Interview: Johannes Khinast – CEO and Scientific Director; Thomas Klein – CEO and Business Director, Research Center Pharmaceutical Engineering (RCPE), Austria

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Prof. Johannes Khinast, CEO and scientific director, and Dr. Thomas Klein, CEO and business director of the Research Center Pharmaceutical Engineering, or RCPE, the world's first pharmaceutical engineering company that combines simulation, formulation and processing for large international companies such as Pfizer, Bayer and Novartis, give an overview of the foundation of the center and its growth, as well as provide an in-depth

analysis of how their revolutionary approach will assist current and potential partners to consistently produce high-quality products.

As Business Director and co-founder, could you introduce the Research Center Pharmaceutical Engineering (RCPE) to our international readers?

Thomas Klein (TK): In 2006, our co-founder Prof. Johannes Khinast, returned to Austria from Rutgers University in the USA, where he was Professor for Chemical and Biochemical Engineering. Together with the local government in Graz and universities he designed a model to establish pharmaceutical engineering as the next big step for the Styrian pharmaceutical industry. He

applied for a COMET K1 funding, the application was granted, and at the end of 2007 Johannes and I partnered with the three key stakeholders in 2008 to create RCPE: Graz University of Technology, University of Graz, and Joanneum Research.

We now have around 130 staff members based in a unique lab infrastructure and the new innovative ISO 9001- and ISO14001-certified pilot plant where we can handle a diverse array of substances. RCPE is unique as we bridge the gap between academia and industry.

Naturally, we worked with mainly local and regional companies in the beginning. However, our research efforts and results have been quickly acknowledged and as our reputation started to grow, we have had the pleasure to attract larger international companies. We now partner with global powerhouses, such as Bayer, Pfizer, Boehringer Ingelheim, Roche, Abbott. Merck, Sandoz, AstraZeneca and many others. In order to cater for their individual needs, we establish an individual long-term vision and a defined collaborative plan with each of these partners.

Our pharmaceutical research is built on three core pillars. Firstly, simulation, where we try and develop simulation tools that predict the performance of pharmaceutical products and processes. Secondly, product engineering, where we optimize formulation for a specific drug based on rational tools, e.g., for oral or pulmonary delivery. The third, and largest pillar, is process engineering, where we develop novel processes, continuous manufacturing lines and Process Analytical Technology (PAT) tools.

The synergy between all three pillars is aimed at achieving the same result; continuous monitoring of the product through all manufacturing lines and steps in real-time, such that the end result is a product of the highest quality and produced at a faster rate for our partners.

RCPE is a worldwide pioneer in combing these three pillars of pharmaceutical engineering in secondary pharmaceutical production. Why did you feel there was such a need in 2008 to start the company?

Johannes Khinast (JK): During the last decade Quality-by-Design (QbD) principles have increasingly been introduced in the filing process for new drugs, as mandated by FDA and EMA. Consequently, a scientific understanding of the formulations and the associated process has become increasingly important. Therefore, using mechanistic simulation tools together with standardized tests and engineering approaches can provide this understanding. Even more, the understanding now allows us to rationally tailor formulations and processes to achieve the highest quality in an economic way. This is the precise reason, why RCPE was created.

[Featured_in]

One step further, with our industrial lab scale and the new pilot plant (including all relevant process equipment and setups) we now can verify our product designs and prove that processes are performing as expected, thus validating our predictions. This differs from universities who generally do not have such a laboratory equipment available.

Does Austria promote engineering innovation?

TK: I strongly think so. Since 1998, the COMET competence centre program of the Austrian Government, managed by the Austrian Research Promotion Agency (FFG) has translated into 45 centres and networks aimed at connecting the industry with academia, supporting exceptional research. This model has attracted the interest of many other nations. Generally, it costs companies a lot of money to collaborate with universities and organizations for research; often resulting in no clear conclusions or difficulties in industrial implementation. RCPE takes the potential hassle out of the process by performing all the work for our partners; a one stop shop. In general, Austria is very science-oriented and industry-friendly, and notably, an ideal place for new company locations and start-ups.

What examples define RCPE´s innovation capacity?

TK: A clear and defining example of what we offer our partners is RCPE´s collaboration with Evestra, a Texas based women’s health company. We have been working with them to fill their pipeline since 2009 by tailoring formulations, protecting intellectual property, designing new drug applications, managing regulatory affairs and assisting in the construction of a state of the art production line. They are currently in phase II of the drug development process and are due to launch their own product within the next 12 months. This partnership illustrates our ability to accompany and positively influence our partners at every step of their value chain.

JK: Another example is an industry-changing discrete element method (DEM) software. In this modelling tool, every single particle in a process is being tracked using the fundamental laws of physics. Already now, there are several DEM codes on the market that can handle a few hundred thousand or million particles. Our DEM software uses graphic cards and handles 80 to 100 million particles allowing the entire process to be modelled all at once, including non-spherical particles and a wide range of particle-particle interaction models, including cohesion and liquid bridging, a revolutionary change.

After we designed our product, we partnered with software powerhouse AVL in Graz, combing the DEM software with their CFD software. Thus, we can also model, scale-up and optimize fluid bed operations which frequently occur in pharmaceutical processing (coating, granulation, drying). The final and important step was to partner with PSE, a well-known UK company working in advanced process modelling in the oil, gas and pharmaceutical industry. We now have a revolutionary product that will be launched in only two weeks all over the world; Europe, North- and South-America and Asia. AVL and PSE provide RCPE with a worldwide global distribution network and further help us foster transformation and innovation throughout the industry.

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Overall how does this impact a company´s production operations?

JK: RCPE has three key strengths: tools for prediction, advanced platform technologies and methods for process sensing and control. Thus, the key element of RCPE’s work is to avoid trial-and-error, speeding up the development of products and processes, and enabling the manufacturing via flexible and robust platform technologies. In effect, we reduce development time and save money for our partners.

What strategies has RCPE put in place to ensure a relatively young company builds success in such a short period of time?

JK: First and foremost, as a company we need to constantly develop new and innovative concepts. If you are creating the same product as four or five other companies it is inevitable that we could fail. We must look into the future, 10 to 15 years down the track, constantly developing new ideas. Our research is the foundation of our success. We believe that the research and work we do will translate into business. Therefore, we much rather focus on investing in our science and scientists, enabling our employees to do what they do best. So far this has worked well.

Of course, another part of our strategy is to foster growth and reputation of our employees. We give the significant space, we ensure that we have diversity in our staff, currently representing 21 nations from pharmaceutical scientists and mechanical engineers to technical physicists and chemists. Moreover, we have people that come from both, the scientific world and the industry.

Another part of our strategy is to have a state-of-the-art facility available where we can test and work with real APIs, including highly active ones. This is unique in a certain sense and gives us an advantage if combined with our modelling tools.

This year the very impressive 5 million EUR (5.75 million USD) RCPE pilot plant was officially opened. How did this come about?

TK: After the first five years of RCPE, we needed to construct an innovative modern working environment to handle highly-active substances and new processes. We discussed this at length with our partners, and with their support started the project 2.5 years ago. On May 1st this year we proudly opened the pilot plant. One year before we already had commitments from our partners for 50 percent of our activities until 2020. All in all, a very exciting time and important step for RCPE.

What do you see in the future for RCPE?

Commercially, we plan to further diversify our turnover. At present, we generate 30 to 40 percent in the US, 20 percent in the UK and the remaining share across the rest of the world and Europe. We see a lot of potential for development, particular in Asia.

All in all, we believe in developing an excellent network with partners and academics, allowing us to be 100 percent focused on science and advancing pharmaceutical engineering. If an area of the business grows that is not science based, such as regulatory affairs, we simply create a spin off, which we have done several times (RCPE has already created 4 spin offs).

What is the next frontier for pharmaceutical engineering?

JK: There are several developments on the horizon that will massively impact pharmaceutical development and manufacturing. For example, personalized medicine will impact product and process development in a disruptive way. Translational pharmaceutics will have an impact on the whole development process. Continuous manufacturing will revolutionize the decade old manufacturing paradigms of the past, embedded in a more flexible regulatory environment. Biopharmaceuticals will continue to grow in market share and relevance, at least for the next decades. Yet other types of medicines will become important too, including RNA vaccines, nano-technology-based drug delivery vehicles and much more.

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