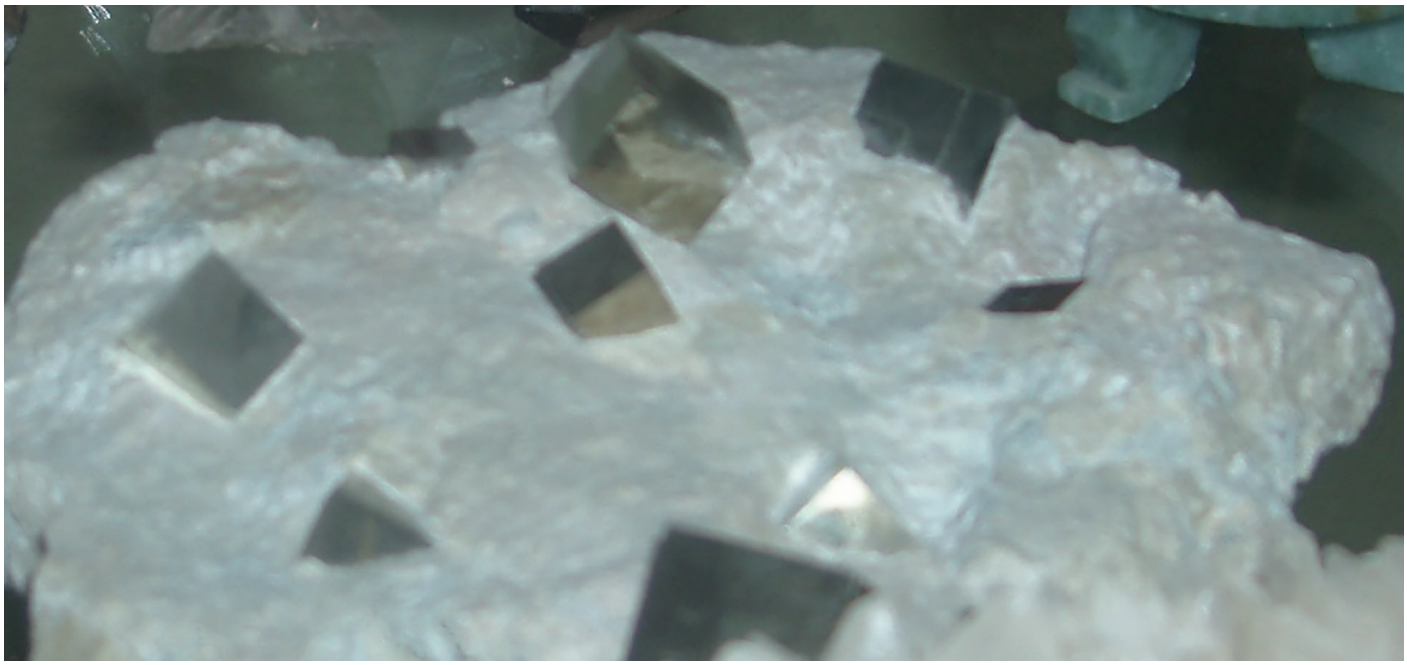

Fig.1.2: Pyrite (FeS_2) cubic crystals showing a highly ordered system of the inorganic world, as a result of «inorganic life». (Courtesy Hans Leuenberger)

of thermodynamics leading to an increase of entropy, respectively, in other words leading to a more chaotic system from Order ➡ Chaos! This latter direction is also called by the human being the **time arrow** since we are currently not able to stop this process of getting older. This fact allows us to estimate the **shelf life** of a food or pharmaceutical product and to label the product with an **expiry date.**

Axiom 3 (Schrödinger): Life = Information = Software = Our Genetic Code.

Axiom 4 (Schrödinger/Prigogine): The human being is a living (super) computer leading to the conclusion that Life = Software and our Body = Hardware (Fig.1.3). Thus, life can be described as a dynamical equilibrium which uses a check and balance mechanism to stay healthy. In case of a disease the biological system is out of balance.

Fig.1.3: Mummy (Mummy – Wikipedia) at the British Museum. (Courtesy: Wikimedia Commons)

Can the mummy of Fig.1.3 be described as the (remains of the) hardware of a formerly living (super) computer being alive as a result of the software stored in the DNA helix = axiom 4? Is it only a coincidence that a computer virus infects the software of a computer hardware, damaging the functionality like a virus infection of a human being, such as the Corona virus?

Axiom 5 (Fröhlich): The evolutionary process uses all existing physical laws of the present (imperfect) standard cosmological model to find a niche for a successful survival of the biological system! Thus, according to Fröhlich (Herbert Fröhlich – Wikipedia) it can be anticipated that there exists between individual cells a nonchemical communication, leading to coherent decisions of the behavior of a living system (organ), similar to a crystalline phase transition in the inorganic world (axiom 2).

Axiom 6 (Zwicky): The evolutionary process uses, also, yet unknown physical laws beyond the present standard cosmological model to find a niche for a successful survival of the biological system!

1.2. What is the Life of the Human Society?

As in case of a human being, the society's health, life, and death depend on framework conditions such as technologies improving quality of life. In addition, the previous six axioms need to be complemented as follows:

Axiom 7 (Mandelbrot): Nature's principle of self-similarity. This principle is an element of the evolutionary process which is linked to systems far from the thermodynamic equilibrium, leading to the fractal non-linear description of the world. Mandelbrot's principle of self-similarity can be found in life sciences of the organic world, but also in the inorganic world with an incredible range of scales from subatomic to galactic size. In this context, it has to be kept in mind that non-linear laws play an essential role.

It makes sense that the achievements of nature are copied by the human being for identifying innovative engineering solutions, which inspired Jack E. Steele to coin the term Bionics (Bionics – Wikipedia) as a synonym for biologically inspired engineering. But this approach does not need to be limited to engineering, but can be extended to philosophy:

Axiom 8 (Steele): Bionic inspired philosophical solutions. In this context, Fig. 1.4 shows the fate of a colony of microbial cells in a closed habitat, which can be interpreted as follows: The growth of microbial cells can be compared to the growth of the world population, which was formerly in a dynamical, but sustainable equi-

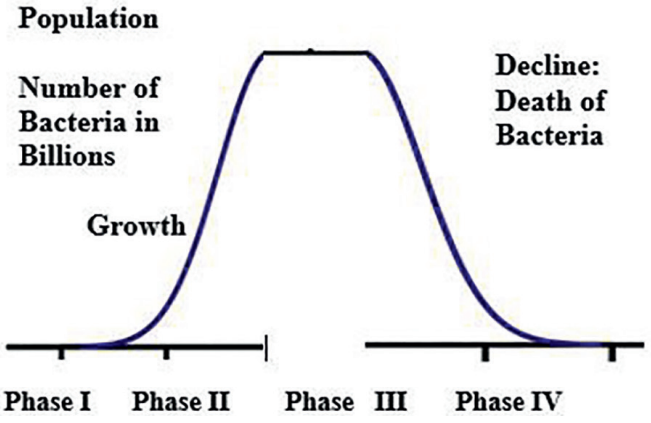

Fig. 1.4: Scheme of growth & decline of a bacteria colony in a closed habitat. (Fig. adapted from **Peleg M, Corradini M G 2011**)

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librium, before the number increased exponentially, exploiting all resources and polluting the environment. This will lead to a stagnation of the further growth of the population of microbial cells, respectively, of mankind. As a result of the pollution and the lack of further resources, the death of the colony is programmed. In case of mankind, i.e., homo sapiens, the lag time of the anatomically modern human is approximately 200,000 years if not 500,000 years. The human growth rate (phase II) is at least exponential. Currently, mankind is in Phase II. It can be safely anticipated that **the time left for mankind till extinction will be an *extremely short fraction* of the experienced lag time.** Thus, the lag time can serve as an estimate of the total time mankind existed on earth. The anthropogenic pollution is illustrated in Fig. 1.5.

Fig. 1.5: Bane of the Caribbean: Pollution beyond air nanoparticles. (Courtesy: **Klaus Eichler,** [Internet] Kandern)

Thus, in order to avoid the human overpopulation of our earth, and for reasons of sustainability, human society needs a birth control as discussed in the conclusions, and/or to adopt the policy of a 1 child family, which was first introduced many years ago in China. Thus, it may be possible to achieve a sustainable solution. In addition, a rigorous interpretation of the book of Prigogine and Sanders leads to

Axiom 9: The human society can be described as a living biological creature consisting of system relevant organs such as the **brain = world pool of scientists, heart = world system of banks** pumping blood (money) to the **muscles = all kind of industry,** to the **lungs = combustion engines,** power plants inhaling O_2 and exhaling CO_2, and to the **digestive system = society needing consumer products,** which creates waste to be recycled or disposed.

1.3. Definition of a healthy and of a sick society

Thus, society's life is in a dynamical equilibrium similar to a human being, using a check and balance mechanism to stay healthy. The check and balance mechanism of the society is part of its culture and of its constitution, adopted. It is important to notice that the evolutionary process in case of a human being and of a healthy society usually follows incremental and peaceful steps. In case of a disease, the society's dynamical equilibrium is out of balance due to failure of the check and balance mechanism. A failure of this mechanism can be provoked by environmental conditions such as lack of food, pollution, lack of money, climate change leading to flooding, drought, large scale wildfires etc. However, a change of environmental conditions can be not only a result of natural disasters such as earthquakes, but also of wars, including trade wars, etc. As history of mankind teaches us, a sick society favors terrorism and is a fertile environment for violent, bloody revolutions leading to collateral damages. Thus, it is important to diagnose and to cure the disease of the society. The cure can be as simple as changing the framework conditions of a society.

Thus, it can be concluded that, as in case of a human being, the society's health, life and death depend on framework conditions, such as technologies, improving quality of human life.

The author's preceding article describes an innovative, aseptic spray freeze-drying process. This process is a safe technology for manufacturing medicinal nanoparticles and from this point of view this technology does not differ from any other medicinal product, as discussed in the following section.

2. The Human Society and Business Ethics in the Pharmaceutical Industry

A medicinal product and process needs the approval of the health authorities such as FDA/EMA to protect the patient/consumer and the manufacturing staff. The approval depends on the scientific integrity and of the integrity of the data submitted to the health authority. The manufacturer of the medicinal product must be committed to the integrity of the science and data in order to enable the health authority to take the right decisions to protect the patient/consumer. This point is generally accepted by the public and by organizations protecting consumers and patients. In this context, scientific integrity and integrity of data are also a must for institutions such as the Swiss Academies of Arts and Sciences providing the Federal Government with data and conclusions enabling optimal governmental decisions. This is also the task of the US agencies (scientificintegrity.pdf (bjs.gov)) delivering statistical information to the US government. In this context, the correct scientific information is a prerequisite, i.e., despite the fact that the agencies are funded by the government, scientific integrity and integrity of data must prevail. The department of the company responsible for the quality of a manufactured product is in the same situation. Thus, the head of the quality department is directly reporting to the CEO of the company and not to the head of the manufacturing department! This concept complies with the constitutional rules of a governmental system with a separation of the powers. However, it has to be kept in mind that the medicinal formulation and manufacturing process is only a small part of the pharmaceutical business and supply chain, discussed in the following section.

2.1. Scientific integrity of developing, manufacturing, distribution (supply chain) and marketing of pharmaceutical products

In the area of pharmaceutical products, the integrity of data regarding the design, the development and the manufacturing process of a new medical product is a prerequisite. The integrity of data is part of the ethical codex of scientists in all disciplines, but is of primary importance regarding research in medicine **(Swiss Academies of Arts and Sciences, 2008).** The implementation and the enforcement **(Bossi, E, 2010)** is a must and should be harmonized globally. This goal is largely achieved in the scientific technical area by the creation and adoption of the rules of **ICH** [Internet], of the **I**nternational **C**ouncil for **H**armonization of Technical Requirements

for Pharmaceuticals for Human Use. In addition, the industrial code of practice embraces a set of enforceable rules and regulations and standard measures in lieu of governmental regulations. Its main purpose is to improve industrial standards by providing low cost and flexible measures of regulations to protect business and customers. Industrial codes of conduct are two types: The first one is mandatory, which means compulsory, enforceable, that protect consumers and is bound by code, and the second one is a voluntary code that is a self-regulated code of practice. In this context, the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) discusses «ethics and compliance in global pharmaceutical industry marketing and promotion»: See the role of «IFPMA and self-regulation» **(Shaw B & Whitney P, 2016)** To be on the safe side, members of IFPMA realized that it is important to strengthen their ethical conduct in adopting their own explicit codes **(Novartis 2020).** It is evident that the harmonization beyond technical requirements is complex and more difficult to realize. Thus, as long as no global harmonization of the ethical codex exists, it is the obligation of each country to establish its own codex **(Salari, P et al. 2013).** It is well known that even an optimal pharmaceutical product needs a marketing effort to be sold, so that the consumer/patient knows the benefits and the risks. In this context, the question arises, to which extent can the ethical codex be enforced regarding marketing and business activities? As a first step it makes sense to extend the tasks of the ICH Council to cover not only technical manufacturing aspects but, in addition, **topics of ethics and compliance in global pharmaceutical industry regarding marketing and promotion.**

2.2. Scientific integrity beyond medicinal products

In case of registered pharmaceutical products, the data integrity is a prerequisite that the scientific technical data cannot be manipulated for marketing and business purposes. However, in case of other products on the market, the scientific integrity of data is not mandatory, leaving more freedom of interpretation and manipulation.

In this context, it is a must to be aware that sophisticated tools exist on how to manipulate the consumer. This point is discussed in the article «Der heimliche Verführer (secret pretender)» by Marc Tribelhorn in the Neue Zürcher Zeitung **(Tribelhorn M 2018).** He describes the life and career of Edward Bernays (**Edward Bernays,** Wikipedia) as the master of manipulation. Citing Marc Tribelhorn (translated): «Edward Bernays advised several US presidents, promoted products such as Lucky Strike, and even provoked a military coup (in South America). If there were a ranking of the most dazzling professions, they would certainly occupy a top position: **Public Relations (PR) consultants.** It has to be noted that the term PR has a more positive connotation than the term **lobbyism,** which is nothing else than **marketing a product, an idea or a policy.** The reputation of PR consultants is dubious and their influence is mythical. In recent decades, **public relations have grown into a multibillion-dollar business worldwide, while quality journalism has been shrinking.** The messages spread by stormy mercenaries of business and politics are meant to **guide** what **we consume,** who **we vote for,** or **what we think!** Facts and truth are elastic and purely matter of interpretation or consideration, it is often claimed.»

In this context, it is a must that the source of financial contributions of PR activities are disclosed. To avoid that truth becomes «elastic», **a rigorous interpretation of scientific integrity and integrity of data is a prerequisite.**

In addition, in order to comply with scientific integrity, it is important to carefully choose the wording to avoid any misinterpretation which may raise anger or hatred regarding a topic, a nation or a race. A typical example is the so-called Spanish Flu of 1918 (**Spanish flu,** Wikipedia) In this context, the use of the wording 1918 flu pandemic or H1N1 influenza, or a virus of unknown origin is appropriate. **The sophisticated tools for marketing and for manipulating people prompt the question, whether there exist legal measures to protect the patient or the consumer in general?**

3. Ethical Issues and Legal Framework

3.1. Religion and Ethics

Religion should be respected and everybody should be free to make his/her choice, commonly known as freedom of religion. Thus, as a result of a personal evolutionary process, people have a chance to get enlightened, enjoying incredible happiness and health. In this context, it is important to notice that common denominator of all religions is an ethical code of conduct. Such a conduct can be essentially realized by implementing the corresponding exemplary rules such as the **Ten Commandments** (Wikipedia). The rigorous application of the Ten Commandments includes the rule that nobody should kill another person. This fact prompts the following questions:

1) Should we support the «death penalty» or should we support the **International Federation of Human Rights** with the following ten questions (10 Questions on the Death Penalty (fidh.org)?

2) Who can be in favor for supporting the religious wars of the past?

The numerous **Crusades** (Wikipedia) that started in the 11th century, led to catastrophic damages. The term **«Holy War»** (Wikipedia) was coined by Bunyan and is still used today by the religious parties involved. The religious war between the Protestant and Catholic Church in the **Thirty Years' War** (Wikipedia) from 1618–1648 led to a death toll of 8 million people in Europe. This number needs to be compared with the **list of countries by population in 1600** (Wikipedia). Thus, it can be concluded that during the Thirty Years War more than the population of the Habsburg Monarchy lost their lives.

3) Who is ready to support priests and politicians preaching revenge and hatred?

4) What are the measures needed to detect and eliminate double standards, double language, hypocritical behavior, mental confusion, premeditation, lack of truthful information, and lack of transparency?

5) What are the driving forces: Is it money or power?

During the Thirty Years War, the **Swiss nobility** (Wikipedia) made a lot of money by providing **Swiss mercenaries** (Wikipedia) to fight on the side of the Catholic Habsburg troupes such as Heinrich von Fleckenstein **(Historical Dictionary of Switzerland),** catholic, and Johann Rudolf Werdmüller **(Hostettler U, 1991),** a protestant supporting the protestant Swedish troupes. Later, after the **Swiss Peasant War** (Wikipedia), Werdmüller became catholic and provided the Habsburg Monarchy with Swiss mercenaries. The human trafficking with Swiss mercenaries was a legal business, not contested by the catholic or protestant church. At that time, religious freedom was not granted. Thus, churches prosecuted dissenters, a policy having the same roots as the crusades. Thus, many **Anabaptists** (Wikipedia), such as the Mennonites and Amish people, found a new homeland in the United States, far from Switzerland **(Leuenberger H, 2019b, 2020).**

Only after the adoption of the **Swiss Federal Constitution** (Wikipedia) of 1848 this unethical human trafficking of mercenaries

was completely prohibited. Switzerland was, in the 19th century, the only European country, which adopted the **Constitution of the United States** (Wikipedia) of 1787 with the separation of powers **and adapted a Swiss version** for the benefit of the federation of cantons (states) with different cultures, languages and religions.

However, the religions cannot be blamed that their ethical conduct is not rigorously implemented. This statement refers to hypocritical politicians and priests tolerating prosecution of the Jews and people of color and/or being actively involved in hiding scandals.

Unfortunately, the business of powerful elite and their disciples/sycophants prevailed and still prevails over the ethical conduct of the religion.

In this context, the statement published in 1930 by Albert Einstein on the topic «Religion and Science» is not surprising and **complies with a lifestyle based on scientific integrity and on integrity of data:** «A contemporary has said, not unjustly, that in this materialistic age of ours the serious scientific workers are the only profoundly religious people». In other words, scientists, whose work is strictly based on scientific integrity and integrity of data, follow these guidelines more precisely, religiously, than church adherents abide theirs.

3.2. Basic guidelines of business ethics

Business ethics (Investopedia) is related to the implementation of appropriate business policies and practices that include corporate governance, insider trading, bribery, discrimination, as well as social and fiduciary responsibilities, and more. **In principle, *it is the law* which provides the basic guideline(s), *but does not go into details* regarding its implementation or *to enforce an ethical conduct.*** As an example, an attorney in Florida is not obliged to inform about the opposing party's right to consult his or her attorney to review the contract to be signed. In addition, the attorney is not obliged to provide a document to be signed by the opposing party, stating that he or she explicitly renounces to consult his or her own attorney. Thus, in a worst-case scenario, the opposing party will realize only later that it was wrong signing such an unfair contract, which may lead to an uphill battle and to an expensive and unsuccessful lawsuit. In the optimal case of ethical conduct, the **collateral damage of such an unfair contract could be avoided.** Ethics tend to deal with what is right. However, as mentioned in the guidelines of Florida real estate continuing education, ***an act can be legal, but unethical.*** Good ethical practices have to do with trustworthiness, honesty and competence.

Depending on the specific issue the collateral damage can lead to incredible and spectacular cases of **legal business practices of dubious ethics** (Investopedia): One of 14 cases reported is summarized: «Bryan P. Marsal, Co-CEO of Alvarez & Marsal, CEO of Lehman Brothers oversaw the proceedings for the largest bankruptcy in history, the Lehman Brothers bankruptcy filing in September 2008. During a presentation to a group of business people, he was asked to comment about the status of ethics in business. His answer, 'there are none'. Marsal's response put a spotlight on the legal yet unsavory behaviors that permeated the financial crisis and led to some big reforms, particularly through the Dodd-Frank Act of 2010».

In other words, a healthy society needs a legal framework mirroring the necessary healthy ethical codex. In such a case, it must be possible to enforce an ethical conduct.

This result prompts the need for a worldwide harmonization of the legal and ethical framework for the benefit of mankind. Such a harmonization is a very challenging task since, e.g., it would first be necessary to harmonize the existing legal framework in the United States, which differs from state to state.

It has to be kept in mind, **that we can travel to the moon and soon beyond, but we are not able to predict the next financial crisis or the next stock market bubble.** Why, is it a question of research funding? We just know that that the **volume of productive capital** of the real economy **is small** compared to the **volume of speculative money in circulation.** In this context, the economic world is compared to the universe, which according to the second law of thermodynamics will in the end suffer from the so called «heat death». In this economic model heat is equivalent to capital. Hence, the question arises, whether the heat or capital death **(Avakian A et al, 2014)** of the economic universe is inevitable? What are the consequences of the death of capital in the world market? Such a problem can only be resolved in the framework of a **worldwide**

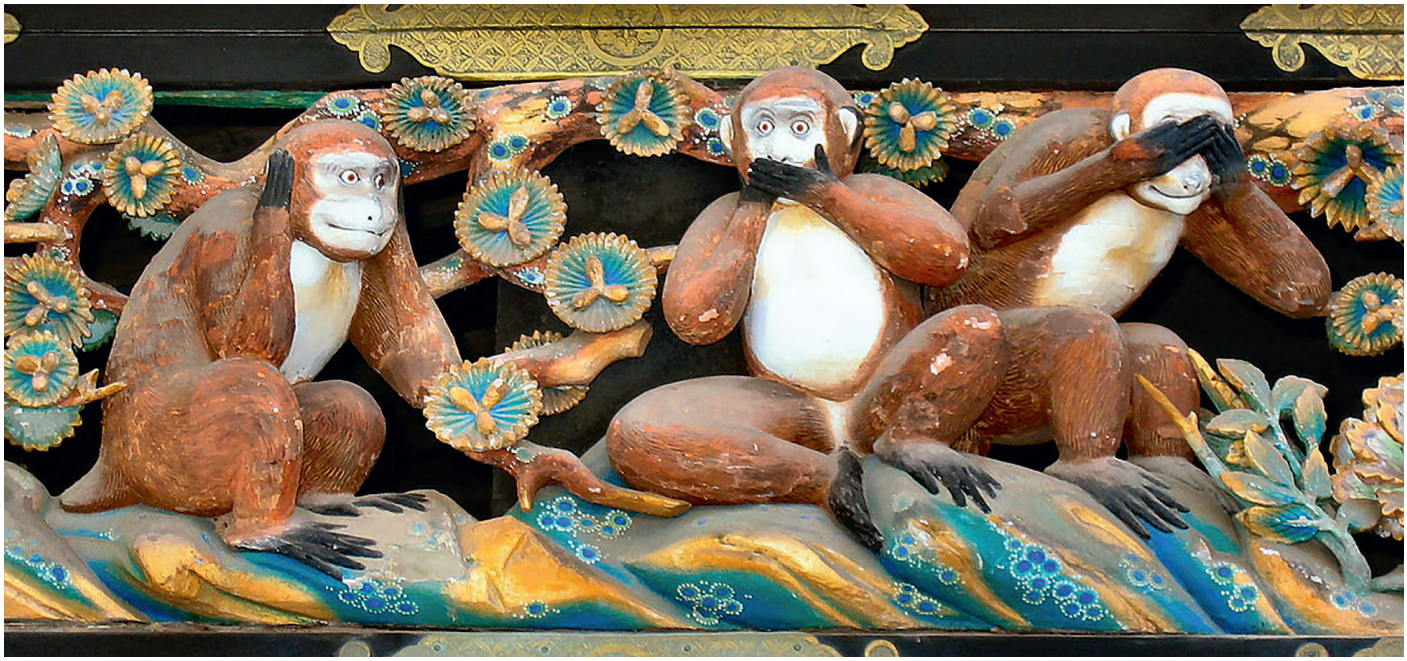

Fig.3.2: The Three Wise Monkeys. (Courtesy: Wikipedia Commons)

cooperation for realizing a win-win situation of all central banks involved, since according to our model previously derived the world system of banks is the heart of **the world society** (axiom 9) **pumping blood (money) to the economy and keeping the society in a healthy state.**

In consequence, **finance and service sectors need special attention** to avoid further financial crises leading to worldwide economic disasters due to the lack of compliance with an ethical codex. Shall we accept this situation by burying our head in the sand like an ostrich? Are we as a **Homo sapient,** better off closing our eyes, not listening and not discussing this problem like the three wise monkeys (Fig. 3.2)? Is such a behavior wise?

4. Conclusions Beyond Business Ethics in the Pharmaceutical Industry

Society can be deemed to be as a biological living being. This term was defined as world society but to some extent, this concept is independent of scale and can be applied also for a community, company or nation. This concept not only allows exploring the necessary prerequisites for securing the public acceptance of medicinal nanoparticles **(Leuenberger 2021)** and pharmaceutical products in general, but can be extended to all technologies that improve quality of human life. For this purpose, the following three additional axioms are required.

Axiom 10: Common denominator of all Religions = Ethical Codex.
Axiom 11: Common denominator of Marketing and Politics = Trustworthy Communication.
Axiom 12: Common denominator of all Trustworthy Sciences = Scientific Integrity.

The 12 axioms support the idea that all sciences converge and are leading to an end of the schism between natural sciences and humanities as already mentioned in the publication «What is Life?» **(Leuenberger, 2019).**

Trustworthy science is teaching us that solutions depend on the framework conditions leading to the following conclusions:

- Successful negotiations and conflict management is a political issue.
- Trustworthy politics need to be based on scientific and data integrity.
- The legal framework needs to concur with the ethical codex.
- Law and Ethical Conduct need to be enforceable.
- The optimization of the framework is not a national but a global issue and the ICH, International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use, needs to be complemented by an
- International Council for Harmonization of Laws and Ethical Conduct.

It is evident that, for securing the survival of mankind, additional measures are needed.

As an example, the **horseshoe crab** (Wikipedia), existing for more than **400 million years,** is still living in peace with its environment. In comparison, mankind as **homo sapiens** (Wikipedia) has existed for only **200–400 thousand years!**

Horseshoe crabs (Horseshoe crab – Wikipedia) are considered as living fossils and their blood has a blue color (of higher royal descent?) since the oxygen carrying hemocyanin (instead of the human hemoglobin) contains copper instead of iron.

To extend the time of the human being on earth it is urgent to establish the necessary framework conditions being supported by the world community of the United Nations.

In this context, the challenges are manifold and solutions need to be engineered by a **Think Tank of the United Nations.**

- For reducing the problem of the overpopulation of the earth: A worldwide birth control is a prerequisite which was known

Fig.4.1: Rendezvous with coastal Horseshoe crabs. (Wikimedia Commons)

already at the time of the high culture of ancient Egypt. In this context, it is important that the society provides the means that the elderly population does not need to be financially supported by their children. For this purpose, the economic systems worldwide need to be strengthened leading to the conclusion that the United Nations must provide a

- **Marshall Plan** (Wikipedia), for countries suffering from economic problems and to avoid a mass migration of people looking for a better life. Thus, there is
- **No necessity to build walls** between nations and a worldwide new Marshall Plan will boost the world economy, after suffering from the Corona pandemic.
- In addition, the world economy needs a **Green Deal** as a powerful **engine** to avoid natural catastrophic events as a result of the climatic change, **boosting innovations** as a result of new economic and research avenues.
- **Trade wars and sanctions** are not part of a **free-market policy** leading to a «win-win» situation of all parties involved.
- In general **wars are part of the Law of the Jungle leading to the extinction of mankind.**
- **Trust** among all parties **needs to be cultivated and validated** among other issues by agreeing to the **policy of an open sky.**
- Such radical rethinking needs to be supported by powerful tools of **Negotiations Engineering and Conflict Management** leading to the application of
- **Science Diplomacy** (Wikipedia) instead of exercising the **Law of the Jungle** (Wikipedia) that the strongest nation is dictating what has to be done. In this context, it is evident that each society should have the freedom of adopting its own political system without being forced by a third party. At the same time, it can be anticipated that every country could agree on the following point that
- In the optimal case politics at communal, county, state, national and international levels are based on **scientific integrity (Swiss Academies of Arts and Sciences, 2008)** and on an ehtical conduct.
- This is a very demanding issue regarding politicians in leading positions having the skills and knowledge to do their job for finding a «win-win» solution for all parties involved.
- The ancient Greek society significantly coined the term **aristocracy** (Wikipedia), meaning rule of the best. In this context, an approach based on scientific integrity and integrity of data will be helpful for choosing the best politicians to be in charge.
- Thus, it is up to the society to define the skills and the curriculum of his, her scientific education, needed to fulfil the job of a leading politician.
- It is necessary to say that a politician in charge needs to have the skills of a manager and a high moral and social competence.
- Tellingly, the founding fathers of the Swiss Constitution of 1848 realized that an optimal educational system, in the spirits of **Jean-Jacques Rousseau** (Wikipedia) and **Johann-Heinrich Pestalozzi** (Wikipedia), is the prerequisite for establishing a society being able to adopt a functioning democratic system.
- In such a situation, the individual human being is able to make the informed choice regarding political programs, which can be trusted by the society and by the politicians in charge. Hence, in the optimal case the individual is able to make the right choice

Fig.5.1: Lonely she-wolf killed by a pack of wolves while entering the pack's territory in the Grisons, Switzerland on January 20, 2021. What was the reason: Overpopulation of wolves or entering unwelcomed into others' territory? (Courtesy: Governmental Office of Hunting and Fishery of the Canton of Grisons)

and does not need any guidance to identify what is the win-win solution for all partners involved.
- However, it is not the goal of Switzerland, as it respects the **freedom of culture,** to export its political and cultural system.
- Last but not least, it must be kept in mind that the **educational system is of primary importance for the society.**

5. Summary and Outlook

Ethical codex exists in science, but should be harmonized globally. In the area of pharmaceutics, the scientific technical harmonization of regulations is largely achieved (ICH) to protect business and customers. However, harmonization beyond technical requirements (especially for marketing and business activities) is complex and difficult to realize globally. Thus, it may be necessary to first establish a national codex. As a matter-of-fact, sophisticated tools exist to manipulate the consumer. After mentioning that, history is teaching us that business has even prevailed in the ethical conduct of religion. Unfortunately, existing business policies and practices do not go into details enough regarding the implementation and enforcement of an ethical conduct. In conclusion, six additional axioms are proposed to better understand our world. In particular, the ethical conduct must be the common denominator of all religions, of marketing, politics, and trustworthy sciences. The natural sciences and humanities should converge. Several framework conditions are proposed (like the set-up of an International Council of Harmonization of Laws and Ethical Conduct) which should secure the survival of mankind! In this context, the Law of the Jungle, which served mankind throughout its existence has to be abandoned. This demand is not only based on our ethical codex but is based on the limited size of the jungle and available resources:

The limited size (habitat) is also a problem of the recolonization of wolves in the Swiss alpine forests of the Canton Grisons. On January 20, 2021, a single she-wolf trying (by accident?) to enter another wolf territory was killed by the pack of wolves defending the habitat (Fig.5.1).

This event prompts the request to officially regulate the number of wolves to prevent an overpopulation and to avoid that wolves need to kill each other.

The situation that a lonely wolf enters by accident the forbidden territory can be compared to a disturbed person entering the property of an owner who was told, to be on the safe side, to «shoot first and to ask later», not vice versa. From the business point of view the pack of wolves defending its territory can be also compared to a drug gang, which does not allow for a member of another gang to expand business goals.

This event also shows the astonishing similarity of behaviour between man and wolf, which will, in the end, **lead to the extinction of man and wolf!**

Thus, the human being needs not only to **adopt a strict birth control to escape the fate of Fig.1.4 but needs to explore new avenues, so that mankind will survive.**

Among other measures for reaching this goal is to boost postgraduate courses such as «Negotiations Engineering & Conflict Management» at the Federal Institute of Technology in Zurich, which is discussed in the contribution by Nora Meier & Michael Ambühl, **Chair of Negotiation and Conflict Management,** in this SWISS PHARMA issue 43 (2021) No.4.

The origin of a conflict can be as simple as a misunderstanding, a lack of trust, a lack of transparency, a lack of eye-level communication in a hierarchical system, a lack of a harmonized legal framework, a lack of emotional intelligence and control, a simple power play, and in the worst-case scenario – quoting Schiller's **William Tell (play)** (Wikipedia) «The most pious can't stay in peace if it does not please his evil neighbor».

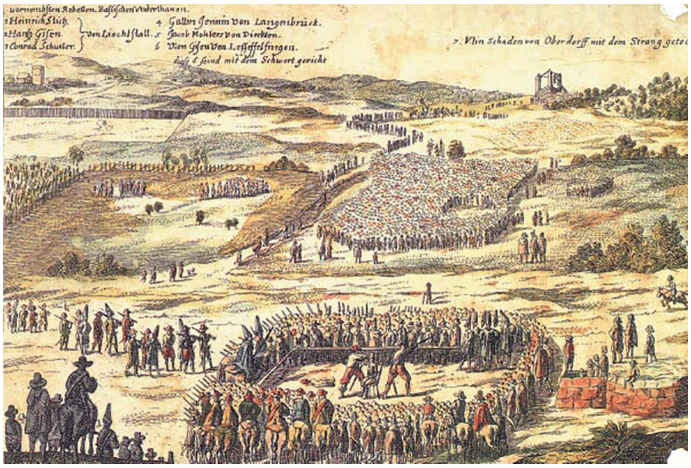

Fig.5.2: Shows trial and execution of the Basel-Land rebels in 1653. These events, dating back more than 200 years ago, are, today, largely forgotten and were not part of «Die Schweizer» of **SFR, Medienportal 2013.** (Courtesy: Wikimedia Commons)

Lack of trust is a difficult issue: The Canton of Basel was split into two half-cantons in 1833 with the provision to reunite later, if the population agrees. All attempts of a reunification failed however, a partnership was established to resolve problems of common interest such as the financial support of the University of Basel and problems regarding hospital planning for the population living in both half-cantons (Basel-City, and Basel-Land).

Evidently, society has a life and a consciousness, being able to recall unpleasant events dating back roughly 200 years.

In this context, in the 19th century (around 1840), the population recalled the events which happened during the peasant war of 1653 **(Hostettler U, 1991, Leuenberger H, 2019b, 2020)** leading to the public execution of the rebels by the Mayor of the City of Basel, **Johann Rudolf Wettstein** (Johann Rudolf Wettstein – Wikipedia) (Fig.5.2).

The society's consciousness 200 years ago, recalling the events of the peasant war in 1653, however, helped to adopt the Swiss Federal Constitution of 1848, leading to an end of numerous peasant revolts since the time of **William Tell** (Wikipedia) and of the **Rütlischwur** (Wikipedia) in 1291, considered as the date of the foundation of Switzerland.

A comprehensive study of the origin and consequences of smaller and larger peasant uprisings is still missing to understand the execution of Hans Waldmann **(SFR, Medienportal 2013),** mayor of Zürich, the confidential message of Niklaus von der Flüe **(SFR, Medienportal 2013),** and the **Appenzell wars** (Wikipedia).

The author of this article believes, and respectfully assumes, that Niklaus von der Flüe proposed in his confidential message not to forbid the Lucerne carnival and not to punish the peasants who criticized the governments during the week of the **Carnival** (Wikipedia) since it is an advantage for the governments to know the real problems of the peasants unrest, to avoid revolts **(Leuenberger H, 2019b, 2020).** The tradition to **celebrate** – during the days of Carnival – **freedom of speech being masked** is deeply rooted **in** the **Swiss society** and **its soul.** The Schnitzelbank singer is a bard **(Car-**

nival of Basel – Wikipedia) that sings **satirical verses** about current events in Basel or from around the world.

Niklaus von der Flüe's message **(Leuenberger H, 2019b)** was evidently related to the Lucerne Carnival (Fastnacht), being not recorded in the **Stanser Verkommnis** (Wikipedia) and was kept confidential since 1481 for obvious reasons. As a result, the carnival in Switzerland could and can also today be compared to a **theatre production with masked actors** having the **right to criticize** the government and events **without being prosecuted for defamation.**

Trust among the partners of the first Swiss Confederation was a prerequisite and needed, in addition, soft skills in the area of communication, negotiation and conflict management.

Trust is inherently fragile and must be preserved. In this context, the parties need to agree about measures to control that a contract is executed. In addition, **the legal framework must comply with the ethical codex to avoid that a contract being signed is broken** following the Machiavellian advice «If people were all good, this proposal would not be good; but since they are bad and would not keep the given word either, you have no reason to keep it toward them» **(Suter A, 1997).**

The author of this article regrets that during his studies at the University of Basel he didn't enroll in specific courses to be trained in soft skills such as to represent a point of view in the best possible way, to carefully study how people communicate knowing the fundamentals of transactional analysis as described in the book of Harris **I'm OK – You're OK** (Wikipedia) as a method for solving problems in life. In this context, I thank Sandoz (today, Novartis) that I was invited to enroll in management courses covering such topics.

Thus, optimal skills in the area of communication/negotiation lead to a «win-win» solution of all partners involved.

In the current world situation, the implementation of **science diplomacy** (Wikipedia), **negotiations engineering, conflict management,** and so on, **based on scientific integrity and integrity of data, is an absolute must for the survival of mankind.**

The emerging disciplines of computational science and artificial intelligence (AI) will lead to additional challenges. In this context, ethical issues play a very important role leading, as an example, to the «Declaration on the ethics of brain-computer interfaces and augment intelligence» by **Zeng Y et al (2021).** Brain-computer interfaces (BCIs) are a transdisciplinary field of, but not limited to, brain science and artificial intelligence. This seminal publication by Zeng et al (Chinese Academy of Sciences) is remarkable, promoting the chance that a world-wide agreement is feasible.

In the publication «Conflict Management and Negotiation» **Shargh et al (2013)** defines how managers in an organization can efficiently manage conflicts and how good managers optimally handle negotiations. The authors from Iran show that a conflict is not necessarily a negative phenomenon and an average level of conflict could raise the performance level. If ethical issues are observed, a sustainable solution of a conflict can be reached.

Needless to say, the convergence of all sciences may trigger a new university educational reform, which will include much more. This latter point will be discussed in detail by Marcel Van De Voorde in this SWISS PHARMA issue 43 (2021) No.4

Thus, future university graduates will be more flexible, following nature's principle that flexibility is the key factor in a fast-changing environment. A major role will play transdisciplinary research being supported by the Swiss Academies offering the **td-net online course,** which is described in detail (http://www.transdisciplinarity.ch/en/td-net/Kompetenzvermittlung/tdMOOC.html), in the February 2021 Newsletter. On the other hand, it has to be kept in mind that transdisciplinary research is not the only element, but additional measures are needed for an optimal new university educational system as discussed by Marcel Van De Voorde. In this context, the question arises, whether the Swiss Pharmacy Curriculum (article by G. Borchard, Ch. Moll) and the Swiss dual educational system at the University of Applied Sciences of Northwestern Switzerland (article by G. Imanidis), both contributions to be published in this SWISS PHARMA issue 43 (2021) No.4, may serve as a first step of such a new model since the graduates are educated as «generalists» and are able to fulfill a broad range of professional activities?

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Studies of Pharmaceutical Sciences in Switzerland

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Key words: pharmaceutical study programs; health care system; pharmaceutical sciences; pharmaceutical industry; pharmaceutical sciences

Academic training in pharmaceutical sciences in Switzerland is oriented towards the interdisciplinary character of the different facets of the profession of a pharmacist as a public health expert as well as a scientist. As highly skilled experts, graduates have a major impact on health care, and the scientific and economic landscape in Switzerland and beyond. Academic curricula in pharmaceutical sciences are supported by excellence in research and are constantly adapted to face the challenges of modern society. Switzerland and her pharmacists are well-prepared for these challenges – now and in the future.

The landscape of pharmaceutical sciences in Switzerland

It is no secret that pharmaceutical sciences play a big role in the Swiss research, economic, and health care sectors. Switzerland offers several regional clusters of academic institutions and pharma/biotech industries from the Basel Area for Life Sciences (1) in the North, the Greater Zurich Area (2), to the Greater Geneva Berne Area (3), together with BioAlps (4) merging clusters in the center and West into Switzerland's Health Valley (5). The success of clustering of academic institutions, start-up companies with the necessary supporting network, and established companies is also positively impacting innovation: the European Patent Office received almost 1'000 Swiss patent applications per million inhabitants in 2019, which is significantly higher than for Switzerland's neighbors Germany (334) and France (150), as well as for the USA (140). In 2020, Switzerland was ranked on top of the Global Innovation Index (6) again, and Swiss pharmaceutical research and development activities did contribute significantly to this success.

In 2018, the workforce of Swiss pharma and biotech companies was 135'000 employees (7), 15'000 of which in privately held and publicly traded biotech companies (8). In 2018, Swiss pharma and biotech companies were producing pharmaceuticals, diagnostics, and vitamins worth CHF 90 billion annually (9). More than one third of Swiss exports are being produced by the pharmaceutical industry.

Nevertheless, the Swiss health care system has to cope with severe drug shortages, which affected almost 1000 drugs (originator and generics alike) in December 2019 (10). In 2020, shortages mostly concerned essential antibiotics, analgesics, anticancer drugs and vaccines (11). Drug shortages may be the result of an unexpected increase in demand in Switzerland or in other countries, problems in the manufacture or procurement of the active ingredients or an excipient, or delays in the regulatory process (inspections of the manufacturing site or the drug). Not only in a global pandemic this signifies the importance of maintaining production facilities for essential drugs and skilled personnel to satisfy demand.

On the drug distribution end, there are 1819 public pharmacies in Switzerland, employing 22'212 persons serving 314'533 patients every day, amounting to 94 million patient contacts per year (11). Compared to the rest of Europe, the density of pharmacies is relatively low with 21 pharmacies per 100'000 inhabitants, as the European mean is 32 pharmacies per 100'000 population. At the same time, in 2018 merely 6.8% of all health care costs and only 3.2% of costs reimbursed by health insurances were incurred by public pharmacies. This is due to the fact that the majority of drugs is applied in hospitals, and about the same number of drugs is dispensed in the cabinets of general practitioners in some cantons as are in all Swiss pharmacies (11).

Of the 5'800 pharmacists currently registered in Switzerland and active in public pharmacies, many obtained their diploma abroad. As an example, in 2020, the number of Swiss federal pharmacy diplomas (184) attributed to graduates of Swiss universities was lower than foreign diplomas were recognized (217) (12), which shows that Switzerland relies on the import of skilled labor also in this part of the health care sector.

Studies in pharmaceutical sciences in Switzerland

According to recent surveys, Swiss universities and especially their Schools of Pharmaceutical Sciences are very competitive and rank among the top 50 worldwide (2020: Basel 38, Zürich 15, Geneva 30, www.topuniversities.com). This position is based on the understanding of Pharmaceutical Sciences as the dichotomy of research and training in fundamental and clinical sciences, as only excellence in research does bode for excellence in training of students.

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Academic training in pharmacy and pharmaceutical sciences in Switzerland has been offered until recently at the cantonal universities of Basel and Geneva, and the Swiss Federal Institute of Technology (ETH) in Zürich. The Universities of Neuchâtel and Lausanne, in cooperation with the Geneva school, are offering the first Bachelor year, as well. Responding to the rising demand of qualified pharmacists as has been outlined above, the School of Pharmacy at the University of Berne has extended its curriculum from the first two Bachelor years to a full 5-year curriculum and has become the 4th academic institution for the training of pharmacists in Switzerland.

All four academic institutions are unique: while the Department of Pharmaceutical Sciences at Basel is part of a cantonal university, the Institute of Pharmaceutical Sciences of ETH Zürich is a federal institution. Geneva's Institute of Pharmaceutical Sciences of Western Switzerland (ISPSO) is based in a cantonal university, however, covers the entire area of French-speaking Switzerland. The School of Pharmacy at the University of Berne is no exception, as its program is organized by two faculties. As a consequence of the interdisciplinary character of the pharmacist's profession, cooperation between pharmaceutical and medical sciences at all universities have been strong in both training and research. However, due to the strong presence of medical sciences at Berne, while the Bachelor program in pharmaceutical sciences is organized by the Department of Chemistry, Biochemistry and Pharmacy, the Master phase is under the auspices of the Faculty of Medicine.

The program consists of a 3-years Bachelor and a 2-years Master phase, which includes a Master's thesis project. Curricula in pharmacy have to undergo a process of accreditation by an independent organisation (Swiss Agency of Accreditation and Quality Assurance, AAQ) every seven years. Students graduate with a Master of Science degree (MSc) from their alma mater. To become a licensed pharmacist, graduates have to pass in addition the Swiss federal exam in pharmacy, which is organized at the national level.

Through a change of the federal Medical Professions Act (13) in January 2019 following the report of a federal commission to explore the role of pharmacists and pharmacies in the Swiss health care system (14), pharmacists were given more competencies, including the dispensing of prescription drugs and drugs for common diseases without prior consultation of a medical doctor. In addition, vaccination in Swiss public pharmacies by specifically trained pharmacists was already introduced in 2015. Today, vaccinations are applied in 60% of all pharmacies in 23 out of 26 cantons, and one third of all pharmacists has received training in injection techniques (subcutaneous, intramuscular), blood sampling, and basic resuscitation skills. Needless to mention that under the current pandemic conditions, pharmacists are well placed to contribute to antigen testing and will be involved in COVID-19 vaccination campaigns. Obviously, the traditional as well as these new activities of pharmacists require a close cooperation and coordination with other professionals such as general practitioners, specialists, hospitals and nurses as partners in the health care system.

The contents of the pharmacy curriculum offered at all Swiss universities is formally based on the common «Catalogue of learning objectives» (15). However, within the general framework given by the catalogue, each school organizes the structure and contents of their programs individually. The teaching philosophy in pharmaceutical sciences is based on the dichotomy of fundamental and clinical pharmaceutical sciences, and the conviction that excellence in teaching is determined by excellence in scientific research. Therefore, the respective research activities of the different Schools influence to some extent the contents of their respective curricula.

The catalogue lists the general topics to be taught to pharmacy students and defines the required level of theoretical and practical knowledge for each subject. A commentary to the catalogue is currently drafted by the APhWS («Ausbildung Pharmazeutische Wissenschaften Schweiz») (16) committee under the auspices of the Swiss Academy of Pharmaceutical Sciences (SAPhS). This commentary further specifies the subjects to be integrated into the curricula and will become mandatory for the academic institutions. The Bachelor phase of the first three years of study provides a solid education in basic sciences, medical sciences and pharmaceutical sciences. Teaching methods include traditional ex cathedra courses, seminars and practical lab courses, but also increasingly advanced problem-oriented methods such as e-learning, inversed classrooms and simulations. The Master's phase includes one year of specialization in pharmaceutical sciences, and a second year is dedicated to at least 20 weeks of research work for the Master's thesis, and additionally internships in a public pharmacy and possibly in a hospital. It is completed by specific courses necessary to acquire the many skills of the profession of a pharmacist.

1. Training of undergraduates in pharmaceutical sciences is facing three challenges, which shall be illustrated by the example of the Section of Pharmaceutical Sciences at the University of Geneva, however, is generally applicable to the other Swiss Schools of Pharmacy. The pharmacist profession is very attractive, especially for female students (e.g., 78.5% female, 21.5% male students in Geneva). Student numbers at Geneva's School have constantly and very significantly increased by 41% over the last ten years, from 321 in 2011 to 550 in 2020. At the same time, the number of students in the other Sections of the Faculty of Sciences, of which the School is an integral part, has risen by about 15% (2331 to 2864).

2. At Geneva, the curriculum consists of 2349 hours of lectures and seminars, and 1098 hours of practical courses, which makes it a rather «crowded» program. In addition, several internships and the Master's thesis project complete the student training. Adding on new subjects like injection techniques into this already crowded curriculum is very challenging. Rational decisions must be taken which subjects should remain in the basic training, and which may be taught in postgraduate continuing education.

3. The profession of a pharmacist in all its facets is based on a rigorous scientific training in fundamental sciences, which is constantly updated according to the scientific progress. On the other hand, skills and expertise in clinical sciences, including interprofessional training and patient contacts are needed likewise to fulfill the role society is expecting from pharmacists. To strike the right balance for time spent between fundamental and clinical sciences is a constant point of discussion in the reform of curricula in pharmaceutical sciences.

In Switzerland, unemployment among pharmacists is virtually absent. According to internal statistics (2019), about 60% of Geneva pharmacy graduates (78.5% female, 21.5% male) work (77% full-time) in public pharmacies, 13% in hospitals, about 8% in the pharmaceutical industry, 7% in academic institutions (43% PhD students, 38% staff, 19% faculty), 1% in federal and cantonal administration, 0.3% in humanitarian organizations, and 10% in other sectors. In addition, over the next few years there will be an increased demand for licensed pharmacists to cushion a wave of retirements and to cope with extended opening hours introduced recently. Furthermore, service offers such as more competences and, for example, extended opening hours are an important reason why more pharmacists should be trained.

In addition to the «classical» curriculum in pharmaceutical sciences, the Schools in Basel, Zürich and Geneva have created courses that are more targeted toward the research and industrial aspects of pharmaceutical sciences.

The School of Pharmacy at the University of Basel, in cooperation with the Department of Biomedicine, the local life science industry, the Swiss Centre for Applied Human Toxicology (SCAHT) and regulatory authorities created the 2-year Master course in Drug Sciences, which prepares its students for a future career in industrial or academic research, product development or in a regulatory agency.

Already in 2007, the Institute of Pharmaceutical Sciences at ETH Zürich introduced the Master's program in Medicinal and Industrial Pharmaceutical Sciences (MIPS). After being revised and renamed MSc in Pharmaceutical Sciences in 2017, the program prepares students for a career in industry and for PhD studies in pharmaceutical or (bio)medical research.

The Section of Pharmaceutical Sciences at the University of Geneva, in coordination with the university's faculty of medicine is offering a Master in Biomedical Sciences, which is building upon the Bachelor program in the same discipline managed by the faculty of medicine. The aim of the program is to prepare students for a career in industrial drug and medical device development. It also opens up opportunities in the biotechnology or food industry as well as in today's genetics and human genomics.

Graduates of all programs presented here are not licensed pharmacists and may complete their training by a successive PhD thesis.

In addition to cantonal universities and federal institutes of technology in Zürich (ETHZ) and Lausanne (EPFL), universities of applied sciences (UAS) enrich the academic landscape in Switzerland. They are «equivalent to but different from» (fhschweiz.ch) other types of higher-education institutions, preparing their students through practice-oriented programs as well as through application-oriented research and development activities. UAS training is aimed at a high level of employability in the Swiss workplace and beyond, and is completed by either a Bachelor's or highly specialized Master's degree. Research in the UAS area is aimed at delivering solutions to practical issues in industry. Thus, teaching at UAS is guided by the principle «Gained in practice, for use in practice» (fhschweiz.ch).

The UAS in Northwestern Switzerland close to Basel offers an 18-months Master's program in Pharmatechnology. The program can be followed also part-time, extending the duration to a maximum of 3 years. Its aim is to enable students to contribute to R&D and manufacturing in the pharmaceutical and biotech industry. A Master's thesis project of eight months, usually carried out on the site of a pharmaceutical company, completes the training. Graduates are qualified to pursue a PhD thesis successively.

Postgraduate studies in pharmaceutical sciences in Switzerland

Public pharmacies are regarded as a low threshold entry into the Swiss health care system, with pharmacists having a crucial role not only in the dispensing of medicines and in giving professional advice, but increasingly in accompanying patients with chronic diseases in an aging society. In order to responsibly direct an existing or open a new pharmacy, a postgraduate title in addition to the federal diploma is mandatory since 2018. This title can be obtained through a two-year extra-occupational education while working at least for 80% in a pharmacy. In accordance with the CanMEDs framework (17), the curriculum offers advanced training in the different roles of a pharmacist: pharmaceutical expert, communicator, partner to other health care professionals, scholar (scientist/educator), health advocate, responsible leader and manager, and professional role model. While the role of pharmaceutical expert is confirmed by a final Board exam, the remaining roles are assessment of the candidate's practical assignments by the candidate's mentor (18). In 2019, 276 postgraduate diplomas in public pharmacy were attributed in Switzerland.

Postgraduate specializations in both hospital and clinical pharmacy are offered in Switzerland as well (19). The postgraduate title in hospital pharmacy requires extra-occupational training lasting between three and six years and is completed under the supervision of a recognized instructor at one or more recognized institutions.

Postgraduate training clinical pharmacy takes place in a recognized training center under the supervision of a recognized instructor, is conducted on a part-time basis and lasts at least 18 months. For part-time candidates, the training must not last longer than four years.

All of these postgraduate programs need to be certified by a federal accreditation body, the Swiss Foederatio Pharmaceutica Helvetiae (FPH).

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Studies in Pharmaceutical Technology at the School of Life Sciences – FHNW, University of Applied Sciences Northwestern Switzerland

Georgios Imanidis, Institute of Pharma Technology, School of Life Sciences – FHNW, Muttenz BL

Pharmacy and Pharmaceutical Sciences encompass every aspect of medicines, pharmaceuticals and drugs, from inception and sourcing to manufacture and from patient bedside to health care system. Being integral part of Pharmaceutical Sciences, Pharma Technology focuses on the technical research and development and the manufacture of pharmaceutical products. As such, Pharma Technology covers all activities and operations required for making an active pharmaceutical ingredient into a ready-to-sell drug product. Individual subjects prominently featured in the topic are dosage form, formulation, delivery, manufacturing process, production facility, quality management, bioavailability and efficacy. Pharma technology has therefore a strong technical character resting on one hand on natural science including physics, chemistry and biology and on the other hand on engineering science.

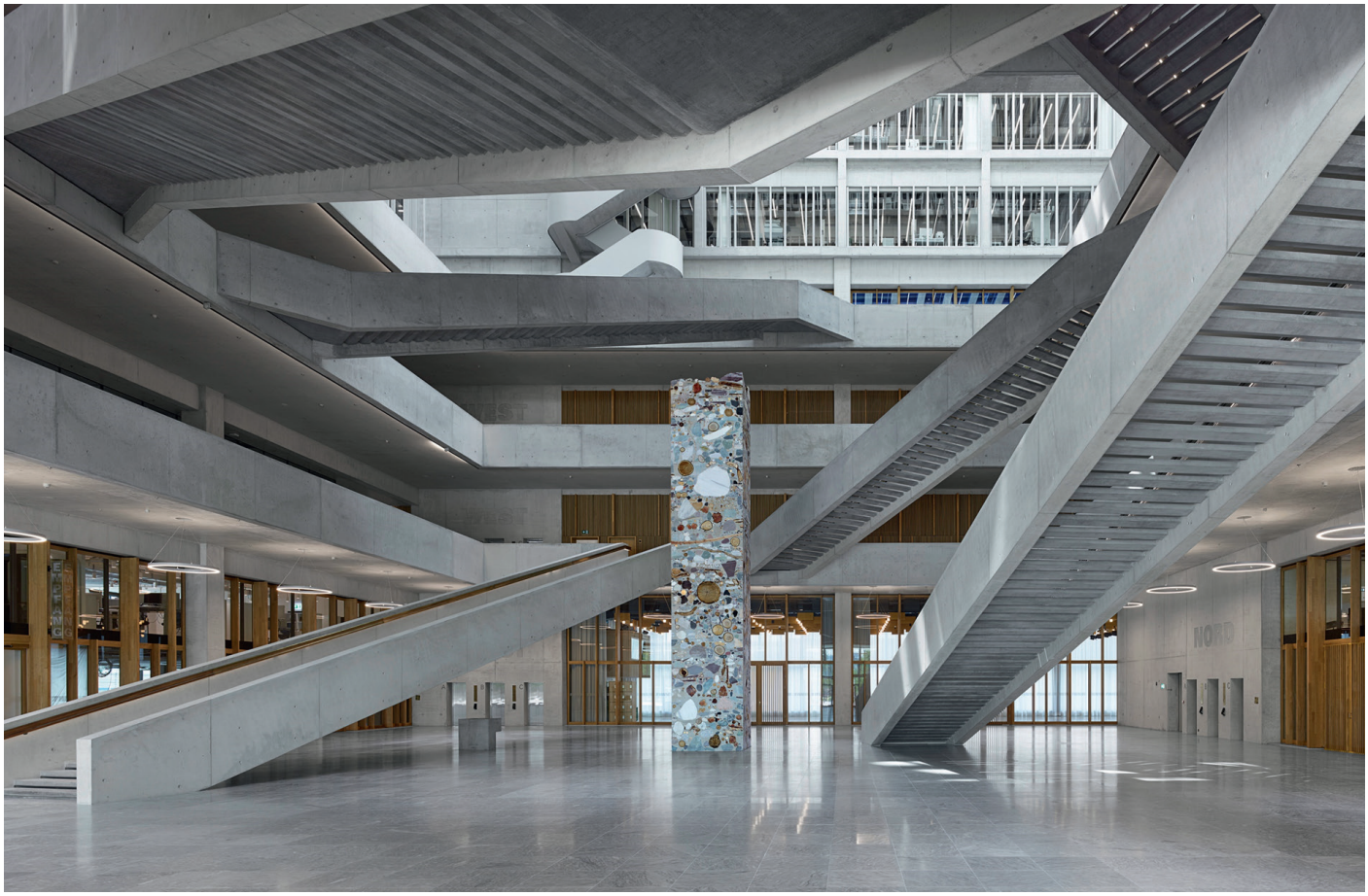
The strongly regulated environment of the pharmaceutical industry and the ever-rising quality standards of health care products require highly specialized professionals to meet today's needs of the industry. A growing variety of pharmaceutical products including next to hitherto established forms, specialized / targeted drug delivery systems, devices, biotechnological products derived from recombinant techniques, precision pharmaceuticals, in combination with emerging industrial working practices such as quality by design, operational excellence, process modeling and simulation, continuous manufacturing, lean and sustainable manufacturing have been evident in recent decade(s). These have immensely broadened the area of Pharmaceutical Technology while the new challenges have increased the demand on depth of understanding, making Pharmaceutical Technology a study subject in its own right.

Objectives

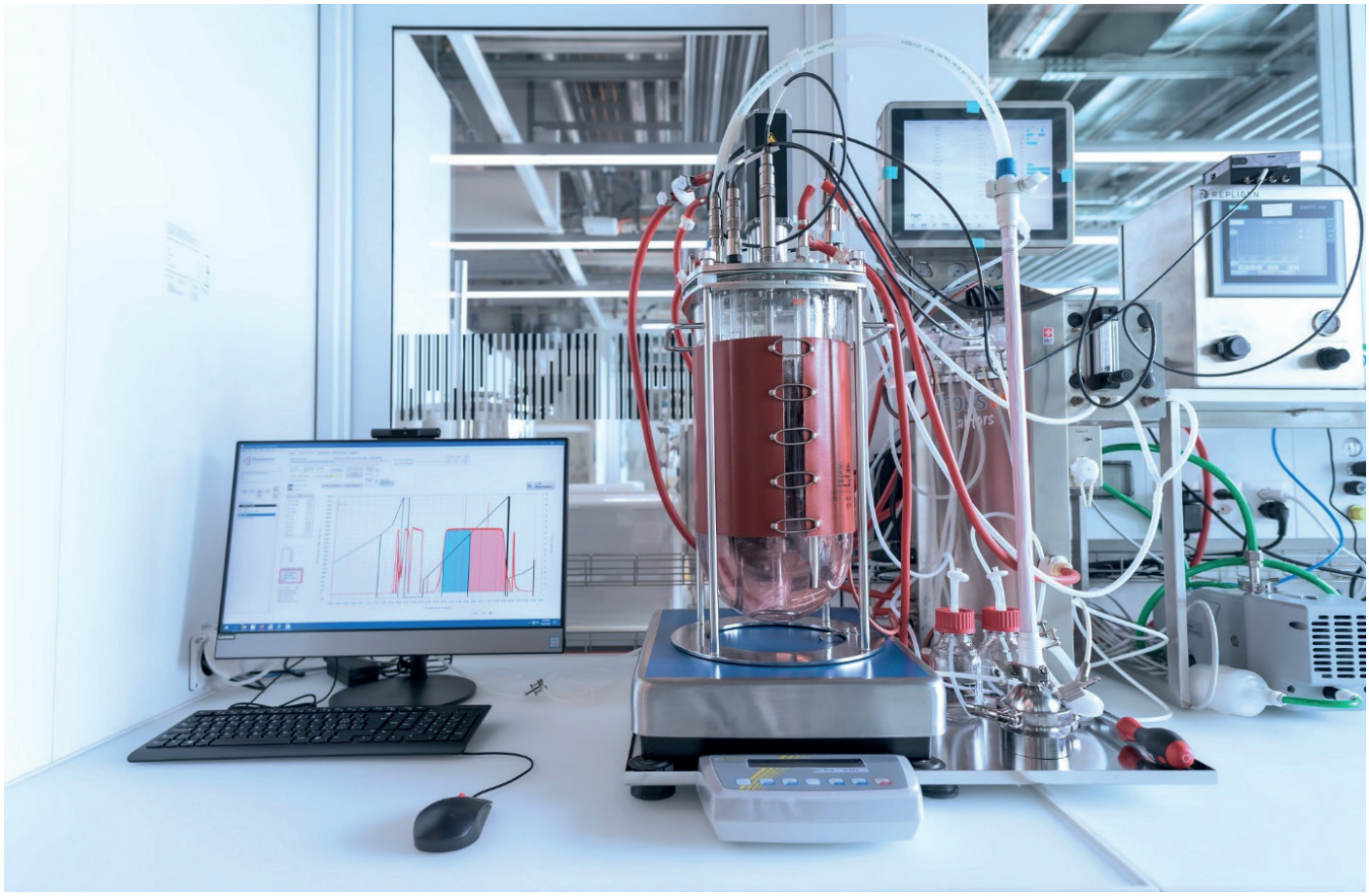
The School of Life Sciences – FHNW established Switzerland's first full study program at Bachelor and Master level in Pharmaceutical Technology. The purpose of the program is to provide praxis-oriented training and education in Pharma Technology addressing the needs of the local, regional and supranational industry. For this, the program is designed to integrate all science and engineering topics that are implemented in transforming the active ingredient into the final drug product. It should provide maximal employability and enable Bachelor as well as Master graduates to immediately enter the workforce with no need for or minimal on-the-job training. To this end, the studies are based on a matrix system of compulsory and elective modules that allows maximum flexibility of earning credit points and whose contents are continuously adjusted to meet the changing demands of industry and future employers. The program is subject to regular supervision by an advisory network of external and industrial partners and peers.

The curriculum

The curriculum of Pharma Technology is embedded in the programs of Bachelor of Science in Life Sciences and Master of Science in Life Sciences comprising the following seven disciplines: Chemistry, Bioanalytics, Chemical and Bio-Process Technology, Medical



View into the entrance hall of the New Campus Muttenz, site of the School of Life Sciences – FHNW. (Photo FHNW)



Process automation laboratory, Process Technology Center (PTC), School of Life Sciences – FHNW. (Photo FHNW)

Technology, Medical Informatics, Environmental Technology, and Pharma Technology. While each discipline has its own backbone of courses, students have the possibility and are encouraged to earn credits from parallel disciplines in order to broaden and/or deepen their set of acquired skills and attain complementary qualification in minor topics such as Materials and Digitalization.

In compliance with the European Credit Transfer System (ECTS), 180 credits are required for the Bachelor's degree and 90 to 120 credits are required for the Master's degree. Study content is praxis-oriented and focused on applicability of acquired knowledge whereas one third of the curricula consist of practical courses. Bachelor and Master studies may be completed in full-time modus within 3 years and 1.5 to 2 years, respectively, or in part-time modus. The final theses at the Bachelor and at the Master level are carried out in collaboration with life science industry and take place in more than half of the cases in an industrial laboratory.

As no standardized curriculum in Pharma Technology exists, the individual modules of the program for the Bachelor's and the Master's degree are listed in the following tables. The curriculum is organized in thematic blocks of modules. Students must take a minimal number of credits from each block.

Bachelor

Basics of Mathematics and Physics 15 Credits	Analysis I – Basic mathematics
	Analysis II
	Linear algebra
	Advanced mathematics – Analysis and inductive statistics
	Statistics and Computer applications
	Mechanics and Heat
	Electrodynamics and Optics
	Dynamic systems
	Technical mechanics
Basics of Biology and Chemistry 21 Credits	General and inorganic chemistry
	Basic analytical chemistry
	Basic organic chemistry
	Basic physical chemistry
	Physical chemistry I
	Physical chemistry II
	Basic biology
	Anatomy and physiology
	Human biology
	Microbiology
	Biochemistry
	Bioanalytics
Fundamentals 15 Credits	Development of drug products, devices and combination products
	Basic pharmacology
	Special pharmacology
	Pharmacokinetics
	Clean room and aseptic manufacture
	Heat conduction and mass transport
Laboratory courses and workshops – Fundamentals 21 Credits	General laboratory techniques
	Microbiology
	Pharmacology
	Biochemistry
	Analytical chemistry
	Physics
	Bioanalytics
	Applied statistics in life sciences
Specialization 27 Credits	Drug profiling – Pre-formulation
	Parenteral preparations and biologics
	Molecular Galenics
	Particle technology I
	Particle technology II
	Process engineering
	Plant design – Production facilities – Logistics
	Packaging and devices
	Quality management and Registration
	Quality by Design and Process analytics
Laboratory courses – Specialization 15 Credits	Drug profiling – Pre-formulation
	Particle technology
	Solid dosage forms
	Semi-solid dosage forms
	Clean room and sterile production
	Packaging and devices
	Plant automation
Informatics 6 Credits	Introduction in informatics
	Introduction in programing
	Programing I
	Programing II
	Data banks and data analytics
Business and Soft skills 6 Credits	Introduction in business administration and law
	Introduction in business economics
	Project management
	Scientific / technical writing
	Self-management
	My future
	Ethics in science

Interdisciplinary & free choice 18 Credits	Any module
	Any module
	Any module
	Any module
	Any module
	Any module
English 6 Credits	English language
	Written academic English
	Spoken academic English
Thesis/& Project 30 Credits	

Master

Specialization 21 Credits	Drug formulation and delivery of solid dosage forms
	Formulation of biologic and Routes of drug delivery
	Continuous pharmaceutical production
	Pharmaceutical production facilities
	Compound profiling in pharmaceutical drug discovery
	Advanced mass spectrometry and NMR Spectroscopy
	Process development and technology
	Proteomics and protein analytics
	Bioassays
Extended specialization 9 Credits	Design of biopharmaceutical production facilities
	Tissue engineering for drug discovery
	Medical devise regulatory affairs
	Bioanalytics in a regulated environment
	Cellular physiology and therapies
Data literacy 6 Credits	Handling and visualization of data
	Design and analysis of experiments
	Modeling and exploration of multivariate data
Soft skills 9 Credits	Business administration for life sciences
	Management and leadership for life sciences
	Innovation and project management
	Politics and society
Electives 6 Credits	Any module
	Any module
Thesis 40 Credits	

n|w University of Applied Sciences Northwestern Switzerland
School of Life Sciences

Concluding remark

Education in the area of Pharmaceutical Technology and Pharmaceutical Engineering is highly dynamic. Several programs have been introduced in recent years internationally reflecting this dynamic. For example, a Master's degree in Chemical and Pharmaceutical engineering has emerged from the collaboration between the University of Graz and the Graz University of Technology (Master Programme Chemical and Pharmaceutical Engineering – NAWI Graz). At the Technical University of Braunschweig, a collaboration between the faculty of life sciences and the faculty of engineering brought about the Master's degree in Pharma Engineering (Pharmaingenieurwesen (Master) (tu-braunschweig.de). Further, the University of Strasbourg offers a Master's degree in Pharmaceutical Engineering in collaboration with industry (https://www.unistra.fr/etudes/decouvrir-nos-formations/par-facultes-ecoles-instituts/sante/faculte-de-pharmacie/faculte-de-pharmacie/cursus/ME181?cHash=b259e6368ef6d1e1933e4efcd001e9f7#data-rof-tab-presentation). (all sites last accessed in February 2021).

These programs address the need of providing technical pharmaceutical training and education to professionals for the pharmaceutical industry. However, they are all based on existing structures and feed on graduates from different Bachelor programs, mostly of Pharmacy or Chemical Engineering. The Bachelor and Master curricula in Pharma Technology of the School of Life Sciences – FHNW are unique in that from their inception back in 2006/2008 and through successive revisions they have been designed as standalone, self-contained programs focusing exclusively on the evolving requirements of the subject of Pharma Technology.

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Negotiation Engineering: Why Quantitative Thinking Can Also be Useful in Negotiations

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Although often complex, negotiations are based on practical problems that can be solved using specialized, ad hoc methods. Based on Negotiation Engineering: A Quantitative Problem-Solving Approach to Negotiation (2017), we examine the approach to Negotiation Engineering developed by the authors therein. Negotiation Engineering is a problem-solving approach to difficult negotiations, inspired by the established solution-oriented discipline of engineering. It is based on the reduction of problems into their most formal structures and the heuristic application of quantitative problem-solving methods. Mathematical language in negotiations can help increase logical accuracy in negotiation analysis and apply various existing mathematical methods to reach a negotiation agreement. We demonstrate the practicability and usefulness of this approach using two case studies in which Negotiation Engineering was applied to reach negotiation agreements. While both case studies stem from the field of international diplomacy, Negotiation Engineering could be useful in contributing to solving a wide variety of problems in different fields and contexts. As such, it could be particularly beneficial for professionals with a technical training and a background in natural science, who could transfer and apply their skills more effectively.

1. Introduction

Solving negotiation problems is often a complex and challenging process. Particularly in the context of more elaborate negotiations (e.g., intergovernmental negotiations), it is important to find viable mechanisms to address these issues. Such mechanisms must on the one hand, be sufficiently sophisticated and on the other hand, sufficiently practical to be applicable to real-world problems.

There has been extensive progress in negotiation research in recent decades (such as in the areas of applied game theory, negotiation analysis, decision theory, behavioral sciences) by using a variety of advanced methods. Nevertheless, it remains a constant challenge to put the findings and techniques into practice. This is especially the case with quantitative methods, which often encounter difficulties in practice, even though they could complement and contribute to solving complex problems. Existing quantitative approaches focus mainly on the general analysis of negotiations (Raiffa, 2007) whereas solution-oriented concepts often limit themselves to the use of qualitative methods (Fisher and Ury, 1981).

While established quantitative analysis-oriented, as well as qualitative solution-oriented approaches exist, Langenegger and Ambühl (2017) identified the need for a quantitative solution-oriented concept. In Negotiation Engineering: A Quantitative Problem-Solving Approach to Negotiation (2017), they introduced such a practice-oriented approach (Negotiation Engineering) to enable the harnessing of the benefits of quantitative methods in finding a solution for real-world negotiation problems.

In this paper, we examine Negotiation Engineering – previously developed by Langenegger and Ambühl (2017) – as an approach that could be useful in contributing to solving a wide variety of problems in different fields and contexts, not only in international diplomacy. As such, we argue that Negotiation Engineering could be particularly beneficial for professionals with a technical training

and a background in natural science, who could transfer and apply their skills more effectively. In doing so, this present paper is based on the above referenced paper.[1]

We first provide the reader with an introduction to the concept of Negotiation Engineering, including its definition, classification and basic elements. We then exemplify the approach using two cases, which are based on the experience of one of the authors (M. Ambühl). Finally, before concluding, we discuss the strengths, weaknesses, and limitations of Negotiation Engineering.

2. Concept of Negotiation Engineering

«Negotiation Engineering» combines the two concepts of (i) «negotiation» and (ii) «engineering»:

According to the Cambridge Dictionary (2021), negotiation is «[a] formal discussion between people who are trying to reach an agreement.» The core of a negotiation lies thus in the parties' efforts to agree on the issues at hand. In contrast, engineering – as «the study of using scientific principles to design and build machines, structures and other things […]» – focuses on finding a viable solution to a problem within the given constraints (Cambridge Dictionary, 2021).

Throughout the solution-finding process, engineering uses mathematical language, which allows for complex issues and dependencies to be formalized and subsequently better understood. Naturally, mathematical language also enables the application of existing mathematical tools. To that end, breaking down problems into smaller sub-problems can help achieve such formalization and ultimately improve or even resolve the problem.

In line with the above definition, the engineering method seeks to better a «poorly understood or uncertain situation within the available resources» (Koen, 1985). This strategy of seeking to ameliorate or solve a given problem is the use of heuristics.

Heuristics does not strive to find the solution but rather an adequate, though often imperfect, solution to a problem (Polya, 1957).[2] In doing so, it looks to any means that reduce the time needed to solve a problem, such as rule of thumb or general simplification and includes learning, discovering and trial-and-error processes (Feigenbaum and Feldmann, 1963). As such, heuristics – when applied – is iterative in its nature and can lead to a multitude of possible solutions.

Finding the optimal solution, however, requires valuation and weighting. Consequently, engineering cannot always be entirely objective and value free. Rather, it is influenced by the social perception of the problem(s) trying to be solved.

2.1. Definition and Differences from Existing Methods

2.1.1. Definition

We define Negotiation Engineering as a solution-oriented approach to negotiation problems that uses quantitative methods in a heuristic way to find an adequate solution. Thereby, we particularly draw on the decomposition and formalization of the negotiation problem and the heuristic application of mathematical methods[3] to facilitate the process of reaching an agreement.

2.1.2. Differences from Existing Methods

A variety of practice methodologies can address negotiation problems.[4] We distinguish these by (i) their methodical orientation and (ii) by the focus on their objectives.[5]

The orientation – referring to the methods used in practice – can range from qualitative to quantitative while the objective can be found on a continuum of «analysis-oriented» (ex post) to «solution-oriented» (ex ante). We classify the concept of Negotiation Engineering as «quantitative» and «solution-oriented» (see graph below).

With its focus on the application of situation-specific instruments and tools and its emphasis on the heuristic utilization of quantitative methods to increase logical accuracy and help structure the negotiation, Negotiation Engineering sets itself apart from other methodologies. Negotiation Engineering also differs from other approaches in that it puts the problem at the center and not the description and discussion of the latter.

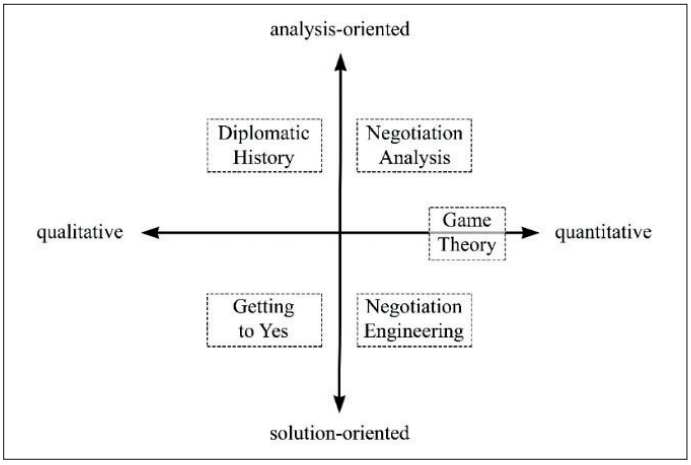

Figure 1: Classification according to orientation and objective of methodology.

2.2. Basic Elements

Based on the above definition, we identified four elements, which form the basis of the Negotiation Engineering concept:

2.2.1. Decomposition

By decomposing a problem, the latter is broken down into its underlying sub- and sub-sub problems. We argue that reducing a problem's complexity in such a way is fundamental to their approach as it not only allows key problems to be identified but also assists in singling out the structure and relationship between the issues at hand.

[1] As one of the original authors (M. Ambühl) is also author of this paper, it is refrained from making any further references to this source in the text.

[2] On the contrary to exact science.

[3] This includes classical methods, such as game theory as well as more recent ideas around principled algorithmic distribution of resources or responsibilities (Grech et. al., 2020).

[4] For instance, diplomatic history, «Getting to Yes» (Fisher and Ury, 1981), negotiation analysis (Raiffa, 2007) and game theory (von Neumann and Morgenstern, 1944).

[5] Langenegger and Ambühl (2017) limited the number of distinguishing criteria to two. While they did consider additional criteria, those were deemed as not fully independent as well as related to the other two.

2.2.2. Formalization

To further break down the problem to its most formal structure and in order to reveal its core construction, each sub-problem, which is decisive for the finding of the solution is then translated and restated into formal mathematical language.

2.2.3. Mathematical Method

Once a sub-problem is expressed in mathematical language (and thus formalized), a variety of mathematical tools, for instance in the area of game theory, can then be applied in order to further analyze the sub-problem based on objective and measurable criteria.

2.2.4. Heuristics

These mathematical tools are applied in a heuristic way, meaning that experience-based techniques, learning and discovery promote a solution that is «good enough for the given set of goals» (Langenegger and Ambühl, 2017). The process of finding a solution is iterative, often undergoing several rounds. As stated above, for all real-world problems – both in the negotiation as well as in the solutions process – multiple reasonable solutions do exist. Therefore, it is important to evaluate the different options based on their merits and to select the solution that best meets the requirements.

3. Cases

The following section illustrates the application of Negotiation Engineering in two specific negotiation situations (cases) to allow for a better understanding of the method and its elements. Even though both cases originate from the field of international diplomacy, the intention is to demonstrate that the method can be applied in other areas as well. Both cases are based on the personal experience of one of the authors (M. Ambühl).[6]

3.1. Case 1: Land Transport Agreement between Switzerland and the European Union

3.1.1. Background

In 1993, Switzerland and the European Union (EU) agreed to start negotiations on a package of bilateral agreements[7] in seven areas (later called Bilateral I): free movement of people, air traffic, road traffic, agriculture, technical trade barriers, public procurement, and science. One year later, in early 1994, the Swiss electorate voted on a federal initiative («Alpeninitiative») regarding the protection of the alpine regions from transit road traffic (Swiss Federal Council, 1999).[8]

With the adoption of the «Alpeninitiative» and of the subsequent new constitutional article (Art. 84 BV) however, Switzerland violated provisions of the transit treaty with the EU (in force since January 1993). This led to the negotiations around the Land Transport Agreement being blocked, which in turn stalled the negotiations on the overall package of the bilateral agreements as the EU insisted on negotiating the entire package of all seven areas in parallel. The blockage of the Land Transport Agreement thus obtained a central role in the negotiations of the Bilateral I.

The two positions of Switzerland and the EU seemed incompatible. Switzerland on the one hand, was obliged to fulfill its constitutional mandate by ensuring that transalpine goods traffic from border to border was carried out by rail (and not on the road) (Art. 84 BV) – a provision which de facto only affected foreign traffic and therefore violated the prohibition of non-discrimination. The EU on the other hand, demanded the elimination of the 28-ton weight limit on trucks as well as non-discriminatory treatment of transports.

Figure 2: Land transport. Source: Flickr

3.1.2. Negotiation and Results

In a first step towards finding a solution, Switzerland proposed interpreting the new constitutional article (Art. 84 BV) not literally, but according to sense and spirit. This allowed (i) for a reduction of the overall volume of all traffic categories (transit, bilateral and national), which in turn contributed to protecting the alpine region from transit traffic and (ii) for a non-discriminatory treatment of EU transports.

The second step was to regulate the demand through market-based instruments in order to reduce goods traffic on the roads. In this context, Switzerland proposed three approaches: (i) a «tariffication»[9] of the weight limit – a proposal which was rejected by the EU as being too academic; (ii) an internalization of the external costs – a concept which was equally not accepted by the EU as it was (and still is) politically not ripe and (iii) a pragmatic Negotiation Engineering method to determine tariff. The EU agreed to this third approach.

In applying this Negotiation Engineering approach, the tariff was first split into three categories according to ecological criteria.[10] In terms of the determination of the tariffs, the parties then agreed

[6] Michael Ambühl was a member of the Swiss negotiation team in case 1 and the facilitator in case 2.

[7] As a non-EU member, Switzerland's relations with its most important partner – the EU – are governed by bilateral agreements. This bilateral relationship is an alternative to an EU-membership, which could be of interest to other states. Inspired by the Swiss method (not the model), the British model could be developed further, namely, to negotiate one agreement at a time when there is a common interest.

[8] The package of the Bilateral I was signed in 1999 and approved in a popular referendum in 2000. This package was later followed by a second package (Bilateral II), which was signed in 2004. For a couple of years now, Switzerland and the EU have been negotiating a framework agreement (institutional agreement), with the intention of integrating all institutional questions of this so-called bilateral way into one agreement. For the time being (March 21, 2021) negotiations are ongoing.

[9] Tariffication: Transformation of quotas into tariffs, often applied in trade negotiations, where e.g., a quota on tomato imports is transformed into an import tariff.

[10] Instead of one price that was dependent on weight and distance.

on a weighted average, depending on the composition of the total truck fleet. This measure ensured that the tariffs would stay the same on average, even when vehicles were to become cleaner in the future.

The calculation of this weighted average is a linear optimization problem in which the weighted average is G, the highest tariff is not above the threshold P, and the tariff split is maximized, but not more than 15% of the average.

$$\max_{x,y,z}(x - z)\ s.t.$$
$$\alpha \cdot x + \beta \cdot y + \gamma \cdot z = G$$
$$x \leq P$$
$$0 \leq x - y \leq 0.15 \cdot G$$
$$0 \leq y - z \leq 0.15 \cdot G$$
$$x, y, z \geq 0$$

where χ, γ, and z are the tariffs for the three truck categories, and α, β, and γ are the shares of the corresponding truck categories.

This mechanism allowed for a mutually acceptable agreement: the 28-ton weight limit for trucks was abandoned without a significant increase of the transport volume and without discrimination of foreign traffic. The Land Transport Agreement between Switzerland and the European Union was signed in 1999 and adopted by the Swiss electorate in 2000.[11] Since then, the numbers of vehicle trips in Switzerland have continuously decreased:

	2000	2011	2012	2013	2014	2015	2016	2017	2018
France	1527	1341	1259	1212	1220	1253	1279	1362	1409
Switzerland	1404	1220	1151	1049	1033	1010	975	954	941
Gotthard	1187	898	843	766	758	730	701	698	677
Austria	1653	1980	2058	2028	2112	2160	2315	2453	2602
Alpine Arc	**4584**	**4541**	**4468**	**4289**	**4365**	**4423**	**4569**	**4769**	**4952**

Table 1: Number of heavy goods vehicle trips, in 1000s. Data includes trucks, freight trains (on road) and semi-trailer trucks with a permissible total weight of more than 3.5 tons. Numbers during Corona pandemic are not included. Source: Federal Office of Transport (2020) and European Commission (2020).

3.1.3. Analysis

Applying the Negotiation Engineering approach allowed the parties to come to an agreement on this matter and to make progress in the overall negotiation package (Bilateral I). In particular, the decomposition of the problem into a single key issue (defining the tariffs) and the subsequent iterative process of defining the solutions, along with the implementation of the mathematical tool (linear optimization), led to a compromise.

The difficult negotiations lasted four years. Progress was made only when the parties agreed to an abstract, algebraic formulation of the underlying problem. As soon as the problem was decomposed into an algebraic formula, the only remaining question was the determination of the specific values – an issue that consequently then became easier to solve.

3.2. Case 2: Facilitating Nuclear Talks between Iran and P5+1

3.2.1. Background

After discovering Iran's uranium enrichment program in 2003, concerns about its possible non-peaceful purpose were raised. Three years later, in 2006, a dialogue between Iran and the P5+1 was initiated in order to (i) ensure Iran's right to enriching nuclear fuel for civil purposes according to the Treaty on the Non-Proliferation of Nuclear Weapons and to (ii) prevent Iran from developing nuclear weapons.

The situation throughout the dialogue was tense, in particular between the United States and Iran, two states that share a problematic past and until today, maintain no diplomatic relations. Accordingly, it was difficult to agree on preconditions: one side demanded the end of all nuclear program-related activities and the other side requested an enrichment guarantee. The U.S.' demand for a regime change and Iran's perpetuation of unacceptable views of historical events further contributed to a charged rhetoric.

It was in this context, that the Swiss Foreign Ministry offered its support for a restart of the negotiations, in consultation with key actors, in particular the Secretary General of the International Atomic Energy Agency (IAEA), Mohamed ElBaradei.[12] As a neutral state that is neither a member of the EU nor NATO and has no colonial past, Switzerland saw an opportunity to contribute by not only providing a platform for the dialogue, but also by introducing new ideas.

3.2.2. Negotiation and Results

Accordingly, in 2007, one year after the start of the dialogue, in a non-paper[13] to the two parties Switzerland suggested to restart the negotiations. This non-paper included both diplomatic-procedural as well as thematic proposals. The former consisted of (i) confidence-building measures (P5+1 will not table any new sanctions, and Iran will not develop any new nuclear enrichment-related activities; the so-called «freeze for freeze» concept), (ii) guiding principles for the negotiations, and (iii) a phased approach for the talks.

The thematic proposal on the other hand, consisted of two sets of formulas. The first set of formulas concerned the construction of centrifuges and created a mechanism for negotiating the exact number of centrifuges and their development over time. In doing so, the formula defined the number of centrifuges at a given time as the number of existing centrifuges one time-period before (for example, two months) plus a rate of increase. This rate of increase was defined as the average number of centrifuges constructed in the time before the mechanism would come into place, multiplied by a factor β. This coefficient was crucial for the development of the future number. It could be between 0 and 1 and defined if the number of centrifuges stayed the same (β=0) or if it increased at

[11] It was not until June 1, 2002 when the agreement entered into force as part of the Bilateral I (Swiss Federal Department of Foreign Affairs, accessed on March 2, 2021).

[12] Switzerland has represented U.S. interests in Iran as a protective power since 1980, when diplomatic relations between the U.S. and Iran were broken off (Swiss Federal Department of Foreign Affairs, accessed on March 10, 2021).

[13] A non-paper is an informal negotiation text for discussion among delegations. It has no identified source or attribution and does not commit the originating delegation's country to the content.

[14] There was no reduction in the number of centrifuges mapped in the model. This was due to the parties not being able to agree on such a reduction at the time. Even in the negotiated agreement of July 2015, Iran and the U.S. could not accept a reduction below the level of 2007. On the contrary, Iran had, according to the data of the International Atomic Energy Agency (IAEA), 656 centrifuges in February 2007. Over the following years, Iran increased its nuclear program and in 2015, the P5+1 agreed to allow Iran 6104 operational centrifuges, with 5060 allowed to enrich uranium.

the same rate as before (β=1), with any possible value in between.[14] The parties would have to agree on this coefficient.

Iranian nuclear program

Construction of centrifuges

Let

t : time [measured in months]

t_0 : time of reference

t_i : deadline i, $i \geq 1$

$n(t_0)$: number of centrifuges at t_0

$n(t)$: number of centrifuges at t

a_0 : average number of centrifuges constructed per month in the time period before t_0

a_i : rate of increase of centrifuges constructed per month during the time period $[t_{i-1}, t_i]$

β_i : coefficient ; $0 \leq \beta_i \leq 1$

Then

$$n(t) = n(t_{i-1}) + (t - t_{i-1}) \cdot a_i \quad ; \quad t \in [t_{i-1}, t_i]$$

Whereas

$a_i = a_0 \cdot \beta_i$; $i \geq 1$

(If a differentiation does not prove to be necessary: $a_1 = a_2 = a_3 = \ldots$)

Figure 3: First set of formulas of thematic proposal in Swiss non-paper, concerning the construction of centrifuges.

The second set of formulas controlled the production of low-enriched uranium in research and development, as well as at industrial plants. It stated that the amount of low-enriched uranium produced had to be smaller or equal to the amount produced before the mechanism was in place, multiplied by a factor γ, which the parties had to agree upon.

3.2.3. Analysis

The decomposition of the problem into the crucial (yet not only important) question of the number of centrifuges, and the formalization of this question through a set of mathematical formulas, allowed the parties to define a key negotiation point and to indirectly illustrate that the problem itself was not unsolvable. The formulated mechanism helped to focus the negotiations on specific, clearly defined dimensions of the problem; in this case, a set of formulas that described and quantified the future development of nuclear enrichment activities. Once this negotiation framing was accomplished, the remaining problem (i.e., the determination of the values of the specific variables) could be tackled more efficiently. This is a typical Negotiation Engineering approach to facilitate the process and promote an agreement.

However, the two parties could not agree on beginning the negotiations at this stage and instead continued escalation.[15] The time was not politically ripe, as neither the U.S. nor Iran saw their respective preconditions for negotiations met.

Despite the fact that the lack of political will could not be overcome by the nature of these two formulas, the Swiss proposals nevertheless laid the groundwork for direct talks in Switzerland in July 2008.[17] Furthermore, elements of the proposals – such as the omission of preconditions, «freeze for freeze», confidence building measures, and phased negotiations – were taken up by the parties in the negotiations, which started in 2013 in Switzerland and came to an end in Vienna on 14 July 2015 with the «Joint Comprehensive Plan of Action».

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- *Swiss Chief Negotiator of the Bilateral Negotiations II with the EU*
- *2005 – 2010 State Secretary [civil service position], Foreign Ministry*
- *2008 facilitator of the dialogue between the P5+1 and Iran*
- *2009 mediator of the Armenia-Turkey Protocols («Zurich Protocols»)*
- *2010 – 2013 State Secretary [civil service position], Finance Ministry; negotiations Tax Agreements with USA, UK Tax, Austria*
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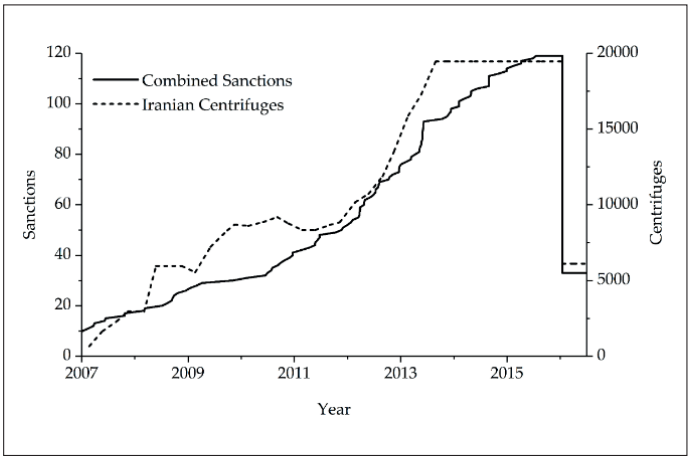

Figure 4: Shows the escalation of the development of the combined sanctions on one hand, and the number of Iranian centrifuges on the other hand (until 2015); and the de-escalation due to the Joint Comprehensive Plan of Action (JCPOA) in July 2015 (Langenegger, 2018).[16]

[15] A more detailed analysis of this escalation and the underlying mechanisms was presented at the International Conference on Group Decision & Negotiation 2016, Bellingham, USA (Langenegger, 2016). The two states are currently in a comparable situation. They cannot agree on preconditions. Iran stated that they would be willing to surrender its recently increased amount of highly enriched uranium if the U.S. took back sanctions imposed under President Trump and returned to the nuclear agreement. However, new U.S. President Biden has signaled that he is only willing to return to the nuclear agreement with Iran if and once Tehran complied with all the terms of the deal (Neue Zürcher Zeitung, 25.1.2021, accessed on March 11, 2021).

[16] This analysis was part of the dissertation of T. Langenegger (2018). His dissertation won an ETH-Medal in 2019, an award for outstanding doctoral thesis projects at ETH.

[17] These talks were the first of its kind between American and Iranian officials since the cessation of diplomatic relations in 1980.

Figure 5: Javier Solana (then EU High Representative for the Common Foreign and Security Policy) and Ali Larijani (then Secretary-General of the Iranian Supreme National Security Council and Iran's chief nuclear negotiator) at the Geneva Talks in July of 2008. Source: Reuters.

4. Strengths and Limitations

We identify several strengths as well as weaknesses and limitations of Negotiation Engineering:

4.1. Strengths

- The reduction of the problem to its most formal structure through the highest possible abstraction helps to reveal the core of the problem and provides an understanding of its underlying mechanisms. Using mathematical language forces an increased logical accuracy. In addition, using such language enables access to many helpful mathematical tools that can be of analytic (e.g., game theory) or solutions-oriented (e.g., mathematical optimization methods) nature.

- The formal description of a problem allows a solution mechanism to be defined without implying the outcome of the negotiated agreement. That way, the solution mechanism can be incorporated in a formula while leaving room to negotiate the values of the variables in the formula. Such a process helps to frame the negotiation, indicating a list of questions to be discussed. A solution can be reached more easily due to more precise knowledge of the issue(s) being negotiated based on objective, measurable criteria.

- The «technical» approach of Negotiation Engineering can lead to a de-emotionalization of the problem, which often helps in finding pragmatic solutions to complex negotiation problems.

4.2. Limitations and Weaknesses

- The method's orientation toward technical problem solving can be perceived as not strategic enough. It can be argued that such a solution-focused approach does not thoroughly consider higher-level inquiries, such as the questions of whether the right problem has been defined or whether solving it is justified in the first place.[18] It is evident that Negotiation Engineering cannot replace the discussion of certain questions of principles. However, it can be an important addition to such a discussion. Both levels have to be considered for real-world problems.

- The formalization of a problem is always a reduction, leaving out some aspects of the problem, which can be controversial for the other party. Therefore, it is important to find the essential underlying problem accepted by all involved parties to increase the acceptance of the formal representation and modeling. If an aspect, which is considered essential by a party, is left out, then a formalization might not be helpful in finding a solution. Furthermore, a reduction should only be applied to sub-problems.[19] A mutually accepted formalization of the larger initial problem is often not possible due to its complexity. It is important to note that there is no universal solution to this process of reduction. The art of formalization in a constructive way lies in using it in a mutually accepted way in sub-problems. This process remains a difficult aspect of negotiations.

- There are limits to where Negotiation Engineering can be applied. Problems may exist that are not quantifiable or should not be reduced to a quantitative level. Examples include deep value disputes or interpersonal conflicts, such as family disputes. The Negotiation Engineering method is most suitable for problems with a particular degree of complexity, involving actors that hold a certain analytical capacity and are open to a rational approach.

5. Conclusions

In this paper, we examined Negotiation Engineering – previously developed by Langenegger and Ambühl (2017) – as an approach that could be useful in contributing to solving a wide variety of problems in different fields and contexts.

With its consideration of complex properties of real-world negotiation problems and the application of proven methods from the problem-solving discipline of engineering, Negotiation Engineering differs from other established practice methodologies. This focus on quantitative methods and on a solution-oriented direction are exemplified by the analysis and conceptualization of two cases.

Negotiation Engineering is based on four elements – all of which help to solve negotiation problems: (i) decomposition of the problem, (ii) translation of a sub-problem into mathematical language along with the reduction to its most formal structure, and (ii) the application of mathematical tools (iv) in a heuristic way. Such a process leads to increased logical accuracy in the analysis using mathematical language and allows for the development of suitable solutions, particularly through the application of quantitative, mathematical tools. Thereby, the focus lies on the heuristic approach to find pragmatic solutions under existing constraints.

Heuristic and quantitative problem-solving methods, such as Negotiation Engineering do not have to be limited to their use in international diplomacy. On the contrary, practical application is possible in many fields in governmental or business (company or individual) negotiations – also in the pharmaceutical industry. Negotiation Engineering could be particularly beneficial for professionals with a technical training and a background in natural science.

[18] An interesting example was the debate around the distribution of the EUR 750-billion corona virus recovery fund of the EU among members states (Grech et al., 2020).

[19] Examples of such key issues are the definition of the tariffs in Case 1 and the number of centrifuges in Case 2. They were identified as key sub-problems to the negotiation and their formalization helped to facilitate the discussion.

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Our Universities: Knowledge Foundries for New Global Challenges

Closing the Gap Between Our Education and Our Future Through Transdisciplinarity Across the Arts, Humanities and Sciences

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Key words: Call for a transdisciplinary research and teaching initiative, specialization and generalization, student mobility, collaboration across all disciplines, combination of expert knowledge as a challenge, cross fertilization of cultures & disciplines enhancing innovations.

The modern approach to University education and research recognizes the need to cut across traditional subject boundaries. However, in order to obtain maximum benefit from research effort globally, Universities need to adapt their existing approaches to the management and organization of research and teaching for transdisciplinary working. This has become an urgent consideration given that we now face unprecedented global threats, ranging from infectious diseases to global warming, which are no longer amenable to single discipline resolution, and which demand a new kind of skilled individual who is technically literate across multiple fields, an intellectual and practical multi-tasker. In Europe, we have already secured a standardization of our degree awards, and actively promote cross-European student mobility. However, for the next generation of students, this will need to be extended globally and to reach out across both continents and language barriers. Only in this way can there be the advancement of global inclusiveness and an opportunity for all to contribute their talents to the global challenges that affect us all. Universities are well placed to take on such challenges because within their existing departmental structures they already harbor the necessary specialization's spanning across engineering to sciences and the arts. Already the new approaches embodied within nanotechnology manifest an unprecedented convergence of disciplines. Emerging in a practical sense, for example, as nano pharma. This new dimensionality to molecular drug development offers now an indispensable means of widening our drug armory as a powerful alternative to molecular scale development. What is urgently needed is to extend the pharma model approach in other endeavors, and to synthesize new Faculties and Departments founded primarily on transdisciplinary science These would be based on combinations of teaching and research that could never have been envisaged before, but which now come into sharp focus as a means for our gearing of a global effort to tackle awesome global challenges. This paper describes the way individual multi-specialist affiliations can be leveraged for student transdisciplinary science covering, respectively, medicine, biological science, geography, pharmacy and humanities. The need for this is for a future that is becoming the present a rapid pace, and one moreover that will demand the greater emphasis on ethics. In conclusion, two decades after the successful Nano Research Initiative, it is necessary to prepare an all-inclusive Transdisciplinary Research and Teaching Initiative embracing all disciplines, eliminating all borders that prevent cross fertilization, and boosting innovative solutions for a sustainable world.

1. Introduction

This millennium will see revolutionary change across a range of key technologies, from medicine to transport, that will transform the way society operates. With increasing insights at the fundamental level, new technological tools will emerge at rates unprecedented in modern scientific history. With this will come a convergence of the disciplines of physics, chemistry, materials science, biology through to computer science, and with this novel and superior products and systems that have been the stuff of science fiction until the 21st century. Without new models of collaborative working across the disciplines, however, this will not be possible.

Up to now, academia has operated within distinct academic disciplines. Yet, most of the major challenge's society faces, notably concerning the environment, energy, and health, and which research and education are supposed to solve, are no longer definable in terms of cognate disciplines. There is no longer a match between the growth of these problems and the development of our scientific culture, increasingly driven by hyper-specialisation.

New topics will also emerge, such as Cognitive Information Processing and Cognitive Computing, as crucial technologies of the 21st Century [1], but these inherently demand competences that extend across diverse fields ranging from solid state and organic chemistry, biology, medicine, physics and mathematics through to information and computing sciences and engineering. Broadly, the imperative is for a transdisciplinary approach to complex industrial and societal challenges. Universities will need to reconfigure current degree programmes so they are 'fit for purpose', losing neither focus nor the needed intellectual depth in this «broad band» strategy. A plethora of programmes that merely give independent pathways to some unified academic qualification will only confuse students, teachers, and employers alike. Nascent fields such as nanotechnology, smart materials, biomimetics, cognitive informatics and computing, especially, will not prosper without intensive crossover effort across disciplines.

The University now operates in a rapid change environment (social, institutional, financial, regulatory) [2]. Also, many traditional jobs will disappear, certainly by the time pupils currently in primary education have graduated. The transformed job market also means that many new jobs will be created, but now a premium will be placed on candidates showing adaptability, an open mindset and transferable skills.

Governments recognise that new university generated scientific knowledge holds the key to future prosperity. The shift in industrial focus in the USA from, say, traditional steel production in Pittsburgh and car making in Detroit to high-technology companies such as those based around MIT, Silicon Valley, Stanford University and the University of California are a 20th century foretaste of change. If Europe is to compete successfully with the USA, and now with Asia, it must focus on high end technology products driven by ideas from our universities. The advancement of a transdisciplinary agenda for universities as a part of this is thus timely.

We need, for example, to make it easy for an Engineering or Science student to acquire knowledge and expertise across multiple topics including extending out to social sciences, economics in the arts, along with foreign language skills. This must also not lead to a more crowded curriculum. Concerning research, so often the most exciting and useful research occurs at discipline boundaries. Thus, many researchers involved with drug discovery may have been trained as biologists, physicists and computer scientists [3]. Functional materials for next generation mobile devices, computers, cars and planes are now being designed and developed by materials scientists working hand in hand with chemists, physicists, and engineers. The traditional university departmental structure is not geared to secure the necessary dialogue to prepare for this New World, and may, in fact, create barriers to transdisciplinary research.

There are tangible challenges ahead of us. COVID-19 has had a partial response, but we do not have the final chapter on this, let alone the alert and template of response for the next lethal pandemic. Our climate change strategy is excellent at tracking global warming effects, but not the gearing of interlinked responses to mitigate these, some of this moves us into advanced information technologies for prediction and information exchange, rather as is being done for weather forecasting, but now needing to be stretched to cause-effect relations of what we do on this planet; herein lies one major test for future AI.

At the individual level it is new endeavours such as nanotechnology which will allow us to bridge the molecular and macro-structural world to allow new, multifaceted tools for measurement and manipulation.

A background concern is the growing administrative burden being placed on universities by burdensome government regulation and reporting. There is compounded by an internal disconnect between the administrative and front-line academic functions of a university.

2. Reformulation of our Education, Research and Innovation Base

University education is integral to the well-being of a global society, and it is recognized that there is a strong link between educational quality and economic prosperity and stability. Our challenge is now to provide a new transdisciplinary education in Europe that can serve as a global model. The impact of any model of teaching and research also has to factor in the ethics of the outcomes, given the increasing potency of our technological advances.

2.1. Multi- Inter- and Transdisciplinary Education

A discipline is a sub-field of science, engineering, humanities, etc. with a specific approach, fundamental concepts, language, methods, and tools that aim to analyse, understand and describe parts of Nature.

Multidisciplinarity is the case where several disciplines come together in parallel to tackle one subject. An early example is the tailoring of isotope-bearing chemicals for imaging and therapies for use in Medical Physics.

Interdisciplinarity is the case where the concepts and methods of one discipline are used in the work of other disciplines. A classic example is biomaterials research which draws on both physical materials science (polymers, ceramics, metals) and the biology of tissue and cellular processes.

Transdisciplinarity is a holistic approach that sees all aspects of the world as interrelated through patterns of interdependent systems. These include natural, social, economic and even political systems. Transdisciplinarity integrates knowledge and methods from any source that can be of value in addressing a particular problem or research question. Essential requirements for any transdisciplinary work are an innate curiosity and patience as well as a basic understanding of other disciplines and their language. This all takes time and personal commitment. Such transdisciplinary research and teaching must not be constrained by traditional subject boundaries. A typical example is the epidemiology of infectious disease. This

requires factoring in of the bio-/physical fundamentals governing organism transmission through to a comprehension of human societal behaviour, psychology and cultural norms, e.g. in relation to health compliance and vaccine uptake. Alternatively, there is a need to understand animal and insect vectors in the context of ecological systems through to the genetics of susceptibility. The requisite disciplines may appear to be too disparate to allow for a single transdisciplinary pathway in teaching, but medical and dental training already provides models for how subject integration can be achieved.

2.2. Challenges for Inter- and Transdisciplinarity (I/T) Activity

- ***Language:*** Each discipline creates its own jargon. (I/T)-disciplinarity requires the appropriation and accommodation of different languages. This means that communication of I/T-disciplinary research and teaching can be difficult since it requires the use of technical terms borrowed from one discipline that are not well understood by the specialists of another discipline.
- ***Methods:*** Disciplines are often devoted to their own methods of investigation. This may lead to misunderstanding and opposition.
- ***Institutional constraints:*** Institutions are mostly discipline organised, creating barriers for I/T-disciplinarity. However, strong, well-defined disciplines are necessary as any interdisciplinary activity starts from a deep understanding of single disciplines.
- ***Cognitive constraints:*** It is often difficult for an individual to become expert in two or more disciplines. An in-depth knowledge of different disciplines is however the requirement for genuine I/T-disciplinary research. This raises a question of the impact of these difficulties in education and achievement of the formalisation of interdisciplinary training programs.
- ***Assessment:*** Experts (reviewers) for evaluating the results of multi-disciplinary research and education are lacking. Standardised bibliometric information is scarce and not representative. New ways of quality assessment need to be developed. In this context, it will be necessary to improve the traditional «closed loop system of the classical university» of Fig.2.2, which is usually focused on a specific discipline and in the worst case scenario experts may not be able to see the «wood for the trees».
- I/T-disciplinarity requires mastering of more than one discipline in depth. Superficial learning of several disciplines does not lead to meaningful I/T-disciplinary research or corresponding solutions of complex problems.
- Experience has shown that learning the essentials of several disciplines has to be done consecutively, not in parallel: for example, doctoral studies in one discipline and post-doctoral work in another.
- New training models and the break with tradition they represent leads to qualifications which may not be obvious to an employer, and this creates a risk to both the student and the employer with respect to both employment and employment success.
- For early and mid-career staff moving to re-designed centres, there is a career risk as their new specialism is not readily recognised.
- Teaching validation and standard setting become more uncertain and quality measures need to be rigorously set.
- For engineering orientated courses, accreditation by a learned institute is indispensable. New training in a new I/T-disciplinary programme makes accreditation more difficult.

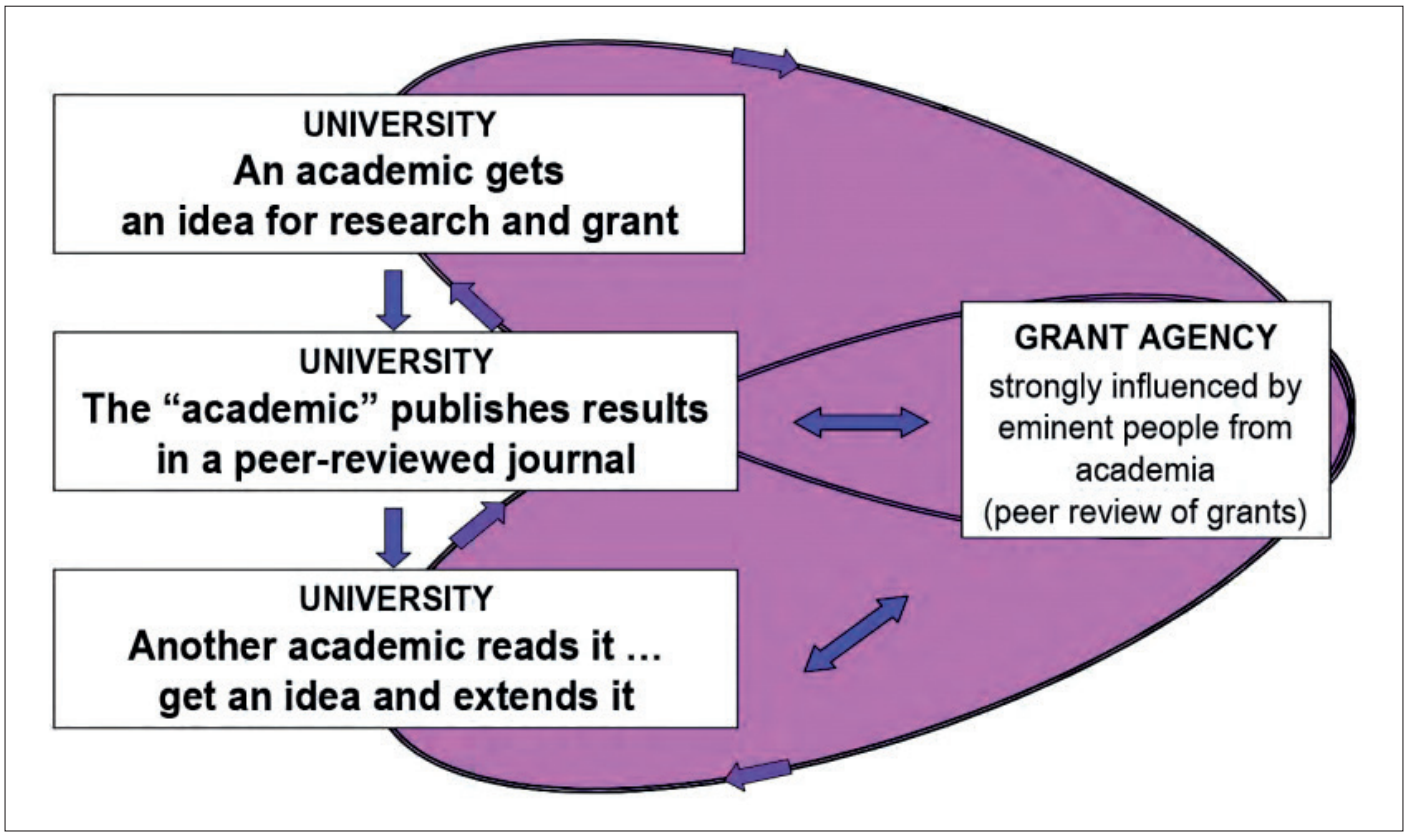

Fig. 2.2: Standard «Closed Loop Model» of an academic institution. (Courtesy: Hans Leuenberger [4])

2.3. Concerted efforts

These challenges are the very reason that a concerted effort needs to be made to create the conditions for transdisciplinarity. There is a need to start early – at secondary school – where the balkanization of topics can create undesirable early specialization. A wider choice of learned subjects here will prepare the student to accept transdisciplinaryarity as a valued norm and not as an inferior generalist. The guiding principle should be the alloying of physical, biological and humanities subjects. Excellence can then be equated with versatility and not with narrowness, which often masquerades as depth. The exact discipline mix is not the critical factor, but it might contain say 6 examinable subjects. The drive for this change needs to come from the Universities and industry jointly to demonstrate the added value to future careers of flexibility and the ability to move between careers in a world where the 'job for life' concept is fast disappearing. Without leaders presenting a convincing case, the status quo will remain. The case would need to identify intellectual, economic and prestige benefits. If curriculum change is not inspired through opinion leaders, why should the student take on the adventure of transdisciplinarity?

2.3.1. Identification of Research Translators, Multi vs Mono Cultural experts

Multi-domain education to high level poses learning challenges for the individual, and not all will reach to the demanding agenda [5]. So some student selection is inevitable; this can be based on the 6 core subject performance. Selection will benefit society by identifying research 'translators' vs those who will do better as mono-discipline specialists. Both will be needed in the future. Selecting out the different aptitudes, in a culture of mutual esteem will be as important for selecting excellent candidates. The triad of knowledge, skills and attitudes must also not be diluted, on the contrary, greater attention to the latter will serve as a guiding thread for the individual through more complex career pathways and promote success in the workplace.

With intellectual openness, the student will take the new education in his/her stride, feeling enriched by the added dimensions. To achieve his there cannot simply be a token move to transdisciplinarity, otherwise failure is inevitable. Precious, valued disciplines need to be embedded in new departmental structures: physics into biology, chemistry into medicine, robotics into bioengineering etc. One such desirable mix is the bridging of biomedical and physical/engineering sciences coupled with new numeracy skills. Other disciplines that can be reinvented thus are environmental sciences, manufacturing, energy and human geography. Beyond the taught elements, a selected project would be chosen to be transdisciplinary. The final output would be a graduate able to accommodate other disciplines and a teacher able to transmit concepts from multi-domains as a normal part of their teaching. Such intellectual convergence will bring down traditional barriers and, in short, achieve the requisite re-invention of the Departmental model. This will also open up space to address the ethical implications, both of the technological approach and its impact. Ethics should be formally taught because no advance can be considered entirely risk free, and choices that are decoupled from ethics will also lead to decoupling from moral cultural standards, a price society may eventually not pay.

2.3.2. Postgraduate Studies

At the postgraduate stage, hyphenated MScs of equal prestige to a PhD could be developed where a sequence of 3 years expose students to tailored, contrasting topics. As an example, a sequence of biology, physical and computation science may have a core thread of engineering science. The graduate then has an appreciation of the universality of fundamental concepts. For partial completion of the MSc there are still benefits to the individual as a transdiscipline lead, and this should be rewarded with an alternative MSc award – not a diploma which would not have the same traction. Accommodation would need to be within the current ecosystem, and complementary to the deep but narrow focus of the PhD.

2.3.3. Importance of Inter-/Transdisciplinarity for University Development

Inter/transdisciplinarity matters because, in the real world, most scientific, technological, and social problems span different disciplines. The present generation of students must be convinced that they will have good careers if they take an integrated-topic study route in their early years. Today someone with inter/transdisciplinary expertise is viewed as a generalist, in the future this capability will be regarded as a specialization in its own right. For example, a graduate with a triple MSc degree in biology, informatics, and engineering, may well, in future, be better off than a PhD specialist in biology. Whilst an ad hoc I/T-disciplinarity might be achieved by a PhD later on, it is preferable that this is properly organized at an earlier stage. Degree structures will need to be carefully organised to avoid simply amplifying the workload. An MSc transdisciplinary degree sequence would involve multiple Faculties. One barrier has been the lack of mutual esteem, but with transparency in the educational process and a clear set standard this can be reversed. Industry, any case, will be keen to hire graduates who have mastered the challenge of studying different fields and are able to work as effective team members.

The further need is for the next generation of scientists to know how to deal with technical problems they have never met before, and on a realistic time-scale with a realistic budget. Future research is going to have to focus on solving unrealised problems that don't fit neat compartments. The US moon-shot program putting a human on the moon was similar in nature to this. Humanity will have to prepare for many more 'moon shots' as the challenges it faces on earth become more complex and more pressing.

The organisational structure of universities has changed little over the past fifty years. Inter-departmental barriers are too high, particularly at «traditional» institutions based around small Departments, e.g. 10–20 academics, and focused on narrow fields. A modern approach, shown to be more effective, flexible, and efficient, is to have teaching activity based within larger Schools, e.g. up to 100 academics, that can be more broadly based and benefiting from a more comprehensive repertoire. Research and teaching can then be either focused within just the School, or be further extended through cross-cutting University Research Centers spanning the Schools with a fluid organization, new skills can be imported into these structures.

A critical opinion former in any University organization is the full professor. They have been the leaders of our scientific advance through the ages, but now beyond being topic specialists we need them to embrace transdisciplinarity; by both renewing their research interests regularly and rejuvenating their teaching portfolio without boundary constraints they would serve as catalysts for the change we need as we dissolve the margins between different topics. A safe intellectual 'space' might need to be evolved to promote such academic entrepreneurship.

A university thus needs to be flexible in its governance, management and culture and to be constantly evolving new interdisciplinary models for the research fields of tomorrow. The immediate

financial 'bottom line' cannot be the dominant driver for this; it detracts from an institution reimaging itself to tackle new challenges.

2.3.4. A template of Inter-/Transdisciplinarity for the University of the Future

There is a need for a change in approach, and a revisitation of current policies to enable Universities to become incubators of successful inter/transdisciplinary research.

For University Leaders, there needs to be:

- Recognition that teaching is primarily for students who may not become future academics, and who also may be pursuing careers that do not exist yet;
- Recognition that research and teaching must be closely allied, so that students will benefit from the percolation of new ideas, knowledge and skills.
- Recognition that research changes very rapidly. It is therefore good practice to develop teaching within larger critical mass Departments with a strong leadership vision for curriculum and continuity, and exploiting central research institutes. This does not require separation of the staff who deliver the teaching from those conducting the research, simply that staff would have a different mix of affiliations.

For Funding Agencies, there needs to be:

- Diversity of approach to funding at all organisational levels, since the challenges of inter- and transdisciplinary science are themselves so diverse.
- Effective communication and co-operation between funders and those who conduct the research, so that funding decisions evolve through better understanding of new identified research challenges.
- Successful models that reward both risk taking and encourage success, but yet impose a low administrative burden.
- Active encouragement of interdisciplinary approaches in the solution of research challenges.

2.4. Intermediate Conclusions for Universities

2.4.1. Globalized Engagement and Responsibility of the Universities

In ensuring that the move towards a globalized strategy in education is meaningful and successful, collaboration between universities needs to have curricula and awarded degrees showing demonstrable consistency. Already, Europe, with its 30 countries and multiple University systems with different curricula succeeded in realising a uniform University education system through the «BOLOGNA Ministers' declaration». The United States has a system quite similar to that of Europe, and other continents such as South America and Asia will hopefully move towards a global unified system in the future.

An intercontinental University education system [6] demands great efforts from both Universities and governments. A global, uniform education system will result in benefits for educational quality, enrichment through mobility and greater cultural understanding. Lowered barriers to the mobility of students and academic staff

Prof. Dr. Dr. h.c. mult. Marcel Van De Voorde

Marcel Van De Voorde studied natural and applied sciences in Belgian and European universities which resulted in various academic degrees. He started his academic career as Professor at the Catholic University Leuven and the State University Ghent in Belgium. In the eighties, he was nominated professor at the Technical University Delft (NL) and visiting professor at various known universities in Europe, US, Japan and China, including the reputed Tsinghua University in Beijing in 1992. In his research career, he had direction and senior scientist functions at CERN (European Organization for Nuclear Research), Geneva, European Commission Research in Belgium, Max Planck Institutes in Germany. He also held important research mandates at the ESA (European Space Agency), Paris and NATO R&D&T in Brussels.

He was/is chairman/member of Research Councils and Governing Boards, worldwide e.a. CNRS (FR), CSIC (ES), (CNR (IT), NIMS (JP), etc; senator at the European and is trustee at the World academies of sciences and arts; honorary professor and doctor honoris causa of multiple universities.

He had/is advisor to Ministers, Directors of research centres, rectors of Universities in Europe and worldwide and at the Science Council of the French Senate and National Assembly in Paris, etc. He received many honors e.g. from the Belgian King, the Luxemburg State, European Commission etc. He is caritative also very engaged: Promotion of the Catholic universities in Bethlehem and Madaba (Jordan), creation of a research institute in the Balkans, a research center in the Middle-East containing eight countries including Israel.

Related to this conference: Important achievements are in University Education in Europe with pioneering work in the BOLOGNA Ministers Declaration with BSc, MSc, PhD degrees all over Europe and the popular EC-ERASMUS mobility programme. In the eighties, he was Co-founder of the IMEC's «Inter-University Nano-Micro Electronics Centre»: a spin-off of the Catholic University Leuven which hosts today 4.000 scientists, engineers, etc from 100 different nations worldwide. The research initiatives on Proton-Therapy for Cancer (PTC) treatments at CERN had, during the last decade, an explosive development in PTC-hospital clinics in Europe.

P.S. My pharmacy experience relates to the Dr Paul Janssen Laboratories, founder of the successful «Janssen Pharma Belgium» now the Janssen/Johnson & Johnson US. At the European Commission I was in close contacts with the European Pharma.

demands that they have prior knowledge of a foreign language and culture and so such teaching should form part of the curriculum. An added benefit is the possible setting up of collaborative education programmes.

A global scale ambition can only be truly realised through the patronage and opinion forming of UN Institutions like UNESCO and UNU (United Nations University in Tokyo). These have targets for the alleviation of poverty, gender equality and widening of participation and transdisciplinarity offer new routes to achieving these. Through their assistance a start should be made with Europe, and then the US, Australia, Japan and China with other regions to follow.

2.4.2. Mobility of Students and Staff

This could be aided, variously, by standardised recognition of qualifications, world-wide delivery of training courses and a formalisation of exchange programmes. An interdisciplinary culture has to be specifically promoted through educational and funding initiatives.

2.4.3. Globalized University Curricula

Criteria needed for a high-level education can be formulated as follows:

- Active advancement of multi-disciplinary knowledge, skills and attitudes as a curriculum norm.
- Competence development across multiple fields to facilitate future student self-development in keeping with new inter-disciplinary challenges.
- Exposure to leading edge research to demonstrate the value of novel approaches and how transdiscipline research in its own right can provide this by virtue of its novel topic linkages.
- Literacy in key technological areas, irrespective of subject boundaries, to be able to critically assess transdisciplinary research needs for solving complex application problems. Early exposure to technological challenges in the field can form a part of this.
- Teaching of social science, management and ethics, and protected time for foreign language teaching.
- Teaching of arts disciplines to provide appreciation of the human and cultural context of transdisciplinary research and how global issues have impacted on human quality of life and wellbeing. Study of international business, law, finance and entrepreneurship as enablers would be part of this.
- Teaching of the linkages between education, research, industrial R&D and innovation, complemented by project supervision from industry. The latter would also stimulate transdisciplinary university-industrial research partnerships.
- Joint supervision of post-docs, Masters and PhD students to foster the mobility of permanent researchers and academics between institutions to help create extended, global teams.

3. Knowledge Transfer between Academia and Industry being facilitated by the Inter-/Transdisciplinarity Research Approach

Technology transfer is the new buzzword in the academic world. Everywhere, researchers look at their American counterparts with envy and respect. To boost innovation, spin-off start-up companies as a result of research findings at academic institutions, it is important to establish the necessary environmental conditions by promoting interdisciplianry skills at e.g. the University of Applied Sciences of Northwestern Switzerland (article by G. Imanidis, in this SWISS PHARMA 43 (2021) No. 4 issue), incubators such as the Technopark (ETH Zurich, Technopark | ETH Zurich) or corresponding institutions close to an university campus. In this context, governmental agencies such as the former Swiss CTI, KTI, today Innosuisse (Innosuisse replaces CTI: Funding opportunities for Swiss researchers, SMEs and industry – accelopment) are able to financially support research projects based on innovative ideas such as the spray freeze-drying technology at the university of Basel (PhD thesis of Marco Mumenthaler, see article on «Spray freeze-drying for Formulations of Precision Medicine & Vaccines» in this SWISS PHARMA 43 (2021) No. 4 issue. Another interesting institutional concept is the Israel Innovation Authority IIA (The Israel Innovation Authority | Israel Innovation (innovationisrael.org.il), matching up to 90% of venture capital to be invested in a start – up company for financially supporting research projects for strengthening the economy by boosting innovative products.

Providing financial and legal support related to patent protection of ideas and results of researchers/inventors will be an additional incentive leading to the foundation of start-up companies. The availability of venture capital plays an important role for the first round, but the start-up company needs at a later stage additional money. In this context, it is important that the legal framework will allow inventors to be awarded and not only exploited. Unfortunately, in the event of capital increase, the inventors/researchers often lose the majority of votes being linked to the share of the capital invested. This problem is a result of the current law in Switzerland that a company is only allowed to issue additional shares with the nominal value 10:1. However, the ratio 10:1 may not be sufficient to become a «family owned» business with the opportunity of evolving into a world leading company such as Roche in Basel.

The ultimate goal of academic research is, of course, to explore new frontiers, but it is also to create industrial innovations that can lead to globally-successful outcomes. These need to be ranked alongside the recognition that is apportioned to the outputs of Nobel Prize winning research. This type of outstanding academic entrepreneur is, however, very rare and likely to remain so, given the risks to commercialization. Promotion of early-stage entrepreneurship through research industry transdisciplinary partnerships will help to mitigate risks. Inter/transdisciplinarity effort in tandem with the exchange of ideas and inspiration to innovate are the building blocks of future success. The synergy between university-based and industry-based research teams has proven to be an important factor in the success of some high-profile US research, exemplified by joint laboratories established variously by DuPont, IBM, AT&T, and Corning. These laboratories have generated globally leading products as well as Nobel Prize winners.

The tension between curiosity-driven science and the practical needs of society is more perceived than real. One needs only to recall the famous encounter between Faraday and King William IV, who once asked the celebrated scientist what his «electricity» was actually good for. Faraday answered, «One day you will tax it».

So, University research is not simply a less useful version of industrial R&D. It has a special cultural responsibility for free thinking. Curiosity-driven research free from commercial constraint serves as an engine for innovative output. Over the long term, private industry and the economy can benefit from these new ideas and associated discoveries, augmented further by transdisciplinary research. However, to reorientate research deliberately for practical success

will likely offer diminishing returns, exactly the kind of 'tunnelling' approach that transdisciplinarity can counter.

As well as the colocation of research by industry on a university campus, it should be possible to use existing funded mechanisms to second industrial staff to universities, undergraduates to industry secondments and cycling of research projects through university and industry laboratories. All this is already in play, but the unique feature here would be the setting up of projects that were intrinsically transdisciplinary and monitored by an appropriate steering group. Such interactions between universities and industry mitigate the risk that research topics are completely detached from the needs of the society. However, it is mandatory that the research is conducted following ethical rules of scientific integrity and integrity of data, which are described in the article «Business Ethics in the Pharmaceutical Industry and Beyond» in this SWISS PHARMA 43 (2021) No. 4 issue. At the same time it is mandatory to declare existing or potential conflicts of interest of the parties involved. The lifestyle based on scientific integrity and integrity of data must be part of transdisciplinary research and of tools used in the area of «Negotiations Engineering and Conflict Management» (article by Michael Ambühl and Nora Meier in this SWISS PHARMA 43 (2021) No. 4 issue).

Computational science and AI are presently boosting the convergence of all disciplines and ending the schism between natural sciences and the humanities.

Hence, similar to the preparation of the National US Nano Initiative in 1999 (http://www.wtec.org/loyola/nano/IWGN.Research.Directions), the implementation of a corresponding «Transdisciplinary Research and Teaching Initiative» is the logic next step and will lead to a new Megatrend in Science [7], boosting innovation for the benefit of mankind. It is important to notice that Mihail C. Roco (Mihail Roco – Wikipedia) invited not only all US research agencies but also leading representatives of the US industry for the successful preparation of the US Nano Initiative in 1999 (see list of participants in the annexe of http://www.wtec.org/loyola/nano/IWGN.Research.Directions). The CASS (today: Swiss Academies of Arts and Sciences) 2000 Symposium was organized by Margrit Leuthold, Swiss Academy of Medical Sciences, (samw.ch), Hans Leuenberger, Swiss Academy of Engineering Sciences, SATW – it's all about technology, and Ewald C. Weibel, 1929*–2019 †, (samw.ch) who invited Mihail Roco being the first informing the participants.

4. Achievements to date and future Ambitions

30 years ago, nationally based education across Europe made cross-European equivalence extremely difficult achieve. Thus, an engineering degree in Italy took 3 years and that in Germany 7 years. Population movement was also constrained across national barriers, translating into reduced exchanges in education and commerce. There were also obvious language difficulties, compounded by cultural difference, between North and South and between Western and the then Eastern Bloc countries.

European Union coordinated University education proved to be the backbone of unified development:

1. The BOLOGNA Ministers' Declaration of 1996 to achieve uniformity in the Education System and in the award of degrees.
2. The EC-ERASMUS Program for student mobility between countries.

The third ambition remains unrealized: Unified ranking of European Universities with respect to quality indicators, teaching quality, delivery to industry, student employment etc.

Appraisal from Australia

Whether we consider some of the complex challenges facing the world or consider increasing our knowledge of solving a problem in a limited part of a single discipline, advances are always more likely when the inputs come from a wider rather than a narrower set. This truism suggests that deliberately embracing transdisciplinarity should be our standard way of operating, and not simply a minor option.

Embracing transdisciplinary approaches in teaching at all levels and in research as well as in innovations in industry does not come easily. Our discipline based approaches especially in universities and in high schools mitigate against transdisciplinary teaching and research.

A key is therefore to promote mobility: of people and of institutions. Examples include forming Institutes in a University that comprise teams from several faculties and industry or cooperative research centres that are virtual and include teams from different institutions (and countries). Such institutions almost by definition need regular review and reforming and disbanding based on performance and the perceived need for the particular approaches. The authors explore comprehensively the need for transdisciplinary approaches and the ways we can increase our efforts. This is a pressing challenge and one that deserves even more attention than what has been achieved to date.

Robin Batterham AO
Former Chief Scientist of Australia

4.1. Present Status

The BOLOGNA protocol for interoperability together with ERASMUS freeing up individual choice have had the following outcomes:

i) Increased familiarity with different cultures and languages at formative career stages.

ii) Broader horizons for employment through better transnational job prospects and employment choices.

iii) Facilitated international communication to facilitate mutual economic, industrial, and political advance.

iv) Greater business efficiency through ease of working and travelling, outside of the home country.

v) A cadre of scientists more able to perceive supra-national dimensions to their work, particulary in relation to global health, energy conservation and recycling, no longer single nation issues.

vi) Better targetting of European legislation to the needs of people living and working outside their national borders.

vii) Accomodation of culturally different modes of working and operating organsations, coupled with newly acquired linguistic skills.

These outcomes have taken 20 years to come to fruition, but have been well justified given the greater impact of research effort in common interest areas such as the evironment, climate, defence and security. Europe has also become internationally more powerful and globally competitive.

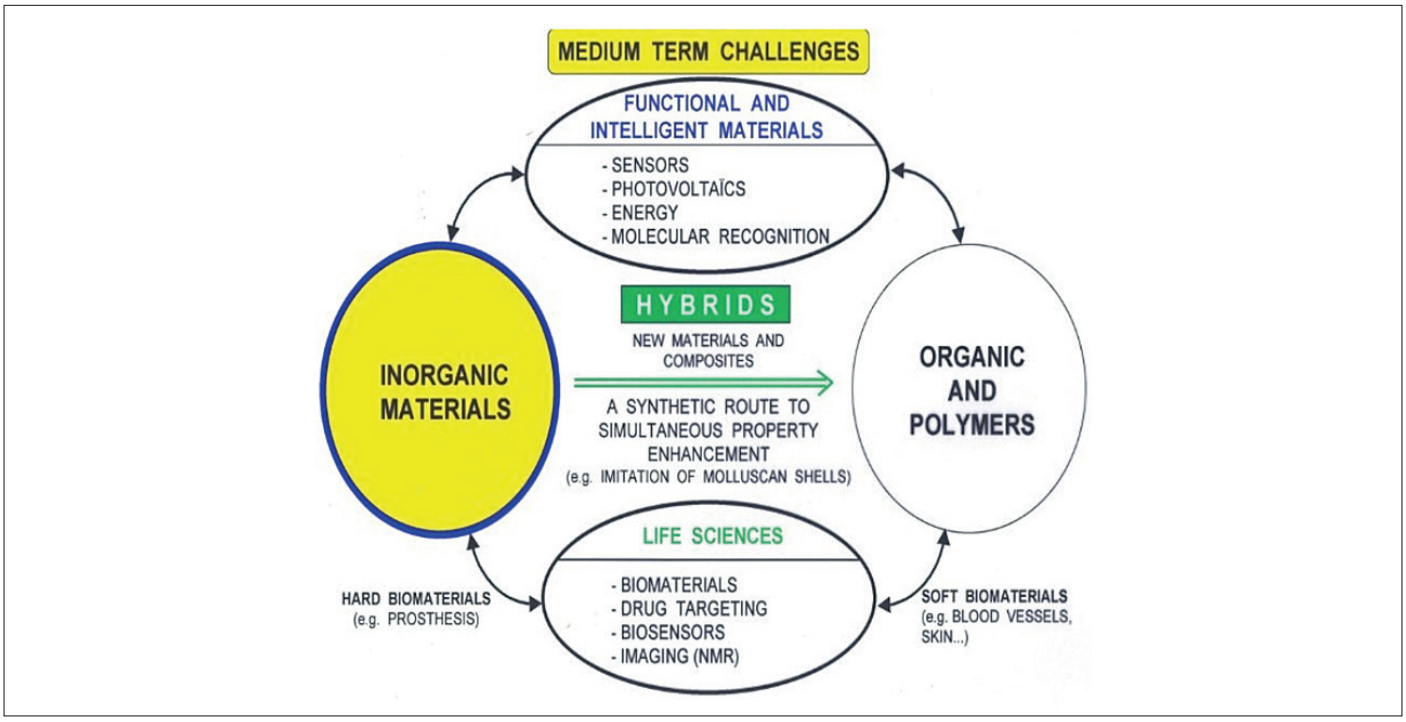

Fig. 4.2.1: Spin-off's of joining departements: Inorganic with Organic Chemistry.

4.2. The Developing Needs based on a New Approach

Cross-EU ranking of universities would provide an integrated feedback on key quality metrics. Countrywide ranking already exists, notably in Germany and Spain, but there is natural resistance to go beyond this because of issues of national prestige. Completing this task would help highlight centers of excellence and achieve better dissemination of 'best practice' to assist others for competivenenes on the world stage. Over time, the ranking of performance excellence should extend to ranking of contribution to transdisciplinarity: objective tools for teaching assessment are already used at national level. There would need to be consensus development in what constitutes excellence. For teaching this would incorporate student satisfaction surveys, examination performance, teaching quality audits, clarity of teaching objectves, innovation in how contact hours with students are used, new use of technical aids, class participation levels, how opportunities for two way exchange and mentoring are taken up, the coherence of formal teaching with tutorial, class work problems and practical classes and student feedback reports on taught modules. All these are classic means for assessment but their ranking would need to be worked out anew for transdisciplinary teaching. Excellence in research already has established measures, but also added could be the level of industry involvement, interinstitutional programmes and adventure in transdisciplinary research.

The internationalisation of educational standards beyond Europe can then have wider global benefit in adressing humanity's challenges: climate, migration, social advance, gender equality, clean technology, renewables etc. A more rapid, consistent approach can then be secured with direct benefit to the global citizen, a practical outcome not just a diplomatic nicety.

4.2.1. Specialization vs Transdisciplinarity

Specialisation is as fundamental to scientific advance, but a focus on this alone creates long term risk in our handling of global scale problems. Transdisciplinarity offers an alternative that focus the full repertoire of human capabilities towards larger goals.

Advantageous of specialization:
- Deeper understanding of specialist topics.
- Development of leading edge tools for more detailed study.
- High level intellectual challenge to inspire new entrants.
- World class leaders with unique capabilities in specific topics.
- New knowledge and understanding at a deeper level.

Disadvantages of specialization:
- Discipline boundaries constraining scientific cross fertilisation.
- Communicating with other relevant disciplines because of diverging research languages.
- Narrowing skills that is no longer a match to the broad nature of new societal challenges.
- Lack of recognition for the role of the research translator linking disciplines.

Industrial progress has never operated through convenient discipline domains; it relies on a pragmatic approach, constantly redefines itself and converges to a product or service though concerted action. Knowledge has to be sifted and collected between disciplines. Current vaccine development is an example of this, moving rapidly from traditional immune protein design to nucleic acid vaccines, now enabled through nanotechnology. These have answered the threat posed by a global pandemic, and a purely mono-discipline approach does not help here.

Advantageous of transdisciplinarity:
- Barriers between Faculties and Institutes are dissolved.
- Humanity's preparation for global threats such as climate change, which do not respect discipline boundaries, is better organised.
- The talent pool of transdiscipline scientists is better able to adapt to new specialisms and to move on from redundant ones.
- Individual employment prospects improve through greater intellectual adaptibility.
- Topic juxtapositions catalyse novel research combinations and outcomes: 'to think that which has never been contemplated before.

A simple example is given in Fig.4.2.1 when inorganic- and organic chemistry departments are put together, resulting in enormous

spin-offs inventions e.a. in life sciences, functional- and intelligent materials, hybrids etc.

Transdisciplinarity need not be considered to be an absolute that does or does not exist. It can be thought of as a spectrum within which degrees of specialism exist. For the best intellectual student, there may be a particular specialist core area that can compete with any specialist, but with sideways integration into other fields. A wider repertoire might not allow for the same level of specialist expertise. A rough guide to an individual might be through an *extensive* knowledge score and and *intensive* knowledge score.

The present stratification of formal degrees should be left as they are, but the components of the BSc should firstly be remodelled to incorporate new topics *(vide infra).* A commitement to lifelong learning should then allow advancement to a transdiscipline 'hoch' MSc. A subsequent PhD would be for those who have the aim of transdisciplinary university research, while others take the route of research implementation.

5. Practical Implementation of the Transdisciplinary Model

Human endeavour is advancing as a global entity with the expansion of international companies and global financial hubs. Education, however, is still a regional or nationally organised endeavour, and accordingly is at a disadvantage. Specialised University studies are pushing us in the opposite direction to global needs. Transdisciplinary approach has the potential to rise to the challenge. Lessons from the past of what achieves breakthroughs have not yet been fully learned; it is through calculated bridging of disciplines that we make our greatest advances. Without this, even the best of our specialists, whether in AI, nanotechnology or informatics, will fail to understand each other or the vital aspects of allied fields; failure to see the bigger picture will lead to failure in solving the bigger problem. In the creation of new disicpline amalgams, there is no single formulaic combination that fits all, more important are the interaction dynamics simply created by the juxtapositions. The following text sets out scenarios for realignments in five sectors by way of example.

5.1. Medicine

Medicine as a pragmatic discipline needs to both respond to both advances in basic science and in practical implementation. The advance of new basic science in molecular biology, genetics, robotics and informatics and the realisation of high throughput testing bring with them new challenges of how to equip the modern clinical professional. In this context, it needs to be mentioned that the EPFL Ecole Polytechnique Fédérale in Lausanne, favors inter-/transdisciplinarity with seed fund, see: https://www.epfl.ch/research/services/fund-research/funding-opportunities/research-funding/interdisciplinary-seed-fund/). EPFL is convinced that an interdisciplinary chair in oncology will especially boost positive results at the interface between engineering and cell biology: https://www.epfl.ch/about/working/faculty-position-in-interdisciplinary-cancer-research/. There is greater pressure on the transdisciplinarity that already existed in medicine. The problem-solving nature of medicine, however, has enabled it to accommodate such new fields to supplant the old, and serves as an example of modern transdisciplinary teaching.

At the preclinical stage classical structure and function teaching can be augmented by treating biological processes as management cascades with nucleic acid as governance for trafficking to protein constructs. This then opens up input from engineering and IT. The student gains a wider perspective from allied disciplines never before envisaged. This can extend to pharmacology, specifically, with teaching of nanodrugs and nanomachines. Without grounding in the physical sciences and engineering the practitioner would be relegated to an empirical end user of therapies. It can be argued that a juxtaposition with physical science and engineering (mechanical, process, chemical) is too radical, but medicine is already heavily dependent on such technologies. Artificial organs are another advance operating on engineering principles and feedback which require more detailed understanding.

The new case mix of biology, engineering, nanoscience, informatics and modelling will introduce a level of transdisciplinarity that will prepare the student for the future integral to the art of patient centred medicine that becomes important at the clinical stage of teaching. Distinct teaching areas have already converged to coordinated teaching schedules, but now are set to extend through further transdisciplinarity [8].

What is needed is the setting up of new curriculum committees with multi-faculty input to advance transdisciplinarity in a way that does not burden the individual student, but on the contrary equips them to deal with a field of especially rapid biological, technological and engineering advance. It will be also important that new discipline incorporation does not occur in an incremental way; this will guarantee low impact. Instead, a step change in teaching design and transdisciplinarity is necessary to justify the effort in the first place. The University hospital is a further venue where such new subject interactions can provide teaching benefit at the clinical stage. A key context for all such transdisciplinary teaching needs to be the ethics of healthcare delivery and its priorisation in a global community, brought into sharp focus in the current global vaccination program.

5.2. Geography

Geography already has a strong culture of transdisciplinarity. Current teaching covers domains such as human populations, pollution, aquatic physical processes, ecology, climate and agronomy. Greater transdisciplinarity will strengthen the teaching platform. This will usefully include teaching of economics, politics, history, genetics (to understand population movements) and epidemiology (the disease – climate link). With such input, future researchers will be better able to institute predictive models for pandemic spread and climate threats to agriculture and the hydrosphere. This 'new' geography will be a reservoir for dealing with global scale challenges, infection and resource related. Other domains can be readily included, such as of the urban and built environment – of direct relevance to infection transmission. As with medicine, competencies should be imported from other University departments including the Arts (business, politics, history) [9], and there should be teaching of ethical decision making given the wider impact of geography cantered policymaking in society.

5.3. Biological Sciences

Biological sciences have seen a revolution through input from chemistry. This has been synthesised into a transdisciplinarity that we refer to as biochemistry, often forgetting this development by last century pioneers. Ultimately biological events converge to being the same as those studied in physics and chemistry. Inclusion of physics, new chemistry and engineering concepts [10] into teaching will create a new type of graduate student able to move readily between biology and the physical sciences. An indication of the transdisciplinary future is shown by the advent of quantum and computational biology and the use of AI to achieve predictive modelling of protein, once thought impossible. Progression to a deeper

understanding of biology from the physical science perspective will bring us ever closer to understanding biological phenomena, inclusive of energetics and free radical effects, of fundamental relevance to ageing. Beyond this physics will provide a probe to the elemental atomistic processes that govern life. The context of biology is also important and ethics teaching will enable future practitioners to critically evaluate both biological techniques and the outcomes of biological interventions.

5.4. Pharmaceutical Sciences

In 1231 Frederick II (1194*–1250 †), Holy Roman Emperor (Frederick II, Holy Roman Emperor – Wikipedia), king of Sicily, was the first to issue a medicinal decree defining the tasks of a pharmacist and of a physician leading to the separation of the two professions and disciplines. Today, the city of Basel not only hosts the headquarters of the pharmaceutical companies Novartis and Roche but also the «Basel Oath of Pharmacists» in the Red Book of the Basel State Archive, being written around 1300. After a candidate with a master thesis in Pharmacy passed the federal exam at the University of Basel he/she does not only receive the federal diploma as eidg. dipl. Apothekerin (Ausbildung zum Apotheker (pharmasuisse.org)), but as well, as a gift, a copy of the historical «Basel Oath of Pharmacists». The article «Studies of pharmaceutical sciences in Switzerland» in this SWISS PHARMA 43 (2021) No. 4 issue by G. Borchard and Ch. Moll describes its societal impact on the Swiss economy. The University of Basel and the nearby University of Applied Sciences of Northwestern Switzerland (FHNW) are surrounded by world leading research laboratories of the Swiss Pharmaceutical Industry that allow extremely fruitful interactions and collaborations. Thus, it is possible that PhD students do their thesis at an industrial laboratory. In such a case, the science faculty and the industry allow the responsible professor at the University of Basel to supervise the thesis at the respective laboratory, (www.ifiip.ch/annual reports). After the PhD exam, most PhD students are directly hired as industrial pharmacists in Analytical Pharmacy, Clinical Pharmacy & Research, Drug Research, Pharmaceutical R&D, Quality Assurance, Pharmaceutical Production, etc.

This is a unique situation ***promoting transdisciplinary research,*** since the PhD student is collaborating with scientists of different educational background and culture. In addition, the following advantages are evident: a) The responsible professor at the University defines along with the industry the topic of the PhD thesis with the goal of a «win-win» situation; b) The PhD student has an official contact person at the industrial laboratory, serving as a liaison officer, who is in the ideal case, but not necessarily, also a lecturer at the university; c) The responsible professor at the university has access at any time to the industrial laboratory to supervise the work of the PhD student; d) The responsible professor discusses on a regular basis the progress of the PhD work with the student and the industrial liaison officer; e) The PhD student is using the high-tech laboratory equipment available at the industry; f) The salary of the PhD student and cost of materials, insurance, etc are covered by the industry; g) The liaison officer at the laboratory thus knows the performance of the PhD candidate before he or she may be hired by the company; h) The PhD candidate becomes familiar with the daily work of an industrial pharmacist, that may motivate the PhD student to apply for a job in the industry. Due to the evident «win-win» situation, there should be no need to apply tools of the article «Negotiations Engineering and Conflict Management» in this SWISS PHARMA 43(2021) No. 4 issue.

As with medicine, pharmaceutical sciences, is a crossroads discipline grounded in transdisciplinarity that covers chemistry, drug design, disease related knowledge through manufacturing. For future pharmacy practitioners, the traditional headings may well remain in place, notably 'retail', 'industrial' and 'research', but their functions will be radically different. A retail pharmacist will go beyond being a purveyor of medicine to one who is a point of contact for patient care, recommending drug therapies and providing diagnostic consultation based on new analytical tools. The retail pharmacist will also have access to patient metrics for individualised drug therapy. This possibility is indicated by work on the human genome, the establishment of biobanks and advances in pharmacogenomics. The future industrial pharmacist will develop manufacturing processes for biological drugs following up from small scale genetic expression systems. This has been seen for current vaccine production. The skill set of today's biochemical engineer, including modelling and molecular need to be included in teaching. The administrative role will be to compress the time between tailored drug production and its point of care delivery for labile biologics. High level management coordination and IT skills are need for this; there is a parallel to 'just in time' manufacturing in the car industry. Delivery of a drug can be to home, retail or doctor's office locations analogous to consumer goods. The pharmacy, however, is at the hub of decision making of a precise drug dose, type and formulation – a more complex task underpinned by IT support. Whilst they refine the therapy in this way and have a more two-way relation with the doctor, the primary decision to institute a therapy, governed by national bodies and the condition of the patient, must rest on a medical decision in consultation with the patient. So, the balance decision making does not change, but it is the complex formulation decision that the pharmacist finally makes.

New teaching therefore needs to broaden the transdisciplinarity agenda. New staff added to pharmacy schools will have molecular modelling/biology, bioengineering, informatics nanotechnology [11] and IT expertise. Combating resistant infectious disease [12] is a particular responsibility for globally positioned pharmacy, and here the adaptation of nanomedicine tools will allow existing drugs to overcome resistance mechanisms. The efficacy of corona virus vaccines through lipid nano packaging are an example.

Advances in nanotechnology are increasingly being utilized in combination in biotechnology as well as pharmacy. The unique properties of materials at the nanoscale, our ability to synthesize them, to visualize their workings and the ability to manipulate and tailor their physical chemistry at the boundary where biomolecular interactions take place opens up a myriad of opportunities in the pharma arena with extension to medicine and biotechnology [13]. It also gives us the unprecedented possibility to directly manipulate interactions at the biomolecular scale. The motivation to create smart nanostructures will not only be because of their chemical and biological activity, but also because they can be targeted delivery vehicles able to reach regions that traditional methods cannot and thus circumvent barriers that prevent the delivery of traditional pharmaceutical approaches: stealth objects. Ultimately, advanced medicine will not progress on the basis of knowledge alone, there will be a need to exploit hybrid technologies such as nanotechnology coupled with the rapid design, processing and implementation that AI can now offer us, now brought within reach of the healthcare professional at the patient interface. The risk to the continued flow of new drugs in the traditional drugs pipeline remains high, and it is likely that nanotechnological re-design of existing functional chemistries will be necessary for future effective drug agents, particularly with regard to antibiotics. The deployment of advanced technologies will bring ever greater need for ethical scrutiny, and teaching of ethics needs to be integral to transdisciplinary teaching; without transparency on this, societal acceptability may be limited whatever the technological merit of a give approach.

Organizationally, where national policy has produced pharmacy teaching in parallel with life sciences teaching to BSc and MSc level, it is beneficial to create a transdisciplinarity for pharmacy by ex-

ploiting the biological expertise directly within their teaching – the advent of biological drugs makes this a timely move. With jointly led reformating, a single merged curriculum can be successfully achieved effecting a reinvention of pharmacy. In view of the above three specialisms for pharmacy practitioners, at later years, students would be able to take up optional modules enabling them to progress along particular pharmacy technological aspects. Within each of these, however, also the principle of transdisciplinarity has to be maintained to avoid a narrow preparation for future careers, and in so called specialism there will be a need for chemical, biological, nanomaterials and other teaching to be included. The nominal specialisms of the retail, research and industrial pharmacist may be kept as such, but their function will develop considerably. Already, the retail pharmacist is providing health guidance to the patient in many countries, and given the complexity of future drugs, they are set to become a specialist who can guide the clinician, already overburdened with managing complex medical treatments and technologies. At research level, the unique combination of physical and biological science the pharmacist will have will result in important leadership roles given that mastery of drug design and biological action will be increasingly needed in combination. For manufacture, biological and bioprocessing knowledge of the pharmacist will be crucial in leading new production processes for biologics; we have seen precisely this kind of skill set requirement for vaccine manufacture. The reality is that the current complexity of healthcare demands the greater input of different professional types, and pharmacy is set to play a crucial role in simplifying the work of the clinical practitioner through contributing detailed drug therapeutic knowledge, from side effects to efficacy, and this may expand to drug diagnostics, monitoring and the individualisation of therapies as we advance our genomic knowledge.

With respect to implementation, such a School would have a leadership represented by physics, engineering, computing, chemistry engineering and biology. They would direct the teaching in partnership with established pharmacy teachers who would also do teaching in these other topics. At each stage, whether BSc or MSc, 30% of the curriculum would be 'non-pharmacy' teaching, and extra space for pharmacy teaching left out at undergraduate level would be provided in the MSc. The first years would have separate modules, but with increasing use of problem-based learning, the student would be tasked with problems that could only be solved by transdisciplinary approaches. Critical to the first years would be the accumulation of fundamental knowledge and principles which would be tested by knowledge and understanding, but in later years this would give way to use of knowledge in multifaceted problems, not in textbook recall.

5.5. Humanities

The rate of change in our cultural and social space is as every bit as fast as for the natural sciences. Accordingly, there is a need to bring together the principles by which we understand human cultural domains, whether these are in the artistic, social, anthropological, philosophical or historical domains. All are interrelated to varying degrees, but a light is seldom shed on the nature of the linkages, how one type has influenced the other, and how all are a manifestation of how humanity has tried to rationalise and communicate higher order concepts in a kaleidoscopic natural world. Transdisciplinary teaching here should have its core set in the teaching of linguistics, philosophy and psychology as human engines of thought, and then bring in history/anthropology, social sciences through to aesthetics and the arts (literature, music, theatre) in subsequent years, including at postgraduate level, as the outward expressions of the human internal mind. History and politics, in particular, will be better understood in terms of the human mind reacting to external complexity. The incorporation of different ethical and cultural value systems teaching will also have an influence on how different fields of the arts are understood and valued in different cultures. This will, preferably, be coupled to the teaching of legal systems. Overall, it is the mutual influence of arts topics that needs to be taught and to thereby impart a holistic understanding of what is beneath the outward manifestations of humanities subjects. Whilst this is necessary for the arts simply as a cultural responsibility, it does also have utilitarian value. Policy making and resource allocation are ultimately rooted in a societal value, and unless a broader teaching has been achieved, our policy makers will have a narrow prism from which to make decision that affect all of us.

Through such changes, the overall university role also shifts. As a specialist arm of society, it can provide new policy input for scientific research on global problems as part of a coordinated consortium with other international and national centres of learning. Science policy departments have been established, an effort that is a reflection of the recognition in university teaching of global priorities. Thus, universities are enabled to be part of the wider policy dialogue with other government. The internal organisational structure of the university also needs to change with governance a 'bottom up' activity rather than 'top down'; this returns academics to a different level of academic freedom, conditioned not by institution norms, but by the local level inventiveness and free thinking that resides at departmental levels close to the teaching and research front. An agile local level organisational structure also is able to rise to new challenges with an ability to network more readily with their equivalent globally on a target driven basis for research and teaching with equivalence in degree awards. The formal structure of the university does not change, it is the level of managerial input and resourcing at top level vs that at the local level that changes in its balance. The cascade of management: Central – Faculty – School – Department can be as before but the balance of decision-making shifts down this cascade. Where critical mass for a particular unique activity is needed, then staff in existing structures can come together under a special research 'home' – the Research Institute, one with a specified research goal and achieving a global reach. Such centres may be of finite lifetime, new ones would come forward and should be limited in number. A centre may also be a more suited for joint activity with industry. Here the University Science Park concept overlaps with the academic research centre concept but the mission limited status would help to focus joint research effort. With such teaching and research centres, the talent pool for industry can also be better tailored to need.

The launch of the transdisciplinary initiative needs to be via a European Rectors meeting who have the unique power to agree general principles and to institute change at demonstrator locations. However, there has to be participation, also, of learned societies, the European Commission and Ministries in order to map out specific details with representation of their 'end user' requirements for a future graduate work force.

5.6. Studies in Nanosciences

Studies in Nanosciences are by definition transdisciplinary. The Swiss Nanoscience Institute (SNI) at the University of Basel offers a Bachelor and Master Program for students interested in biology, chemistry and physics with enthusiasm to explore the nano cosmos. The Bachelor of Science with Major in Nanosciences is the prerequisite for follow-up studies to obtain a Master of Science with Major in Nanosciences or with Major in Biology, Chemistry or Physics. In this context, Joel de Beer (Study | Swiss Nanoscience Institute), master student, declares «*The advantage of the Nanoscience program lies in the linkage of a very broad selection of contemporary science disciplines and the applications thereof. While providing a unique insight into completely different mindsets, it simultaneously*

allows the exploration of common denominators and mediates a wide fundamental understanding of nature. During my undergraduate and graduate studies, I experienced the University of Basel as a progressive center of research and innovation that encourages international mobility and maintains a close partnership with global industrial players.»

Since 2001, the Swiss Nano Science Institute (SNI) of the University of Basel is hosting the National Competence Center in Research in Nanoscience (NCCR Nano). Partners in the network of SNI are: University of Applied Sciences of Northwestern Switzerland (www.fhnw.ch), Paul Scherrer Institute (www.psi.ch), Swiss Federal Institute of Technology Zurich (ETH Zurich – Homepage | ETH Zurich), University of Zurich (UZH – University of Zurich), EMPA (www.empa.ch), IBM Research Laboratory (IBM Research | Zurich), Swiss Center for Electronics and Microtechnology CSEM (Industrial Research and Development | Technological Innovation (csem.ch), University of Neuchatel (https://www.unine.ch/), University of Fribourg (https://www.unifr.ch), and the Swiss Federal Institute of Technology in Lausanne EPFL (École polytechnique fédérale de Lausanne – EPFL). Head of the SNI is Christian Schönenberger (Christian Schönenberger – Wikipedia).

6. Conclusions

Universities have historically focussed their education and research within specific academic disciplines [14]. Many of today's problems that research and education are needed to help solve are not defined in terms of convenient disciplines, yet these are precisely the problems that humanity needs to solve with urgency, covering especially the environment, energy, and health.

It is not enough to *value* individual experiences, disciplines, creativity and ideas. It is imperative we have practical strategies and practices that transform interdisciplinary links into more effective connections. We have to recognize the importance of discipline interdependence in order to actualise it, and we have to know how to act once we have developed that «recognition» [15] .

In ensuring a broadly-based education, that is both globally recognized and allows for the global mobility of students, there is a need to develop a World University System that promotes networks of universities with shared qualifications and close research collaborations.

This higher-level ambition can only be realized through structural change in the teaching case mix for the new generation of students. It cannot simply be a matter of topic 'add-ons', but a reinvention of curricula is needed with participation of new disciplines from across different sectors. Technical literacy in multiple fields and the ability to synthesize novel ideas and concepts are not always possible from a single discipline standpoint. Trans discipline effort brought to bear on multi-faceted problems is the most efficient way for society to win the race against the threats and to allow us to exist in equilibrium with the natural world. Achieving this transdisciplinarity is not set to be easy, not least because traditional thinking sets barriers. However, as a matter of urgency, what was correct for the quiet past is not appropriate for the turbulent future. For this reason, reputed universities in the United States

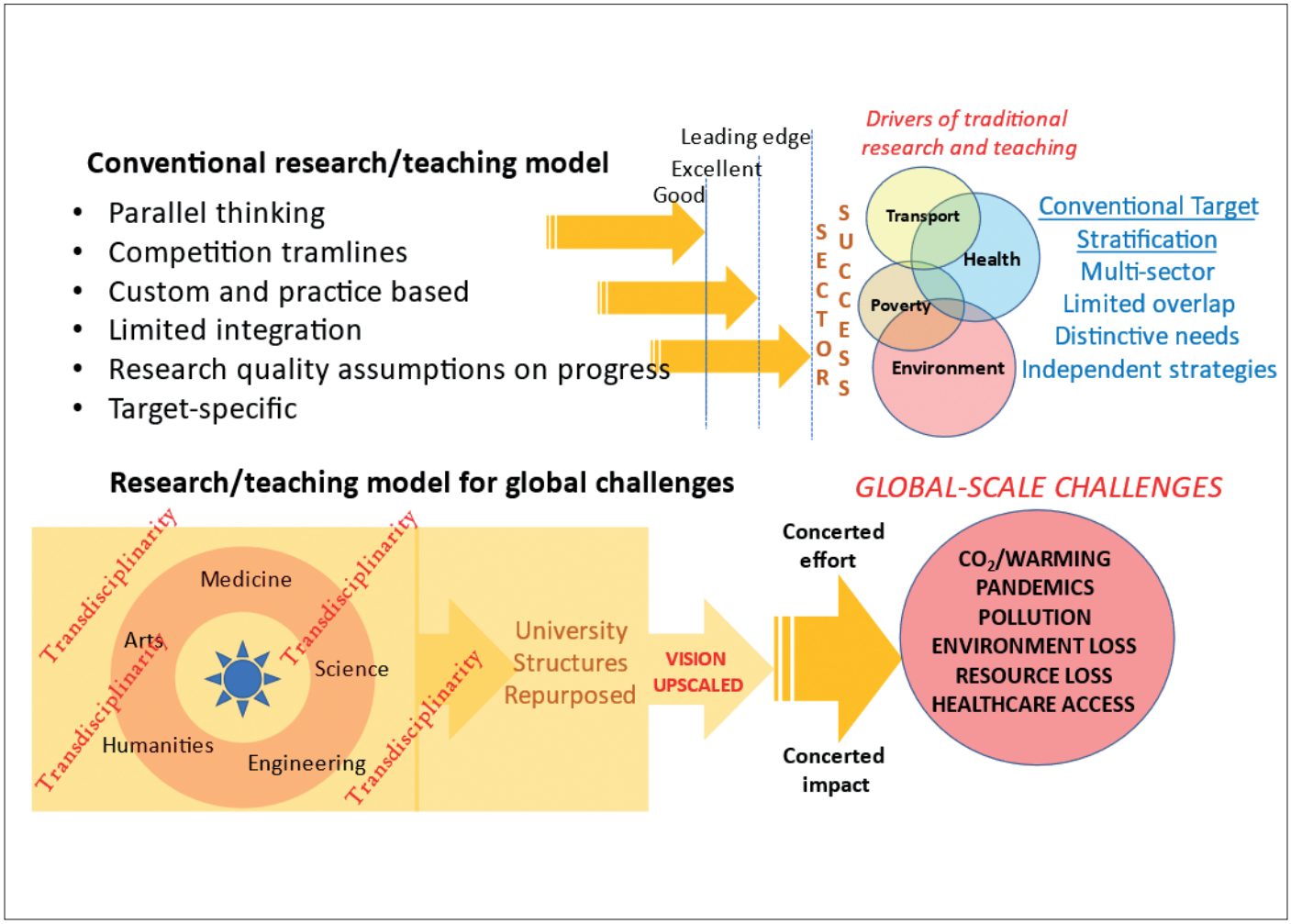

Fig. 6.1: The Model of Transdisciplinarity

started to create inter-/transdisciplinary chairs being followed in Europe. In this context, EPFL – Ecole Polytechnique Fédérale in Lausanne opens an inter-/transdisciplinary faculty position: https://www.epfl.ch/about/working/faculty-position-in-interdisciplinary-cancer-research/. There may be risks to radical educational change, but the bigger risk is educational stasis.

There are also huge intellectual benefits for the transdiscipline empowered individual with proficiency across different fields. Hitherto such a capability came about in exceptional individuals through unorthodox careers. It is no accident that the Chief Scientific Advisor to the US Government is mathematician who moved into molecular biology. However, such innovative combinations cannot be left to chance, but need to be a structural part of our teaching policy. The capacity to do this is already within grasp, since universities already have the requisite skill sets; they simply need to realign them in the service of a human need that transcends just the world of learning.

Governments, Ministries for Education, Research and Innovation together with Presidencies of universities, all over Europe, should take action to reform our university systems and academic structures for the future welfare of our economies and greater society.

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Member of the Cantonal Council
Head of the Department of Economics and Internal Affairs, Aarau

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