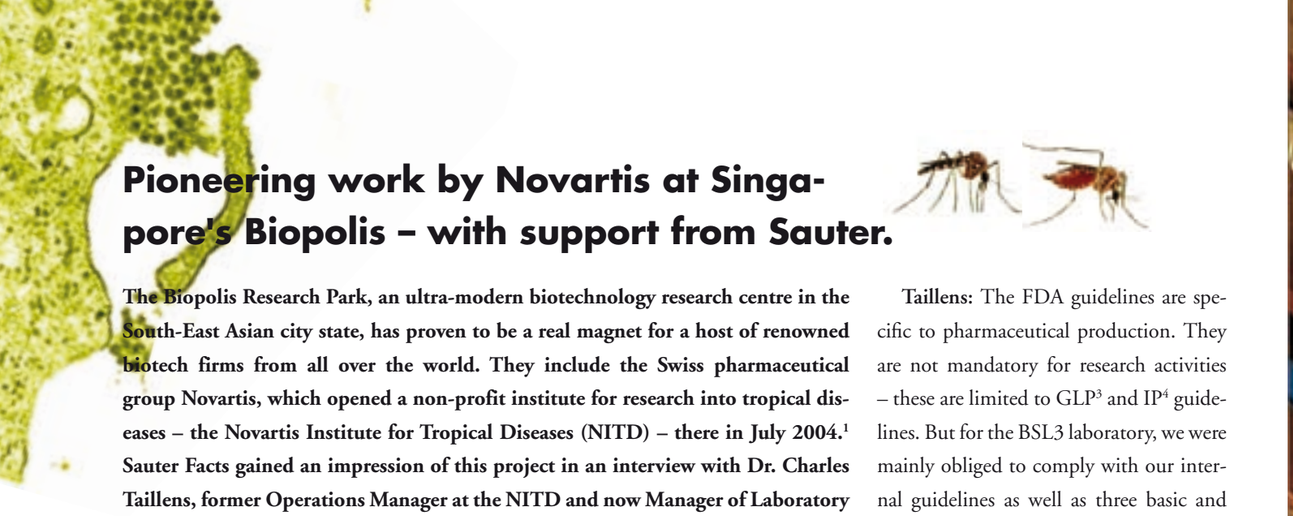


Pioneering work by Novartis at Singapore's Biopolis – with support from Sauter.

The Biopolis Research Park, an ultra-modern biotechnology research centre in the South-East Asian city state, has proven to be a real magnet for a host of renowned biotech firms from all over the world. They include the Swiss pharmaceutical group Novartis, which opened a non-profit institute for research into tropical diseases – the Novartis Institute for Tropical Diseases (NITD) – there in July 2004.[1] Sauter Facts gained an impression of this project in an interview with Dr. Charles Taillens, former Operations Manager at the NITD and now Manager of Laboratory Technology at Novartis, Global Pharma QA.

Facts: Mr Taillens, can you give us an idea of your functions in the development of the NITD and your responsibilities at present?

Taillens: I am currently responsible for developing and implementing a laboratory technology programme within Novartis Pharma QA (Quality Assurance), Technical Operations. My previous post in Corporate Research gave me responsibility for developing and operating the NITD. I'm actually a qualified chemist, but I have been working in other fields for many years now – robotics and automation, quality assurance, quality control and project management in a variety of sectors. Novartis entrusted me with the responsibility of developing the NITD on the basis of my technical experience. At the start, I was virtually left to my own devices on this project – I had to start and finish everything in terms of technology, structure and operations. Our ultimate aim was to create the first Drug Discovery research institute and the first certified BSL3[2] laboratory in Singapore.

Facts: Were you also responsible for the installation work that was required?

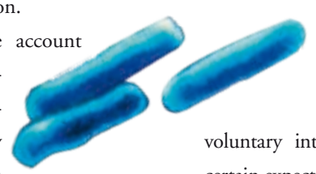
Taillens: Yes. My remit was not only to make the office and laboratory infrastructure available, but also to commission it – in compliance with international and local official conditions regarding health protection, occupational safety, the environment and plant security.

Facts: To FDA guidelines?

Taillens: The FDA guidelines are specific to pharmaceutical production. They are not mandatory for research activities – these are limited to GLP[3] and IP[4] guidelines. But for the BSL3 laboratory, we were mainly obliged to comply with our internal guidelines as well as three basic and very important bio-safety principles: protection of people, products and the environment. Incidentally, this topic is covered in a publication that we shall be bringing out this year – a compendium of advice for anyone who intends to carry out BSL3 projects of this kind. We also drew up a comparison between the guidelines for various countries (such as Canada, Switzerland, Singapore and the USA), the EU and the WHO[5], and we always worked on the basis of the strictest regulation.

Facts: So you always take account of the strictest regulations, although that might not be necessary in each particular country – doesn't that mean that you also take increased costs on board?

Taillens: Yes, that's right. We apply the global Novartis guidelines in all areas of our business. They correspond to the local and international regulations, and they also take account of our Corporate Citizenship guidance – the guidelines for responsible social conduct by the Group. This approach pays off in the long term and it results in a positive image.



Facts: But doesn't this voluntary internal standardisation create certain expectations?

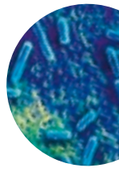
Taillens: Yes, of course! We focus on 'Quality First'. But the most expensive option is not always the best or the safest here. The solution also has to be cost-effective. As well as a risk analysis, we can also compile a business case that identifies the benefits, drawbacks and risks. Safety – that is to say, the health of the employees – naturally takes equally high priority.

Facts: Novartis sets very strict requirements for itself. How do you guarantee this for the weakest link in the chain? When you are selecting suppliers or materials, for instance? Are there any guidelines here? How do you arrive at your preferences for one firm or another?

Taillens: Of course, Novartis has a level of requirements that many providers simply do not have the technical ability to meet. We often specify requirements that call for development work or further clarifications – and special partners. The important point is that the supplier can comply with our guidelines and also our safety principles.

Especially in the BSL3 laboratories, for example, it has to be ensured that a negative pressure is always present in relation to adjacent areas. This is ensured by using variable volume flow and cascaded room pressure controls. We introduced this complex cascade air pressure system on the BSL3 laboratory project in Singapore.

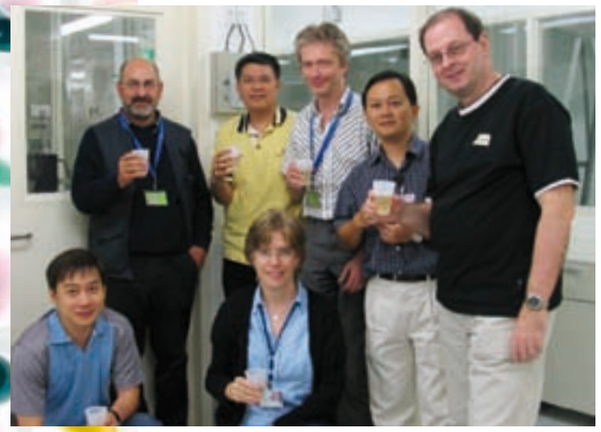
We split the rooms up according to risks. This called for lengthy consideration as to how the pressure range from -5 to -65 Pascal can be guaranteed, taking account of external factors – for instance, if a wind is blowing at over 35 km/h, this can cause a reversal of the pressure conditions. In other words, how can we ensure that a pressure of -65 Pascal continues to prevail inside the BSL3 rooms? Another key question is this: where do we position the pressure reference sensor? A building can never be entirely airtight. We eventually arrived at a solution involving the use of the 'shell within a shell' principle.



"We often set requirements that call for development work and special partners – such as Sauter."

Dr. Charles Taillens

Heinz Schibler, Sauter Basle, Dr. Charles Taillens, Novartis



The Novartis project team

Facts: So a double-walled corridor was built?

Taillens: Yes, that provides 100% ongoing security. The outer shell as such already meets the criteria. The first barrier to deal with pathogenic substances is formed by the substance container itself. The second is the BioSafetyCabinet. The third is the outer shell of the whole unit. As a general rule, we have three or four barriers, although this means that the costs are about four times more than for a normal laboratory.

Facts: Are these safety barriers monitored as well?

Taillens: Of course. On-the-spot monitoring in the laboratories is handled by several EYT 250 touch-panels from Sauter. If there is a failure – for example if the set negative pressure can no longer be guaranteed – an alarm is triggered. Sauter's EY3600 novaPro Open management software takes over control of the entire air-conditioning technology in the laboratories so that a fault can quickly be located and rectified.

"Mutual respect and friendliness prevail, even when the work and stress levels are running high."

Dr. Charles Taillens

Facts: Now for a business question. Why has Novartis made this investment in a sector that is not lucrative?

Taillens: NITD was born out of Novartis' Corporate Citizenship approach, with the objective of facilitating access to therapeutic products in developing regions. Novartis believes that a long-term commitment is important in order to help to reduce the problems caused by certain tropical diseases, so as to improve the health and well-being of people in developing countries. Dengue fever and tuberculosis have been selected as the focus diseases with the possibility of expansion to include other diseases later on. In the developing countries where these diseases are present as epidemics, Novartis aims to enable needy patients to obtain treatment at all times, without profit for ourselves.

Facts: And why did you choose Singapore as a location?

Taillens: Singapore is in the middle of several South-East Asian regions where many patients need medicines to treat dengue fever and tuberculosis. We were also looking for a country with a good infrastructure and a network of excellently trained people. There is also a heavy concentration of research organisations and pharma groups here. This is a 'Life Sciences' environment that includes pharmaceuticals, biotechnology and medical technology.

Facts: Interaction among everyone involved is very important on a project like this. What led to you choosing Sauter?

Taillens: We had prepared the technical concept, and were asking ourselves what was needed to implement it. Together with other competitors, Sauter was selected for an expert report and its performance was convincing. The planned solution offered a guarantee of success.

Facts: So Novartis in Basle issues guidelines, but the decision is made locally?

Taillens: Yes, the decision is made by the staff responsible for the project. If the required quality is available locally, we select local companies. But we only recognise one level of quality – after all, we're talking about human life here!

Facts: Time and again, sales managers tell us that the price is what counts. But on closer enquiry, we're told that requirements and safety are important. But isn't it ultimately a matter of price?

Taillens: To put it simply, the cost-to-benefit ratio is what counts. In principle, everyone is able to provide high quality for their products, and likewise everyone can offer favourable prices. But the providers' know-how and flexibility are also decisive factors.

Facts: Sauter can rely on employees with many years' service, and that also ensures accumulated know-how.

Taillens: Yes, and that's important as well. Another point is that you always learn an enormous amount on the spot in projects of this kind. Everyone can make a contribution. And although the stress level is high, people's dealings with each other are always marked by respect and friendliness. A huge number of different cultures came together here, and we had to be responsive to them all.

Facts: How strong an influence did Prof. Paul Herrling, Head of Corporate Research, have on the technology?

Taillens: Prof. Herrling put his trust in me. He allowed me plenty of freedom within my area of competence, and he provided the resources needed for the project to succeed. I could always turn to him for support in difficult situations, and it was very pleasant to work with him for these three years. Commitment is required from management as well as acceptance from the future users of the laboratory. I was able to count on both. We built the first, and the largest, BSL3 laboratory in Singapore. We were pioneers – and that fills us with pride.

Dr. Charles Taillens casts an eye over the BSL3 air-conditioning system

Facts: We too may take some pride in the fact that Sauter was able to make an important contribution to this outcome with its systems, products, services and its large stock of know-how.

Taillens: That's right.

Facts: In the Chromos building, one of the seven buildings on the Biopolis site, four floors accommodate many BSL2- and BSL3-type laboratories where ultra-modern technology is deployed. How long is the life cycle for laboratory equipment, in fact?

Taillens: The technology of the equipment is obsolete after three to five years, and for the infrastructure the figure is about eight years. Human relationships often last for longer! We, at any rate, always got along very well and have learned a great deal from one another in these last three years. And we are still meeting regularly today!

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[1] *www.nitd.novartis.com*
[2] *BioSafety level 3*
[3] *Good Laboratory Practices*
[4] *Intellectual Property*
[5] *WHO Interim guidelines 2003, Laboratory Biosafety manual 2nd Ed*