



21 June 2021

TAKEDA, RCPE, INSILICOTRIALS AND THE UNIVERSITY OF GRAZ PARTNER UP TO OPTIMIZE MANUFACTURING PROCESS OF BIOPHARMACEUTICALS

The joint project will allow one of the world's largest pharmaceutical companies to increase scientific understanding of current and future manufacturing processes while accelerating the go-to-market of new drug formulations

Graz, Milan, Vienna – Biopharmaceuticals are large and complex drugs that mimic the action of the molecular mechanisms in living organisms. In the past decade, the number of deaths due to cancer and HIV/AIDS have been significantly reduced and the treatment of several chronic diseases, such as diabetes and cardiovascular diseases, has been enhanced due to the emergence of biopharmaceuticals.

Biopharmaceuticals represent one of the fastest growing segments in current drug pipelines, but their large-scale manufacturing and processing pose specific challenges to the drug formulation scientist, as these large and complex molecules are rather sensitive to variations of environmental conditions and process-induced stress. Filling is the final step of the manufacturing process for liquid protein formulations and the focus of this project.

A 36-month joint project between the manufacturing site in Vienna of Takeda, one of the world's largest pharmaceutical companies, the Research Center Pharmaceutical Engineering (RCPE), the technology company InSilicoTrials, and the University of Graz has been initiated to establish the mechanistic basis of the relationship between process parameters and the effect of the resulting stresses on the characteristics of protein based drugs. Takeda and RCPE are in the process of building an ongoing partnership which has been and is currently being used to increase the scientific knowledge for biopharmaceutical products and processes.

This project will enhance the understanding of the process-induced mechanisms for protein-based biopharmaceuticals. Participation in collaborative programs of this kind will also be supportive to product and process development of protein-based drugs in the future, resulting in reduced material requirements and drug development timelines.

This collaboration will adopt an innovative approach between Takeda and the partner companies where a lab scale version of one of Takeda's filling line will be designed and assembled. The line will be used to simulate the Takeda filling process on a smaller scale, comparing the effect of various settings of process parameters (filling speed, vial shape, protein concentration etc.). In addition, computational fluid dynamics simulations will be performed to estimate the shear forces, as well as size and dynamics



of interfaces the concentrated protein solution is exposed to during the filling process. The generated experimental and simulation data will then be used to train and test algorithms based on state of the art machine learning models, to predict the potential impact of these parameters on the properties of the protein molecule. The final goal is a set of in-silico tools that can be used to guide the design and parameterization of the filling process.

Optimisation of manufacturing processes is frequently requiring a high number of experiments, which is time-consuming, and is depending on the availability of sometimes large amounts of expensive material. "The machine learning algorithm we are going to develop will allow Takeda to narrow down the process parameters in-silico and focus on a few targeted experiments." reports Dr. Thomas Klein, CEO and business director of RCPE.

"Our innovative approach to continuously improving our processes is demonstrated by partnerships like this one. With this project, we aim to improve our manufacturing process while reducing costs and accelerating the development of new drug formulations - in the service of our patients.", says DI Karl-Heinz Hofbauer, Site Head Takeda Vienna.

The process data generated during this project will be handled through the simulation platform of InSilicoTrials, a start-up specialised in modelling and simulation based on cloud technologies for scientific data management, pharmaceutical and biomedical research and development. "The opportunity to use the platform that we developed for modelling and simulation will allow a quick and efficient data management activity, a key factor for this project", says Luca Emili, CEO of InSilicoTrials. "Leveraging the potential of a cloud-based SaaS platform is an element of huge acceleration of activities that, until recently, required complex and heavy processes of data handling. The researchers at Takeda, RCPE, InSilicoTrials and the University of Graz will be able to cooperate and benefit from cutting-edge, high-performance and reliable features."

TAGS

RCPE, Takeda, InSilicoTrials, University of Graz, Pharma, Pharmaceutical Manufacturing, Biopharmaceuticals, Biologics, Science, Research, Life Science



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About Takeda and Takeda in Austria

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people and the planet. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Rare Genetic and Hematology, Neuroscience, and Gastroenterology (GI). We also make targeted R&D investments in Plasma-Derived Therapies and Vaccines. Takeda Austria serves the entire value chain: from sourcing human blood plasma in ten plasma centres, through the production of medicines from human plasma and other medicines,



to the worldwide shipping of finished products. The domestic research and production facilities are located in Vienna, Linz and Orth an der Donau. Every day, round 4,500 employees contribute to bringing medicines from Austria to the whole world and giving people in Austria access to Takeda's innovative medicines. www.takeda.com / www.takeda.at

About RCPE

The Research Center for Pharmaceutical Engineering GmbH is a global leader in pharmaceutical engineering sciences. We help our partners to create and manufacture advanced medicines for patients around the world, through optimising products and processes. RCPE's services encompass the entire value chain of pharmaceutical product development: continuous API synthesis, advanced formulations, next-generation manufacturing, and also device design and optimization. As a non-profit, private company owned by Graz University of Technology (65%), University of Graz (20%) and JOANNEUM RESEARCH Forschungsgesellschaft mbH (15%), we link outstanding science, application and industry in a business-oriented approach. RCPE is a K1 COMET Centre within the Competence Centers for Excellent Technologies (COMET) programme. The COMET programme is operated by the Austrian Research Promotion Agency (FFG) on behalf of the Federal Ministry for Climate Protection, Environment, Energy, Mobility, Innovation and Technology (BMK) and the Federal Ministry for Digital and Economic Affairs (BMDW). Our projects are also funded by Land Steiermark and the Styrian Business Development Agency (SFG).

About InSilicoTrials

InSilicoTrials is an emerging startup founded in 2018 by a team of life sciences, cybersecurity, and digital innovation experts, which aims to revolutionize the Healthcare sector thanks to an innovative digital simulation platform. Today, the very long and expensive development, as well as the subsequent registration/certification processes for new drugs and medical devices, are becoming unsustainable, especially for SMEs. Modeling and simulation can reduce these costs up to 50% and greatly accelerate the go-to-market of new products, allowing companies to exploit patents for a longer period. Regulatory agencies are recommending companies to adopt these practices, but many of these lack the high expertise, expensive software, and IT infrastructure, needed to develop and use models. InSilicoTrials solves these problems by selecting and collecting the best models from top researchers around the world and then by integrating them with the solvers in a scalable IT platform, which makes it easier to use validated models without specific computational knowledge, paying only for the used resources.

About University of Graz

At the University of Graz, researchers and students work across a broad spectrum of fields to find solutions for tomorrow's world. The scientists address some of the key challenges of our society and are working to develop strategies for tackling them. How to respond to climate change, for example, and how to fight diseases of the metabolism and of old age – these and other important topics are studied through our innovative programmes. Students learn to apply their knowledge and findings effectively to help shape our future.