SWISS PHARMA

Vifor Pharma
A Manufacturing Network to Serve our Patients

Swiss Journal of the Pharmaceutical Industry

Schweizerische Zeitschrift für die pharmazeutische Industrie

Revue suisse pour l'industrie pharmaceutique

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4/17

60 Jahre Gesellschaft der Schweizerischen Industrie-Apotheker(Innen) «60 Jahre Industrie-Pharmazie»

SWISS PHARMA 3/16

60 JAHRE GSIA

SYMPOSIUM «60 JAHRE INDUSTRIE-PHARMAZIE»

Pharmazentrum der
Universität Basel

21. Juni 2016

Editorial

La Société suisse des pharmacien(ne)s d'industrie jette un regard rétrospectif sur 60 ans d'histoire et se prépare pour l'avenir

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1956 – 2016
60 Jahre GSIA – SSPI

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Vifor Pharma

A Manufacturing Network to Serve our Patients

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(Photo Vifor Pharma database)

Vifor Pharma – A Manufacturing Network to Serve our Patients

Dear Readers,

Vifor Pharma was always seen as the Pharmaceutical Division of the Galenica Group. At the Annual General Meeting on 11 May 2017, the name change of the Galenica Group to Vifor Pharma Group was approved and the transformation of Vifor Pharma Group was effectively completed into a stand-alone, global pharma company focused on innovative, patient focused solutions.

Vifor Pharma's goal is to be a global leader in iron deficiency, nephrology and cardio-renal therapies and strives to help patients around the world with severe and chronic diseases to lead better, healthier lives.

Vifor Pharma Group researches, develops, produces and markets its own pharmaceutical products and is the partner of choice for innovative, patient-focused solutions. The Company has a strong business history of producing and distributing pharmaceutical products in Switzerland. The ability to manufacture and supply the market with the products is ensured through a network of manufacturing sites, based mainly in Switzerland and Portugal.

We are very happy that this current edition is dedicated to Vifor Pharma's manufacturing network. SWISS PHARMA is a specialist journal designed for experts working in the Pharmaceutical sector. You will find in this edition, information on the industrial activities of Vifor Pharma, which form the foundation of the business to ensure reliability in supplying Vifor Pharma's quality products to our customers and patients. You will discover the multitude of tasks and activities needed from product Development, Manufacturing, Quality and Supply Chain to get high quality products to our patients. Most of these activities take place in our industrial sites across Switzerland and Portugal.

Realizing the production of medicines is only possible through the expertise and knowledge of our employees, along with advanced techniques and an Operational Excellence mindset. In order to ensure a stable employment environment and loyal employees, we have committed to the training and development of our people by investing in our own Vifor Pharma Academy, and building relationship and network across education and academic stakeholders in Switzerland.

I wish you an interesting journey with the Vifor Pharma Manufacturing Network, always keeping in mind the satisfaction and the health of our patients is paramount for us.

Dirk Schrader
Head of Global Technical Operations, Vifor Pharma, Glattbrugg ZH

Hans R. Mühlemann

Pionier der Erforschung der Mundkrankheiten Karies und Parodontitis

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Zum 100. Geburtstag
* 26. August 1917 in St. Moritz (GR)
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Vifor Pharma: Our Vision – Our Expertise

Operational Excellence and Technology in Services for our Patients

Interview with Dirk Schrader, Head of Global Technical Operations, and Thomas Kaspar, Head of Global Quality Management, Vifor Pharma, Glattbrugg ZH

In a series of several live interviews, SWISS PHARMA reports in issue 3/2017 in German and in issue 4/2017 in English on the Vifor Pharma Group, which was formed from the Galenica Group and has been operating as an independent company since early April 2017. Vifor Pharma is a specialised Pharmaceutical Company, operating internationally and a world leader in the discovery, Development, Manufacture and Marketing of pharmaceutical products for the treatment of iron deficiency. The corporate goal is to become a global leader in the three areas of iron deficiency, nephrology and therapies for heart and kidney disorders. The operational headquarters of Vifor Pharma is in Glattbrugg, Zurich. The Company has production sites in St. Gallen, Villars-sur-Glâne FR, Ettingen BL, Meyrin GE and Lisbon, Portugal. Vifor Pharma employs about 2,500 staff. Around 550 of these work in pharmaceutical production, which is the focus of our interview series. Therefore our first visit was to Dirk Schrader, Head of Global Technical Operations, and Thomas Kaspar, Head of Global Quality Management. We wanted to find out from them how these specialist areas are organised at the company's six sites and how they operate.

◆ **Interview: Dr. Felix Wüst**

Mr. Schrader, Mr. Kaspar, thank you for agreeing to talk to SWISS PHARMA at the Operational Headquarters of Vifor Pharma in Glattbrugg, just outside Zurich. On the way here I heard on the radio that Vifor Pharma has presented an impressive set of half-year results. So are you happy with the start that Vifor Pharma, now an independent company, has made?

Dirk Schrader: Yes, it is our first half-year result as an independent company. Galenica, our parent company, from which we were part of, has been delivering outstanding results for many years, with excellent performance and profits increasing year-on-year. It is gratifying that Vifor Pharma is now managing to continue in the same way.

Is everything really going according to plan?

Dirk Schrader: The Pharmaceuticals Market is evolving rapidly. It is not always possible to plan far ahead. But we are agile enough to be able to respond quickly to favourable market developments. As you can see from our half-year report, we have been entering into partnerships and making acquisitions that will bring us a lot closer to our corporate goal. We are very happy with our development.

Where do you fit into the corporate organisation, with the Global Technical Operations division which you lead?

Dirk Schrader: The Technical Operations division firstly comprises the production sites. We used to call it «Industrial Operations». Technical Operations now also includes the Global Supply Chain organisation, the Global Quality Management organisation, Technical Project Management and Pharmaceutical Development. In other words, all those technical departments that are concerned with the product. Our focus is on the 'end-to-end' product flow. In organisational terms we are both members of the Extended Executive Committee.

Vifor Pharma is active at various sites in Switzerland, and even has a site in Portugal. Is that a problem for Technical Operations?

Dirk Schrader: It is important to remember that Vifor Pharma has undergone an extreme transformation over the years. We started out as a manufacturer, as a pharmaceuticals manufacturer and also to a large extent as a contract manufacturer. We took the opportunities that arose to use our own production facilities to manufacture for other companies. However, over the years a quite clear focus developed towards the field of pharmaceutical specialities.

On 8 August 2017: Dirk Schrader (in the middle of the picture), Head of Global Technical Operations, and Thomas Kaspar (right), Head of Global Quality Management, Vifor Pharma, interviewed by Felix Wüst, SWISS PHARMA editor.

I assume that not all your production plants produce everything. The work must be allocated according to their technical capabilities?

Dirk Schrader: The interesting thing about Vifor Pharma, and which also fascinated me when I joined the company five years ago, is that Vifor Pharma covers almost everything there is in pharmaceutical production, with almost no overlaps. In St. Gallen we have a site at which chemical substances are produced. We have a site in Geneva where we have established a biotech production facility. And we have a large site where we manufacture various pharmaceutical dosage forms, such as tablets, ointments, capsules and liquids. That site is in Villars-sur-Glâne where we now produce many of the OTC products for our former sister company, now known as Galenica Santé, among others. We also have a site which is used almost exclusively for Contract Manufacturing for third parties, namely our factory in Ettingen in the canton of Basel-Land. You see, we have the chemicals site at St. Gallen, the biotech site in Meyrin, near Geneva, and Villars-sur-Glâne in the canton of Fribourg as the main formulation and packaging site. When we acquired OM Pharma, a biotech company based in Meyrin, near Geneva, a pharmaceutical production site in Lisbon, Portugal, came with it. This was highly significant for us as it enabled us to gain a foothold in the EU. There had also previously been a further site in Wigan in the UK, where herbal active substances and herbal remedies were produced. That was the company Potter's Herbals, but we have since sold it.

Kaspar, how are you handling the challenges of Quality Control and Quality Assurance at so many sites?

Thomas Kaspar: Certain processes and systems are indeed managed and administered centrally, but responsibility and competence for the individual products is handed over to the different sites. They produce, test and approve products for distribution. Local responsibility is therefore important, because the people at the sites have expertise in their products. Product-based organisation is not a problem, as far as I am concerned. Ideas for alternative forms of organisation tend to emerge when we are looking at ways of increasing efficiency between the individual sites, by introducing global systems or harmonising them in order to standardise them and thereby promote internal cooperation. For example, it makes sense to ask whether each site needs its own microbiology laboratory or whether individual sites might be able to take over a kind of service function. Another current issue is digitalisation. This is important for us as it is an area in which we can achieve efficiency gains across the sites.

On the topic of the EU: what Mr. Schrader mentioned certainly also has consequences for Quality Control and Quality Assurance.

Thomas Kaspar: Yes, especially as regards approval, i.e. the approval of the products for distribution in the European Union Market. Switzerland has a bilateral agreement with the EU, which explicitly states that our product tests are also valid in the EU. Even though

this is an advantage, it nevertheless requires a further formal approval by an Authorised Person who is geographically located in the EU, which necessitates additional management of data, processes and documentation.

Dirk Schrader: Currently the approval of our products for EU countries largely takes place in France, at our French site. It is not absolutely essential for us to have laboratories in Europe for this purpose, but having the opportunity to produce in Europe and channel things through Europe is certainly advantageous, quite apart from the salary costs. Costs in Europe are generally lower than in Switzerland and, within Europe, Portugal is a highly attractive location. Since we already had a site there, is has now also become a focus for our investment.

Can you tell us more about the investment programmes for the various sites?

Dirk Schrader: Investment programmes are ongoing for all sites. We are investing tens of millions in the sites every year. The latest major investment was made in Portugal and is currently being implemented there. The investment is in the production facility for Veltassa®, the latest product in the Vifor pharmaceuticals portfolio. We took advantage of the fact that we have a competent organisation at the site. And we had building land, which we were able to put to superb use in this case. This investment safeguards jobs, which was also an important aspect for us. I should mention at this point that we always have to make comparisons these days to decide whether to produce ourselves or go into Contract Manufacturing. These comparisons are regularly made, since we have to remain competitive. They have shown us that we are achieving by far the best conditions with production at our site in Portugal.

You mentioned salary costs in Switzerland. But is it not the case that you find good employees in Switzerland, well qualified people, possibly better qualified than in Portugal?

Dirk Schrader: Just as in Switzerland, we have also had a base of highly qualified employees in Portugal for quite some time. We have always had a highly competent organisation there, with extremely capable staff and we can also find sufficient qualified personnel on the job market in Portugal.

What is the situation like in Switzerland in this regard? Is there a skills shortage?

Thomas Kaspar: As a Pharmaceutical Company, we find that there is quite a strong regional variation in Switzerland in this regard.

Dirk Schrader: There are certainly posts that we have difficulty filling. The Pharmaceutical Industry has not become widely established in St. Gallen, in eastern Switzerland. That makes it more difficult to find employees with the right experience. Things are

Vifor Pharma Headquarters located in Glattbrugg near Zurich Airport

Open-plan office at the Headquarters of Vifor Pharma, Glattbrugg ZH

different in the Basel area, where we find ourselves in competition with the large pharmaceutical companies. And in the Geneva area, the HR recruitment situation is in turn quite different.

Mr. Kaspar: Can you find the people you need for Quality Control and Quality Assurance?

Thomas Kaspar: For Quality Control, and certainly for the laboratories, most posts can be filled within a reasonable period of time. For Quality Assurance, it is more difficult in those places you would not describe as having a pharmaceutical connection. Such areas include Villars-sur-Glâne and St. Gallen. It sometimes depends on being lucky and meeting someone who has roots in the region or would like to return there.

On the subject of the Supply Chain: how does it operate in view of the different locations of your production facilities?

Dirk Schrader: It is in this area that we have made the most changes in the last five years. Five years ago the Supply Chain was heavily fragmented. The logistics process was handled in the commercial sales organisation. Then there was the production organisation, which had been producing goods or making them available according to the requirements of the sales organisation. We have completely reorganised that. We needed an end-to-end Supply Chain organisation, starting with the customer's needs, through the Production process, to Purchasing and Development, and including Quality Control, approval, etc. Today, everything dovetails together seamlessly and is covered within a larger Technical Operations organisation. This has helped us make significant progress, particularly with regard to speed and responsiveness. We are continuously reducing manufacturing throughput times. Without this change we would not have been able to bring to market as efficiently some of the products that we now have in our portfolio. I am thinking especially of a biotechnological product from another manufacturer, which we are marketing exclusively in the U.S.A. We make it in Germany, transport it to the U.S.A. and distribute it in cold chain conditions, at a controlled temperature between 2 and 8 degrees Celsius. We are doing all this in collaboration with many external partners. This would not have been possible at all under the old structure without an end-to-end Supply Chain. Today we have more and more products, which we purchase or license-in. With our recent acquisitions, we are in many cases no longer producing ourselves, but have built up a network with contract manufacturers, logistics companies and service providers. We must take control of the Supply Chain and continuously improve it.

Thomas Kaspar: The same also applies in the area of quality. The Regulatory Authorities are indeed focusing increasingly on distribution, on sales channels, for example in the area of counterfeiting or temperature monitoring of transport routes. If we organise ourselves in the way that Mr. Schrader has just explained, the Quality organisation means we can deal with the processes more effectively than if everything is fragmented.

Dirk Schrader: Global markets are difficult to plan. We have strong fluctuations in the plans. This means that we must also be faster with the Supply Chain and must be able to respond quickly. That requires short manufacturing throughput times, and lead times need to be far shorter than before. We also need this in order to manage

New technology: «Augmented Reality», i.e. smart glasses that help our employees to work better, more easily, more quickly and more cost-effectively. (Photo Vifor Pharma database)

our working capital. We can no longer afford to put endless quantities of stock in warehouses. Yet we need to be ready to deliver at all times. We have managed to respond to all these variables without ever being unable to deliver. The Pharmaceuticals Industry is unfortunately coming under increasingly harsh criticism. We hear the accusation that, yet again, products which can sometimes save lives cannot be delivered. This is a problem that we have so far managed to avoid at Vifor Pharma, and we will also know how to avoid it in the future. We do not produce food or sweets, but highly efficient pharmaceutical products on which our patients depend.

I would like to return to the topic of Contract Manufacturing Operations, CMO, and the network's own operations. Can you tell me more about this?

Dirk Schrader: Yes, I did previously address the comparison of our own costs, capacities and capabilities with those of third parties, namely contract manufacturers. We are constantly putting these «make or buy» decisions to the test. We have even brought production allocated to third parties back in house, if we were not satisfied. There are also cases where, for various reasons such as product complexity, for example, we outsource portfolios or products to contract manufacturers and use our own capacities for other purposes.

Do you prefer to use contract manufacturers in Switzerland?

Dirk Schrader: The contract manufacturers have to meet our quality requirements. This is the same regardless of whether you are in Switzerland or another country. However, we do not work with contract manufacturers, and certainly not with other suppliers, that do not satisfy our own standards. And not just quality standards, but ethical standards, too. We do not order any product, any input material or any service from a supplier that does not meet our standards in the areas of environmental protection, safety and business ethics.

I am surprised that a well known pharmaceutical company entrusted you with the marketing of one of its products in the U.S.A.

Dirk Schrader: That is because we operate a joint venture via our partnership with Fresenius Medical Care and are therefore very strong in the areas of nephrology and dialysis. The said product goes to the U.S.A. in the dialysis centres, to which we have good access.

Is it possible that even more partners might come to you for marketing of products in the areas of nephrology and dialysis?

Dirk Schrader: Yes. I am thinking particularly of the company Relypsa, which was recently acquired by Vifor Pharma. With their Veltassa® product we are able to offer a potassium binder, which is primarily used to help nephrology and dialysis patients. This has resulted in even more licences and cooperation ventures in the nephrology field. As you see, we are highly attractive in this product area.

On the subject of «Industry 4.0»: what does this development mean for Vifor Pharma?

Dirk Schrader: It is particularly important to me personally, because I believe that Industry 4.0 is very much in vogue at the moment, even though it is also rather vague, in that the concept is somewhat unclear. We are using an application in which we apply the very latest technology. We use «Augmented Reality», i.e. smart glasses that help our employees to work better, more easily, more quickly and more cost-effectively. This really is a great step forward. This is how Industry will work in the future. I believe that we at Vifor Pharma are well ahead with this process.

Final question: what will Vifor Pharma look like two to three years from now?

Dirk Schrader: We are highly focused on our strategic areas. We want to safeguard these main areas and the product supply. These of course include the iron replacement products with the main product Ferinject®, and then there's Veltassa®, which we are just in the process of launching (August 2017; ed.). This product came to us with the acquisition of the company Relypsa. Our third focus is in the area of cardio-renal therapies. We must quickly bring to market maturity those products that the new acquisitions have brought us. And we must do all this without neglecting our established business. The OM pharma product programmes are important, biotechnology is important, the Contract Manufacturing in Ettingen is important, the Contract Manufacturing such as we are now doing for generics and the OTC area, is important. We are still the manufacturer for Algifor®, Triofan®, for Perskindol®, i.e. brands that are no longer Vifor Pharma brands, but which are nevertheless still manufactured in our production facilities. We must not neglect all this. We need to strike a balance between requirements and our opportunities. This is challenging and extremely exciting.

Mr Schrader, Mr Kaspar, many thanks for this interesting discussion.

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Vifor Pharma: Our Centre of Competence for the Manufacture of Iron Supplement Products

An Overview of the main Investments and Competencies

Interview with Hans-Martin Müller, Site Manager, Vifor Pharma, St. Gallen

The journey back to the roots of Vifor Pharma Group takes us to Vifor (International) Ltd. in St. Gallen. In 1857, Caspar Friedrich Hausmann, who had moved to St. Gallen from the Kaiserstuhl region in Germany, opened a pharmacy in Hechtplatz in the centre of town. By 1952 this was known as Laboratorien Hausmann AG , which was acquired by the Galenica Group in 1983 and was renamed Vifor (International) Ltd. Today, Vifor Pharma in St. Gallen is the Vifor Pharma Group's centre of competence for the manufacture of iron supplement products. The Company's main pillar, the iron deficiency treatment, was enhanced in recent years by the addition of further pillars or segments of related products, before the division of the Galenica Group into the independent companies Galenica Santé and Vifor Pharma in April 2017. In the nephrology segment, a joint venture has been established with Fresenius Medical Care, and with the takeover of the U.S. firm Relypsa, the Company has broken into a completely new product area. We visited Vifor Pharma, in the Sitter valley just outside the city of St. Gallen, to learn more about the production of active ingredients for iron supplement products. In this area Vifor Pharmas a global market leader.

◆ **Interview: Dr. Felix Wüst**

Mr Müller, thank you for welcoming us to Vifor Pharma. In order to reach you, we travelled by taxi through a thick forest, well outside the city of St. Gallen and into the Sitter valley. There is no bus service. My first thought was whether this remoteness might cause problems with the recruitment of staff?

Hans-Martin Müller: Welcome, Mr Wüst. Did you know that it has almost been exactly 40 years since you were last here at our premises? Our predecessor company, Laboratorien Hausmann AG, celebrated its 25th anniversary in 1977. On 6 September of that year, there was a press conference to which you were also invited as the then editor-in-chief of the newspaper «Chemische Rundschau». You published an extensive report in your newspaper. I would like to give you a copy of it when you leave.

Mr Müller, I was aware that I once attended a press conference at Laboratorien Hausmann AG. However, since I do not have access to the documents from that time, I was not able to find out the reason for the press conference. Now that you have reminded me though, it is all coming back. The newspaper you mentioned has not existed for a few years now.

Hans-Martin Müller: Now, to answer your question: yes, we are certainly tucked out the way, down here in the Sitter valley, but that also has its advantages. For example, we have very few neighbours. There are certainly disadvantages when it comes to public transport. As you will have seen when you arrived, we are building new car parks for our employees. This is necessary because there are no public transport operating from St. Gallen to our site. We are constantly in contact with the city of St. Gallen about this, but a bus service also has to be economically viable for the city. We have about 280 employees here at the site. They arrive in the morning and only leave again in the evening, because we have our own staff restaurant where they can have lunch. This means that there are peak times at the beginning and end of the day, and no regular transport requirement during the day. There is however another industrial operation here in the Sitter valley - the waste incineration plant. Perhaps you have also heard of the geothermal energy project, which has been the subject of intense debate. This was a project launched by St. Gallen, yet abandoned in 2013/2014 following a violent earth tremor. There are only two companies on this side of

The Vifor Pharma site in St. Gallen is located in the Sittertobel valley, surrounded by lush vegetation.

the river – the waste incineration and waste water treatment plant, and us. There is however an interesting project in the pipeline, but it is still in the early stages: the city is planning to pilot a service using a self-driving bus. We might be one of the locations to be served by it, but even if things actually did get that far, no decisions are to be made until 2018.

Your website www.viforpharma.com provides readers with a very attractive and well-designed summary of the history of Vifor Pharma. We need not go into great detail, but should at least mention that in 1857 a Caspar Friedrich Hausmann in St. Gallen carried out pioneering work in the area of iron replacement products. He moved his place of work from Kaiserstuhl in Germany to St. Gallen, after meeting and marrying a woman from the town. The success story of Vifor Pharma started at Hecht-Apotheke St. Gallen and Laboratorien Hausmann AG.

Hans-Martin Müller: That is correct. The company Hecht-Apotheke still exists to this day, in fact. It is still operating and is located in the market square, in the middle of the city of St. Gallen. The aforementioned Mr. Hausmann ran other businesses in addition to his pharmacy. Perhaps you know the company Hausmann Spitalbedarf AG in Wil? The development and production of Hecht-Apotheke Hausmann's own new medications, mainly iron supplement medications and infusion solutions, was outsourced in 1952. From then on, this activity was carried under the name of Laboratorien Hausmann AG, which was finally taken over by the Galenica Group in 1983.

Do you know why Laboratorien Hausmann AG moved from the city to the Sitter valley?

Hans-Martin Müller: At that time the city of St. Gallen was endeavouring to ban industry from the city centre. That is why the location in Sittertobel was chosen. Work started on the construction of the factory in 1952, and operations commenced in 1955. The Sitter valley is now a conservation area, which sometimes makes it difficult to obtain building permission. The hydraulic power station, which is being built in our neighbourhood, had to wait more than five years for its building permit. but we have not had any problems so far, despite brisk the continuous extension of our buildings and activities.

Do you know how Caspar Friedrich Hausmann came up with the idea of manufacturing iron-supplement products?

Hans-Martin Müller: It was in fact a certain Professor Theodor Bersin, who came to Switzerland from Germany after WWII and was appointed as the Head of Research at Hausmann, who was given the task of developing new medications. His philosophy was to develop medications that would combat the causes of deficiency syndromes, and this included iron deficiency.

Was the company Laboratorien Hausmann AG already a world leader in iron supplement products at that time?

Hans-Martin Müller: That is a good question. In the report I mentioned above, from the newspaper «Chemische Rundschau», I read that Laboratorien Hausmann AG had already enjoyed initial success with their products as early as the fifties. The first ferrous medication was licensed in Switzerland way back in 1949. It is worth pointing out that iron deficiency was less of an issue in those days than it is now. The medication clearly generated sales on the market, otherwise its production would have been discontinued. The

issue of iron deficiency is still relatively recent and only became recognised in the nineties due to the growing awareness of erythropoietin, abbreviated to EPO. This is a glycoprotein hormone, which is important as a growth factor for the formation of red blood cells, especially their protein shells, during blood production. Iron is an essential component of the haemoglobin in blood. Put very simply, haemoglobin contains iron cores which are completely covered with proteins. Without protein, iron does not make haemoglobin and a protein shell is likewise useless without iron: both are needed. And so, with EPO, there was a trend in the nineties towards intravenous iron, which continues to this day.

Does that also apply for the earlier Laboratorien Hausmann AG and the present-day Vifor Pharma?

Hans-Martin Müller: Yes. It applies for our oldest intravenous product, Venofer®. It was being produced in 1955 at around the time the factory was opened and is still manufactured to this day. We are right now in the process of building a new manufacturing line. Even though this product has not been patented, it is still very much in demand and production is constantly increasing.

Is the global market supplied exclusively from St. Gallen?

Hans-Martin Müller: When it comes to iron as an active ingredient, we are the only production site in the Vifor Pharma Group. All of our company's iron, wherever it is sold, has passed through our plant in St. Gallen at some point.

What about competitors? In other words, do you have a monopoly in the market?

Hans-Martin Müller: We are the world leader in the intravenous market. The oral market is far more fragmented and we are just one supplier amongst many. Yet even in the intravenous market, there is still competition but iron might be a special case. I am a qualified Organic Chemist and I am used to working with defined structures. You can take them, recrystallise them, clean them, etc., and organise them to a desired structure via various synthesis routes. Here in St. Gallen, we make molecular weight distributions. These are not defined combinations, but distributions, defined via the manufacture. The distribution must correspond exactly to the specification. If there is any deviation, the product cannot be salvaged by recrystallisation or similar processes. We have to get it right first time. Process expertise is the main requirement for the production of our active ingredients. We regard the production of active ingredients as our core business. We hand over the pharmaceutical formulation to contract manufacturers. This applies entirely for the intravenous area. In the oral area we also have our own company in Fribourg produce the finished product. For the last six months or so we have been packaging our intravenous products ourselves here at the site, as well.By this we are more flexible and are able to respond more quickly to country-specific order quantities, which are becoming increasingly smaller.

The vial and ampoule packaging line with serialisation option for the production of intravenous products such as Ferinject®.

If you want to develop further, you have to look for new active ingredients. Do you receive any input from the group Management regarding which areas are to be targeted for further development?

Hans-Martin Müller: All the iron ingredients that we currently sell were discovered, developed and ultimately also produced in-house here at the St. Gallen site. Alongside older active ingredients, we also have newer products. Our latest iron product was first approved and launched in 2013.

But I would like to know who gives you the go-ahead to develop a new product or a new active ingredient?

Hans-Martin Müller: As I mentioned already, we have an old product from the fifties, an intravenous iron, which is still a very good seller. In the nineties, the Management promoted the development of a new intravenous iron which was launched for the first time in 2007 under the name Ferinject®. We are motivated by our patients, and we want to make their lives better by providing new treatment options.

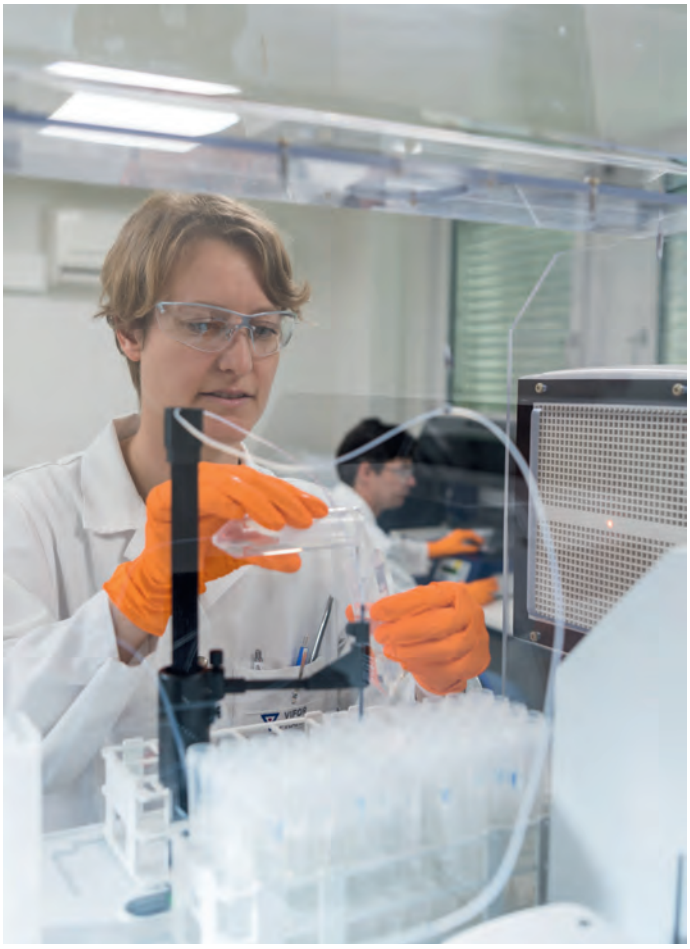
Would it be more logical to adopt a market-oriented approach, in which you observe the market and find out what is missing from the market and what is required?

Hans-Martin Müller: That is exactly what we are doing. We realised that our old product has potential for improvement, that the market needs a new product and that iron can be used in more therapeutic areas than simply nephrology. For some time we have also been developing an iron-based phosphate binder (Velphoro®), which we put on the market a few years ago.

Anyone sitting in the reception area of Vifor Pharma in Glattbrugg and looking at the pictures and labels around the walls would quickly get the impression that the Company deals solely in the field of iron supplement products.

Hans-Martin Müller: Iron supplement products are indeed still very important for our Company. Our iron supplement products business is at the root of our success story and is the guiding thread that runs through it. However, since Vifor Pharma has been standing on its own feet since early April 2017, we have been pursuing a new strategy, which focuses on three medium-term growth drivers. Alongside the iron supplement products business, with which we have achieved good sales so far, we are focusing on the area of nephrology, to which our joint-venture, Vifor Fresenius Medical Care Renal Pharma, contributes its expertise. And then, last year, we purchased the company Relypsa in America, with its own product, a potassium binder, and so we have laid the foundations for the third growth driver – cardiorenal therapies. As a result we have a completely new product, which was launched in the U.S.A. in 2016. It was also approved for the EU, Iceland, Liechtenstein and Norway in July 2017.

Are you still «number one» in the Vifor Pharma Group, with the St. Gallen site and its production?



Meticulous work in the laboratory is the prerequisite for success.

16th August 2017: Hans-Martin Müller, Site Manager, Vifor Pharma, St. Gallen, talks to SWISS PHARMA editor Felix Wüst in front of a drying tower.

Hans-Martin Müller: Iron is certainly the business area in which the greatest investments have been made. That is where we continue to reap the greatest rewards.

It must be highly motivating for you and your employees, that the birthplace and one of the main cornerstones of the Company is right here in St. Gallen.

Hans-Martin Müller: Yes, it certainly is motivating. The market is growing and demanding ever increasing quantities which in turn means we need to expand our facilities. As you can see from the window, we are in the process of building on the entire Company site. The employees sense the positive development, and also that they do not have to worry about their jobs.

Are you able to find enough skilled workers for the St. Gallen site, or do people maybe prefer large cities such as Zurich, Basel or Geneva?

Hans-Martin Müller: The Sales, Marketing, Medicine and Registration departments were originally based here, until 2008. When another company was purchased, it was decided to move the Headquarters to Glattbrugg, near Zurich. One argument for this move was that we were really struggling here in St. Gallen to find suitably qualified staff for Sales, Marketing, Medicine and Regulatory Affairs. It is easier to find new employees in Zug, Zurich or Basel. Part of the Research Department was still based in St. Gallen until recently. That department has now been moved to the Bio-Technopark in Schlieren (near Zürich). Here at this site, you will still find Development, Analytical Research and Production. We have no difficulty recruiting personnel, mainly science graduates. Many of them come from Germany and Austria, as well as Switzerland. We have staff from seventeen countries. One must not forget, we live in a beautiful area here. St. Gallen and its surroundings, the mountains, nearby Lake Constance - is an extremely attractive prospect for many people. I would like to add that, in my case, it was chance that brought me to St. Gallen. The post for which I applied, as a resident of Appenzell, was advertised in the greater Zurich region. I thought I was applying for a job in Zurich but apparently the person who placed the advertisement counted St. Gallen as belonging to the greater Zurich region.

Who are you looking for currently?

Hans-Martin Müller: We are always on the lookout for committed Laboratory Technicians, Production Operators and Managers to work in the Laboratories, Production or Supply Chain. As already mentioned, production quantities are constantly increasing which means we need to expand our workforce.

Do you also train apprentices?

Hans-Martin Müller: Of course, and we have been doing so for a long time. We currently have eleven apprentices training with us. That is a very good quota out of a total of about 280 employees. We are now attempting to break into other areas, for example con-

trol Engineering. We rely on automation Engineers to operate the systems, but qualified people are difficult to find for these occupations. This is a gap we could fill with apprentices. The question now is whether we are able to offer all aspects of an appropriate training programme. This is something we are currently working on with the involved departments.

Do you collaborate with the University of St. Gallen (HSG) or other educational institutions in St. Gallen?

Hans-Martin Müller: In the area of Operational Excellence, we have been collaborating with HSG for years and even working on exciting benchmarking projects. In Research and Development, we are constantly collaborating with the Swiss Federal Laboratories for Materials Testing and Research (EMPA) in various areas.

What about the issues of safety and the environment? Do your production plants fulfil the usual safety requirements?

Hans-Martin Müller: Of course. Safety and the environment are absolute priorities for us, particularly since our manufacturing processes are extremely demanding. We work mainly with highly corrosive reagents such as concentrated acids or even strong alkalis. With the iron itself, some stages of the manufacturing process are highly corrosive. We are unable to use normal non-corrosive equipment. It would be perforated within a day. We generally work with enamel, but enamel vessels are not ideal for heat transition. We therefore use mainly nickel-based alloys and other rather unusual materials. Since we are a Pharmaceutical production company, we are regularly inspected. Our processes and materials must satisfy the highest requirements.

And where do you find these specialised facilities?

Hans-Martin Müller: There are Swiss companies or companies in neighbouring countries, which produce equipment to suit our requirements. The challenge lies elsewhere, however. Materials technology is evolving and there are new and «better» alloys coming onto the market. Before we purchase a new item of equipment, we carry out extensive material testing. But even then, it may still happen that we find pitting and corrosion after ten, fifteen years and need to replace the equipment. Replacement is always a challenge and involves production shutdowns. Such things are annoying, but also add to our wealth of experience.

I assume you also face particular environmental problems?

Hans-Martin Müller: We are subject to the Major Accidents Ordinance because we store hazardous chemicals in excess of the quantity thresholds. Additionally, our production plant is located beside a river, the Sitter. Suitable safety measures need to be in place in case of an accident. Thanks to our neutralisation plant on the site, we are able to feed all of the waste water into the municipal Waste Water Management System.

Is there an organised exchange of experience among the various sites within the Vifor Pharma Group for dealing with matters related to safety and environmental protection?

Hans-Martin Müller: This exchange of experience does exist, and we want to enhance it still further. However, it is important to remember that the Vifor Pharma sites are very different. Fribourg, for example, is a Pharmaceutical production plant. Geneva is geared more towards Biotechnology. We are the only site within Vifor Pharma, which produces Chemical agents. Having said that, each site has its specialty and therefore its specific requirements as well. However, there are certain synergies among the sites that we can use; for example in purchasing, in the ventilation systems or even - to a limited extent - in spare parts.

Over the years, you have acquired enormous expertise in your field of active ingredient production. Is there ever a danger that you could lose this?

Hans-Martin Müller: That is a good question. With reference to processes, as a GMP-regulated business we are legally obliged to write them down in the form of SOPs. As regards knowledge, things used to be done differently. When I started working at Vifor Pharma in the nineties, knowledge was kept in our heads rather than in books. I can still remember an earlier time, when an experienced Chemist had to decide whether or not a batch was usable on the basis of an in-process tube test, which only he understood. The situation has changed drastically since then. Today, everything is documented.

Is there a risk that something might get lost?

Hans-Martin Müller: Processes and expertise are depersonalised today, so to speak.

For the production of active ingredients, is there a two or five-year plan with targets?

Hans-Martin Müller: We plan in the medium-term and with some room for man-oeuvre, because we have to stay flexible. Usually, in fact, we have to produce more than stipulated in the specifications, and therefore we need to ensure that we always have some free capacity in the meantime. We have now reached a critical point. We are working at full capacity and have very little flexibility but we need to be equipped for such cases. That is why we currently have various construction projects under way.

In other words, there is no risk that you might not be able to deliver one day?

Hans-Martin Müller: No, we have always kept something known as «policy stock» in reserve. This is essential, because we are the only production site for active ingredients.

You have described various investment projects. What will the St. Gallen site look like two or three years from now?

Hans-Martin Müller: We have some construction projects and I hope that these new buildings will be functioning production facilities within a year or two. Since I started working here, we have been constantly improving and expanding. There have occasionally been a few quieter years but we have many new projects running at the moment. After a new facility is started up for the first time, we see the well-known «bathtub curve». The error rate is high at first and improvements need to be made here and there. This is followed by the low-error phase and finally the object reaches the end of its life with the error rate rising again. I call this the «bathtub curve». It is what keeps us on our toes year in, year out. One area that might suffer during intensive construction work is process optimisation. With Operational Excellence, which has already been implemented in our Company for several years, we are able

to counteract that effect. We are particularly proud of our continuous improvement project: our employees are constantly submitting improvement suggestions regarding productivity, safety and quality, which we are gradually implementing. This is reaping benefits, slowly but surely. In packaging, for example, we are endeavouring to reduce changeover times using so-called «augmented reality» glasses, which are worn by the employees. It is pleasing to see that production quantities have steadily grown over the years, and we are able to handle more today than we could before. Optimisation projects of this kind can be implemented far more effectively with the employees in an expanding environment.

Mr. Müller, it remains only for me to congratulate you, your staff and the entire St. Gallen site on your successful work. Thank you for this interesting discussion.

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1960 – 2010

50 Jahre

Klinik für Orthopädische Chirurgie am Kantonsspital St. Gallen

SWISS MED 3/10

The Vifor Pharma Pharmaceutical Production Network in Fribourg FR, Meyrin GE and Ettingen BL in Switzerland and Lisbon in Portugal.

Production of Vifor Pharma's Pharmaceutical Portfolio is spread over several Sites

Interview with Frédéric Zwahlen, Head of Pharmaceutical Manufacturing Fribourg-Ettingen-Geneva-Lisbon, Vifor Pharma, Villars-sur-Glâne FR

Vifor Pharma stepped into the Industry limelight in early April 2017 when, having previously operated as part of the Galenica Group, it became in one fell swoop an independent company. Whereas Vifor Pharma was previously able to build predominantly upon its main pillars, namely the production and marketing of iron supplement products within a larger group, it must now stand on its own two feet and concentrate on expanding its product portfolio. This involves not only making changes in Manufacturing, but also, extensive investments. We wanted to find out more from Frédéric Zwahlen, who is the person responsible at Vifor Pharma for the production sites in Villars-sur-Glâne near Fribourg, in Ettingen in the canton of Basel-Landschaft, in Meyrin near Geneva and in Lisbon, Portugal. A further production site in St. Gallen is excluded since only pharmaceutical ingredients, and not end products, are manufactured there.

◆ **Interview: Dr. Felix Wüst**

Mr Zwahlen, thank you for seeing me here in Villars-sur-Glâne. It has been over a year since we recorded an interview for SWISS PHARMA. That was in June 2016, at the Ettingen site. The interview was on the subject of «60 Years of GSIA, the Swiss Society of Industrial Pharmacists», a professional organisation which you have now led for over a year as President. The interview appeared in SWISS PHARMA issue 2/2016, and can be seen on the websites of the publisher and GSIA (www.gsia.ch). How are things at GSIA?

Frédéric Zwahlen: GSIA is doing very well and is on a growth path again. Since we began offering specific networking platforms where our members and interested parties who wish to find out about GSIA can meet in an informal atmosphere, the number of members is constantly growing. What I am most pleased about, though, is that GSIA has succeeded in strengthening its ties with the universities and the universities of applied sciences. This enables us to convey an insight into the pharma industry to an increasingly wide circle of students and masters graduates, and introduce them to the work of Pharmacists in Industry.

That is a pleasing development and I would like to congratulate you and your colleagues on the Board. However, and especially now that Vifor Pharma is sailing under its own flag, you have become very much a part of the company's day-to-day business. And yet you find the time to exercise the office of President of a pro-fessional organisation with over 700 members. That is remarkable.

Frédéric Zwahlen: Our Swiss Pharmaceutical Industry is successful and it will re-main so if we manage to recruit good and superbly educated staff. I have always been interested in paving the way for young people into the Pharma Industry and motivating them to branch out into pharmaceutical production. This is certainly one of the reasons why I took the role at GSIA.

At Vifor Pharma you are responsible for product manufacture at the sites in Villars-sur-Glâne, Ettingen and Meyrin, and at the plant in Lisbon, Portugal. How have you organised this? Are these pro-ducts, the technology used or the markets supplied?

Frédéric Zwahlen: The deciding factor is the technologies used. We have formed «Centres of Excellence». The largest site in terms of

On 23 August 2017 at Vifor Pharma in Villars-sur-Glâne FR: Frédéric Zwahlen (right) , Head of Pharmaceutical Manufacturing Fribourg-Ettingen-Geneva-Lisbon, talks to Felix Wüst from SWISS PHARMA.

production activity is here in Villars-sur-Glâne, where I am based. The longterm focus of this site is on the production of solid dosage forms, such as tablets, capsules, granules, etc. Liquid and semisolid formulations are also produced here, however. This site is our basis for new products, both in Pharmaceutical Development and in Production. The second «Centre of Excellence» is Ettingen, where we produce Rectalia. These are specific forms for rectal application, such as suppositories and enemas. There is a further «Centre of Excellence» in Lisbon, Portugal. That site clearly has a different focus, as it specialises in the filling of sachets. It is a specialism in which we are currently investing heavily. Finally, there is the Meyrin site near Geneva, which might seem a slightly exotic member of our Pharmaceutical Production Network. Geneva is where we carry out vertically integrated bioprocess manufacturing, from active ingredients to finished packaging.

I would be interested to hear how you put together your Manufacturing portfolio.

Frédéric Zwahlen: Before the spin-off of Vifor Pharma from the Galenica Group, the Manufacturing portfolio was concentrated mainly on iron supplement products, as well as on production for third parties as well as OTC products for the Swiss Market and local products in Portugal. This enabled us to better utilise the capacity of our plants. Since becoming an independent company and embarking on new areas, for example through the acquisition of the U.S. company Relypsa and the expansion of Vifor Fresenius Medical Care Renal Pharma, a joint venture with Fresenius Medical Care, we have been focusing our attention on a small number of products, new products and on global marketing.

As Vifor Pharma does not actually have a research facility and therefore is not researching any new medications, any expansion of the product portfolio can only happen through the acquisition of other companies. Is that correct?

Frédéric Zwahlen: No, that is not correct. We have had an R&D Department for some time at Schlieren, near Zurich, which carries out research into iron deficiency. The company Relypsa also has a research unit. But it is true to say that we are expanding our product portfolio by purchasing licences and product rights, in order to ensure our growth.

Are there developments in pharmaceutical production that force you to abandon previous paths and search out completely new approaches?

Frédéric Zwahlen: Yes, that is indeed so. Right now we are seeing a trend away from production in batches. Instead of producing in batches, the machines are set up so that small quantities are produced during a specific period, for example an hour or longer. In

this way products can be manufactured in the most suitable time intervals. This is leading to a change in mindset and in the technology used.

That must also cause problems. Previously, you had one batch and everything from that batch was identically labelled.

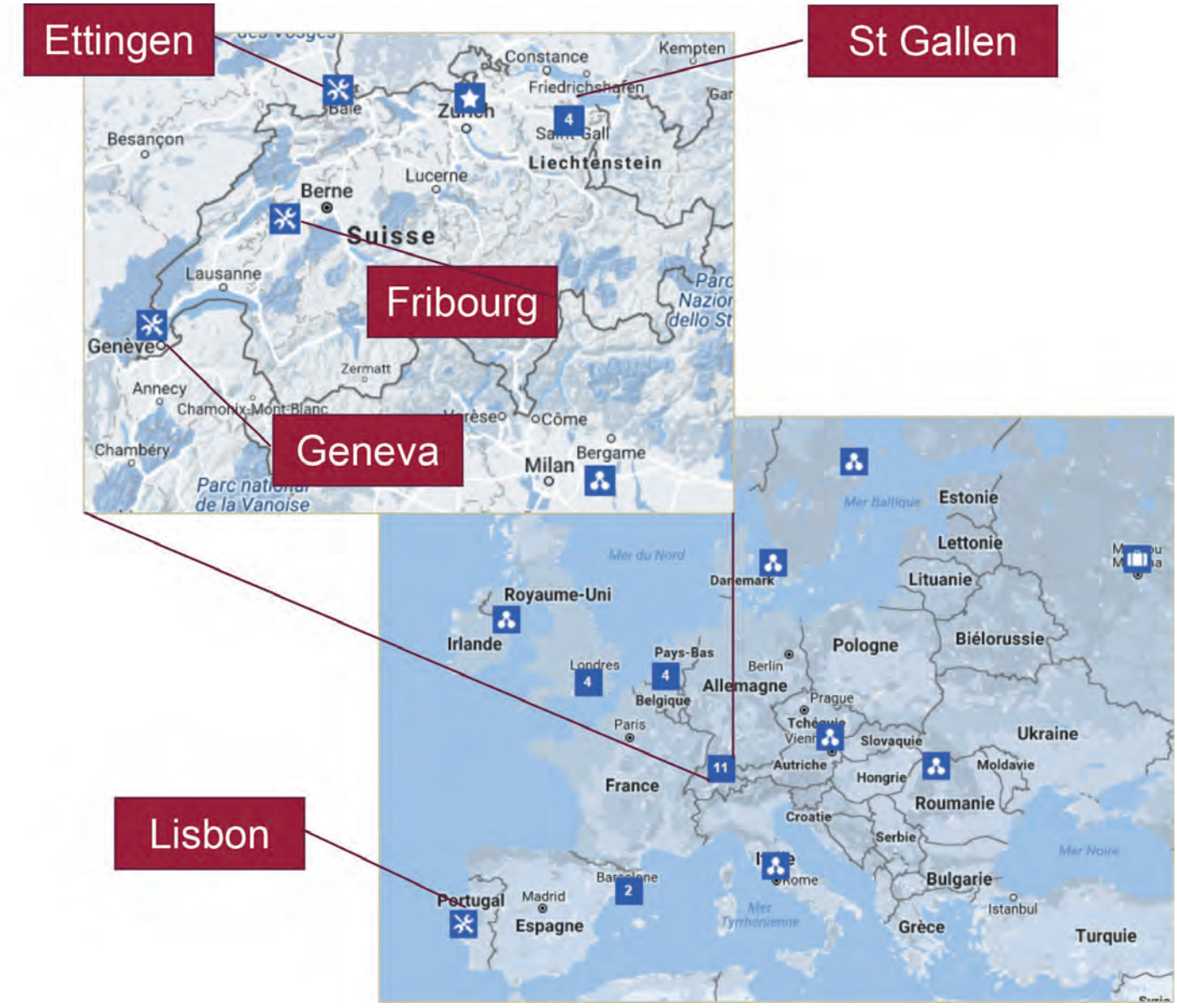
Frédéric Zwahlen: Yes, but like I said, we are increasingly moving away from that model. This is because, firstly, we often have to produce smaller quantities these days, and secondly, because we can produce entirely according to requirements using the «stop-and-go» method described above. Technically, it is quite feasible and is already being implemented by many companies, including approval by Authorities. We discussed this matter here at length and decided, on the basis our own study, whether or not we wished to implement these innovations in our production facilities. The results of the study showed us that there is little sense in using the new production methods for an existing product that has already been launched on the Market. The new production methods are more suitable for the manufacture of new products.

Do the Quality requirements of the Authorities represent a obstacle for you?

Frédéric Zwahlen: I would not call them an obstacle, as this matter is very important for us and influences our approach as well as our way of working. Firstly, it concerns the safety of our products and therefore the welfare of patients. Secondly, the extremely rigorous Quality requirements are also a challenge for us and they influence our agility and the speed of innovation in Manufacturing. Yet, thanks to our expertise, we are able to fulfill worldwide and highly varied Quality require-ments.

A question about staff training. Fribourg and Ettingen are some distance from the large cities. Is that an issue when it comes to training and development?

Frédéric Zwahlen: No, we have an excellent solution for this problem. We are investing heavily in our own staff training at every level. Training in the specialist areas of Operational Excellence and Lean Manufacturing is provided for all our production sites by



Vifor Pharma production sites

OM Pharma in Lisbon: construction of a new production building for the manufacture of Veltassa®. (Photo Vifor Pharma database)

means of a standard tool. And even the language problem is not an issue for us. Training for senior Managers is conducted in English, while for other employees or first line Managers, courses are held in English, German or French.
Learning methods, which correspond to a recognised standard, are an attractive opportunity for our staff and give them the chance to develop further within the Company.

Your role at Vifor Pharma also includes maintaining links with universities and uni-versities of applied sciences. Is your training and development also based there?

A new bottle filling line was commissioned on the site of Villars-sur-Glâne for the packaging of Velphoro®, a product launched in 2014 in the U.S.A. and since then launched in numerous countries around the globe.

The manufacture of solid dosage forms and in particular of tablets is the core business of the site in Villars-sur-Glâne. Modern, high-performing compression machines assure a high output.

Frédéric Zwahlen: Yes, of course. The person in charge of handling these requirements is located at our Management base in Glattbrugg. Jost Gloor is also featured in this issue, he is responsible for University Relations.

Do you have major investments planned?

Frédéric Zwahlen: Yes, at the Lisbon site where we are constructing a second facility alongside the existing production buildings, which will be used for production of the Relypsa product Veltassa®. This product is currently produced by contract manufacturers. It has already been introduced to the Market in the U.S.A. and is now being prepared for launch in Europa. We will be producing it ourselves in Lisbon. It is a product that we prepare using a blending process and then have to fill into sachets and keep cool. We know that there is a great need for this product on the Market. We require the appropriate cool chain for the distribution, and we work closely with the companies specialising in refrigerated transportation.

But did you make these major investments in Lisbon because you were already dealing with temperature-controlled products there, or because the Lisbon site is in the E.U.?

Frédéric Zwahlen: No, the choice of location for this investment had nothing to do with refrigerated products. Before that we had not been involved with refrigerated products, as a rule. We are new to this. Two other aspects prompted the decision in favour of Lisbon: the first, of course, being access to the E.U., which will give us a more solid footing. Secondly, the necessary technology: in Lisbon we have a wealth of experience in the filling of sachets, and the new product is also in sachet format. This made Lisbon the obvious choice for this investment.

But Lisbon is not the only place where you have made investments?

Frédéric Zwahlen: No, there are ongoing investments being made across all the sites. For example, a major investment area concerns the security of our products. To protect them against counterfeiting, they must be provided with an individual and unique identifying feature. In Meyrin, further investments are needed due to increasing production volume. Here in Villars-sur-Glâne, in the last year we have been expanding the manufacturing area for working with high potency active ingredients. For 2018 and 2019 we are planning to renovate our facilities for the processing of solid dosage forms, including granulation technology in particular.

What role does automation play in this?

F. Zwahlen: It is a general trend. All of our new, modern machines have a significantly higher degree of automation than the older models. The advantage is obvious: fewer staff are required, and fewer interventions in the production process. However, the saving on personnel is not the actual reason. It is mainly a question of being able to reliably stabilise and standardise the processes.

Enema production at Vifor Pharma, Ettingen BL (Photo Vifor Pharma database)

Will we be seeing further changes in Pharmaceutical Production at Vifor Pharma in the next few years?

Frédéric Zwahlen: There are still opportunities for further development. One is digitalisation, i.e. data processing by computer. A number of initiatives towards the «paperless factory» have already been planned for St. Gallen, Villars-sur-Glâne and Geneva. However, there is one area that is far more important, in which we are investing a great deal: our employees. Our training courses in Operational Excellence enable our employees to work more efficiently and learn how to avoid unnecessary steps in the work process and potential sources of error. It is an investment in the Corporate culture and in the Management processes.
We see here an opportunity to set ourselves apart from others through smart management. Anyone can buy technology. It is the organisation and the people that make the difference.

Now that Vifor Pharma is holding its own, are you able to act more quickly or with greater freedom? Has it triggered any decisive action?

Frédéric Zwahlen: Absolutely. At Management level we realise that we clearly have to step up a gear. We now have fewer products than before, when we were part of Galenica. The products we have in the pipeline show promise or even have the potential to become blockbusters. However, we still have to develop them successfully over the years and maximise their potential as well as we can. The eyes of the outside world are now upon us, and they are watching us closely. Before, we could hide behind the great structure of Galenica. Now, we are challenged. But we enjoy that, and it helps us progress.

Mr Zwahlen, this confidence, this willingness to face new challenges, is impressive. I wish you and your team every happiness and success in all your future ac-tivities. Thank you for the interview.

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Meyrin: The Global Hub for the Vifor Pharma Infectious Disease and OTC Prescription Drugs (ID/OTX) Franchise

Operational Excellence, Global Markets and new Opportunities

Discussion with Julien Storaï, Site Head, Head of Manufacturing & Technical Engineering, OM Pharma, a company of Vifor Pharma, Meyrin GE

The Vifor Pharma manufacturing site in Meyrin features a large OM next to the distinctive triangular logo. The letters are a clear legacy of its origins in Omnia Medicamenta, a company founded by the enterprising Jean-René Ricard in 1927. OM Pharma, as it became known, was acquired by the Galenica Group in 2009 as part of its pharma branch Vifor Pharma, now a separate company. Since becoming part of Vifor Pharma, the Meyrin site has benefited from strong investment support, making it today a full-service, state-of-the-art, dedicated biotechnology centre operating to highest GMP standards and specialising in immunomodulators. Site manager Dr Julien Storaï joined OM Pharma just before it became part of Vifor Pharma and he has been Site Manager since May 2016. With an MSc in Biochemistry and a PhD in Microbiology, Dr Storaï previously worked for Sanofi Pasteur, the vaccines division of Sanofi and the largest company in the world devoted entirely to vaccines. He is a man clearly passionate about bacterial cultures and their therapeutic future in the area of immunomodulators.

◆ **Interview: SWISS PHARMA correspondent**

OM Pharma has just celebrated 80 years. In an industry sector where companies come and go, what accounts for OM's longevity?

JULIEN STORAÏ: Strictly speaking, it's actually 90 years old! Omnia Medicamenta was founded in 1927 near Barcelona, in a place called Esplugas. But with the outbreak of the Spanish Civil War, business became impossible, so the founder Jean-René Ricard moved the company to Geneva in 1937. And that's what we have been celebrating this year, 80 years of continuous operations in Switzerland. From the start, OM was dealing with live bacteria developing what were then referred to as vaccines but that have evolved into the immunomodulators we know today. This dedication to bacteria in the service of medicine goes back to 1932 with the first extractions from a culture of Escherichia coli. Since then, OM has registered more than 50 families of biological and synthetic patents. So, innovation – in process as well as product – has always been a company strength. Entrepreneurialism has also been a feature: the Ricard family set up a manufacturing site in Portugal in 1954 to capitalise on post-war growth. From here, OM developed strong links with Brazil, further expanding into Latin America when they created an affiliated company in Peru in 1964. The global headquarters was built on the Meyrin site in 1970, increasing production capacity, adding new active principles, opening up new markets. OM has always been profitable and has shown consistent growth. It's been successful because of good management, strong partnerships – and good science. Today, the OM ID/OTX (infectious diseases and OTC prescription drugs) franchise consists of a portfolio of products that physicians around the world are happy to prescribe for their patients for a wide variety of complaints and conditions – from microvascular complications to chronic obstructive pulmonary diseases. More and more key opinion leaders are convinced by our products. A characteristic mix of innovative thinking, rigour and entrepreneurialism made OM a good match for Vifor Pharma. Culturally, the two entities have a lot in common. It's a classic example of one plus one adding up to considerably more than two!

What has OM brought to Vifor Pharma?

JULIEN STORAÏ: First, a wider portfolio with access to emerging markets and the sectors of infectious diseases and OTC prescription drugs. With that came well-developed capability in biotech and an experienced, highly qualified team. Of course, drug manufacture, whether it's chemical or biological, demands rigorous compliance with operational standards and regulations. That's a given. But microbes are living beings, they don't always behave as predictably as chemicals. So, on top of rigour, biotech specialists also need to develop skill in anticipating problems and to be creative in getting our «bugs» to perform as they should! Our proactive way of working maybe explains how the Meyrin team was the first in Vifor Pharma

30th June 2017: Vifor Pharma Meyrin Site Manager Julien Storaï talks SWISS PHARMA correspondent through the fermentation process. In 2018, the biotech team will be adding another unit.

to design and deploy a comprehensive approach to operational excellence (OE), becoming the reference site within the company for OE and project management governance. In the years since the two companies came together, Vifor Pharma has been pursuing a very successful growth strategy and that's in no small part due to the stable, profitable performance of the OM products. Vifor Pharma management considers our entity as an essential stabiliser for the group and the biotech business is highly complementary to pharma, not least in geographical terms given that OM has established international experience and strong partnerships in emerging markets, notably Russia, Latin America and China.

And what has Vifor Pharma brought to OM?

JULIEN STORAÏ: The Meyrin site has benefited from important investment support in recent years notably to increase capacity and in the interests of continuous improvement. This has been a priority for Vifor Pharma as it invests heavily in new product development and launches – all of which takes time to yield results. By contrast, investing in the Meyrin site gives immediate dividends! We've also benefited from more resources in the areas of Regulatory and Quality Expertise, and I think it's true to say that being an employee in a global company with nearly 2'000 people offers more career options, but it's still on a human scale so here in Meyrin we get the best of both worlds! Another thing that occurs to me is that as a biotech specialty within a specialty pharma company, we have been able to keep a degree of autonomy and independence.

What facilities do you have on this site?

JULIEN STORAÏ: The Meyrin biotech centre is unusual in being a full-service facility covering the whole supply chain from active ingredient to packaged product and supported by on-site R&D, Quality, Regulatory and Medico-Marketing teams. We have everything here! Working with preclinical and clinical colleagues, R&D is looking at analytical techniques to determine immunopharmacological data that reinforce the body of scientific proof supporting the efficacy and safety of the products with patients. Looking to the future, R&D focuses on the development of immunomodulators of both synthetic and biological origins as well as the synthesis of new iron ligands.

What do you produce?

JULIEN STORAÏ: Within the context of Vifor Pharma, Meyrin is the global hub of the company's infectious disease / OTX franchise, notably manufacturing the immunomodulators Broncho-Vaxom® and Uro-Vaxom®. Both products are based on active bacteria and have well proven advantages in treating respiratory and urinary infections. In many developing pharma markets like Russia and Brazil, these mature products have become established as the gold standards in treating these conditions. Both are well-appreciated for their efficacy and safety. They are also products with enormous potential; many healthcare specialists around the world endorse the fact that these products represent alternatives against antimi-

crobial resistance. Current developments for other indications are expected to accelerate geographic expansion in the medium-term. Broncho-Vaxom® and Uro-Vaxom® are bacterial lysates, composed respectively of 21 and 18 bacterial strains. The fermentation process produces one bacterial strain at a time, which makes for extremely complex production in terms of both planning and operations. We also provide active ingredients for our ‹sister› site in Portugal where they produce part of Broncho-Vaxom® and Uro-Vaxom® finished products as well as synthetic products like Doxium® and Dicynone® that go to make up the OM brand ID/OTX portfolio.

Can you talk us through the biotech process?

JULIEN STORAÏ: We operate on four floors, working down through a closed and fully automated system. As I mentioned, Broncho-Vaxom® consists of 21 different strains and Uro-Vaxom® has 18. Each strain has its own properties and there are six steps in the process that takes three to four days to complete, depending on the strain. As well as being monitored in situ, each step is batch sampled by Quality Control. Starting with pure culture of live bacteria for each batch, this is added in small volumes to the medium at pre-fermentation stage and the mixture flows down into the parallel fermenters on the floor below. It's a procedure that needs very precise conditions so we have developed a highly robust process that, thanks to constant monitoring and rigorous maintenance, now delivers almost 100% success rate. After fermentation, the live bacteria are deactivated in a rapid heating and cooling process that preserves their morphology. Next comes a centrifuge that separates out the culture medium and dead bacteria, leaving a concentrated biomass that is frozen and held in stock for the production of finished products. Given all the permutations, scheduling the final stages of production to meet customer demand is a complex process that demands not only operational excellence but also accurate forecasting. The final production steps start with purification, solubilising biomass to create a lysate of each strain. The lysates are then mixed to create a polylysate and the resulting concentrated liquid is lyophilised. Subsequently, the freeze-dried polylysate is rendered into a homogeneous power which is then mixed with excipients for encapsulation, serialised blister wrapping and packaging. We have a three-month delivery cycle and we're very proud of our 95% on-time delivery performance!

The OM Timeline

1927	*Laboratorios Lus Om established near Barcelona*
1937	*OM operations move to Geneva to stay in business during the Spanish Civil War*
1954	*OM affiliate starts up in Lisbon*
1970	*Purpose-built OM HQ opens in Meyrin (now B1) for administration, manufacturing and R&D*
2009	*OM acquired by Galenica*
2017	*Separation as part of Vifor Pharma*

Integrated into Vifor Pharma since 2009, OM Pharma this year celebrated 80 years of continuous operations in Switzerland. (Photo Vifor Pharma database)

Which regulatory bodies control your production site?

JULIEN STORAÏ: We have a federal inspection by Swissmedic every second year as a matter of course, and they also inspect any new production unit. In any year, we can be visited by the authorities from our big overseas markets like the China Food and Drug Administration and Brazil's national health surveillance agency ANVISA.

You're now the only biotech production company left in the canton of Geneva. Is that an advantage – or not?

JULIEN STORAÏ: I don't think it's significant that we are the only biotech company in the area. But it is certainly very much to our advantage that we are here. The old OM management showed great foresight in acquiring this very valuable site that's logistically ideally positioned – and incidentally, still has plenty of room for future growth. We can also rely on a pool of highly qualified people for recruitment and we have strong links with scientific and academic network institutions like the biotech campus and Geneva University. We play an active role in economic development motors including the Bio Alps Cluster, Geneva's Life Sciences association and the enterprise federation of the Swiss Romande. Recently, we have also joined with other Swiss biotech companies to network with the World Health Organisation here in Geneva. WHO is on record in identifying increasing antibiotic resistance as a global health crisis. We've seen from our initial contacts with them that they are impressed and excited about the potential for immunotherapy to contribute to solving the problem.

What characterises the workforce here?

JULIEN STORAÏ: Highly qualified, experienced, diverse and extremely loyal: on average people have worked here more than 10 years. I think that can be explained by the fact that the work is, in itself, interesting and intellectually stimulating. But it's also true that this is a good place to work, with a sensible life / work balance, flexible hours, home office options, equality of opportunity. We have excellent amenities; a restaurant that is the envy of the rest of the company, a fitness room, sports clubs and congenial meeting spaces for exchanging ideas and experiences. So, I would say we are pretty happy, as a workforce. Also, in my experience, these are typical biotech people. They're mentally flexible and adaptable; they love a good challenge – the more complicated, the better!

Looking to the future: OM's mature products are generating a new pipeline. R&D focus at the Meyrin site is to develop immunomodulators of both synthetic and biological origins, as well as synthesising new iron ligands.

With them staying so long, how do you keep them up to scratch?

JULIEN STORAÏ: Operational Excellence is all about continuous improvement – and that means people too. We have a comprehensive in-house training programme that allows us to refresh and upgrade individual capabilities. And of course, each year brings new projects and challenges each of which is an opportunity to learn and improve the way we do things. What has impressed me from the start since I came here in 2008 is that we have a learning culture; we are not the same company that we were five years ago. In five years' time, we'll have changed some more…

What changes have you seen since you've worked here? Has there been much investment? Are investments planned for the future?

JULIEN STORAÏ: The process of integration into Vifor changed a lot of ways of working, and the investment strategy was strongly supported to deliver capacity increases and meet regulatory requirements. For example, installation of a large capacity lyophilizator increased the site's production capacity and a new packaging line incorporating next generation serialisation has allowed us to ensure optimum traceability. We are still investing actively to support our growth and we plan to add another fermentation unit next year. We'll also be focusing on R&D where we aim to become a key player so we'll be upgrading labs and investing in high level competence. This is a growth business living a high pace of change so investment is a given.

As site manager in Meyrin, how much contact / interaction do you have with other Vifor Pharma colleagues?

JULIEN STORAÏ: I'm in daily contact with colleagues based at the different manufacturing sites – particularly Portugal; we supply them with APIs for their production of Broncho-Vaxom® and Uro-Vaxom®. Most days I am in touch with people at Headquarters. Even if I am strongly dedicated to operations at the local level, my role is also to be part of several global initiatives which support the Vifor Group as a whole; for example, I am co-lead of a multi-functional team that is working on the long-term strategy for the ID/OTX franchise.

Meyrin site laboratories are a key part of Operational Excellence programme's success.

What's the future for biotech in Vifor Pharma?

JULIEN STORAÏ: The OM brand flagship products are performing strongly, showing unprecedented growth in Russia, China and Brazil thanks to strong partnerships with global ‹heavyweights› like Sandoz and Merck Serono. And there's big promise in the United States – which will be a new market for OM. The National Institutes

The Vifor Pharma biotech centre in numbers

202	employees of whom…
98	women and
104	men
40%	managers are women
2	global brands in Uro-Vaxom® and Broncho-Vaxom®
40	tonnes of concentrated active principle per year
6	tonnes of lyophilizate
130	million capsules
5	million boxes
9	million blister packs

The fermentation process produces one bacterial strain at a time, a procedure that needs very precise conditions. The robust OM process delivers a success rate that is very close to 100%.

of Health (NIH) has initiated a five-year clinical study into the effectiveness of immunomodulators to treat respiratory problems in children. As one of the world's foremost medical research centres, their $25 million investment is positive proof of the scientific community's belief in the validity of our approach. We're continuing to transform ourselves; mature products are generating a new pipeline. Today, there are close to 700 authorisations to market products in around a hundred countries in Europe, Asia, Africa, Latin America and the Middle East. Our focus and capability in the area of immunomodulators promises to expand that list considerably in the coming years given the urgent need to combat antimicrobial resistance, defined by the World Health Organisation as, «an increasingly serious threat to global public health». Our pipeline has promising early stage developments and we plan to bring several ideas to the next step. In the short- to medium-term, we see significant all-round growth for biotech products: growth for our existing products in current markets, new indications and also in new markets like the United States for current and new indications. Further in the future there will be new products for new therapeutic areas. And all this growth will be driven by a changing environment where immunomodulators are increasingly seen as an important part of the solution to anti-microbial resistance. The potential is phenomenal, and with our experience and know-how we are ideally positioned to make the most of it!

Celebrating 80 years: According to Site Manager Julien Storaï, «typical biotech people…they love a good challenge – the more complicated, the better!» (Photo Vifor Pharma database)

Thank you, Dr. Storaï. It's clear that the Vifor Pharma biotech team is ready to take on an exciting global challenge.

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ARTHROSKOPIE – GELENKCHIRURGIE

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Pharmaceutical Development at Vifor Pharma in Villars-sur-Glâne FR

Technological Expertise in Formulation and in the Production Process

Interview with Miriam Spichiger, Head Pharmaceutical Development, Vifor Pharma, Villars-sur-Glâne FR

In the series of interviews with experts from the Vifor Pharma Group, our journey this time took us to the French-speaking part of Switzerland: Villars-sur-Glâne on the outskirts of Fribourg, and to Vifor Ltd, a Vifor Pharma Group subsidiary. Pharmaceutical production at Vifor Pharma Group takes place at five locations: at Vifor Pharma in Ettingen (Basel-Land), Villars-sur-Glâne (Fribourg), St. Gallen, at OM Pharma in Meyrin (Geneva) and in Lisbon, Portugal. Non-sterile, liquid dosage forms such as oral drops, syrups, suspensions and enemas, semi-solid forms (including ointments and creams) and solid forms such as capsules, tablets and film-coated tablets are produced at the Villars-sur-Glâne site. Just like at all of the Vifor Pharma Group's sites, Vifor Pharma in Villars-sur-Glâne also has a department that deals with Pharmaceutical Development. Its main activities are new product development, development of new dosage forms for existing products, production transfer plus numerous tasks involved in improving the production processes for existing products and for the implementation of new production systems. In Villars-sur-Glâne, Miriam Spichiger, Head Pharmaceutical Development, took time out to answer our questions.

◆ **Interview: Dr. Felix Wüst**

Ms Spichiger, I am delighted to be able to interview you as part of our series for the readers of SWISS PHARMA. Your business card tells me what your role within the companyis Head Pharmaceutical Development VsG, in which «VsG» stands for Villars-sur-Glâne. This means that you are responsible for Pharmaceutical Development at Vifor Ltd. What does this role involve?

Miriam Spichiger: The Pharmaceutical Development Department is responsible for developing the dosage form of a medicinal product. This means that we bring the active ingredient together with excipients into the desired pharmaceutical form, for example tablets or drops, in order to ensure that the medicine can be administered in a way that is comfortable for the patient. In addition, by adding specific excipients we can influence where and how quickly the active ingredient is absorbed in the body. The choice of excipient and packaging materials are important parameters for ensuring the stability and efficacy of the product throughout its shelf life. Alongside formulation development as described above, which is carried out in the context of laboratory testing, a further core function is the process development. By process development we mean the choice or appropriate technologies and process parameters for product manufacturing. To achieve this, various tests are carried out under laboratory conditions and then on a production scale. Finally, we carry out a validation of the production process to ensure that the process is robust and guarantees that the medication is always manufactured to a consistent standard. Formulation and process development is covered by one area of my department, Galenic Development. Appropriate analytical methods are needed in order to check whether the developed products meet the required quality standards. Analytical Development, which makes up the second area of my department, develops these appropriate analytical methods, validates them and analyses the development and validation batches. Stability tests are also carried out for the purposes of development. Alongside the development of medicinal products with new or existing ingredients, we also ensure that the quality of existing products remains consistent in the event of any changes, such as a new source of raw materials, manufacturing improvements or a change to new production systems. The same applies in the case of analytical methods, which have to be adapted to these new requirements or changes. Methods are reviewed, and are redeveloped and validated as required.

How is this area of work organised in the Vifor Pharma Group as a whole?

Miriam Spichiger: In addition to Villars-sur-Glâne, we also have teams working on Pharmaceutical Development at the Ettingen site and at OM Pharma in Meyrin. Pharmaceutical Development is part

On 23 August 2017 at Vifor Pharma in Villars-sur-Glâne FR: Ms Miriam Spichiger, Head of Pharmaceutical Development, talks to Felix Wüst from SWISS PHARMA. The picture was taken in the analytical laboratory.

of the Vifor Pharma Group's Technical Operation division and does not come under Research and Development, as is sometimes the case in other companies.

Who provides the impetus for Pharmaceutical Development activities? Who says what is to be developed, when and at which site?

Miriam Spichiger: We receive demands from various sources. Most of the activities that relate to existing products are initiated by the site itself. In Villars-sur-Glâne, we manufacture as contract manufacturers for others customersin addition to manufacturing our own products. These customers, or even new customers, are a further source of work for my department. Finally, we receive inquiries from the global organisation. This is particularly true in the case of new developments or production transfer of products. Planning different projects for different clients is challenging. It calls for good coordination of the priorities for the various projects. The assignment of a project to one of the sites is predefined on the basis of the different technologies and dosage forms that are made at the site. In Villars-sur-Glâne we specialise particularly in solid formulations, but we can also develop and manufacture semi-solid and liquid medications. In Ettingen, the focus is on suppositories, enemas and suspensions, with Meyrin specialising in the production of lyophilised biological pharmaceutical ingredients and medications based on them.

Your focus is on Pharmaceutical Development. What is the difference between Pharmaceutical Development and R&D? Is there also a Research and Development Department at Vifor Ltd., and if so, how does the collaboration work?

Miriam Spichiger: Research and Development is about discovering new active ingredients that can be used to treat diseases. Put simply, this includes the synthesis and characterisation of active ingredients. Modes of action and potential side effects are tested over the various stages of the clinical study. As mentioned, the Pharmaceutical Development Department is responsible for developing the dosage form, so that the active ingredient can be optimally administered to the patient. This involves a number of aspects, firstly the application of the medication, and secondly, ensuring that the active ingredient is absorbed by the body and that the effective concentration in the body is achieved. In the case of tablets, for example, we take care to ensure that they are as small as possible. Elongated shapes are easier to swallow than round ones. A coating can conceal a bad taste in the active ingredient and makes the tablet easier to swallow. If the product is to be used for children, a suspension is more suitable than a tablet since the dose can be individually adapted to body weight. In the case of active ingredients that are poorly absorbed, an intravenous form is possibly best. For active ingredients that are unstable in an acid environment and would therefore be rendered ineffective by stomach acids, we can circumvent this by using enteric coatings. Or if an active ingredient is broken down in the body very quickly, a patient would need to take a tablet several times a day to have the desired effect. By using special excipients, we can formulate tablets that allow the delayed release of active ingredients over several hours. Alongside the development of the suitable dosage form, we are also responsible for manufacturing the medication for clinical testing. Close

collaboration between R&D and the Pharmaceutical Development Department is therefore important, so that all relevant properties of the active ingredient, which are investigated by the various experts in the R&D Department, can be taken into account in the development of the formulation. For this reason, experts from both Pharmaceutical Development and from R&D are represented in any development project team.

Am I right in assuming that the development sites in Villars-sur-Glâne, Ettingen and Meyrin are geared primarily to manufacturing processes on a smaller scale?

Miriam Spichiger: Yes, that is correct. In the Development Department we have a laboratory and manufacturing facilities similar to those in production, but smaller. A new active ingredient is expensive, and so when we develop new formulations we start with only small quantities. For products that have already been on the market for some time, the active ingredient is more cost-effective. In that case, you can certainly perform the development work using slightly bigger development batch sizes. For formulation tests in which we define the excipients, we work on the gram scale up to 1 kg. The development of the production process, namely the choice of appropriate technology and definition of process parameters, is mostly done using various batch sizes. We can produce batches of up to approximately 20 kg here in our laboratory. We switch to the production plants for larger batches.

Does that mean it is an advantage for the Development Department to be based near the production facility?

Miriam Spichiger: In other companies, Pharmaceutical Development is carried out in a different location from production. In my view, however, there are great advantages in having the Development Department close to the Production facility. The staff from the Development Department are aware of the challenges involved in production and know which systems are used in production. This means that many aspects can be taken into account at an earlier stage of development, and incorporated into the manufacturing processes. For example, take a manufacturing process in which a screening is required. If I am working in the Laboratory, I take small quantities – even if the screening takes a bit longer. However, if I know that this screening will lead to extremely long screening times with a large batch size later in the production process, I try to come up with a more efficient solution and test it on further development batches. In this way I have a direct influence on the production duration and therefore on the costs of production, and ultimately on the medication. In order to keep a Swiss production site competitive, even taking pharmaceutical prices into account, I think it is important that LEAN principles and economic aspects are incorporated as early as the development stage.

At the start of our conversation you mentioned that your department is also responsible for developing analytical methods and carrying out stability tests. During which phase of a product's development does this area become important?

Miriam Spichiger: Analytical Development is involved in the projects from the very start. Even in the early stages it is important to be able to assess the stability of the active ingredient in combination with excipients or determine the influence of excipients on the release of active ingredients. That is why we have established all current analysis technologies here in our Analytical Laboratory. Stability testing is an extremely important aspect of the development phase. The product generally needs to have the same properties over its entire shelf life, in order to guarantee that the effect on the body remains the same. If tablets become harder, for example, this could affect the disintegration time and thus the absorption in the body. Any increase in a degradation product within medication could cause side effects. Climatic cabinets and chambers for the various climate zones are available for carrying out stability testing according to ICH guidelines.

You have already mentioned that your activities here do not always lead to new products, but that many activities relate to existing products. Can you tell us more about this?

Miriam Spichiger: The constant changes during a product's life cycleare supervised by the Pharmaceutical Development Department. This also applies to existing products, which have been in production for a long time. If a raw material source changes, we ensure that the change does not affect the processing or quality of the medication. We do this by running comparable tests in the laboratory and, based on these results, we determine whether further tests need to be carried out on a production scale.
The importance of our activity also becomes evident if the machine park in the production facility is expanded and existing products are to be transferred to a new plant. In this case we carry out technical trials on the new systems first. If these trials have positive results, a process validation is performed in a second stage. Our expertise is also called upon if unexpected manufacturing problems arise dur-

In the Galenic Laboratory, state-of-the-art laboratory equipment enables us to replicate the subsequent commercial manufacturing processes as early as the initial formulation and process development stage.

Determination of the dissolution time and thus the absorption in the body is one oft he basic methods of drug analysis.

ing production or if process stages are to be optimised. The transfer of the manufacture of an existing product to our production facilities also falls within our area of responsibility In this case we carry out initial feasibility trials in the laboratory, to familiarise ourselves with the product. Depending on the complexity of the product, one or more technical batches are produced – at least one of which is made on a production scale – before the process is validated.

What special expertise in terms of dosage forms or technologies does the site in Villars-sur-Glâne have?

Miriam Spichiger: At the Villars-sur-Glâne site, we have established standard technologies for the production of solid, semi-solid and liquid medications. We also have a high level of expertise in the development and production of microtablets and tablets with a modified release profile. Microtablets have a very small diameter, of approximately 2 mm. They can be filled into capsules or sachets. With the sachet variant, we can produce different dosage strengths. A further special technology that we have available is the lubrication of the pressing cylinders on the tablet press. This technology makes external lubrication possible during the tabletting process. This enables the lubricant content in the tablets to be reduced thereby minimising their possible negative effects while still ensuring that the tabletting tool is kept properly lubricated. These technologies enable formulations to be tabletted which, in some cases, have been considered impossible to process.

With regard to development, we hear a lot about «Quality by Design» these days. What does this expression mean?

Miriam Spichiger: «Quality by Design» is an approach that has become increasingly popular in Pharmaceutical Development over the last few years. It is used for estimating the risk potential of each product manufactured. It enables one to consider where the risk lies in a product and its manufacture from the very start. During the development phase we carry out a statistically structured series of experiments. This enables us to clarify which properties of raw materials or concentrations of excipients affect product quality and to test the impacts of various process parameters.

How many people do you have in your team? I assume they are Pharmacists and Chemists?

Miriam Spichiger: My team consists of almost 20 people. The Galenic Development Team includes formulation and process specialists, who also have the role of Project Managers. They all have Pharmaceutical training, which is an advantage but not essential. Pharmaceutical Technology is a key topic in the study of pharmaceutics. Besides Pharmacists, persons with an educational background in natural sciences and life science can also be considered for specific roles. The experiments in the Galenic laboratory are carried out by our Pharmaceutical Laboratory Assistants. While some large pharmaceutical companies offer specific training courses for Galenic laboratory staff, we do not. Our Laboratory Assistants come to us as fully trained Pharmaceutical Assistants. Chemists or persons with qualifications in life science may also be considered for this job. All of these educational backgrounds provide a good basic knowledge of pharmaceutics. The specific expertise in manufacturing is something they learn and improve on the job. In Analytical Development we employ Chemists as well as Laboratory Technicians.

Villars-sur-Glâne is on the outskirts of Fribourg. That means you are some distance away from the country's main towns and cities. Do you have problems with recruiting the necessary staff?

Miriam Spichiger: True, that is not always easy. Especially when we are looking for people for Galenic Development posts. There are not very many formulation and process experts on the job market. However, as a medium-sized company, and because of our vicinity to the production facility, we are able to offer a very exciting place to work. Personally, I see this as an advantage.

What style of management do you cultivate?

Miriam Spichiger: For me, it is very important that my staff engage in the work in their own individual way and are able to develop further. I think that this – and being part of a well functioning team - is essential for lasting job satisfaction and the achieve of their own goals. I discuss the projects and tasks with my staff to establish the key elements and objectives. I then leave it very largely up to them to decide how to go about this. I hold regular meetings to ensure that the projects are still moving in the right direction. We discuss specific challenges in the projects and specialist topics. Issues such as work organisation, communication and well-being are important topics of discussion with my staff. One key management task for me is to set priorities in the various ongoing projects and to communicate these clearly to my staff. The challenge for me lies in seeing that the objectives of the site are coordinated with the objectives of the global functions along with those of our customers, in a way which achieves our overall goals I also need to ensure that we check within the various Development teams to see whether there are resources at the other sites, so that we can help each other.

Do you collaborate with any universities or universities of applied sciences in Fribourg?

Miriam Spichiger: We cultivate collaboration with the universities of Geneva and Grenoble. An increasing number of Master's students from these two universities are coming to us to work on their Master's theses. This is extremely valuable cooperation. On the one hand, it enables us to exchange ideas with the universities and the talent of the future. The postgraduates, for their part, are able to work in depth on a project for us, which also represents an added value for us. The Master's thesis often also provides a direct springboard into the Pharma Industry. There are currently two people in my team who worked with us as Master's students and are now

employed here on a permanent basis. We see great potential for further collaboration with the two universities I mentioned. This is something we wish to foster. There is also a collaboration between the Development team at OM Pharma in Meyrin and the University in Geneva, with Master's students having the opportunity to do a work experience placement at OM Pharma. The Ettingen site has already collaborated on several occasions with the University for Applied Sciences of North-Western Switzerland (FHNW) in Muttenz, resulting in the production of some valuable Master's theses.

Has the spin-off of the Vifor Pharma Group had any consequences for your area of Pharmaceutical Development?

Miriam Spichiger: Many products for the OTC segment are produced at the site in Villars-sur-Glâne for Vifor Consumer Health. Before the Vifor Pharma Group became independent, we belonged to the same family. Today, we are two independent companies and Vifor Ltd. is now contracted to manufacture products for Vifor Consumer Health. The change has affected the nature of the collaboration in particular. New processes needed to be defined, for example costs and priorities are now presented more transparently. I also have the impression that the spin-off has enabled us to become more focused. I regard these changes as being altogether positive.

Do you have any plans or wishes for the next two to three years in your Department?

Miriam Spichiger: I think that we already have a very fine Galenic Laboratory with excellent facilities. We have a state-of-the-art laboratory rotary press, which works in the same way as the presses in the production facility, and we have been able to obtain a new system for the production of film-coated tablets. I would like to invest more in other laboratory facilities, so that we can make further progress into newer technologies together with the Production Department. I also hope that, in the coming years, the Development Team in Villars-sur-Glâne will be able to take part in development projects for medications, which open up new therapy options for patients.

One final question: what steps would I have to take in order to do your job?

Miriam Spichiger: I trained as a Pharmacist. After graduating I spent a good two years gathering experience in various pharmacies. I felt that was very important, in order to learn about the needs of patients. I then wrote a doctoral thesis at the Institute of Clinical Research in Bern. The work was multidisciplinary and, besides giving me an insight into basic research, enabled me to build up a good practical knowledge of analytics. This has turned out to be extremely useful in my later roles. After obtaining my PhD I ventured into the Pharmaceutical Industry, where I worked on formula development from the start. Formulation and process development fascinate me. I love being able to be creative while at the same time following a scientific approach. I started as a Laboratory Manager in the Galenic Development Department and later had the opportunity to take responsibility for the team and finally for the whole department.

Vifor Pharma's specific expertise: Development and manufacture of microtablets with a modified release profile (Photo Vifor Pharma Database)

Ms Spichiger, I hope you and your team continue to enjoy your work and wish you much success in all your activities. Thank you for talking to me

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Vifor Pharma – Our Links with Universities and Higher Education Institutions

As a Medium-sized Pharmaceutical Company, Vifor Pharma goes its own Way when it comes to Recruiting Talents

Interview with Jost Gloor, Head of Global Talent Management, Vifor Pharma, Glattbrugg ZH

The original headquarters of Vifor Pharma was in St. Gallen, where a production facility for iron supplement products, Laboratorien Hausmann AG, was created from the pharmacy founded in 1857 by Caspar Friedrich Hausmann. This was taken over by Galenica, Vifor Pharma's former parent company, in 1983. After further company acquisitions, it was decided to move the company group headquarters to Glattbrugg in the Greater Zurich region. Even at that time, Human Resources were already crucial for the further development of Vifor Pharma. The Global Talent Management Department led by Jost Gloor is also based in Glattbrugg. We wanted to ask him how recruitment of the necessary personnel is assumed, in light of the fact the production sites are spread throughout Switzerland in the cantons of Fribourg, Geneva and Basel-Land. Vifor Pharma has been using a progressive approach to recruitment since 2012. Furthermore, the Vifor Pharma Academy, the company's internal training facility, has been continuously expanded since 2016 and now reaches all levels: from apprentices to senior managers. This commitment to fostering talent makes Vifor Pharma an attractive prospect on the employment market. The company features in three categories of the Universum Top 100 rankings: In the top 100 most attractive employers, and in Life Science it even comes in 20th among the top 100 most attractive companies for graduates.

◆ **Interview: Dr. Felix Wüst**

Mr. Gloor, I would like to know more about the collaboration between the Company and Universities. You have responsibility for that. How would you ensure that you are able to attract the finest and the brightest minds for Vifor Pharma?

Jost Gloor: That is basically correct, but I would prefer to put it slightly differently. It is not just the best people we look for, but the people who is best for us, who fits into the team and is suitable for the vacancy. We analyse the market, the potential in the universities and we are able to inspire new talent in our favour. In my role as Head of Global Talent Management, my task is to find suitable potential employees, make contact with them and, eventually, recruit them.

And do you carry out this role for all sites throughout the Vifor Pharma Group, including Lisbon?

Jost Gloor: I am actually responsible for recruitment worldwide and look for talent in Europe, America, Asia – everywhere.

It must be something of a Herculean task, having a network that covers all the universities and technical colleges worldwide?

Jost Gloor: It depends very much on which posts we have to fill. Worldwide, there are not many posts that we can offer directly to new graduates from universities or technical colleges. The Swiss Market, on the other hand, is more oriented to university graduates. One initiative that we have just started is the Graduate Programme, which is aimed directly at new graduates. They spend two years training with us in various departments, with the aim of developing them into competent specialists for our company.

I assume that someone in this programme must provide a written undertaking to remain with Vifor Pharma following their in-house training?

On 29 August 2017 at Vifor Pharma in Glattbrugg ZH: Jost Gloor, Head of Global Talent Management, talks to Felix Wüst from SWISS PHARMA.

Jost Gloor: Since we invest a great deal in providing that person with practical training, we believe it is important that they continue to work for Vifor Pharma for a certain length of time. In return, they receive management training and can gain experience and learn from four different departments.

Did I understand correctly, that you are not particularly interested in recent graduates?

Jost Gloor: Not quite – it is just that many of our vacancies are not suitable for new entrants. For example, if we want a product group Manager with qualifications in chemistry, then we look for someone with two to four years' experience. Young people who have just graduated from a university or university of applied science are unlikely to be able to meet our requirements. We do however receive many inquiries from graduates who want to join us after leaving university. We are delighted by that, but we have to think very carefully about whether and where we can employ them.

How do you go about your task, when you receive a request from the various Vifor Pharma sites to find an employee with a very specific profile?

Jost Gloor: This is handled by our Talent Acquisition team. This function is otherwise known as «staff recruitment», but the term «acquisition» is better suited to the changed market situation. If we advertise a position for a highly qualified person online, as we used to do as a matter of course, we might get two or three applications. We therefore need to find new ways of acquiring people.

How can you explain that?

Jost: Gloor: In certain areas, for structural reasons, there are quite simply not enough people qualified in fields such as Regulatory Affairs, for example. There are no university qualifications in this subject in Switzerland. Some universities offer similar subjects, but there are no Master degrees or postgraduate qualifications in the specialist areas of Regulatory Affairs or Drug Safety. I have been trying for years to make universities and universities of applied sciences aware of the importance of these subjects. But since the Bologna reform, a CAS or MAS must be profitable and pressure is needed from outside and at international level in order for such training to become established. For example, if we needed to locate someone for Regulatory Affairs for our St. Gallen site, who must also be able to speak German, we would find it extremely difficult. In that case we would have no other option than to search actively for people with the right qualifications. People known as Talent Scouts approach suitable people directly and in person. In Germany, for example, we are working hard to find Medical Science Liaison Managers. These are specialists who form the active Medical Department in the field. They talk to doctors about the benefits of treatment with one of our products, without selling the product. In Germany there is hardly anyone suitable for this job on

the free market. That means we have to actively approach people. We usually know that we are going to need someone for a certain post within six months or a year. Our Talent Scouts therefore start early by putting out feelers, getting in touch with suitable candidates and cultivating these contacts.

That must make your competitors really hate you.

Jost Gloor: It is standard practice, and other companies also do it. Many of them work with an independent headhunter. We can cover this function ourselves.

Talent – what does that mean?

The term «talent» often calls to mind a small, secret group of people, known as «high potentials». We define talent broadly, and do so quite deliberately. For us, talent means someone who has a positive impact on the company, in other words someone who generates added value and acts in accordance with our values. That is all, really. This thought is behind what we do: Talent Management's mission is to ensure that the company finds the right person, at the right time, in the right place and that this person has the required managerial skills. This means that we need to know the strengths and weaknesses of a new employee and consider how we can develop the individual accordingly. If we cannot find anyone within our own circles, our Talent Scouts have to search actively on the market.

Still your job involves more than just headhunting. It also requires you to maintain ongoing relationships with the universities and universities of applied science.

Jost Gloor: That is correct, but our approach is slightly different to that used by other companies. For five years we have been working closely with the University for Applied Sciences of North-Western Switzerland (FHNW) in Muttenz, and for five years we have been part of their Bachelor Degree programme. Every year in December and January we talk to the undergraduate students about the current job application market. We explain to them what the situation will be like in practice when they leave university and how best to conduct themselves in this new environment. There are of course a great many guides available that explain how to behave in job interviews and how to draft a Curriculum Vitae, but young graduates are still uncertain about entering the world of work, and have lots of questions. We engage with them and try to prepare them for this important step. We would very much like to expand our commitment and enter into collaborations with other universities.

Further education event at the Vifor Pharma Academy

Do you also provide teaching, or are you involved in universities in other ways?

Jost Gloor: We are in contact with the Pharmaceutical Department of the University of Geneva, in order to attract Pharmacy graduates to work in the Industry. The same applies for the ETH Career Center, with which we are constantly in contact. These personal contacts are valuable for us and often have a more lasting impact than attending various careers fairs and graduate conventions, where it is easy to get lost in the crowd. Here at Vifor Pharma, we decided to go about things differently from the mainstream. For example, for the last four years we have presented an award to the «Student of the Year in Life Science». This is done in collaboration with UNIVERSUM, which authors the Top 100 study. The company produces rankings of all universities and technical colleges, and asks students – 12,000 last year – to name their favourite employer. I can only influence this ranking by increasing my visibility among the students. Just over six years ago, when we started our Talent Management Department, we were not even mentioned in this ranking. Now, we appear in the top 100 in three categories. Students even ranked us 20th in Life Science. We considered how we could generate added value for students, even though we are not able to offer very many jobs for new graduates. So we came up with the idea of running the «Student of the Year in Life Science» Award, in which we formulate a problem and invite the students to submit possible solutions. The best idea is selected and the winner is invited to spend a fully paid, three-month internship with us. The students who have won in the past have all stayed at Vifor Pharma for at least one year or have even been appointed to permanent positions.

What does Vifor Pharma have, that others do not? What good reasons would a student have for applying to you?

Jost Gloor: The fact that we are represented at a number of locations in Switzerland and have branches worldwide certainly makes us an attractive employer. We also have a lean organisation, short decision-making processes and flat hierarchies. These are ideal conditions for enabling people to make a difference. An employee of ours does not disappear anonymously among thousands of others. If someone has an idea or a question, they can bypass the hierarchy and go quickly and easily to the most suitable person. We are not a start-up company, nor are we Big Pharma, but we offer the security and structures of a medium-sized company. This is something that we can definitely bring to bear as an advantage. I frequently find, in practice, that the size of our company is often a crucial factor in a new employee's decision to join us. When a company is a manageable size, such as ours is, it is more likely to be able to offer people opportunities for further development. We encourage this by offering mobility and further training.

Is further training also included in your remit?

Jost Gloor: Yes, that is also part of my job. Even before the IPO of Galenica Santé, we started to build our own Vifor Pharma Academy, an actual learning hub. Part of this Vifor Pharma Academy is the Leadership Academy, where we provide training in management skills. There are also a number of functional Academies, which deal with Technical Operation, Medical, Sales and other topics, for example.

The in-house training facility, the Vifor Pharma Academy, offers a wealth of training opportunities for all functions.

And do you handle this widely varied programme of education and training using your own trainers?

Jost Gloor: We mostly manage with our own staff, with our experienced Managers and specialists engaged as lecturers. The situation regarding our four-stage comprehensive Management Training is different. For the third stage there is a collaboration in place with the University of St. Gallen (HSG). Together with the university, we offer our "Vifor Pharma Leadership Programme", which consists of three modules.

That sounds interesting, but the programme does not actually lead to an official academic title?

Jost Gloor: That is correct. It is not an official title, but anyone who successfully completes this training course receives a certificate issued jointly by the University of St. Gallen and Vifor Pharma. This is a very attractive incentive. We also offer a Management Programme lasting six months. Last week I was in San Francisco in the U.S.A. for the launch of the fifth year. We have trained over 120 Managers since April 2016.

So far we have been talking about training opportunities for future managerial personnel. What about apprenticeship training?

Jost Gloor: We train apprentices at various sites in five different areas of work. These are Commercial, Logistics, IT, Chemical and Pharmacological Technology (CPT) and Laboratory Work. We are proud of our contribution to the training of specialist staff. We also ran our Vifor Pharma Family Summer Internship for the first time this Summer. This four-week internship is open to the children of our employees: school pupils or young adults who are still at school or are about to start an apprenticeship or degree. During their internship they are given an insight into the Pharmaceutical world as well as a Curriculum Vitae check. The project was a complete success and the feedback extremely positive. Just this morning I heard that one young person who came to us for the four weeks of the school holidays enjoyed being with us so much that he wanted to extend his stay by a further two months.

You are certainly breaking new ground. That is something I have never heard of before, in all my discussions with Managers from the Pharmaceutical Industry.

Jost Gloor: We are in fact delighted that this idea has met with great interest among the mothers and fathers employed with us. We plan to offer this project again in 2018. This initiative ultimately goes to the heart of our philosophy, as being something we can offer our employees in addition to a job and a salary. The fact that Vifor Pharma has identified the provision of above-average support for employees as one of its corporate goals, is one reason why I work for this company. The Vifor Pharma Family Summer Internship has shown me yet again that ideas can be implemented quickly and easily at our company. Our Corporate culture offers fertile soil for trying out new approaches and bringing ideas to fruition.

Returning to the subject of apprentices: are they all trained at your sites or is this managed centrally?

Jost Gloor: Almost all sites are dedicated to the training of apprentices. They all face similar challenges and must make tangible efforts to inspire young people to go into this branch of industry. This is also one of the tasks of my department. Last year we made a video in which we got all our trainees to describe their apprenticeships.

Let us assume that you have managed to fill your vacancies with the best candidates and that many committed employees are now working at your company. Do they have the opportunity to progress and make a career within the company?

Jost Gloor: Making that possible, is one of the main objectives of Talent Management. We aim to reconcile the interests of employees with the interests of the company. The more coherent these interests are, the greater the motivation for both sides. I have already described the advanced training and education opportunities we offer within and outside the company. However, it is not only a matter of attending courses. A great deal of learning takes place «on the job», when you are thrown in the deep end or pluck up the courage to change something. With the acquisition of our U.S.

company Relypsa, we now have even more opportunities for mobility. There are employees from Relypsa working with us, as well as Vifor Pharma employees in the U.S.A. Again, it is necessary to balance the mutual interests for the benefit of everyone concerned.

I could also imagine that an internship at Vifor Pharma, a diverse yet quite large Pharmaceutical company, might be regarded as a stopover when planning a career path. Does this sadden you?

Jost Gloor: Staff turnover at our company is about average. Personally, I do not think it is a bad thing if someone who has gained experience and made progress with us, is considered valuable by another company, and that company then wants to employ them. That is actually a compliment for us. However, we do go to great lengths to retain good employees.

That is a generous attitude to take!

Jost Gloor: Yes, it is a generous attitude, but it is a small world in our line of business. There have already been cases in which former employees have acquired new skills at another company, and then returned to us. I think it is quite normal for ambitious and proactive individuals to have a tendency to move on. As a company, and even as a Manager, I can only be proud and pleased if someone wants to develop further. Our company and our employees have many interests in common, and this increases the motivation to stay. We want to be hard-working and innovative, and create good products for the well-being of our patients. We want more people to be healthier.

Mr. Gloor, I could not think of a better note on which to conclude our interview. Thank you for this stimulating and frank discussion.

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SWISS BIOTECH

Swiss Journal of Biotechnology
Schweizerische Zeitschrift für Biotechnologie
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Rivista svizzera di biotecnologia

SWISS MED

Swiss Journal of Medicine and Medical Technology
Schweizerische Zeitschrift für Medizin und medizinische Technik
Revue suisse de médecine et de technique médicale
Rivista svizzera di medicina e tecnica medica

SWISS DENT

Swiss Journal of Oral Preventive and Curative Medicine
Schweizerische Zeitschrift für orale Präventiv- und Kurativmedizin
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Swiss Journal of Veterinary Medicine
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