SWISS PHARMA

Roche Kaiseraugst

Swiss Journal of the Pharmaceutical Industry

Schweizerische Zeitschrift für die pharmazeutische Industrie

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SWISS PHARMA

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Special issue SWISS PHARMA 2/2017

Published in cooperation with
the company F. Hoffmann-La Roche Ltd,
Basel and Kaiseraugst

This issue of SWISS PHARMA 2/2017
also is available as SWISS PHARMA 1/2017
in a German version.

COVER

SWISS PHARMA 1/16

«PHARMA PACKAGING»

Vorträge

RhyTech Materials Event 2015
Neuhausen a.Rhf.
21. September 2015

Veranstalter

Suisse Technology Partners AG
Badische Bahnhofstr. 16
CH-8212 Neuhausen a.Rhf.
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Einzelhefte Print: CHF 50.– + MWSt. + Versandkosten
Einsehbar auf unserer Website: www.verlag-dr-felix-wuest.ch

SWISS PHARMA – Verlag Dr. Felix Wüst AG
E-Mail: felixwuest@bluewin.ch

IMPRESSUM

Verlag, Einzelhefte, Anzeigen:
VERLAG DR. FELIX WÜST AG
In der Hinterzelg 4 • CH-8700 KÜSNACHT ZH (SCHWEIZ)
Telefon +41 (0)44 918 27 27 • Telefax +41 (0)44 918 29 70
E-Mail: info@verlag-dr-felix-wuest.ch
www.verlag-dr-felix-wuest.ch

Redaktion:
Dr. rer. publ. Felix Wüst

Im VERLAG DR. FELIX WÜST AG in unregelmässigen Zeitabständen erscheinende Fachzeitschriftentitel

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SWISS PHARMA Schweizerische Zeitschrift für die pharmazeutische Industrie
ISSN 0251-1673 Revue suisse pour l'industrie pharmaceutique
Rivista svizzera per l'industria farmaceutica

SWISS BIOTECH Schweizerische Zeitschrift für Biotechnologie
ISSN 0253-9675 Revue suisse de biotechnologie
Rivista svizzera di biotecnologia

SWISS MED Schweizerische Zeitschrift für Medizin und medizinische Technik
ISSN 0251-1665 Revue suisse de médecine et de technique médicale
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ISSN 0251-1657 Revue suisse d'Odontostomatologie préventive et thérapeutique
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SWISS MATERIALS Schweizerische Zeitschrift für Materialwissenschaft und Technologie
ISSN 1013-4476 Revue suisse pour la science et la technologie des matériaux
Rivista svizzera per la scienza e la tecnologia dei materiali

Bestellung von Einzelheften

Preis pro Exemplar in der Regel CHF 50.– exkl. MwSt. und zuzüglich Versandkosten.
Bei grösseren Ausgaben gilt der Preis auf Anfrage bzw. gemäss Angebot.

Prepress und Druck

Bubenberg Druck- und Verlags-AG • Monbijoustrasse 61 •
CH-3007 BERN (SCHWEIZ)
E-Mail: info@bubenberg.ch

Swiss Journal of
the Pharmaceutical Industry

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farmaceutica

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Concept and Coordination:

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Roche

Roche: Continuing the development of the Basel and Kaiseraugst site

Roche in Kaiseraugst – expansion on a grand scale

The continuing development of Roche's Basel and Kaiseraugst site

Dear readers

The pharmaceutical industry is one of Switzerland's largest employers. The sector's Swiss workforce totals around 41,800, and it is directly responsible for creating added value of over 25 billion francs. And for every franc of this added value, its suppliers generate another 80 cents. If we add the direct and indirect added-value contributions, the total for 2014 came to around 45 billion francs. That's equivalent to 7.1 percent of Switzerland's gross domestic product (GDP). What's more, the sector creates large numbers of interesting jobs. Roche alone, the world's largest biotech company, has more than 10,000 employees in Switzerland. This makes it one of the most important service providers in the nation's pharmaceutical industry.

As Head of the Department of Economics and Internal Affairs of the Canton of Aargau, I find these figures hugely important. The pharmaceutical industry is a major employer and economic driving force in the canton of Aargau, particularly in the Fricktal. The pharmaceutical sector's sites in the Fricktal – Münchwilen, Kaiseraugst, Kaisten and Stein – generate around 14 percent of the canton's GDP. Roche currently employs 1,800 people at its Kaiseraugst site. That easily makes it the largest employer in the 5,650-inhabitant municipality with an international outlook, and the situation is not set to change any time soon. In the next few years, in fact, the headcount at Roche in Kaiseraugst is set to rise to as many as 3,500. This is most encouraging from the viewpoint of the Aargau government, the result of many years of business-friendly policies and targeted location development.

As Kaiseraugst is located in the canton of Aargau and Roche is of such economic importance to us, I am delighted to have been invited by the publishing director of SWISS PHARMA to pen a few lines to the publication's readers.

The current edition is dedicated to Roche as a global corporation and its expansion plans at the Kaiseraugst site. SWISS PHARMA is a specialist journal designed for experts working in the pharmaceutical sector. However, the present issue is also intended for a broader readership, including Roche employees and the population of Kaiseraugst and its environs. The articles highlight Roche's commitment to Switzerland, our canton and our region with its new, substantial programme of high-value capital investment.

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

Roche: Continuing the development of the Basel and Kaiseraugst site

F. Hoffmann-La Roche Ltd – one billion Swiss francs for expansion in Kaiseraugst – three billion Swiss francs for transformation of the Basel site

Operational and strategic tasks for Basel and Kaiseraugst site management

Discussion with Jürg Erismann, Head of the Basel and Kaiseraugst Site, F. Hoffmann-La Roche Ltd, Basel

The core business of F. Hoffmann-La Roche Ltd is researching, developing, manufacturing and marketing medicines and diagnostic solutions. But a company as large as Roche is confronted by matters other than this core business, in quite different dimensions. These are very specific problems, such as: How do 12,000 employees get to work? How should workspaces be configured so as to ensure efficient working processes? How should HR be organised in global functions like development, research, IT, finance or Group functions? We sought answers to these and other questions from Jürg Erismann, Head of the Roche Basel and Kaiseraugst Site. The response was immediate and straightforward: he invited us to meet him for the following discussion.

◆ **Interview: Dr. Felix Wüst**

Mr Erismann, you are Head of Roche's Basel and Kaiseraugst site. If the information I have is correct, you run an organisation involving around 1,300 people. What exactly are the duties of a site head?

JÜRG ERISMANN: In a smaller company, things are clear and manageable: there's a production area, maybe a few offices, and a reception service, which also deals with internal mail. In a large company like Roche, in addition to our actual core business of researching, developing, manufacturing and marketing medicines and diagnostic solutions, we are confronted by other issues in quite different dimensions. For example: How do 12,000 employees get to work in the most environmentally friendly way (key word: mobility)? How must the various workplaces – laboratories, offices, workshops, staff restaurants etc. – be designed so that they facilitate efficient working processes? I'm thinking of our Technical Services or Real Estate Management teams, which are currently working on new office concepts for the site. Or in Basel: how can we continue to develop a site that has no free buildable space left? Then there are naturally questions of working together with the authorities, our neighbours and much more besides. Site management is an extremely multifaceted task.

I notice that you are responsible for making sure that everyone who works at Basel and Kaiseraugst gets fed, and that all the equipment and machinery works.

JÜRG ERISMANN: That's not the half of it. You have to draw a distinction between site management's two functions. It has a purely operational remit, which really does cover such matters as employee catering, supplying the site with water and power, and constructing new buildings, which is the province of highly qualified engineers. But there is also a whole series of strategic responsibilities, such as site development, with all its many different facets, and also the question of how Roche's headquarters is changing, and what support it needs in order to do so. But that in turn is heavily dependent on business development. My organisation also has to address the Group's objectives. The requirements for these tasks differ widely. Some molecules developed in Research, for example, are produced by chemical processes, others by biotechnology, and the required infrastructures are not the same.

You have a team of employees who are undoubtedly motivated and hard-working. Who would not like to work at Roche?! Can you tell our readers how these people are divided between Basel and Kaiseraugst, and how the «Basel and Kaiseraugst Site Head» package is organised?

Visiting on 7 September 2016: Site Head Jürg Erismann (right) shows Dr Felix Wüst from SWISS PHARMA Roche's Kaiseraugst site (Canton of Aargau), where more than 3,500 employees will work in future. (Photo Roche)

JÜRG ERISMANN: We treat Basel and Kaiseraugst as a «single» site, so my organisation's employees carry out their duties for both locations. When it comes to Real Estate Management, for example, we have key account managers who deal with the needs of individual departments. And it's by no means unknown for departments to have people in both Basel and Kaiseraugst, so separation would make no sense. The site organisation is also responsible for HR in Basel and Kaiseraugst, so besides looking after the site organisation's employees, the teams are also responsible for Development, Research, IT, Finance and Group Functions – the global departments in other words. We work very closely together, and on a cross-departmental basis. Our supreme objective is to keep Roche competitive and attractive. And that's a job that it takes all of us to do.

As we speak, Roche is doing a huge amount of building work, particularly in Kaiseraugst. There is a forest of construction cranes. Does that make you the developer in chief?

JÜRG ERISMANN: The building work is indeed a focus of attention at present. We are investing around 1 billion Swiss francs in Kaiseraugst and 3 billion Swiss francs in Basel.

Would you tell us how that is organised? Planning, awarding contracts to suppliers from Switzerland, from abroad, from the region and so on.

JÜRG ERISMANN: Given the scope, this is naturally a labour of Hercules, and one that requires cross-disciplinary and cross-departmental work by my teams. Procurement has a decisive role to play in awarding the contracts: it works with suppliers, but obviously also with Technical Services and Real Estate Management, which plan, build and fit out our buildings. The future tenants, which means the representatives of the global functions, are involved too. Incidentally, we were able to award around 75% of the contracts for Building 1 in Switzerland. Swiss companies make up for the drawback of higher costs by providing particularly innovative, efficient and high-quality solutions.

Roche is surrounded by neighbours in both Kaiseraugst and Basel – people whose houses and flats are right next door to your site. How do you take account of these neighbours and their needs? Tell us how you approach the problem.

JÜRG ERISMANN: It's important to us to maintain good relations with our neighbours. The site has grown in both Basel and Kaiseraugst, and so has the neighbourhood. For many years we have been inviting the neighbours in regularly to inform them at first hand when we are planning a new project. Apart from that, they can use our indoor pool and post office in Basel, for example. The neighbours were the first people we invited to look round the new high-rise. At this particular moment, when we have so many plans, we maintain a regular, lively dialogue with them. That's what makes a good, constructive neighbourhood, after all. We don't always agree, but

so far we have always arrived at a consensus. We close the high-rise blinds at 9 p.m., for example, so that the light doesn't disturb anyone. Or we pay for neighbours who are especially exposed to have soundproof windows installed, so that building noise isn't a problem. We are in touch with the neighbours and local authority in Kaiseraugst too, so that we can discuss their concerns and ours.

But you also deal with everything that falls under the heading of «services» You are responsible for making sure everyone at Roche is provided with a good, nutritious meal on time, to keep employees happy and productive at work.

JÜRG ERISMANN: Yes, my organisation does provide services such as catering, and also the shuttle service, Roche's own internal bus operation for the Basel and Kaiseraugst region. And then there are various exercise options, cultural events in the region, the provision of parking spaces and good mobility offers, or also childcare. These are all hugely important if we want our staff to feel at ease.

Extensive experience of Roche: Jürg Erismann (Photo Roche)

A feel-good service for all?

JÜRG ERISMANN: We want to give employees an environment in which they feel at ease, and that spurs them on to perform at the highest possible level. That naturally includes other things like Medical Services, Employee Counselling, the Pension Fund, and HR, which we've already mentioned. On top of that, Procurement and the Finance department for the Basel and Kaiseraugst sites make sure everything runs smoothly. As I've said, site management is a topic for generalists.

From 2017, more than 3,500 Roche employees will work in Kaiseraugst, Canton of Aargau. Roche is creating a major IT hub there, and the site will also be home to additional site management functions. Not only does the site have its own cafeterias and a staff restaurant, there is also a gym and multipurpose park area. (Photo Roche)

Bird's-eye view: The Roche site in Kaiseraugst has sufficient space for growth. In 2017, around 1,300 employees will move here from Basel, to a modern, attractive working environment that uses the «Activity-Based Working» principle. This means that employees will no longer have personal workstations, but can choose a space that best suits whatever they happen to be working on. (Photo Roche)

You went through all that rather too quickly for me. Our readers could well be interested in some of the details. If I might pick out one area, you're responsible for procurement for Basel and Kaiseraugst. But by that you mean procuring the things you need for your functions, don't you, not the procurement of raw materials and active ingredients for production? And does it cover things like buying production facilities too?

JÜRG ERISMANN: Site Procurement is responsible for purchasing in the areas of construction and building services, plant and automation, facility services, general & administrative services, engineering services & temporary external staff, project procurement and procurement support. In close cooperation with the specialist areas, Procurement conducts purchasing in accordance with the valid regulations and compliance rules. Medicines manufacturing, however, has its own specialist procurement function that deals with the required active substances and excipients.

It would also definitely be of interest if you could give us a few details about the Medical Services organisation. I presume its role is to prevent and treat accidents at work?

JÜRG ERISMANN: Exactly. Medical Services is an independent medical centre of excellence for all staff. It provides services that treat and prevent illness and promote health. There is also an open clinic for acute illnesses and accidents, as well as comprehensive occupational healthcare services. Medical Services also offers confidential consultations for employees who have problems at home or in the workplace, or who want to look after their health – again both at home and in the workplace.

You mentioned that you oversee HR for Basel and Kaiseraugst, and also in a supportive role for the whole of Switzerland. Does this mean that your teams hire employees in Basel and Kaiseraugst? Are Group Human Resources not involved in that?

JÜRG ERISMANN: That's correct. My teams are business partners for the various global functions, so they recruit and support employees at both sites. Group HR develops global solutions that are rolled out at all the company's sites, both in Switzerland and abroad. All employee data, for example – address, payroll account, time sheets, annual goals, training record and much more besides – are kept in a single system that's used worldwide. Some managers have teams with half their members based here and the other half in the United States. Having a common system makes a lot of things easier and it ensures we're working efficiently.

One thing particularly interests me. You liaise with the authorities: the Kaiseraugst municipal council, the governments of Basel-Stadt, Basel-Land and Aargau. Is it sweetness and light all the way?

To the very west of the site is the logistics centre, from where the company's products are sent to destinations all over the world. Roche medicines are produced, packaged, stored and – following a comprehensive quality control procedure – dispatched in various different buildings. This part of the site is also home to clinical packaging, as well as technical development and pre-launch manufacturing. To ensure all these activities are perfectly orchestrated, there are other buildings accommodating offices, Medical Services and the site fire service. (Photo Roche)

JÜRG ERISMANN: We are generally on good terms with the authorities, who understand our needs very well. 12,000 jobs are important to local authorities, cantons and Switzerland as a whole, of course. It should also not be forgotten that the pharmaceutical industry accounts for more than 30% of Switzerland's exports. Obviously we might occasionally disagree, in which case it's important for everyone to put their concerns on the table so that we can talk them out. In the final analysis, we need viable long-term solutions that are acceptable to all sides.

I've heard that you also have an artistic bent. You sit on the boards of the Museum Tinguely in Basel and Roche Forum Buonas. Could you tell our readers something about these two institutions and the nature of your involvement with them?

JÜRG ERISMANN: Roche presented the Museum Tinguely to the city of Basel to mark the company's centenary in 1996. We maintain and operate it for the city. Fostering modern art and culture has always been very important to Roche, and I'm happy to be involved in the museum because I'm very interested in art myself. Roche Forum Buonas is quite a different matter: it's Roche's training centre in the Canton of Zug. I know the Forum very well from my years as head of the Rotkreuz site, and I do what I can to promote its continuing development. It's an ideal place for a retreat, where you can fine-tune strategies and bring teams together to work on innovative ideas and initiatives.

I've been warned about your tight schedule, Mr Erismann. I've been told I have to be brief when talking to you. You're said to be a very busy man, and I'm sure that's true. But I can also confirm that we have had a relaxed, extremely interesting conversation. Just one final question: are you jacks of all trades?

JÜRG ERISMANN: We are a sort of a firm within the firm. Our areas of responsibility are diverse and encompass a wide range of topics, as we have seen. In addition to our highly specialised researchers, we also need generalists to operate the site and continue its development, keeping it attractive to the employees whose work and achievements Roche needs for its future prosperity.

I am impressed, Mr Erismann. Thank you for this discussion. I wish you and your teams continuing success and happiness in the fulfilment of your tasks, which really are extraordinarily diverse.

Contact
E-mail: basel.ps_standortleitung@roche.com

Roche: Continued development of the Basel and Kaiseraugst site

Kaiseraugst: one of three Centres of Excellence worldwide for the sterile manufacture of parenterals

The combination of sterile manufacture, packaging facility, warehouse with integrated refrigerated storage, clinical supply, logistics, quality control and state-of-the-art infrastructure on one site generates ideal synergy effects.

A discussion with Dr Rainer Schmidt, Site Head Kaiseraugst, Drug Product Manufacturing, Pharma Technical Operations Biologics, and Dr Ulrike Falk, Site Quality Head, F. Hoffmann-La Roche Ltd, Kaiseraugst

A newly constructed facility for the sterile manufacture of parenterals came fully on stream in 2012 at the Kaiseraugst site operated by F. Hoffmann-La Roche Ltd, giving Roche access to a state-of-the-art production facility. Roche in Kaiseraugst has grown greatly since it first went into operation. The site is currently being expanded to accommodate up to 3,500 employees in the future. At the end of October 2016, SWISS PHARMA was given the opportunity to pay a visit and find out what is currently happening in the sterile manufacture/parenterals/ packaging/ high-bay warehouse with integrated refrigerated storage/shipping areas and in the quality control function that works alongside all these activities and is housed in a separate building.

◆ **Interview: Dr. Felix Wüst**

Dr Falk, Dr Schmidt, the last time I came to the legendary «Building 235» at Roche in Kaiseraugst for an interview with you, Dr Schmidt, was four years ago. Insiders know that this building is where the sterile manufacture of parenterals takes place. And four years ago, the building that would house the future centralised quality control function was still under construction nearby. I'm delighted to be here with you both today for another interview. Many thanks. Mr Schmidt, what are the major changes that have taken place here on the Roche site in Kaiseraugst since 2012?

RAINER SCHMIDT: Welcome to Roche, Mr Wüst. You asked what has changed. Well, a lot of things have changed! The site has grown a lot since then, and a number of new functions have been added, particularly in the quality area. Quality control and most of quality assurance have been transferred from Basel to Kaiseraugst and are now installed in their new building. You've probably also noticed that things are happening on the eastern side of the site too. Several new buildings have been constructed there. The Roche Training Centre is already up and running, and employees from the IT department and regional service departments will soon be moving from Basel to the new buildings.

Roche has concentrated the global manufacture of parenterals in three Centres of Excellence: Kaiseraugst, Mannheim in Germany and Hillsboro near Portland, Oregon, in the USA. Have the various additions to the Kaiseraugst site made it larger than the other two Centres?

RAINER SCHMIDT: No. We haven't grown bigger than the other two Centres; the relative size hasn't changed. Kaiseraugst is now taking up its intended position as a manufacturing centre in the global Roche supply chain network. Most things have remained unchanged, or in other words as planned, but we now have more volume and more products in Kaiseraugst, including a few new ones.

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On 27 October 2016 outside the warehouse and shipment centre in Kaiseraugst (from right to left): Dr Rainer Schmidt, Site Head Kaiseraugst, and Dr Ulrike Falk, Site Quality Head in Kaiseraugst, talking to Dr Felix Wüst from SWISS PHARMA. (Photo: Roche)

To kick off our interview, can I suggest that you both briefly describe the work you do? Ladies first.

Ulrike Falk: I've only been working for Roche for two years. My function is head of the quality organisation, and that covers all areas relating to quality. A good 400 people are employed here in all. One of the things we do, of course, is quality control in the classic sense, or in other words the analysis and release of all starting materials and control of the final product. We also have a big packaging facility here, so a lot of stability analyses are initiated, analysed and evaluated by us in Kaiseraugst. Our activities cover not only the products manufactured in Kaiseraugst but also products that come here from other sites in the Roche network or from contract manufacturers for further processing. So we work both with small molecules and with the sterile dosage forms from biological manufacture.

Mr Schmidt mentioned the new quality control building that came on stream in 2012. That was the final step in bringing together all the aspects of this work under one roof.

Ulrike Falk: Yes, the quality organisation for Basel and Kaiseraugst is now basically housed in one building. It includes the chemical processing of analyses and microbiology. We also do quality assurance and quality control work in the various manufacturing facilities so that we can stay as close as possible to the product and perform analyses and monitoring on the spot. As mentioned before, the entire quality assurance function is our responsibility, including the aspects of document review, correct performance of and compliance with processes, release of products for the next processing step or, in the case of ready-to-use products, release for the market, and much more.

Mr Schmidt, was quality control your responsibility before Ms Falk joined the company?

Rainer Schmidt: No. There has to be a clear division between manufacturing activities and the manufacturer's responsibility on the one hand and quality control and quality assurance on the other. That doesn't mean that the two areas shouldn't or mustn't work together closely, but for regulatory reasons alone they must be clearly separated from each other to ensure that they are independent of each other and do not influence each other. The release decision that the quality department has to take must be based on facts and reached without any influence at all from third parties.

Mr Schmidt, can you tell us now about the work you do?

Rainer Schmidt: I started in 2006 as head of the new-build project for sterile manufacture in Kaiseraugst. When commercial production began in 2012 I handed over the project to my successor and became head of the Kaiseraugst site. The title of my present function is Site Head Kaiseraugst, Drug Product Manufacturing, Technical Operations Biologics. In this function I am responsible for the new parenterals facility and for the Rocephin facility that has been operating since the mid-1980s. We have now combined these two facilities to form a single area under the name Sterile Manufacturing.

Starting with the active pharmaceutical ingredient, a ready-to-fill solution is produced. (Photo: Roche)

I am also responsible for the packaging facility, which employs around 350 people, and Materials Management. That means the logistics, order planning and warehouse on site.

So sterile manufacture of parenterals and the manufacture of Rocephin were recently combined. Yet Rocephin is still being produced in its own building.

Rainer Schmidt: It has to be done like that because Rocephin is a very potent product used to control bacterial infections, and the health authorities insist on special requirements for this type of product. It is an antibiotic, and cross-contamination – Rocephin getting into other products – must be avoided at all costs. That's why it is vital to have a separate building for antibiotics and a clear separation from other products.

The product solution is filled into vials (pictured) and prefilled syringes on filling lines. (Photo: Roche)

Is the building still working to capacity even though the patents for Rocephin have expired?

Rainer Schmidt: It certainly is. And the volumes we produce every year are stable. That says a lot about the product. It's a very good product that is still used as an antibiotic in many countries, frequently as a reserve antibiotic too. Rocephin is often the drug of choice when difficult cases of resistance are encountered; the one that is used as a last resort.

I still have a question about the three Centres of Excellence that you mentioned: do they all produce everything, or are the products divided up among the three centres?

Rainer Schmidt: We use a dual sourcing principle, which means that we try to manufacture important products at two sites. We are then equipped to deal with situations in which there are production difficulties or bottlenecks at one of the sites, environmental factors affect production or there is sudden and unexpected demand from the market. This organisation enables us to supply the market as effectively as possible and means that we are prepared to cope with any risks arising from day-to-day business and are as flexible as it is possible for us to be.

How are quality control and quality assurance organised if the Centres of Excellence are in three different parts of the world? Is the function managed centrally for all three?

Ulrike Falk: Yes. The quality unit is managed in the same way as the manufacturing areas at the Centres of Excellence – centrally from Basel for the entire world. And we take the same organisational precautions in the quality organisation as manufacturing does. We are organised so that we can analyse products at several sites. I should add that it's not exactly the same, but the concept is comparable.

Are further manufacturing facilities being planned or even under construction already?

Rainer Schmidt: Yes, the Late Stage Development & Small Molecules Launch Facility (LSL). On your way here from the multi-storey car park you passed an empty construction site on the eastern side of the campus. The initial excavation work has just been started there.

How does this project affect the existing manufacturing structure and the quality control and quality assurance functions?

Ulrike Falk: The main function of this Late Stage Development & Small Molecules Launch Facility (LSL) is to manufacture medicines. The analytics for these medicines can also be done on site, if not in the same building. In this way everyone can benefit from the set-up.

Rainer Schmidt: Another advantage for the new facility is the existing infrastructure, water supply, medical service, fire brigade – that's all here already and doesn't have to be set up from scratch. The distribution department, the warehouse, the logistics, it's all here. We are fortunate in benefiting from a perfect combination of various synergies that offer advantages in terms of both cost optimisation and the rapid availability of medicines, new solid dosage forms, for patients.

You have to keep your employees constantly up to date with the latest knowledge. How is that organised?

Rainer Schmidt: We have a central department in Kaiseraugst that is responsible for coordinating employee learning and training. That has deliberately been made a decentralised function to ensure a good level of standardisation of general learning content. At the same time, the specialist functions at each site and in the various facilities organise detailed training on subjects specific to their department.

After the product has been filled, each unit undergoes a 100% inspection. Pictured: manual inspection of prefilled syringes. (Photo: Roche)

All manufacturing steps that involve handling open product are subject to strict hygiene regulations to ensure that the medicines are sterile. (Photo: Roche)

Are employees tested periodically to check their knowledge and skills?

Ulrike Falk: There are job profiles for each workplace, some of which are even person-specific. The profiles describe exactly the requirements that have to be fulfilled. These are primarily the local or global Standard Operating Procedures (SOP). There are also management seminars for employees with managerial functions, not forgetting the external training courses organised outside the company to handle topics in greater depth. We send colleagues to external courses like this as the need arises and to keep them up to date.

Rainer Schmidt: We have to fulfil regulatory requirements in terms of training our employees. We have to document that they have a certain level of training. We have recently come up with yet another idea. We want to train our employees' attitude to their work. We do this with the respective line managers with the objective of achieving continuous improvement and encouraging people to take responsibility for their daily work. Employees shouldn't wait until they are told what to do by their line managers. They need to be proactive and make an effort to optimise their workplace on an ongoing basis – it's a task that never stops!

Ulrike Falk: We even ask them specifically to do it! It's about give and take. It's the responsibility of the employee to do it and it's our responsibility to insist on it. The aim is to be up to date with knowledge and skills at all times.

Mr Schmidt, in 2012 I asked you what you would do if one day the capacity of Building 235 was insufficient. You asked me to look out of the window at an enormous, empty plot of land and said that, if the need arose, you could easily «mirror» your production building on this land, or in other words you could double the existing plans. Is that time approaching?

Rainer Schmidt: No, not yet. We would like it to happen, but at the moment we still have enough capacity in the Roche network as a whole. We also make sure that we balance product volumes optimally between the three sites in Hillsboro, Oregon, in the USA,

Mannheim in Germany and here in Kaiseraugst in Switzerland. On the other hand, though, capacity utilisation in our vial filling facility is very good. Prefilled syringe production will also be working to capacity in 2017. Freeze-drying is the only area in which we have free capacity.

So there are parts of manufacturing that have almost reached capacity. Does that mean you will have to start thinking about building again soon?

Rainer Schmidt: No. We are working at full capacity in some areas, as I said, but the manufacturing facilities that we have at our disposal are adequate for our needs. Once there are new, promising products on the horizon – and there certainly are some in our pipeline – we'll have to see how their development goes. That's the point at which we might consider increasing capacity in the future with new lines and a new building.

Most of the equipment you work with is pretty expensive. What is the service life of this type of equipment?

Rainer Schmidt: We currently assume a normal operating life of around 15 to 20 years. That aspect is monitored by our Life Cycle Asset Management team. We use certain criteria to determine the extent to which equipment is still in keeping with the state of the art and can continue to operate for 15 or 20 years or more. We develop these criteria in collaboration with our Engineering team and review the situation from time to time. Depending on whether or not they fulfil the criteria, machine parts or even entire machines may have to be replaced.

One final question about manufacturing: do you work completely without paper nowadays?

Rainer Schmidt: In some cases, yes. When we designed the parenterals facility in 2006/2007 we established a manufacturing executive system (MES) that allows practically paperless operation. But that's a new facility. We're not that advanced in the other facilities, but we always have an eye out for ways of using less and less paper. We focused on the parenterals facility because it is here that paper is our biggest «enemy» in terms of particles and micro-organisms.

Now I'd like to take a look at Packaging. What developments have there been here in the past four years?

Rainer Schmidt: There has been a particularly interesting development in Packaging – one that is posing a challenge too. Order volumes are getting smaller all the time! The big packaging jobs that we used to handle are history now. Another tendency is for the countries supplied from Kaiseraugst to require a country-specific finish for their packaging. They are no longer willing to use the shared presentation that used to be deployed for certain regions. We provide country-specific finishes even for small countries.

And is that forcing you to adapt your equipment?

Rainer Schmidt: Exactly. Equipment manufacturers used to find it difficult to adapt machine types to suit smaller order volumes. But that has changed now because the entire pharmaceutical industry is going through the same development worldwide. The products we manufacture are becoming increasingly expensive. As a result, the countries don't stockpile as much product as they used to.

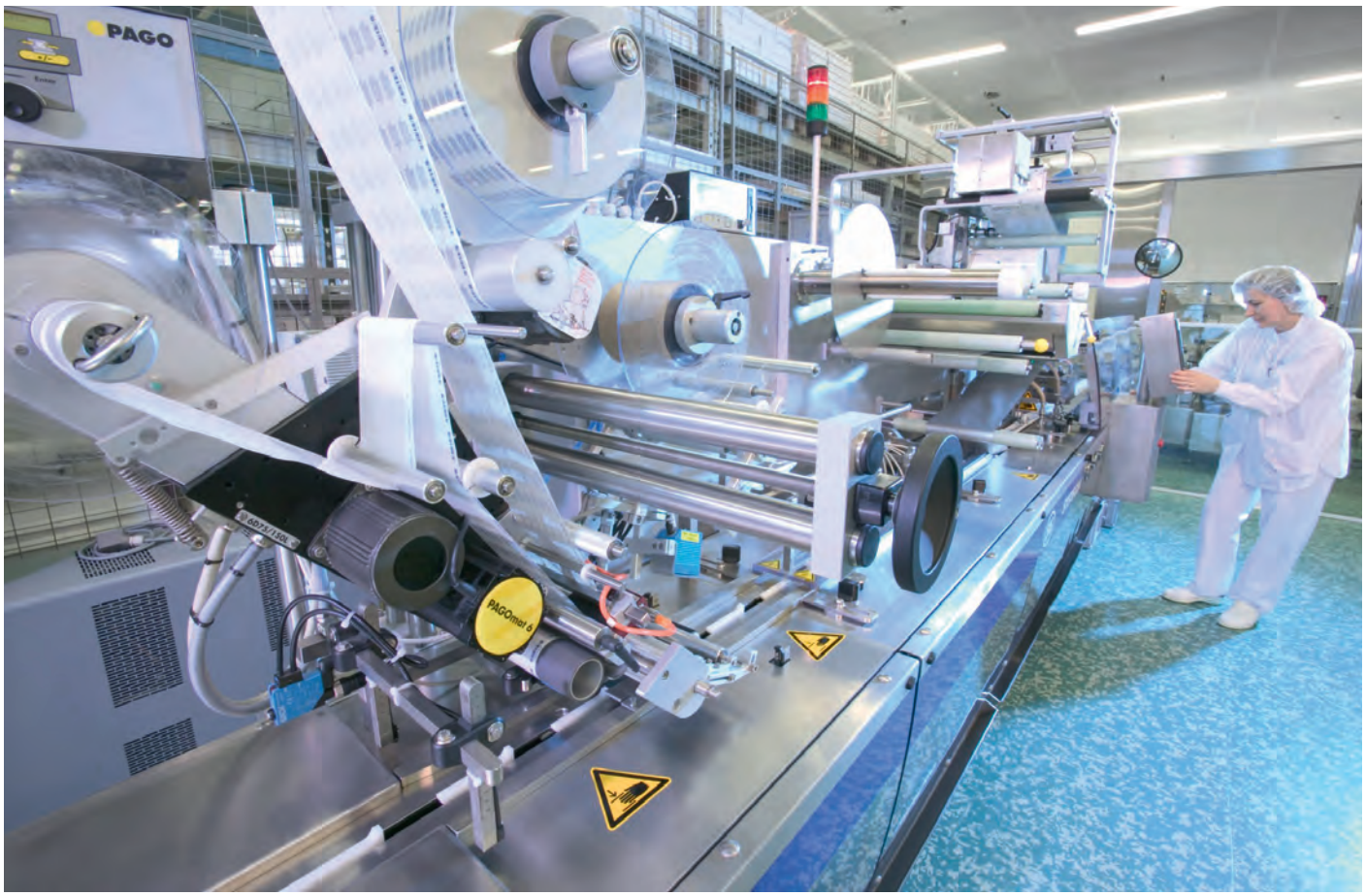
In the packaging facility, filled vials are inserted by machine into assembled and glued folding cartons. The cartons are printed with country-specific information, and once they are filled they are automatically closed and printed with variable data. (Photo: Roche)

They order small quantities that we have to adapt to in our production and packaging facilities.

Ms Falk, what is your involvement in the quality control and quality assurance aspects that we have been talking about?

Ulrike Falk: The packaging materials, the patient information leaflets, the boxes that go into the packaging, the vials – they all have to be tested when the good are received. We have to ensure that the quality of the goods supplied is in line with what we at Roche expect of Roche. As soon as the goods are released, quality assurance picks up the baton. This function has to check whether every step is performed the way we have recorded it. It has to ascertain whether the variable data, the manufacturing data, the expiry date and the batch designation have been added correctly and whether the medicine can therefore be brought onto the market safely. Our tasks also include issuing the certificate that enables the medicine to be imported into the countries we supply. We also have to confirm the conformity of the product. This shows that all the regulatory requirements in the corresponding country have been fulfilled.

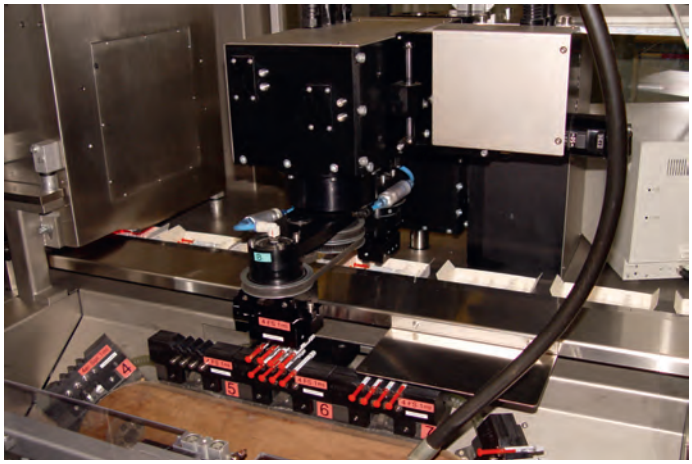
A boxing machine collates blister packs, folding boxes and patient information leaflets. (Photo: Roche)



Plastic ampoules are labelled and sealed into film on a tubular bag machine. (Photo: Roche)

How does Roche influence the work done by the packaging manufacturer?

Ulrike Falk: That's the job of our Supplier Qualification Management team. A supplier has to be qualified by us before he can supply goods to Roche. We select our suppliers and check whether they meet our quality requirements. Then we look to see whether the way the supplier works tallies with the way he describes his services. If it does, we confirm this to the supplier. Equally, a certain number of batches have to be tested in parallel with the supplier so that we can compare the results. If all the requirements are met, the supplier is considered to be qualified, he is included in the approved suppliers list and can supply us.



Syringes are labelled, fitted with a plunger and placed automatically into folding boxes with specially manufactured format parts. (Photo: Roche)

Do the Swiss packaging manufacturers meet Roche's requirements?

Ulrike Falk: The manufacturers of packaging materials for some of our products are located mainly in Switzerland. Yes, they are able to comply with our strict requirements. This is something we're pleased about because we like using local suppliers – they are nearby, which makes it much easier to get together with them and work with them to ensure the quality that we want at Roche. We're happy to have good Swiss manufacturers of packaging materials.

Rainer Schmidt: Wherever possible we try to work with suppliers from the region. They are naturally all competing on price and quality. We look first at the quality, then at the price. Both have to be right. But all other things being equal, we are quite likely to give preference to a supplier from the region. We do keep the regional aspect in mind.

We still have to talk about warehousing and shipping. If I remember rightly, Kaiseraugst is a pioneer in the storage of temperature-dependent products.

Rainer Schmidt: Yes, since we last talked four years ago we have built a refrigerated warehouse in Kaiseraugst with a capacity of 8,000 pallets for refrigerated products that have to be stored between 2 and 8°C. As a result, we now have our refrigerated products under more automated control than was previously the case. Before we opened our own refrigerated storage, this was handled by an external company. That meant additional transportation and additional expense. The process we have now is simpler and leaner.

Incoming materials and dispatch are located in a design-optimised warehouse in Building 231 at Roche in Kaiseraugst. All the warehousing, processing and material handling areas are climate-controlled and largely automated. Any goods that are put into or taken out of storage may only be used after the Quality department has tested and released them.
(Photo: Roche)

On my way here I saw enormous double-trailer lorries coming onto your site or leaving it practically every few minutes. It was a really impressive sight! Who organises this traffic to make sure it runs smoothly? Do you have your own haulier at Roche?

Rainer Schmidt: We don't have our own haulier, but we do have a department that looks after these things. That's our Materials Management department. These people work closely with the Global Logistics department and thus with Distribution too.

How many countries are supplied from Kaiseraugst?

Rainer Schmidt: Between 100 and 130. A delivery to Ecuador, for example, is packed ready for shipment here in Kaiseraugst and our global logistics partners then see it safely to its destination.

Medicines are stored at room temperature or refrigerated as specified for the product. Specially developed transport packaging or equipment ensures that the cold chain is maintained between 2 and 8°C – or at other temperature ranges such as 15 to 25°C – from the factory to the recipient country.
(Photo: Roche)

How many people work at Roche in Kaiseraugst in manufacturing, packaging, warehousing and shipping?

Rainer Schmidt: If we convert all the employees into full-time equivalents, then we have 1,050 people working here at the moment. If you include the people working in quality control, we have 1,500 employees on site. If we add in the service partners who handle the infrastructure, we have around 2,000 employees on site who take care of the manufacturing processes and the supply of products to our customers.

Do you have trouble recruiting suitable people?

Rainer Schmidt: In Kaiseraugst we have our own way of working that involves everyone here. You could call it «togetherness». We all want to have a good relationship to each other, strongly focused on our work and respectful in our dealings with each other. Word has got around, within Roche and within the region, so it's hardly

In the warehouse, medicines are packed for shipment and then sent to more than 130 countries. (Photo: Roche)

surprising that employees want to join us. Whenever I've had vacancies to fill, I've never had any problem finding a suitable candidate. It looks like Roche in Kaiseraugst is an attractive employer.

Ulrike Falk: As a newcomer to Roche I can certainly confirm that! Before I came to Kaiseraugst two years ago, I worked for another major pharmaceutical company. There's no harm in saying that I worked for Pfizer, an American company. I'd always said that there weren't many companies for which I would voluntarily leave the company I was working for. But Roche was definitely one of them, and in fact the Number One company that I would have considered moving to. Roche has an excellent reputation as an employer. I know I'm advertising the company, but I really can confirm what has been said.

Mr Schmidt, what would you say to an employee who came to you and told you he'd like to go elsewhere for a couple of years – to another Roche site?

Rainer Schmidt: We're flexible about how people work for us. We could agree with this employee that he could take a look at other parts of the company too. In fact we support people who want to work at another Roche site, but it has to fit in with the larger scheme of things. We certainly benefit from new people coming to work with us, people from other cultures too, or if we are able to send people to work in other countries. It's about give and take. As a site it's a prime opportunity for us to develop and learn from others.

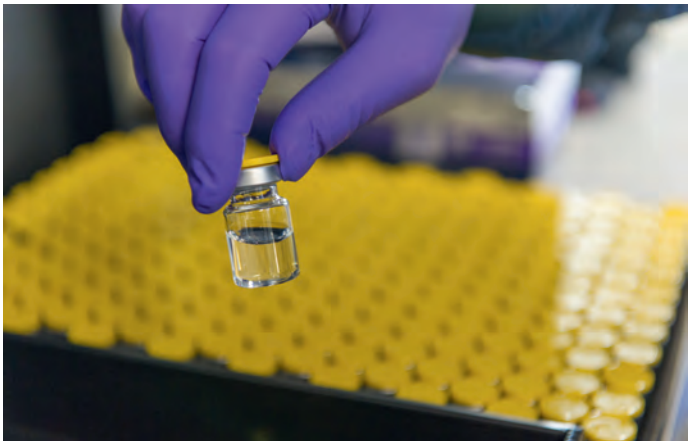
Roche also sets a fine example in vocational training. In Kaiseraugst we have the Roche Learning Centre, where a large number of apprentices are trained every year. About 100 of them earn good marks in their final exams each year. An apprentice doesn't necessarily have to stay at Roche. And if he wants to study for his vocational school-leaving certificate, he gets massive support from the company.

Rainer Schmidt: Yes, you're quite right. Our aim is to be such an attractive employer that people are happy to come back to us. It can only be a good thing if they gain experience in other areas. And when they return they bring their experience with them, enabling us to develop continuously and move on from what we were doing before.

Have all the facilities constructed in Kaiseraugst been inspected by the authorities?

Ulrike Falk: Yes. Otherwise we wouldn't be able to manufacture anything here or bring products onto the market. The main regulatory activity is oversight by the national therapeutic products agency Swissmedic and the Regional Medicines Inspectorate of North-Western Switzerland (RHI) that performs inspections on its behalf. This authority visits our site regularly and audits our facilities. We have our processes thoroughly under control and therefore have no problems with the authorities.

Product analysis in the QC laboratory (Photo Roche)



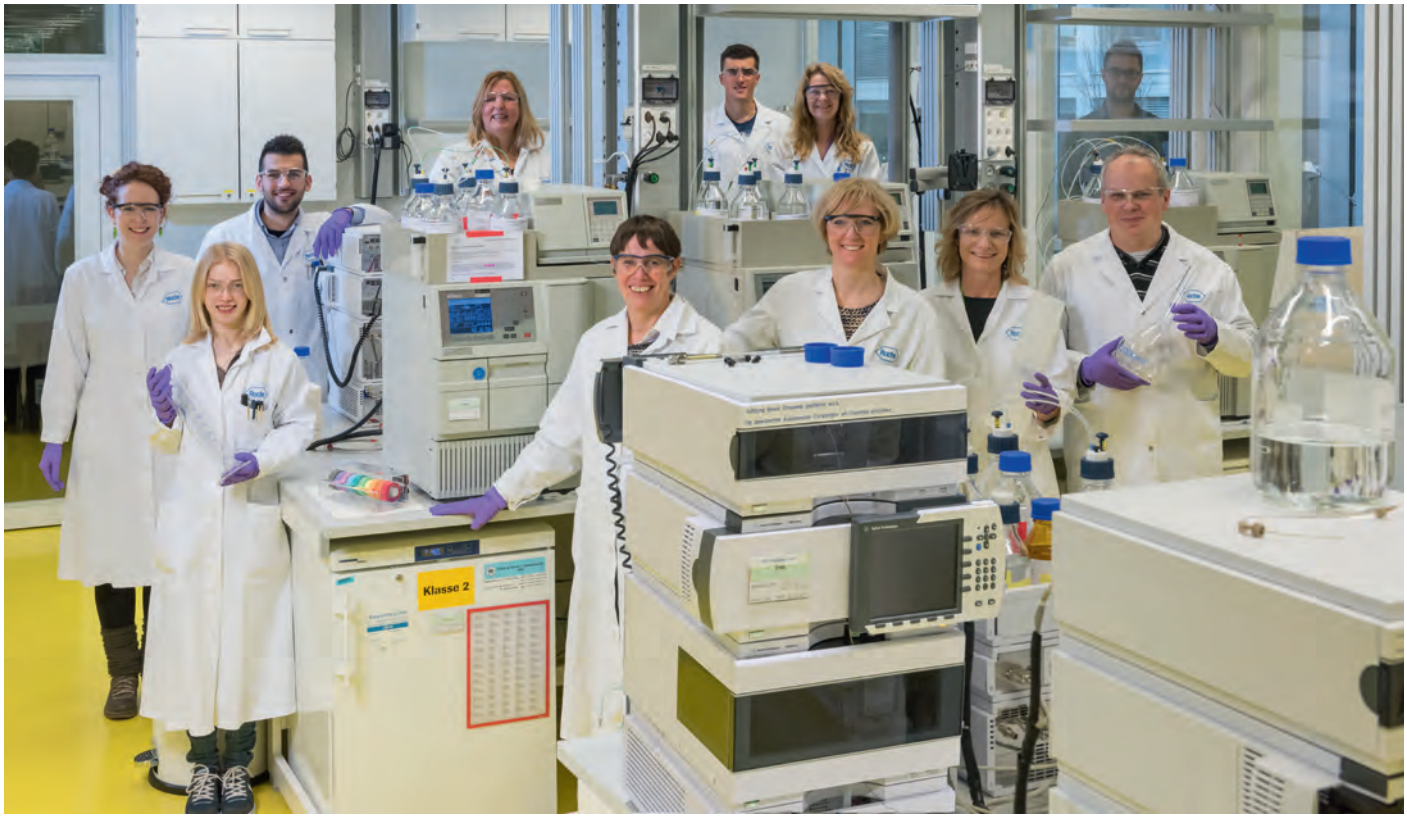
Materials needed for packaging are provided in exactly the right quantities. (Photo: Roche)

Mr Schmidt, we're talking one superlative after the other. Isn't there anything that gives you a headache?

Rainer Schmidt: You mean things we worry about? I think as a company in general we have to be equipped to handle the challenges the market throws at us. These challenges include the smaller order volumes you mentioned earlier. The quantities we pack are getting smaller all the time. We are facing the challenge of how to cope with these small orders in the future. We have to get even small orders to the customer as quickly as possible. We have to be in a situation in which we have no major inventories and no capital tied up, and in which we can keep our employees motivated – including the young people who come to us and are no longer used to writing e-mails. How can we face up to all these challenges in the future? Our thoughts are focusing on the question of how we can remain attractive and interesting for good employees in the future too. We mustn't become complacent. We have to think about what we're going to do and move forward.

I can see that your work doesn't give you any headaches – that you're facing up to the challenges and want to maintain and even improve on what you've achieved. So can we expect the Roche success story, and in particular the success of Roche in Kaiseraugst, to continue?

Ulrike Falk: Let's keep things low-key and just say that we are very well positioned at Roche and here in Kaiseraugst. We are in a phase in which we are transitioning from stabilising to optimising. This optimisation is moving in exactly the direction outlined by Dr Schmidt – we need to ensure that we remain competitive in the future. We are a company that must ultimately take steps to ensure that our costs are in relation to what we can reinvest in new medicines. One thing is clear, though: costs are increasingly enormously. And the requirements for bringing good medicines onto the market and being competitive are not getting any easier. We have to ensure that, despite rising costs, we can supply medicines that are competitive and, above all, provide the greatest possible benefit for patients. If we can manage that, then it will definitely be a success story. I'm confident that we are prepared for the future. But, as Dr Schmidt said: we can't afford to rest on our laurels!



Employees in the QC laboratory (Photo Roche)

Rainer Schmidt: Something else we ought to mention in this context is Industry 4.0 This means that automation is playing an ever greater role, which in turn means that we will probably have to invest more in technology. How do we get the masses of data that we generate with our equipment out of those systems? How do we interpret them so that we can use them to improve all our processes continuously? That's going to be the next quantum leap that we have to manage in our work.

Very soon, in the spring of 2017, the IT centre that is currently in the final stages of construction and will serve the entire Roche group will be inaugurated. What does that mean for your work?

Rainer Schmidt: One of the things that these specialists will be doing is trying to get a handle on the topic of Industry 4.0 that I just mentioned. We will be working intensively with these IT people. We will need a new employee profile for Big Data. We now have to define how we are going to make the best of this leap into Industry 4.0 or, as we like to say, how it can best be realised.

Analytics under laminar flow to protect people and products (Photo Roche)

I've just thought of another question relating to the Late Stage Development & Small Molecules Launch Facility (LSL) that we were talking about earlier: this facility will manufacture solid dosage forms such as tablets and capsules for the first time in Kaiseraugst. Does that represent a paradigm shift for Roche in Kaiseraugst? Is it just the start of further expansion of the site here?

Rainer Schmidt: As things stand you might as well be looking into a crystal ball. We both hope that Roche Kaiseraugst continues to develop. We have enough space in the eastern part of the site. We set up the parenterals facility here on the western part of the site in 2012. We really would be delighted if we could be part of a further expansion of this site. We don't know whether it will be sterile products, solid dosage forms or both. It depends how the development and establishment of new products goes.

Dr Falk, Dr Schmidt, that was an interesting interview. I can see that you are working in a very dynamic environment in Kaiseraugst. Your will to master the future challenges of the human and professional environment both working with each other and with your emloyees is truly palpable. Thank you for talking to me.

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Roche: Continuing the development of the Basel and Kaiseraugst site

Setting a new course at Roche in Kaiseraugst: In addition to sterile products, solid dosage forms such as tablets and capsules will now also be produced

In 2019 the Late Stage Development & Small Molecules Launch Facility (LSL) will begin producing and launching new, innovative medicines

Ir. Ing. Frans W.J.M.M. Hoeks, Site Head, Pharma Global Technical Operations, Basel Solids Manufacturing, F. Hoffmann-La Roche Ltd, Basel

Roche's development pipeline contains a number of innovative and highly effective small molecules for new medicines. The aim is to make some of these products available to patients as quickly as possible. However, the increasingly time-consuming regulatory requirements imposed by the health authorities mean that close cooperation between the technical development and manufacturing functions at the production site are essential in achieving accelerated market launch. This is why Roche is building a new Late Stage Development & Small Molecules Launch Facility (LSL) in Kaiseraugst. The facility, which will come on stream in 2019, will be where the key activities in the late-stage development of new medicines will take place. New solid dosage forms, i.e. tablets and capsules, will also be launched from here. The Kaiseraugst site is ideal for this role because it is close to both the technical development of new medicines in Basel and Packaging in Kaiseraugst. The new facilities in Kaiseraugst meet the appropriate special production requirements because closed lines to handle highly active molecules and active substances will be in use. These new facilities will also be adapted to the lower production volumes that will be handled in future. In the past, Roche Kaiseraugst was mainly responsible for the manufacture of sterile products and for the packaging, warehousing and shipment of pharmaceutical products. The planned Late Stage Development & Small Molecules Launch Facility (LSL) marks the beginning of a new chapter in Roche's activities in Kaiseraugst. Frans Hoeks, Site Head Basel Solids Manufacturing at Roche and «Owner Representative» in the LSL project, will be the promotor of the new facility. SWISS PHARMA had an opportunity to talk to him about the major new developments at the Roche site in Kaiseraugst.

◆ **Interview: Dr. Felix Wüst**

Mr Hoeks, now that we've had a chance to visit the future construction site in Kaiseraugst, where the new Late Stage Development & Small Molecules Launch Facility (LSL) will be built, I am delighted to be able to talk to you about the details of this major project. We are now in Building 74 on the Roche site in Basel, opposite the impressive new high-rise.

FRANS HOEKS: Yes, the new high-rise really is impressive. I carried out my first project for Roche in Building 95, just opposite. I have fond memories of that time, during which we constructed a new cell culture facility.

So where did you work before?

FRANS HOEKS: I used to work for Lonza. When I started there, Lonza was a big chemical company. In the mid-80s Lonza decided to move into biotechnology. Our dynamic team was able to help create the successful biotechnology operation that Lonza runs today.

When you talk I can hear the music in your voice that immediately tells me where in Europe you come from – the Netherlands. Did you move straight from there to Lonza?

FRANS HOEKS: I studied chemical engineering at Delft University and then spent about five years with Gist-Brocades NV (now part of DSM NV) in the Netherlands, where I worked in biotechnology. From there I moved to Lonza in Switzerland.

View of the main entrance to the building that will house the Late Stage Development & Small Molecules Launch Facility (LSL) at Roche in Kaiseraugst, due to come on stream in 2019. The excavation work started in November 2016 (visualisation © Burckhardt+Partner AG).

With a career path like that it's hardly surprising that you've been put in charge of the Late Stage Development & Small Molecules Launch Facility (LSL) project at Roche. Is this a new departure for Roche?

FRANS HOEKS: The LSL project is a first for Roche in Kaiseraugst, but not for Roche as a whole. Up to now Roche Kaiseraugst has always focused primarily on sterile production, parenterals, packaging, high-bay warehousing, shipment and the related quality control activities. Solid dosage forms have never been produced in Kaiseraugst before. Seen in strategic terms, the aim of the LSL project is to deliver new, innovative medicines to patients as fast as possible.

In other words, this is not going to be a conventional production facility.

FRANS HOEKS: The new Small Molecules Drug Products facility will be scaled to produce small quantities of highly active substances that will be handled as far as possible in closed units. Our main focus with these processes is on product quality and, no less important, employee protection.

You receive the dosage forms of these new active substances from Development. Is that the end of Development's involvement, with you performing all the downstream stages alone?

FRANS HOEKS: No, it's not like that. On the contrary, it's vital for us to work closely with Technical Development. That's the only way to achieve the acceleration we're looking for, and the only way to get products to market as quickly as we want to. You mustn't forget that we need stability data for the filings we submit to the health authorities in order to obtain regulatory approval. Wherever possible, these stability data should be obtained using medicines from the production site and the facilities here. And for that we need to collaborate closely with Technical Development.

Can you name an example of an accelerated drug project to give us a better idea of what it involves?

FRANS HOEKS: Cotellic is a good example. It's a medicine containing the highly active substance cobimetinib. In November 2015, the US FDA approved Cotellic and Zelboraf as a combination therapy for advanced malignant melanoma, or skin cancer. These two Roche products contain the active substance vemurafenib. Given the impressive clinical phase I data for Cotellic, the decision was taken to skip phase II and move directly into phase III trials. Even at that stage it was clear that this new portfolio had the potential for rapid clinical development and launch readiness. In a situation like that, special conditions have to be created and things need to move fast. Then we don't have a development time of up to nine years, and we don't have much time to prepare the regulatory submission.

The medicines produced in the facilities being set up in your LSL project will be the first solid dosage forms to come out of Kaiseraugst. Is this just the start of a general expansion of solids manufacturing in Kaiseraugst, or will LSL be a one-off?

FRANS HOEKS: It's not really possible to say at the moment. For the time being it's enough to say that the LSL project represents a strategic orientation; we decided that in the future new solid dosage forms should be produced in Kaiseraugst to ensure proximity to Development in Basel. This will equip us to accelerate projects involving new medicines, and the immediate proximity of Kaiser-

7 September 2016 on the construction site at Roche in Kaiseraugst, where the «Late Stage Development & Small Molecules Launch Facility (LSL)» will come on stream in 2019: Ir. Ing. Frans W.J.J.M. Hoeks (left) explains the various construction phases to Dr Felix Wüst from SWISS PHARMA. (Photo: Roche)

augst and Basel will enable us to work closely with Technical Development on any accelerated processes that require attention.

Where will the employees working on the LSL project come from? Will they all be new hires?

FRANS HOEKS: No, we are fortunate in already having very experienced people within our organisation. They are currently still working in older buildings in Basel. Some of them are working in an 80-year-old building that now houses state-of-the-art facilities. A set-up of this type, new facility inside old walls, was built for Cotellic, for example. We had to do things in a bit of a hurry. We set up the SLF 27 production line, had it inspected and approved by all the official bodies and were ready on schedule for the launch – all in under two years. That is actually a good example of a tactical decision in favour of a medicine, while LSL is a strategic decision in favour of a portfolio, one that commits us to launching solid dosage forms of new medicines from Kaiseraugst in the long term.

Your work in Kaiseraugst is bound to benefit from the immediate proximity of people from various other parts of Roche, isn't it?

FRANS HOEKS: Definitely. But it's not that new for our teams. We've been working with our partners in commercial and clinical packaging for a very long time now, because Packaging generates the samples we need for our stability data. In addition, approved medicines that are produced in Basel are analysed in Kaiseraugst prior to release. New facilities with which we also work closely have recently been built in Kaiseraugst. Building 235, Sterile Production, is a good example here. As newcomers, we can benefit from the experience of the people already working in the many more recent buildings here. We benefit in areas including various types of documentation, calibration methods, maintenance methods and experience in microbiological testing.

Coming back to Basel, you already mentioned Development, located in Building 97. Will that all be staying in Basel?

FRANS HOEKS: Building 97 houses Technical Development for small molecule drug products in the early and late clinical phases. Building 97 and all the people who work there will be staying in Basel because Roche Basel and Roche Kaiseraugst are very well networked.

That raises another question. If you want the LSL facility to be in the immediate vicinity of Development, why didn't you transfer the whole of Development, Building 97 in its entirety, to Kaiseraugst?

FRANS HOEKS: I understand why you're asking that. You see, Building 97 is also a recent construction. It's not a new facility inside old walls. It's a completely new build with state-of-the-art infrastruc-

ture. It is extremely important for Technical Development to be close to the Basel-based early-phase research and development teams. In addition, the technical development and commercial production of new, innovative active substances is also based in Basel.

What construction stage is your LSL project at?

FRANS HOEKS: As things stand today, 7 September 2016, excavation is scheduled to start in November this year. The shell is expected to be complete in the third quarter of 2017. We've found that shells are generally fairly quick to build. It's the interior fittings, the assembly work and the qualification that will take a relatively long time. We expect to be on stream in about the second quarter of 2019. You can imagine how exciting it is to be on board a project from the very beginning. Like raising my own baby and teaching it to walk. It's an incredibly enjoyable task and one that I find immensely motivating.

The point of the LSL project is to bring medicines to market as quickly as possible. But you still have to go through the regulatory process. What's the use of manufacturing rapidly if it still takes ages to pass muster with the authorities?

FRANS HOEKS: It doesn't take all that long in cases like ours, which usually involve urgently needed, new, innovative medicines. In Switzerland we are fortunate in having a regulatory body, Swissmedic, that gets very involved in the process. That applies to the USA and the EU as well. We usually expect the approval process to take about a year. Global launch in the other countries worldwide takes a bit longer.

Most modern medicines are effective in very low dosages, which provides patients with the greatest possible benefit. When these highly active medicines are produced, it is vital to protect employees from direct contact with the substance, which is why they are made in closed facilities. The raw materials are weighed out in an isolator. (Photo: Roche)

When tablets are manufactured, the powder blend is first granulated. This produces a flowable powder that is easy to process in the high-performance tablet presses. (Photo: Roche)

A year is still a year. You have to put the medicine on ice for a year until you are allowed to market it. Can you cope with that?

FRANS HOEKS: We don't have a choice. Those are the rules we have to play by. Getting a medicine approved is a process that normally takes several years. For cancer therapies, in particular, however, the FDA has accelerated approval procedures so-called breakthrough designation that make it possible to get novel medicines for severe or life-threatening diseases with unmet medical need to patients faster and thus avoid delays. This also means that in some cases diseases can be treated more rapidly if no adequate treatment is otherwise available. In such cases the authorities grant a fast-track approval procedure in which not even the quantity of documents that have to be submitted, often several running metres of files, can be allowed to slow the process.

You mentioned that LSL works with highly active substances. That surely means specific production requirements.

FRANS HOEKS: That's correct. It also means that we have to work closely with the suppliers. We need closed facilities to ensure that our employees are protected. Otherwise work with highly active substances would not be permissible. Picture the entire facility as a clean room. In addition, we have to document everything electronically because there is a risk of contamination with paper. We are currently working with suppliers, Roche Engineering and Roche IT specialists to develop a software, a so-called manufacturing execution system or MES. That will allow us to document batches electronically and make the entire production documentation paperless. You look sceptical. You're probably thinking it's

Tablets containing highly active medicinal substances are usually coated with a very thin polymer layer. This film coating protects the environment against accidental exposure to the medicinal substance. At the same time it can also mask an unpleasant odour or taste and make the medicine easier to swallow. (Photo: Roche)

Tablets are produced in closed facilities. Fully automated in-process controls are carried out in an isolator attached to the press. (Photo: Roche)

a risky way of doing it, that the data could get lost in a system crash. But I can assure you that all the necessary precautions have been taken. Electronic batch documentation is already in use in several locations, in Building 95 for example.

Another question about your employees: are they all specialists?

FRANS HOEKS: Yes, they're specialists in solids manufacturing, but within that field they can perform various functions. Our aim is to build facilities that more or less correspond to those used in Technical Development. That's something that's taken into account at the design stage, and it enables us to perform tabletting or granulation, for example, in the same way in both Development and Manufacturing. The design of the facilities is as uniform as possible. This means that employees can follow production processes from Development up to production scale and can work with them in the same way.

The current issue of SWISS PHARMA also features an interview with Ueli Grossenbacher, Head of Vocational Training at Roche. The article focuses on the Roche Learning Center. Have you already asked the Learning Center for the apprentices that you will need to bring the LSL project on stream in 2019?

FRANS HOEKS: We don't really have to request apprentices as such. Our apprentices are already working in the facility in Basel and new ones arrive every year.

You're obviously very enthusiastic about your project and become animated when you talk about it.

FRANS HOEKS: That's true. Initiating a project of these proportions with a big team is certainly a major undertaking. About 150 people are working on this project at the moment. The project manager is Hans Tanner from Roche. A large number of work stream managers, all from Roche, report to him. There are also a large number of Roche engineers and companies outside Roche, architects, engineers and specialists who are helping to shape the project. I often feel it's like a major symphony in which a large orchestra is doing its best to put all its knowledge and ability, its experience and creative energy, into giving the perfect concert.

Mr Hoeks, we started our interview with a little music; let's end it with music. I wish you and everyone involved in the LSL project great pleasure and satisfaction in working on a major project that will ultimately benefit not only Roche but a large number of patients too.

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SWISS PHARMA 3/16

60 JAHRE GSIA

SYMPOSIUM «60 JAHRE INDUSTRIE-PHARMAZIE»

Pharmazentrum der
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21. Juni 2016

1956 – 2016
60 Jahre GSIA – SSPI

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Einzelhefte Print: CHF 50.– + MWSt. + Versandkosten
Einsehbar auf unserer Website: www.verlag-dr-felix-wuest.ch
Einsehbar auf der Website: www.gsia.ch

SWISS PHARMA – Verlag Dr. Felix Wüst AG, E-Mail: felixwuest@ch

Roche: Continuing the development of the Basel and Kaiseraugst site

Roche Global Clinical Supply Chain Management, Kaiseraugst

A top-level centre supplying patients with materials for clinical trials worldwide

Discussion with Dr Anita Maurhofer, Head of Global Clinical Supply Chain Management, and Mattie Coolen, Head of Clinical Supply Operations Kaiseraugst, F. Hoffmann-La Roche Ltd, Basel

For a research-focused pharmaceutical company, good results from global clinical trials are a key success factor. Once a product has successfully undergone preclinical testing, Roche's Global Clinical Supply Chain Management is responsible for supplying patients worldwide with clinical trial materials. Roche has established two facilities for this purpose – one at Kaiseraugst, in Switzerland, and the other in San Francisco. Dr Anita Maurhofer is in charge of Global Clinical Supply Chain Management at both sites. At Kaiseraugst, Mattie Coolen leads a team of around ninety employees responsible for packaging study drugs and supplying clinical trial centres all over the world. The Packaging and Distribution units are located in Building 204, together with Global Planning – which also reports to Dr Maurhofer – and Quality Assurance. The interview published below gives readers insights into an important stage in the life cycle of a pharmaceutical product.

◆ **Interview: Dr. Felix Wüst**

Dr Maurhofer, Mr Coolen, I'd like to thank you for inviting me here today to discuss the packaging and distribution of clinical trial materials. It is impressive, and an honour for Roche's Swiss operations that you, Dr Maurhofer, here at Kaiseraugst, serve as Head of Global Clinical Supply Chain Management – in other words, that you're responsible for supplying materials to patients participating in clinical trials all around the world. You manage this function globally, while Mr Coolen is in charge of the packaging and distribution of clinical trial materials here at this site. I'm sure this will be a fascinating discussion.

ANITA MAURHOFER: You're very welcome, Dr Wüst, and we're glad to have this opportunity to give you and the readers of SWISS PHARMA some insights into Clinical Supply Chain Management. We appreciate the fact that you wish to inform your readers about this particular function, which involves special responsibilities.

OK, let's get started! When a compound has successfully undergone preclinical testing, it's then administered to humans for the first time. That's the point where you get involved, taking responsibility for supplying materials to all the patients participating in clinical trials.

MATTIE COOLEN: That's right. We're responsible for planning and implementation of the entire clinical supply chain. That essentially involves clinical packaging and distribution of study materials all the way to the patient. We provide this service for all clinical trials – during drug development, that means Phases I, II and III.

ANITA MAURHOFER: Trials conducted during clinical development certainly make up the bulk of our activities, but we also supply clinical studies involving products that are already on the market – for example, for a new indication. Say we have a drug for the treatment of lung cancer on the market, and now we want to investigate whether this drug may also be effective in other types of cancer. That means carrying out new clinical studies to assess whether the drug is also safe and effective in the new indication. It should also be mentioned that we test a lot of combination therapies. Roche is a leader in oncology, and we focus on finding the best treatment for patients with cancer. This involves combining drugs that attack the disease using different approaches. In a so called patient kit, the patient receives multiple study drugs – they could be Roche development products or marketed products, but also products from other companies. In those cases, procuring and packaging all the products is highly complex and particularly challenging.

Can you explain the steps involved in the process?

MATTIE COOLEN: As soon as packaging is required for a clinical study, we get a request to propose a packaging design. This is coordinated in detail with the study team. Next, we procure all the materials and components needed to prepare the packaging. We produce the templates for our multilingual labels. We create the necessary master data in our SAP CLARA system, which we've specially adapted for clinical supply purposes. If necessary, we obtain other companies' medicines, as well as packaging materials and placebos – pharmaceutical dosage forms that do not contain an active substance. Placebos are needed if the study design involves blinding, so that

neither the doctor nor the patient will know which treatment the patient receives. Once all the necessary elements have arrived, they are assessed by the independent Quality Assurance department for compliance and quality. We then start the packaging job. Depending on the complexity and the number of units, this can take anything from a few hours to several days. At the end of the packaging job, QA issues final release and we then ship the patient kits to the depots, and from there to hospitals all over the world.

Mr Coolen, if we talk about packaging in your field, then of course it's not the same as packing a parcel for the post office. Packaging clinical trial materials must be much more complicated.

MATTIE COOLEN: Let's assume that we have all the components and materials required for the packaging of a study. The job is now sent from our preparation service to the Packaging unit. Here, the job is scheduled and all the materials are made available for the packaging job. The required labels are printed in our internal printshop, and the cabin where the packaging process takes place is set up. If we produce blinded combination packs containing a placebo and an active drug, it must be fully traceable where placebo tablets and where active drugs have been placed in the blister. That means all the packaging processes have to be documented in detail in our batch records – the documents specifying how the packaging jobs are to be carried out. These details are not just applicable for the initial packaging job but also have to be repeated for every subsequent packaging job in the same study, in other words when patients are resupplied. That's often the case when studies run for several years. To ensure that no errors occur, we have well-trained staff, robust processes and helpful IT systems, and we've introduced a variety of quality controls to eliminate any risk of unblinding. It's a particular challenge to ensure that, in the end, all the packages look identical, so that the study materials cannot be distinguished in any way. To give you an example: if, in a placebo packaging job, the label were affixed in a lower place than for the active drug, then this visual difference could lead to unblinding, with the doctor discovering that the pack with the label lower down is the inactive one. That would jeopardise the integrity of the whole study. It would no longer be recognised by the authorities as blinded. That would be not just a considerable financial loss for the company, but also unacceptable for patients, whose continued participation in the study would be called into question.

Clinical packaging solutions have to meet special requirements. Here, for example, a child-resistant blister pack is being produced, to prevent the study medication from falling into the hands of children. (Photo: Roche)

Now, of course, the organisation of the studies has to be initiated. From Kaiseraugst, you have to set this huge machine in motion.

ANITA MAURHOFER: The studies themselves are not managed by us here in Kaiseraugst. That's the task of Clinical Operations, which is responsible for the clinical trial protocols in which the studies are precisely described. The hospitals participating in a study receive the protocol and additional detailed instructions, and they are assigned a so-called trial monitor (appointed by Roche), who oversees the conduct of studies at hospitals. There's also a dedicated Quality Assurance function, which is responsible for compliance with Good Clinical Practice (GCP), while our Packaging operations in Kaiseraugst and San Francisco have to comply with Good Manufacturing Practice (GMP). Incidentally, the Clinical Operations unit isn't our only internal customer, we have several. Firstly, there's Genentech Research & Early Development in the US, Roche Pharma Research & Early Development and then, in a later phase of development, Global Clinical Development across the two locations, as well as the local Medical Affairs department in the US and Medical Affairs in Germany. This means our customer interactions are rather more complex than if it was just one department. At the same time, everyone starts with a clinical trial protocol, which serves as the basis for the packaging design.

But you get this protocol from the clinical organisation, not from Development, which manufactures the product.

ANITA MAURHOFER: Yes, we distinguish between technical R&D, to which our organisation also belongs, and clinical R&D. Technical Development comprises the departments that develop the technical processes for small-scale and later large-scale drug manufacturing. That includes technical research and development for biotech medicines and also for chemically synthesised medicines, as well as the associated analytical development. Analytical methods make it possible to characterise the various compounds, inspect manufacturing processes and thus ensure consistent quality standards. Clinical R&D comprises the departments that are concerned with effects in humans, investigate biological processes in the body and think about how clinical studies need to be conducted so as to demonstrate particular effects, also in terms of statistics. This «how» is described in the clinical trial protocols and approved by independent ethical committees.

What information in a trial protocol is relevant for clinical supply chain purposes?

ANITA MAURHOFER: Information on, for example, the number of patients, the number of participating hospitals, the countries where the trial is to be conducted. That's important so that we can prepare the labels in the right languages and set up the supply chain. There's also the question of what drugs are to be used, in what dosage, open-label or blinded. Blinding is always particularly interesting. We are the only department within Roche that ultimately knows which patient number is linked to which drug, and we have a duty not to disclose this information to anyone. Mr Coolen has already mentioned the difficulties involved in blinded packaging. Blinding also represents a complex challenge in terms of procurement. To illustrate that, let me give you a simple example: In a study, two different dosages are to be compared in a blinded fashion. So the patients participating are assigned to two groups: Group A is to receive 20 mg of the active substance per day, Group B is to receive 40 mg per day. What we have available are 20 mg tablets and placebo tablets – that is, tablets which look identical but contain, say, lactose instead of the active substance. Simply giving the Group B patients twice as many 20 mg tablets

On 8 September 2016, on the top floor of Building 204 at Roche's Kaiseraugst site, Dr Anita Maurhofer, Head of Global Clinical Supply Chain Management, talked to Dr Felix Wüst of SWISS PHARMA. As soon as packaging is required for a clinical trial, Clinical Supply Chain Operations is requested to propose a packaging design – some samples can be seen in the display cases. (Photo: Roche)

is not an option; it would then, of course, be obvious who was receiving which dosage. In such a case we have to take a creative approach and the employees from Mr Coolen's department get together with members of our planning department, the Clinical Demand and Supply Leaders – they're the ones in direct contact with Clinical Operations. In the simple example I just mentioned, the colleagues will decide to produce a weekly blister strip with two rows of cavities for seven days. For patients in Group A, seven 20 mg tablets will be inserted in the top row, and seven placebo tablets in the bottom row. For patients in Group B, seven 20 mg tablets will be inserted both in the top and in the bottom row. That means Group A patients taking two tablets per day will receive a total of 20 mg active substance, and Group B patients, with two tablets per day, will receive a total of 40 mg. The blister packs look exactly the same. Only when we've determined the packaging design can we calculate how many 20 mg tablets we need and how many placebo tablets are required.
You try it: How many 20 mg tablets do you need if a total of 100 patients take part in the study for 4 weeks? That was a simple hypothetical example to illustrate the problem. Often, things are much more complicated, with three different drugs and the corresponding placebos, three or four different groups, and crossover designs, where patients switch from A to B halfway through the study. In cases like that, procurement is preceded by intensive design efforts and then detailed calculations.

Does that mean that materials for each individual study are packaged in a different way?

ANITA MAURHOFER: On average, we supply around 500 global clinical trials per year, not counting local studies in the US and Germany. And yes, the components and the packaging design are different. That's essentially the fundamental difference from commercial packaging, which of course we also have here at the Kaiseraugst site. Unlike them, for each new job, we first have to design the product that we ultimately deliver. We don't have any ready-made bills of materials in the SAP system.

What happens after Phase III has been successfully completed? At that point, you've done your job. Who's responsible for the next steps in the life cycle of the product?

MATTIE COOLEN: At Roche, our development products are managed by Technical Development Teams, known as TDTs. These teams include representatives of the various development functions, such as technical process development, technical regulatory affairs, analytical services and ourselves, to mention just a few. During Phase III, another team is formed, but now comprising functions responsible for commercial manufacturing and market introduction. These two teams then work in parallel until the product is launched.

During this period, product knowledge and product management are progressively handed over to the commercial team. After the launch phase, the TDT gradually withdraws and the commercial Technical Product Team (TPT) takes over completely. With this transition, we ensure that the right experts are responsible for the product at the right time. If studies are to be conducted in additional indications, then we remain on board.

So Clinical Supply Chain's job is done as soon as you've created the packaging required for the clinical trials and completed distribution of the study materials?

ANITA MAURHOFER: Yes, when the patients have received their drugs, we've done our job. We have a distribution network specially tailored to clinical supply. We work with contractors and specialists in the various regions and countries where we conduct trials. We have depots in those locations, which we use to supply the individual hospitals and medical specialists. We monitor this network and know exactly where our products are located and what quantities are available. We can control how much a particular hospital receives at a particular time, because we don't initially know how many patients with the required disease profile will be admitted to any given hospital.

Now of course you also carry out clinical trials in which your own products are compared with rival products. Do you then go and make your competitors' day by purchasing large quantities of their products?

MATTIE COOLEN: Many manufacturers are prepared, on a reciprocal basis, to make their products available for studies. If we approach the competitors directly, they can inspect the trial protocol and know what we're planning to test. There are also cases where we use a company specialising in this area to purchase products on the market. It also ultimately depends on the quantities we require.

To the layman, it's surprising that rivals should supply each other with products for clinical trials. That means there are no cloak-and-dagger efforts to buy up competitors' products?

ANITA MAURHOFER: No, there's nothing cloak-and-dagger about it! In the first place, all the trials a company conducts require the approval of an ethics committee. Then, it's a legal requirement that every pharmaceutical company's trials are listed in a publicly accessible registry. We know what our competitors are doing, and they know what we're doing. In certain cases, we want to compare the effects. In others, we want to combine different treatments. But as we've said, there are various ways of getting hold of the comparator drug.

As the product portfolio evolves, increasing numbers of vials are being used. These vials have to be labelled and securely packaged to withstand the rigours of worldwide transport and ensure product quality. (Photo: Roche)

Why is there this legal obligation to disclose all clinical trials?

ANITA MAURHOFER: It promotes transparency and the availability of information for doctors and patients. Every trial conducted by a pharmaceutical company is listed in a publicly accessible registry, and the results have to be published, regardless of whether the study drug performed well or not. The results of trials are presented at specialist conferences – such as ASCO, the annual meeting of the American Society of Clinical Oncology – where new findings and study data are discussed. The participants are drug researchers, pharma companies, physicians and patients. For certain groundbreaking products, this can lead to pre-approval prescription, because some patients cannot afford to wait for official authorisation.

It would also be interesting to hear some facts and figures about clinical supply chain operations here at Kaiseraugst.

MATTIE COOLEN: Here in Building 204 at Kaiseraugst, we have available a floorspace of around 12,000 m2. That's roughly the same area as in the nearby Rocephin production building. We have three floors: our offices are on the top floor, Packaging Production is on the ground floor, and our drugs, packaging materials and products are stored in the basement. Around 150 people work here in Building 204. That includes the Clinical Demand and Supply Leaders from Global Planning, and the clinical quality assurance staff. The QA colleagues are not part of our organisation, but their proximity to packaging operations helps to speed up our processes.

In terms of size, how does the Clinical Supply Chain Management centre in San Francisco compare to Kaiseraugst?

ANITA MAURHOFER: Our centre in the US has around 105 employees. At Kaiseraugst we have about 125. So altogether about 230 people work for Global Clinical Supply Chain Management (PTDS).

Do you have peaks and troughs in clinical supply operations?

MATTIE COOLEN: Our workload certainly fluctuates over time. But there's no recurrent, regular cycle that you could plan for. There are times when we have a lot of work, for example, if the company is launching a large, complex study – or often several studies at the same time. Or there may be less work, if a product is shelved because the active substance hasn't shown the desired effects and development of the compound is terminated. Then there might well be a lull. But then, based on our advance planning, we try to bring forward other jobs, and we usually manage to do so.

ANITA MAURHOFER: Your question raises a very important point. In general, our procedures have to be geared to highly dynamic operations. We must have processes that enable us to respond in a highly flexible way. Not just because different trials involve different amounts of work. There are two other factors shaping

the dynamics of our work. Firstly, there's what's called compassionate use – these are special cases, individual patients with a life threatening condition who are dependent on a new development drug. We had that recently with a hemophilia patient who almost bled to death at the airport in London. We have to give jobs like that absolute priority and get the drug dispatched for this one patient in the shortest possible time – while also, obviously, complying with all the regulations and the QA release procedure. The other point is that we often have to deal with unprecedented situations. We've just been confronted with a case where a supply chain had to be set up at minus 20 degrees. In the early phase of technical development, it wasn't yet possible for the stability of a product to be optimised in such a way that its efficacy would be maintained for an extended period at 2 to 8 degrees, but only at minus 20 degrees. Something like that requires a lot of preliminary investigations, not just because it's the first time we've done it, but also because it's very unusual. But here at this site we have excellent partners, such as Logistics and the Transport department, who work alongside us, seeking – and finding – solutions. Together, we can solve any problem.

Mr Coolen, you mentioned that Roche organises trials involving 100 patients, but also others involving 30,000. Let's take the case of 100 patients. There, of course, you'd hardly be able to make use of machines or robots. So it would all have to be done by hand?

MATTIE COOLEN: Here, we do a lot of manual packaging. Products are packaged and labels are affixed by hand. The degree of automation here is fairly low. But there are certain processes that can't be handled manually. Consider, for example, our blister packs, which have to be machine-sealed. For us, machines are useful aids. You could call it a hybrid process – partly machines, partly manual work. That's also the reason why, on your tour of the site, you didn't see a lot of machinery. We have two very well equipped blister lines, designed for flexibility and relatively small quantities. We also have a bottle filling line and several labelling systems for bottles and vials. But, as I said, a great deal is actually packaged by hand.

Quality and in-process controls are an important element of the packaging process. They ensure that no defects arise during packaging. Here, the print quality of labels is checked on a random sample. (Photo: Roche)

A barcode reader is used to monitor and document the various packaging steps. Here, for a double-blind study, it is ensured that the serialised (patient-specific) medication is assigned to the appropriate kit. At the same time, the computer system generates the necessary report for release by Quality Control. (Photo: Roche)

Doesn't that introduce potential hazards?

MATTIE COOLEN: All our systems and processes, including those carried out manually, are validated or qualified. That means our employees have to meet stringent training requirements. Not everyone is allowed to carry out every process. The individual employee must be specially trained for a particular packaging process – for example, packaging for a double-blind study or the production of combination packs.

So your employees have to undergo systematic internal training?

MATTIE COOLEN: That's right. All our employees are enrolled in a training and development programme. Unless you're committed to that, you don't really belong here.

ANITA MAURHOFER: Let me just pay our staff a compliment! We're very fortunate to have extremely reliable employees, who also come up with good ideas, which are implemented by – I'll call them our «creatives». For example, templates have been created which are used for manual blister packaging. In the study I mentioned earlier, there was a blister strip where active 20 mg tablets had to be placed in the top row and placebo tablets in the bottom row. That could work like this: the first team member lays a template over the blister strip, so that the bottom row is covered and only the cavities in the top row are visible. That's where she now inserts the tablets, which she has in her cabin – only active 20 mg tablets. Then the blister strip is passed through a hatch into a second cabin. The team member sitting in this cabin first checks that the first row has been correctly filled, and then covers this row by laying another template over the strip. She then places in the unfilled bottom row the tablets that she has in her cabin – only placebo tablets. So the procedure for this hypothetical example could look something like that.

MATTIE COOLEN: We frequently use aids of this kind to assure quality and avoid errors. They're available for labelling, for filling blister strips, for filling bottles manually, etc. Here, there are no limits to the creativity of our staff.

On the ground floor of Building 204, which accommodates Packaging Production, Mattie Coolen (left), Head of Clinical Supply Operations, Kaiseraugst, explains to Dr Felix Wüst of SWISS PHARMA the stringent conditions under which sample packs are produced for clinical trials. (Photo: Roche)

Now we should look at the final stage of your activities – distribution.

MATTIE COOLEN: Distribution is another really challenging task. A lot of recently developed Roche drugs are refrigerated products, which have to be shipped at between 2 and 8 degrees. If these products are to be used in regions with less stringent quality standards, then it's a challenge to make sure they reach the customer within the required temperature range and in the right quality. Our packaging efforts at the Kaiseraugst site are plain for all to see. But a lot of efforts are also made in transit and during distribution. The goal of delivering products to hospitals, doctors or even patients in the desired quality at the desired time is a real challenge. We've set ourselves ambitious goals for reliable delivery.

ANITA MAURHOFER: Imagine for a moment that you're a cancer patient whose condition has not been improved by any of the products available on the market. Your last hope is now a new drug with a highly promising mechanism of action. For two weeks, you've been taking part in a clinical trial, and you're feeling better by the day. Now suppose your doctor tells you: «I'm afraid we can't treat you this week, the manufacturer couldn't deliver the drug in time.» How would you feel then? We do our utmost to make sure that never happens. Of course, there are occasionally obstacles, which we're not able to overcome in time either. Then we control the supply of available drugs in such a way that interruptions are avoided, which can lead to a delayed study start for another patient.

This means you also need your own shipping department.

MATTIE COOLEN: We maintain a clinical supply-specific distribution network. We established this network over the past few years, and we continuously monitor and improve it. We work with reliable contractors who are familiar with our requirements, and with whom we have regular interactions. In addition, we have terrific partners here at the Kaiseraugst site – Roche's Logistics and Transport departments.

ANITA MAURHOFER: Our Global Clinical Distribution Leaders track every movement and ensure timely distribution of products to our depots and beyond. We can't allow products to be held up somewhere along the line.

To the layman, it sounds as if you have an immense responsibility.

MATTIE COOLEN: Yes, now and again, things do get a bit tense. Of course, a further complication is that we don't necessarily know in advance how many patients there'll be at a particular hospital. So we could, for example, have drugs available on one side of the world, where at first there's only a trickle of patients, but they'd be needed much more urgently on the other side of the world because they enrol far more patients there. For this reason, we're very cautious about product distribution, we keep stocks in central depots until we have a better idea of how patients are distributed geographically. In other words, we have very limited planning certainty.

In the primary packaging cabin, where blister strips are produced, stringent safety measures are observed to protect patients and staff. For clinical trial materials, it is essential to place the right drugs in the right blister cavities. Operations performed manually are facilitated by the use of aids such as templates. (Photo: Roche)

Sometimes only low volumes are produced, especially in the early phases. Then we have to be very economical. And then there's the fact that the shelf life of new drugs changes with the availability of newly developed stability data. We also control that through our distribution network. The depots are trained to attach extension stickers to patient packs. All this we manage from Kaiseraugst.

Will the expansion of Roche at Kaiseraugst, once it's completed, have a positive influence on your activities, or do you think Clinical Supply Chain Management will be largely unaffected?

MATTIE COOLEN: There won't be any major changes to our day-to-day operations. But the site will increasingly become larger and more attractive. As a result, it will probably be easier for us to recruit good people.

ANITA MAURHOFER: The construction of the launch facility for small (i.e. chemically produced) molecules does have a certain influence. There, we'll be able to source our product directly for packaging. It would also be conceivable that, with our specialised low-volume manual packaging capacity, we could help out commercial secondary packaging, if necessary. Our drugs are becoming increasingly effective and are designed for highly specific patient populations. That means the volumes required are not as high as they were some years ago. Commercial packaging jobs for smaller countries are increasingly on the same scale as clinical supplies. In this area we can interact more than in the past.

That sounds promising. As a visitor here, I'm slowly but surely getting the impression that there's still enormous potential for growth in the «spirit of Kaiseraugst». Many people on the Roche Kaiseraugst site will have new neighbours. That means new contacts, new ideas, it's terrific!

ANITA MAURHOFER: Yes, it's very good news. On the one hand, we're a global organisation, which depends on effective transatlantic collaboration, and on the other hand, we're fully integrated into this site, which is just as important. We have close contacts with Dr Rainer Schmidt's Production/Packaging/Storage/Shipping leadership team and with Dr Ulrike Falk's Quality Control here at Kaiseraugst. All our employees are invited to participate in joint activities. In areas such as GMP training, we already work closely together so as to avoid duplication of effort.

Finally, may I ask you about the Roche hierarchy above you? This may not be essential for an understanding of your responsibilities, but I'm simply curious.

ANITA MAURHOFER: We're part of Pharma Technical Development (PTD). My boss leads this organisation from San Francisco. She in turn reports to the global head of Pharma Technical Operations (PT), who is based in Basel.

Thank you, Dr Maurhofer, and you, Mr Coolen, for taking time out for this interview, and for your interesting explanations. As we've heard, the expanded Kaiseraugst site will ultimately not only bring you new colleagues, but also open up new perspectives and possibilities in your existing field. For that, you're to be congratulated

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Orthopädie – Traumatologie – Chirurgie Arthroskopie – Sportmedizin

SWISS MED 1/11 (208 Seiten) Gespräche/Beiträge in SWISS MED aus den Jahren 1979 bis 2010

CHF 80.– + MWSt. (Schweiz) + Versandkosten

Editorial
Prof. Dr. med. André Gächter
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Zitat aus dem Editorial:
«In diesem Erfahrungsschatz (SWISS MED 1/11; Red.) finden sich so viele Beiträge von prägenden ‹Grössen›, auch von umstrittenen Persönlichkeiten oder Weggefährten, die ohne ein grosses Aufheben davon zu machen bedeutende Weichen gestellt haben: Eine wichtige Fundgrube für alle, die sich für die Entwicklung der Orthopädie und Chirurgie – sowie deren Unterspezialitäten – interessieren.»

Gespräche / Beiträge
Auf mehr als 200 Seiten findet die Leserin/der Leser
eine Kompilation der in SWISS MED seit der Gründung der Zeitschrift im Jahre 1979 bis und mit 2010 veröffentlichten Live-Interviews mit den damals aktiven Persönlichkeiten.

Zitat aus dem Editorial:
«Wir finden auch Perlen von Interviews und Beiträgen in dieser Ausgabe von SWISS MED (1/11; Red.) zu Themen wie der Entwicklung der Osteosynthese, der Arthroskopie, der Thromboseprophylaxe, der Technischen Orthopädie und Sportmedizin an den verschiedenen Kliniken von Fribourg bis nach St.Gallen.»

Verlag Dr. Felix Wüst AG, In der Hinterzelg 4, CH-8700 Küsnacht ZH, Telefax ++41 44 918 29 70, E-Mail felixwuest@bluewin.ch

Roche: Continuing the development of the Basel and Kaiseraugst site

The Roche Learning Center in Kaiseraugst – the best possible environment for aligning Roche's vocational training activities to the needs of the specialist departments and apprentices

Roche provides training: As a contribution to society and the economy in Switzerland, the company's own, first-rate and integrated vocational training facilities qualify trainees as professionals

Discussion with Ueli Grossenbacher, Head of Apprenticeship Training, F. Hoffmann-La Roche Ltd, Basel

On 19 January 2015, Roche opened its new Learning Center in Kaiseraugst. Besides offering a superlative infrastructure for trainees, the Learning Center contains a state-of-the-art school laboratory, the only one of its kind in Switzerland. Investments in the building ran to approximately 86 million Swiss francs. Apprentices have access to leading-edge laboratory and workshop facilities in the new learning complex. Roche's rationale for installing the new school laboratory is also to give children and young people an opportunity to explore and spark their enthusiasm for scientific and technical professions. It is no exaggeration to say that, in terms of design and quality of its facilities, the Roche Learning Center is a pioneering project for the region and for Switzerland as a whole. The theme of this issue of SWISS PHARMA is «Roche in Kaiseraugst – Expansion on a large scale», looking at the ongoing development of the Roche sites in Basel and Kaiseraugst, so a visit to Ueli Grossenbacher, Head of Apprenticeship Training and the «main man» at the Roche Learning Center is a must.

◆ **Interview: Dr Felix Wüst**

Mr Grossenbacher, the Roche Learning Center complex, which opened back in 2015, is surrounded by cranes, construction work, hammering and concreting work. The Center has been fully operational for over a year. I'm delighted to be here with you today and hear all about the exemplary learning environment that awaits apprentices at Roche.

UELI GROSSENBACHER: The pleasure is all mine, Mr Wüst. I've seen your name a number of times in issues of SWISS PHARMA focusing on Roche Kaiseraugst, and now I finally have the occasion to welcome you in person to the Roche Learning Center.

Your time is valuable, so let's get right on with the interview. What career path does one pursue to head the Roche Learning Center?

«Train for your future. Train at Roche» are the words that visitors read in the brochures and information media about vocational training at Roche that are displayed in the Roche Learning Center. On 13 September 2016, SWISS PHARMA visited Ueli Grossenbacher (right), Head of Apprenticeship Training at Roche. It quickly became clear to Dr Felix Wüst that the professional future of a great many young people begins at the modern Learning Center in Kaiseraugst. Roche trains apprentices for jobs at the various areas of Roche, laying the foundation for the professional development of the next generation. In doing so, Roche makes an important contribution to the economy and society in Switzerland. (Photo Roche)

Ueli Grossenbacher: Well, we actually wanted to talk about vocational training at Roche and about our apprentices, but I'm happy to answer that. You need a number of things, in my view. First of all, you need technical expertise as well as training in teaching methods. I, for instance, completed an apprenticeship as a chemistry lab technician before earning a university degree in chemistry. Additionally, I completed a post-graduate qualification in Education Management at the Institute of Applied Psychology in Zurich. Both of these help me manage vocational training at Roche today. I understand the requirements and training needs of the various professions and am able to provide support in all kinds of areas. Besides your own training, however, you need to be enthusiastic about training apprentices and passionate about supporting young people throughout their apprenticeships and helping them enter the world of work. The combination of science and technology, teaching tasks and working with apprentices on a daily basis never fails to be a challenging and satisfying task.

Your position according to your business card is «Head of Apprenticeship Training». That's a pretty broad term. It would certainly help our readers if you could define it more precisely.

Ueli Grossenbacher: My area of responsibility encompasses everything to do with «basic vocational training». It starts with advertising and recruiting suitable young people for an apprenticeship with us and ends with the additional services we offer to those young men and women once they have completed their training. Apprenticeships are pretty much our raison d'être.

This issue of SWISS PHARMA contains interviews with key individuals at Roche who work around the world. Can I just clarify one thing before we continue: if I have understood correctly, the Learning Center is exclusively a local facility?

Ueli Grossenbacher: The training follows the cantonal guidelines, yes; but we train young people to become professionals who will quickly become aware of our global environment at Roche. We also have training places at all Roche sites in the region, make use of the public vocational colleges and run an in-house training centre in Kaiseraugst. More recently, we have also begun offering training places for lab technicians specialising in biology at Roche Glycart AG in Schlieren near Zurich. Our apprentices come from all over Switzerland and from just across the border in neighbouring countries. A good command of German is essential to successfully completing the training.

Roche also has the Rotkreuz location in Central Switzerland. Are you also involved in training apprentices there?

UELI GROSSENBACHER: No. Rotkreuz has its own training organisation, which is geared heavily towards the needs of Rotkreuz as a diagnostics location. However, we do engage in regular exchanges and provide each other with support in overlapping areas.

Let's talk now about the young men and women, your apprentices. In your information documents, you say that you supervise around 300 apprentices at any one time in fourteen different professions and that you provide them with first-rate, integrated training. Confession time: do you use rigorous screening at the selection stage, to ensure that you only get the best people for Roche?

UELI GROSSENBACHER: Allow me to explain exactly how it works. Our aim is to inspire enthusiasm as early as possible among school students for the professions in which we offer apprenticeships. To this end, we run a school laboratory called «Experio Roche», to which teachers can bring their Year Six onwards school classes to gain hands-on experience of all the STEM disciplines (science, technology, engineering and mathematics). Depending on the school level and age of the classes, we also offer various workshops, in subjects including biology, chemistry, robotics and mechanics to introduce students to the whole spectrum of science and technology. These are the first encounters these very young people have with Roche and, for the vast majority of them, with the world of work. The facility has proved extremely popular. By the end of this year, we will have welcomed around 4,000 school students. But, at that stage, it has nothing to do with the recruitment of apprentices. It is purely an information service and the sole aim of our school laboratory programmes is to awaken interest in the STEM disciplines. However, we are already seeing that – when choosing a career – the students apply for an apprenticeship with us. As part of our recruitment activities, it is important to us that we share a lot of vocational information early on, to demonstrate what the relevant professions entail, what vocational training at Roche has to offer and what they can expect. We have a whole range of ways of doing this, from the information day to visits to schools. We advertise our apprenticeships in various media; print media are very much a key channel for us right now. We also introduce vocational training at Roche on our website and are currently enhancing the visual experience with videos in social media.

How does it work, exactly? A girl interested in chemistry reads your advert and gets in touch with you. What happens next?

UELI GROSSENBACHER: There is a clearly defined process for this. The interested girl fills in an application form and is invited to attend a trial apprenticeship, provided she satisfies the basic requirements. At this stage, we first take a close look at the school reports. It is very important to us that the recruitment process is conducted fairly and both sides have clarity about what is involved, that transparency is assured. If somebody has done a trial apprenticeship and enjoyed it, they should be given the opportunity to progress with the recruitment process.

If I have understood correctly, the candidate starts an actual job at Roche as a trial apprentice?

UELI GROSSENBACHER: Correct. But, depending on the profession, a trial apprenticeship only lasts one to four days. It depends on what we want to show the young person so that they know all about the profession. After the trial apprenticeship, the students are given the application forms. They then go home and reflect on their experiences. We are very keen for them to discuss it with their parents and tell them about their impressions during the trial apprenticeship. If they then decide to apply to Roche, they get in touch with us or return the completed forms to us. We then invite them to more tests. Students can prepare for the aptitude test beforehand on the website www.startklar.roche.ch, so that they know exactly what to expect. The aptitude test lasts one day. A written test is held in the morning, which involves two mathematics tests and a multiple choice test. The questions cover subject knowledge that has been taught at school. However, the tests also check whether students already have a degree of insight into the profession concerned, so that we can see whether they have already given consideration to their potential future career. In the afternoon, we discuss the test results with all the candidates and hold interviews with them. We look at school exercise books, we evaluate the test results and then we decide at the end of this conversation whether or not the person will be offered an apprenticeship with us, and explain our decision.

The process is comprehensible, accurate and fair. But for a candidate, it is pretty tough if they had their hopes pinned on an apprenticeship at Roche and leave empty-handed. An early encounter with the harsh reality of life and competition. How many apprentices succeed in getting an apprenticeship at Roche each year?

UELI GROSSENBACHER: Yes, you're right. It's really not always easy to turn down an applicant if they don't have what it takes to successfully complete an apprenticeship. However, the interview is an opportunity for us to really look at people's personal aptitudes and explain why it didn't work out this time. At the same time, we can point the way ahead and show them what they can do in order to pass our aptitude test next year, for instance. Around 450 young people sit our aptitude tests each year. Usually, around a hundred of them start an apprenticeship with us every year.

Great! So now we have these hundred or so capable apprentices at Roche. According to Roche's brochures, you now provide them with top-class training according to the tripartite training model. Could you please explain to us how that works?

UELI GROSSENBACHER: Our tripartite training model simply follows on from and expands upon dual training. First, there's the training centre. That's what you see here in this building; a fully-fledged, completely standard school for our apprentices. Then there's the vocational school, where the relevant theory and general training are taught. Two examples are Basel's public vocational school and the commercial-industrial vocational school in Muttenz. The third learning location is on-the-job training, where the apprentice is fully immersed in professional life and can experience everything that entails.

Is it possible that there is some overlap between your training centre and the vocational college?

UELI GROSSENBACHER: To a degree, yes, you're right. At the training centre, we run focused training, ranging from introductory courses to exam preparation, relieving the line management of these activities. At the same time, we coordinate the three learning locations and ensure that apprentices receive comprehensive support. So the training centre is the link between the vocational college and the line management here at Roche. This means we are able to offer a combination of theory and practice, which generates a very welcome and lasting repetition effect. We incorporate the theoretical aspects from the college and training centre and put them into practice in the work environment at Roche.

Now I'd be grateful if you could explain what the apprentice experiences while training on-the-job at the company.

UELI GROSSENBACHER: At the workplace, the apprentice encounters qualified vocational trainers who have successfully completed the cantonal course for vocational trainers. We run these courses in partnership with the Basel-Stadt training supervisory authority. Those who successfully complete the course are awarded the Cantonal Vocational Trainer Certificate. This proves that they have appropriate teacher training and are officially competent to train apprentices. Apprentices integrate into existing teams at the workplace with the vocational trainers and are introduced to day-to-day operations. This first happens after the introductory courses, which last around six weeks. This means they quickly work on real projects and are already productive. We have noticed that apprentices learn very fast and in an action-centred way at the workplace. Over the course of the apprenticeship, we transfer more and more responsibility to them and the apprentices become increasingly independent, until, finally, they are fully trained and can embark upon a career as professionals.

Are the apprentices graded?

UELI GROSSENBACHER: Yes, the law requires apprentices to be assessed at all learning locations. At the training centre, apprentices receive an assessment for some courses that rates their performance and provides information about their current level of educational attainment. Graded tests to check that the subject matter has been learned are periodically conducted in the school or college setting. In addition, the line management performs an end-of-term assessment. Again, the primary objective is to ascertain the level of attainment compared with the learning goals achieved. At the training centre and during on-the-job training, methodological and social skills are also assessed in addition to the purely subject-related assessment points. These tools are used to nurture the apprentices in a focused way and regularly document their attainment level.

Training centre, vocational college and on-the-job learning – is this a layered approach, does it all take place concurrently? Have I got that right?

UELI GROSSENBACHER: Yes, it all happens concurrently. Apprentices spend around two days at school and three days in a practical setting throughout the entire duration of their apprenticeship, the practical setting being either on-the-job training or a course at the training centre.

The new infrastructure in Kaiseraugst enables us to provide training according to the very latest methodological and educational principles. Apprentices develop the necessary skills through self-directed learning. (Photo Roche)

IT apprentices build their own IT infrastructure as part of their training at the centre. In the process, they learn the theoretical principles and familiarise themselves with all the requirements of a modern IT environment. Experiences gained at the training centre and the specialist knowledge they acquire form the basis for working in the Roche IT landscape. (Photo Roche)

Judging by everything I've heard so far, the average grades of Roche apprentices must all be at the top end, right? I mean, shouldn't all Roche apprentices graduate with an average grade of over 5.0 after all that intensive support?

UELI GROSSENBACHER: We have been training apprentices since 1957 and have an above-average success rate of around 98.5% for the final examination. So our apprentices are indeed highly successful. Roche apprentices achieve grades of over 5.3 in around 25% of final examinations. However, one thing is very important to me: we do not focus primarily on the final examination, because what we absolutely don't want is a desperate race for the finish line. We want to prepare young people for professional life and for lifelong learning, so that they can thrive as specialists on the labour market and continue to develop. Our aims are therefore ambitious – our apprentices have completed an excellent apprenticeship even if they don't get a final grade of over 5.0. When people later do really well in their professional lives and climb the career ladder, school grades often matter a lot less than the ability to apply what they have learned in a professional environment.

Do any Roche apprentices fail the final examination?

UELI GROSSENBACHER: Unfortunately that does occasionally happen and is, of course, disappointing for all concerned. But they are almost always exceptions and only very rarely does it come as a big surprise. If somebody has not achieved the necessary standard, meaning they have not earned a professional qualification, then it is only right that they do not pass the examination. Ultimately, it's a form of quality assurance, figuratively speaking. Don't get me wrong, I am absolutely not saying that somebody has to fail the exam. However, an examination system that does not ultimately differentiate will lose credibility. If an apprentice fails the exam – and there may be various reasons for this – and provided they are willing to put in the effort, we offer them our assistance for another year of training and nurture them in an even more specific way, so that they pass the next exam.

They've passed the exam, and their apprenticeship is over. Presumably the hope now is that the successful young professionals will stay at Roche?

UELI GROSSENBACHER: That is certainly an objective but we are well aware that we have trained outstanding young people who will be able to hold their own in their professional lives. But I must point out that we deliberately train more people than we need, because, in principle, Roche is pursuing two aims. As well as meeting our own needs, we want to act as a feeder for universities of applied sciences and, as a major employer in Northwest Switzerland, we are keen to take social responsibility for strengthening the job market with well-trained professionals. Naturally, though, we are delighted if somebody returns to Roche after earning a degree or after working elsewhere for a few years.

Do apprentices still have access to your coaching after their training?

UELI GROSSENBACHER: Yes, our programmes extend well beyond the completion of the apprenticeship, which is something newly qualified professionals greatly appreciate. For instance, we offer them the Berufsmatura (vocational baccalaureate) through two models. For four-year apprenticeships and for commercial trainees, there is the option of completing the Berufsmatura concurrently. The three-year apprenticeship is less well suited to this, as a lot is packed into those three years at the training centre and vocational school and working at the company. Because of this, we have developed a model we call «Lehre + 1». This model involves offering young men and women who have completed their apprenticeship another training contract for a further year, during which they attend the BMS 2, which means they complete a full-time year of school, spend all their time at the school on a Roche training contract, obtaining the Berufsmatura. It should be remembered that we pay them a salary for that year, roughly equivalent to the salary for the fourth apprenticeship year. The positive effects of this «Lehre + 1» model are twofold. On the one hand, people are not absent for too long during the three years of practical experience and on the other, they have to make a conscious decision to obtain the Berufsmatura and then proceed to enrol in a study programme. Thanks to this system, we have virtually no drop-outs these days. As you can see, at Roche we provide a solid basic training while adding the Berufsmatura on top and channelling people towards universities of applied sciences. This system has proved its worth and I am a fervent champion of it. If people complete the Berufsmatura during their apprenticeship, it is often without a specific objective in mind. We are seeing a trend nowadays for people to do the Berufsmatura simply because it «looks good». With the «Lehre + 1» model, however, as I've already said, they have made a conscious decision with a specific goal in mind. And to be frank, the additional year is neither here nor there; it makes no difference whether you complete a bachelor's degree at 23 or 24.

Chemical and pharmaceutical technicians gain a detailed understanding of systems and procedures at the training facility, so that they can independently control chemical, pharmaceutical or biotechnological production. Working on the process control systems in the control room is a core component of the training. (Photo Roche)

The equipment and the practical work in the training centre, here in the biology teaching lab, are the same as in a research laboratory. Thus the basics taught on the courses at the training centre can be directly applied in real projects when working on the job with the vocational trainer. (Photo Roche)

I assume the universities are eternally grateful to you for the commendable work you do!

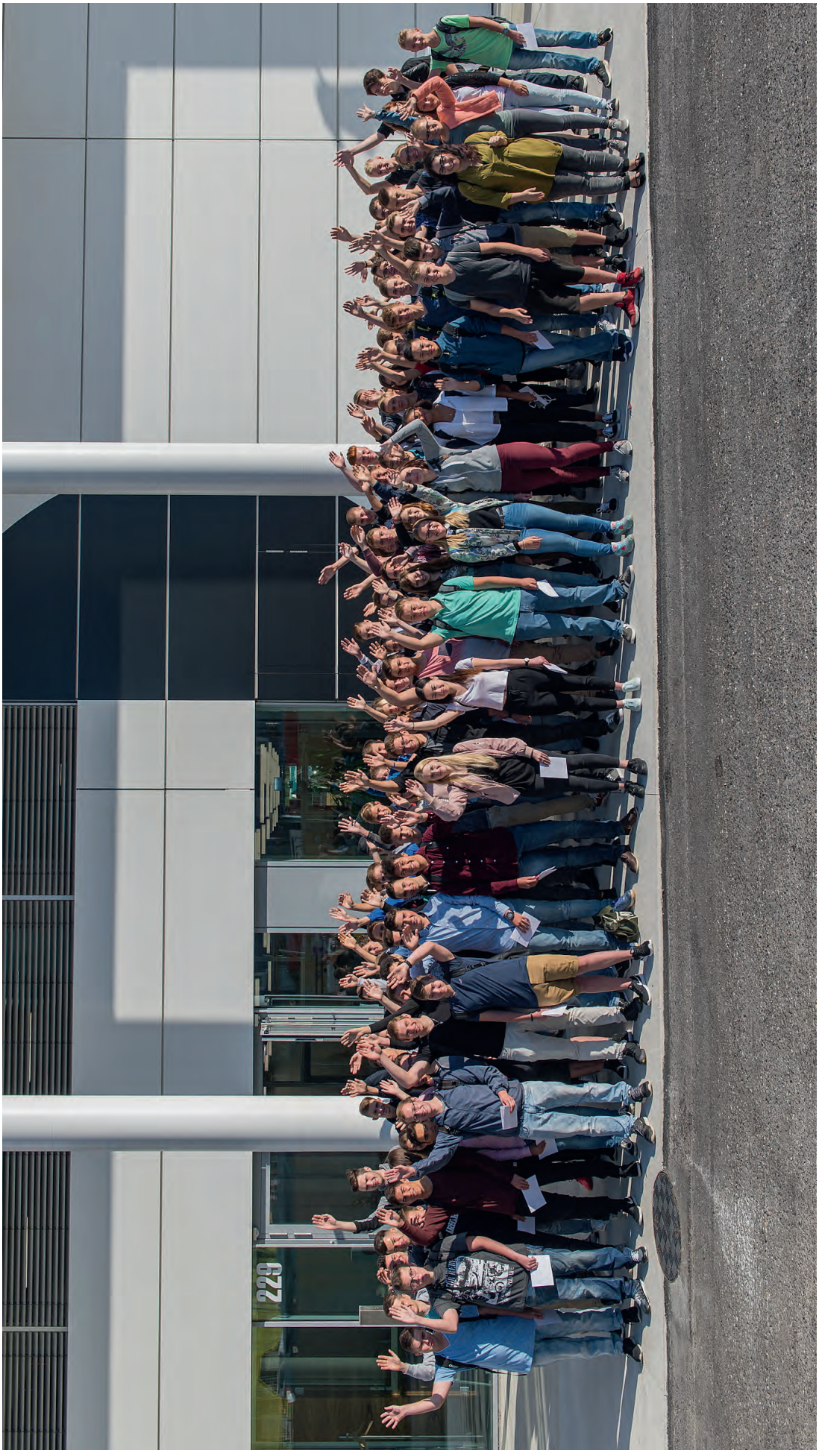
UELI GROSSENBACHER: That would be an exaggeration, but the feedback on our «Lehre + 1» model is uniformly positive. Looking at the present-day Swiss educational landscape, we are clearly very much on the right track. In practically every position in that educational landscape, there are people who are graduates of our «Lehre + 1» model. We take some pride in the fact that our training system makes a substantial contribution to vocational training in Switzerland. I mean that not only in terms of the number of graduates we send out in the professional world, but also in terms of the quality of our training.

Another impressive thing about Roche is that you do all that without going cap in hand to the government to ask for any financial contribution. But are your efforts at least appreciated and recognised by the government?

UELI GROSSENBACHER: We enjoy a very pleasant and constructive relationship with various cantonal authorities and they absolutely do appreciate the good work we do. We also enjoy excellent working relations with the vocational colleges. I always see myself as a partner and find it quite exciting to be able work with these teachers on the important, indeed fascinating project that is training young people.

You have around 300 young people at Roche at any one time. They don't all come from Basel, and some of them aren't even from the region. Many live too far away from Kaiseraugst to commute.

UELI GROSSENBACHER: To help apprentices who don't live in the Basel region, we run a hostel in Basel, very close to Roche, which is managed by a professional head of facility and looks after the young people. They live there from Sunday evening to Friday evening and return to their family home at the weekend. Roche pays their accommodation costs and we make sure everything is going smoothly.

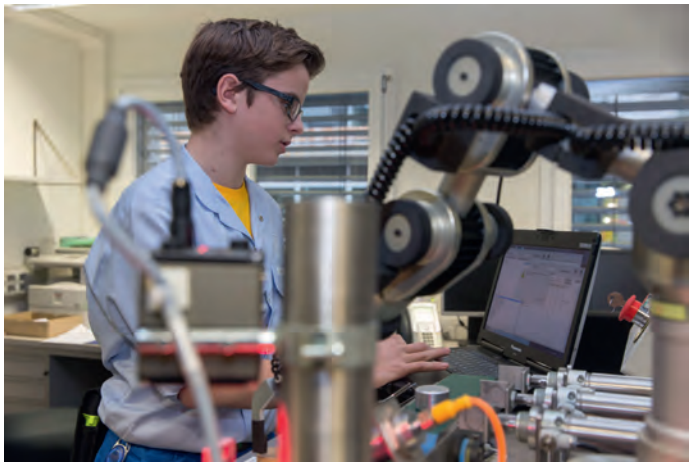


Around a hundred apprentices start their training at Roche in August each year. As well as a thorough introduction to their new environment, they quickly get to know one another. It doesn't take long for efficient teams to form which, gradually, develop into qualified professionals. (Photo Roche)

This ensures they have as much Roche as they need, but only as much as is really necessary. We want to avoid giving young people the impression that Roche is dominating their lives, around the clock. The hostel is home to around seventy people in their first and second year of apprenticeship. If we have enough space available, we also take in people in their third year. If we don't have enough space, we fund part of their accommodation costs and the youngsters can rent a suitable apartment between two or three of them in their third year. This generous scheme is available to anyone who lives so far away that a daily commute to Basel/Kaiseraugst is impossible or unreasonable. Our hostel is tremendously important, including on a very human level. Imagine a girl or boy aged fifteen having to leave his or her family and start an apprenticeship in Basel or Kaiseraugst. They are leaving their family back home, their familiar school and their peers behind them and moving to Basel, to live alone and organise their own lives. Often, that proves very challenging for the people concerned. That said, I can assure you that this «change of scene» marks a huge step in the development of these young people, who learn to take responsibility for themselves and become adults. When I see this, let me tell you, I am often amazed how the young people suddenly change in a positive way when they have only themselves to rely on. This can indeed be considered part of their training: guiding them to become independent people with a strong character.

Getting back to the expansion of Roche's Basel and Kaiseraugst site. As we know, Kaiseraugst in particular will grow exponentially. Several big new buildings are currently under construction and, eventually, around 3,500 people will be employed here. Are you ready for this explosion at your unit?

Ueli Grossenbacher: Yes, we are ready. After all, we work very closely with the line management and know their needs and requirements. The fact that vocational training is provided within the company proves to be a major plus point, particularly in this respect. We know in a flash if something is changing in the line and are able to offer an immediate, proactive response. I can give you a good example. When it was announced that Roche in Basel would be embracing biotechnology, we knew it would take around two years for the facilities to become operational. Right away, we added biotechnology to our training programme. We immediately built a biotech lab and recruited a biotechnologist. We were able to supply the first chemical and pharmaceutical technicians, trained by us, when the biotechnology facilities started operating in Basel. At the same time, we devised and implemented a package of training courses for existing employees in close cooperation with the internal training department. You can only act that fast if you have the right information early on and if the company allows a rapid response.



At the training workshop for automation technicians (EFZ), control systems are built and programmed. The programme just described records the signals from various sensors, and controls the robots on the sorting machine. (Photo Roche)

Your example leads me to assume that line management contacts you with requests for suitable apprenticeship graduates.

Ueli Grossenbacher: In a way, yes, and we want to fully satisfy the demands placed on future professionals by line management. We receive inputs that show us the new techniques and new technologies for which people are needed. Conversely, we can feed new ideas emanating from us, in the educational or technological sphere for instance, to line managers and ask them whether they are appropriate and useful for them. We are always very closely associated with the line. It's important to do so in order to stay up-to-date.

In Kaiseraugst, you provide training in fourteen different professions, but not all of them. What does your programme cover, and what doesn't it include?

Ueli Grossenbacher: We are responsible for the whole of vocational training at the Basel and Kaiseraugst site. The training centre offers courses for lab technicians in the chemistry and biology discipline, chemical and pharmaceutical technicians, commercial employees and IT specialists. Training for the mechanical/technical and other professions is provided at the workshops in Basel. The on-the-job training positions, however, are found at all of Roche's sites throughout the region. The training centre for everyone is here in Kaiseraugst, so all apprentices spend some time in Kaiseraugst on different courses.

What's the situation at Roche in Rotkreuz?

Ueli Grossenbacher: As I've already mentioned, Rotkreuz is an independent organisation. This is mainly because vocational training is subject to the cantonal laws. Naturally, we work closely together in many areas and are constantly sharing experiences. Twice a year, we meet up and learn from each other.

You mentioned at the start that vocational training at Roche is «local in Basel and Kaiseraugst». But don't you have any contact with expert colleagues at Roche in other countries?

Ueli Grossenbacher: After apprentices have completed their training, we offer them a temporary position if they don't immediately find a permanent job. As part of this temporary role, we offer three to six particularly suitable professionals the opportunity to spend six months working abroad, mainly in the United States. This creates a global network, if you will, as it draws attention to the Swiss education system.

Wouldn't it be a good idea to enable your Roche colleagues in our neighbouring countries to benefit from the experiences of your successful vocational training system?

Ueli Grossenbacher: We do. We inform colleagues from abroad about our training system and vocational training at Roche at every available opportunity. Moreover, we are in regular contact with our colleagues from Germany and hold courses and training in our infrastructure with apprentices from Roche sites in Germany.

I get the impression that the structure of vocational training at Roche is rather federal; presumably – as you have already mentioned – everything is dependent on the local legislation in each area. Because of this, isn't there a «Head of Global Vocational Training»?

UELI GROSSENBACHER: No, there isn't, nor would there be any point in that. Just look at Switzerland and Germany. Both countries have a well-developed vocational training system. Yet the two systems have very different legal bases and operate in very different settings. As I've said, however, that in no way prevents us from cooperating in various disciplines wherever it is useful and expedient to do so.

One last question. There's obviously a budget and a plan that covers at least two years in vocational training. Can you tell us anything about that?

UELI GROSSENBACHER: In this respect too, we are part of the company and faced with the same issues and tasks as any normal company. We meticulously budget for our activities and plan the training. Over the years, we have operated with almost constant numbers of apprentices. Quite simply because we firmly believe that we should not follow fleeting trends – otherwise, you're always playing catch-up. Our new vocational training building, which opened in 2015, was a huge investment. It can also be seen as evidence of Roche's commitment to tripartite vocational training going forward.

Thank you very much for talking to us, Mr Grossenbacher. If I were younger and had daughters or sons who were interested in one of the apprenticeships you offer, I would certainly advise them to apply to Roche Vocational Training in Kaiseraugst.

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(Stand 1. Januar 2017)

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