

## Interview: Kurt Reichen - VP Technical Operations, PaxVax Bern, Switzerland

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*Kurt Reichen, VP Technical Operations at PaxVax, an American-headquartered fully integrated specialty vaccine company focused on infectious diseases, discusses the establishment of the company's only site outside of the US in Bern, Switzerland, following the 2014 acquisition of a former Crucell manufacturing site from J&J.*

**The establishment of your Swiss site was a crucial step in PaxVax's development as it enabled the company to have its first ever commercial vaccine on the market (Vivotif). Secondly, it provided PaxVax with a manufacturing facility in Thörishaus near Bern. Can you tell us more about the Swiss base today?**

For PaxVax, Switzerland was a coincidence. PaxVax wanted to acquire a derivative which perfectly fitted into their division and portfolio. The site we acquired, which was part of Crucell, was being closed down, so PaxVax was able to acquire the site from Johnson and Johnson (J&J). PaxVax is of course a growing company, we have a good portfolio and are developing new products which are currently going through phases I and II or in preparation for phase III. We are looking to transfer more products here to Thörishaus as we have quite a large infrastructure not fully utilized and also substantial land available to build new production facilities. Secondly, Switzerland has three significant additional advantages. The tax situation is fair for international companies. Staff which are available for employment in Switzerland are at a good education/training level. There are good resources to build up a company and very qualified staff. It is easy to attract staff from Germany

and other parts of Europe as well. Third, logistically, from a supply chain to manufacture point, you can easily source materials or qualified vendors and the electricity system is stable to prevent production interruptions. There are good connections, as Switzerland is very much a logistics hub right in the center of Europe. Moreover, the culture, the society, and the environment are very favorable and politically stable. It is safe and the infrastructure is very good. There are a lot of advantages that you won't find in every country.

### **What is the role of this site today and how might it evolve in the future?**

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We are the number one commercial site for PaxVax. We have a smaller commercial production in San Diego, but San Diego is focusing on development research essentially. Our commercial production site is here. We have a full international health authority qualification, from the FDA, Swissmedic and by any other country authority where we distribute our products. Currently we only have one commercial product here, which is Vivotif (a typhoid vaccine) but we are transferring a second vaccine here, Vaxcora which is focused on cholera. It is currently only sold in the US (-20°C stable), and we want to make a second-generation 2 to 8°C stable product and distribute it from Switzerland globally. For the mid to long term, we are actively looking to transfer more products here to be commercially distributed.

### **Tell me a bit about the current portfolio.**

Vivotif is well established. The transition from J&J to PaxVax was well received by the market, so we didn't lose market share. We are actually gaining some at the moment. We have a very reliable supply chain which in the vaccine industry is never a given. There are often supply interruptions. Even through in the transition we were able to sustainably bring the product to the market. Also Vaxcora, we are planning to sell out of Switzerland. We are planning to start validation lots in the beginning of next year. At the end of 2018, we will start the filing process. We are planning in mid to end 2019 to commercialize the product out of Bern. It is always a lengthy process to get a product to the market, but I am confident we shall manage.

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The whole production campus here is huge. We have idle buildings and empty shell facilities at the moment, which we can quickly transfer new products to. The whole infrastructure of utilities is designed to absorb 3-4 products right now, but as I said, our capacity is not fully utilized yet. This should however change in the next 3-5 years.

**In August 2016, PaxVax announced that it had entered into a marketing and distribution agreement with Seqirus (the second largest influenza vaccine company in the world) whereby PaxVax will market, sell and distribute two of Seqirus' influenza vaccine products in Switzerland, Agrippal® (surface antigen, inactivated) and Flud™ (influenza vaccine, adjuvanted). Tell us more about this agreement.**

PaxVax is basically a fully integrated company. We do everything from research and development, to commercial products, to the supply chain, and also to marketing sales. We have a significant marketing sales team in the US and the rest of the world including Europe. We distribute two products for flue from Switzerland, and we distribute Ixiaro and Dukoral in three other European markets where we have a strong marketing and sales team (Spain, Italy and Portugal)

**Tell us a bit more about your exciting pipeline and where it stands.**

Chikungunya is the third-most advanced product in our pipeline and is currently being prepared for phase II. The plan is to start manufacturing phase III materials in less than 12 months. We are going full speed ahead with Chikungunya. It is an interesting product with a big market need, and where there is a lot of potential. It has a very good safety profile.

The next product we are currently pushing is Adenovirus 4/7 vaccine against leading cause of acute respiratory distress. It's basically for the military. People in the armed forces are in close quarters with lots of people and there is a risk of infecting each other with adenovirus a pulmonary disease. This product is advancing, we are repeating phase I clinics and moving to the next step. We have various collaborations for HIV, with planned phase I studies with different constructs which are under evaluation. For Hepatitis A, we have an established commercial production facility. We are in the process of re-developing a virosomal hepatitis A vaccine that was previously licensed in more than 40 countries. It is a good candidate, aluminium free and it has a very good reputation on the market although it was discontinued. Here, we have a lot of requests from end users to bring this product back to market, but we have not begun this process yet. PaxVax would like to have a partner to develop this product.

**What type of partnerships are you looking forward to establishing in Switzerland?**

This is an interesting question, and one that comes up when looking at our strategy. We are fully integrated; we do everything just like Big Pharma. Therefore, we want to grow our pipeline and our commercial products. We have a good investor. We definitely want to grow in size too. We are therefore looking for either partnerships or acquiring products that fit with our portfolio. PaxVax's vision and strategy are to grow so interesting opportunities will be strongly considered.

**The field of vaccines is overcrowded. How does PaxVax manage to remain independent and survive in this crowded marketplace?**

It used to be crowded I would say. To some extent, it is still crowded. In vaccines it is difficult to generate revenues. The problem for vaccines is they prevent diseases. They do not cure diseases. Obviously, healthcare systems and patients are not willing to pay very much money for prevention. Therefore, some players are stepping out or are becoming more conservative with their investments. PaxVax sees this as an opportunity. The global risk of a severe disease outbreak requires that new vaccines can be produced fast. This field has the potential to stop diseases if we have the right platform. There for Paxvax is currently expanding is VLP platform. It is a very interesting area. Prevention is much better than cure and it is the right way to fight diseases.

**All ministers of health we have recently met with indeed want to invest in this prevention side...**

I think we see that also. Even the Bill Gates Foundation sees this as a problem. Vaccine companies have joined forces to combat critical diseases that may arise in the coming decades. There are 7 billion people on Earth, so there is a steadily increasing risk of a pandemic having a severe impact on civilization. There is a need to do something which is seen by the different global organizations. The question is who is paying for it. It is interesting to see that an outbreak of some sort, for example SARS, bird flu or HIV – which is under control somewhat – but an HIV with a different route of infection would be a disaster. There is a huge risk for the global population and if we have a fast-track platform to fight new devastating diseases quickly and bring it quickly to market, it is the only shot we have to prevent mankind from falling back to medieval times or even worse. It is more than just money or a job. It is a responsibility to be successful in what we are doing.

**Skepticism of vaccines is increasing in first-world nations. People are striving for better communication to the public and to society. What role can PaxVax play in this regard?**

First of all, I'm obviously not neutral on this point as we earn money from vaccines. However, it is always good to take a step back and look at why public opinion is in some cases against vaccination and what their motivations are. To some extent, it is purely conspiracy, and we simply cannot influence conspiracy theories; it will backfire on us, and that not the avenue we wish to pursue.

The questions are what are the risks and benefits, and for vaccines there is an extremely high risk to benefit ratio. That's what people often completely forget when they make their arguments. I think it's difficult to prove that vaccines are responsible for critical adverse events like MS. Let's

assume that the HPV vaccine can cause MS. Let's assume that two people out of 100,000 get MS. If you take the amount of people that would have developed cancer due to not have taken the vaccination, the ratio would be 1-2000 per 100,000. You need to look at the big picture rather than the single patient that got MS. I think it is unlikely that a patient contracts MS due to the vaccine. The benefit of not getting cancer is so much higher than contracting MS. I think that is something that is completely forgotten.

Also, people who do not vaccinate their children, once they lose their children due to measles or another disease, it is way too late for those people. They will suffer the rest of their lives. Like everything in life, there is a risk no matter what you do. The question is which risk you want to take. Parents that do not vaccinate their children benefit from parents that do and prevent diseases from spreading. It is a selfish thing to rely on others. If we did not have vaccines nowadays, there would not be 7 billion people on this planet.

**As a Swiss national, how do you explain Switzerland's ability to nurture domestic talent and attract talent from neighboring countries?**

There are multiple factors here. First of all, sustainability in Switzerland is very good. People do not move jobs often like they do in California, for example. That really helps smaller companies which need knowledge and cannot have too much brain drain. In Switzerland we have a good standard of living too which is very attractive to foreigners.

**When we come back in five years, what will be new with PaxVax?**

Our key goals are to grow. We have released two commercial products on the market in five years. We will have two more commercial products sold on the market soon, and we will have more products manufactured here in Switzerland, 3-5 I would say.

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