Interview: Nicolas Hug – Head of Industrial Biotech COE & Bulle site GM, UCB, Switzerland

"Our aspiration is to become the biopharmaceutical, patient-centred, company of choice internationally."

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Nicolas Hug reveals how UCB´s new facility in Bulle, Switzerland, is one of the largest microbial derived pharmaceuticals plants in Europe; how the key challenge for manufacturers today is to guarantee supplies by building a robust network; and why manufacturing is where dreams become reality, taking the results from a clinical trial and turning them in to something tangible.

UCB's 300 million CHF investment, the largest biotech project seen in Europe in recent years, has recently become fully operational. To what extent has this facility been a game changer for the Group?

This biotech plant has been a game changer for UCB; the first investment of such a scale for the manufacturing of biopharmaceutical substances. The facility has been designed to manufacture drugs from microbes. It is one of the largest microbial derived pharmaceuticals plants in Europe; with 45,000 litres of nominal volume fermentation.

We conduct pharmaceutical manufacturing at this site; namely APIs for the treatments of allergies and epilepsy. We also have a history of making pills here in Bulle. Indeed, UCB´S industrial history has been in making such products. Our aspiration is to become the biopharmaceutical, patient-centred, company of choice internationally.

The biotech unit was supposed to be operational from 2014, when a large explosion delayed the start of production by nine months. How challenging has been to put to

work such a modern facility, while overcoming such a setback?

For the team working on the start-up of the facility, this incident was a major setback. The explosion occurred just before the first fermentation process was due to begin. We learned many lessons. For example, that the electricity connection to the grid should be located outside of the building. Recovering from this incident required the team to re-group, and define a remediation plan to have the facility up and running again with minimal delay. Within nine months of the incident, the plant was back on track. One of our major concerns at the time was to ensure that we would be able to continue supplying patients with Cimzia, our product for Crohn's disease and rheumatoid arthritis. We were greatly helped in this regard by CMOs, who increased their output, allowing us to overcome any shortages due to the delayed start-up of the plant.

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I became general manager of the facility in April last year, just as the site was about to become fully operational, having completed the validation batches. In 2015, the challenge was for our team to demonstrate that they had mastered the process, with the necessary documentation to receive approval from the authorities to utilize the drug substances of this facility in supplying Cimzia both to the US, as well as to the EU. We received approval from the FDA in December 2015 and from the European Commission in April 2016. Ultimately, we met on our objectives on time, and with the necessary volume and quality, having overcome an initial setback.

Much has been said about manufacturing in the pharmaceutical industry. Many criticize the fact that, compared to other sectors, this industry has not embraced manufacturing reforms as fast as other industries, leading to inefficiencies. What is your perspective?

The challenge for manufacturers today is to guarantee supplies by building a robust network. Key is to ensure that your own capacity fits into a global network that is able to deliver both flexibility and robust supplies. When you treat patients that are suffering from complicated diseases, when the patient has to go through an optimization of their treatment, the worst thing that can happen is for them to suffer a disruption in the supplies. UCB´s industrial mission is to guarantee that there is never a lack of supplies. We take great pride in both the quality of our products and the robustness of our network. We have a network of facilities, that are both internal and external, allowing us to compensate for the disruption of a particular facility.

When it comes to efficiency, biopharmaceutical facilities have to deal with a number of significant unknowns regarding the quantity of output. There is a tendency to either build something too big, or too small, given you have to make decisions over a five-year period. Key is to have a system in

place that allows you to either ramp up, or slow down, your manufacturing output.

With the current analytical power available to characterize large molecules and a possible path for the qualification of an optimized new cell-bank, more performant processes could be used.

You have a long experience in both the operational and managerial side of manufacturing and now head UCB's global industrial biotech operations, as well as being general manager of the Bulle site. What do you see as being the key to a successfully manufacturing strategy?

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The future of UCB, and in particular our biopharmaceutical business, is linked to transforming a very attractive development portfolio into industrial solutions, to serve patients in the diseases that we are targeting. We face the same challenges as any other biopharmaceutical company: serving patients by providing solutions that add value. New treatments must not only be effective, but must be more effective than what is already on the market. Forecasting upfront your capacity to serve patients over a five-year period, when you do not yet have the results of your existing clinical trials, is always a challenge. In the meantime, if you do not address your biomanufacturing capacity at an early stage, if the product turns out to be success, you will have nowhere to produce it.

I like to say that process development and manufacturing is where your dreams become reality. It is where you take the results from clinical trials, and turn them in to something tangible; a product, a treatment which is then supplied to patients.

Many European countries are seeing their attractiveness as a place to manufacture questioned in today's pharma new world. Why does UCB believe that Switzerland remains a place to be for manufacturing, and is it sustainable in the future? What made Switzerland, and in particular Bulle and the canton of Fribourg, the clear choice for such a considerable investment?

UCB is not alone in having chosen Switzerland as a manufacturing location for biopharmaceutical drug substances and products. There are a number of companies that have chosen to invest in Switzerland. The country has a lot of expertise in the area of biopharmaceutical industrial know-how. This goes beyond any specific region. More relevant is the network of innovation, development and manufacturing that is present within what we call the Greater Geneva Berne area, composed of six cantons.

UCB has been present in Bulle (canton of Fribourg) for 20 years. The cultural match for a Belgian company, such as UCB, based in the municipality of Braine-l'Alleud near Brussels, to have a subsidiary in the Canton of Fribourg, is clear for all of that have worked in both places, as indeed I have. Both areas have a spirit of achieving the best possible results, with the resources that are available.

What will be your key priorities as the head of UCB´s industrial bio COE and Bulle site general manager, over the next five years?

My number one priory is to continue building robust supplies, while meeting the expectations that we have of delivering both the required quantity and quality of products. Key is to develop the talent that we have within the subsidiary. With the opening of this new facility, we have a lot of new talent that has joined the business; and we need to maximize their development potential.

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