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RCPE AWARDED TWO FDA CONTRACTS FOR NEXT-GENERATION PHARMA TECHNOLOGY

Graz, Austria – The Research Center Pharmaceutical Engineering GmbH (RCPE), a global leader in pharmaceutical engineering sciences, has been awarded FDA funding for two projects commencing in the 4th quarter of 2020. The projects will focus on utilising advanced technologies to improve production processes within Pharma. With an average of only 5 – 10 projects awarded to EU companies by the FDA each year, this development represents a landmark achievement for RCPE and reflects the potential impact of these projects within the global pharma industry.

In partnership with major global pharma companies, including MSD and Pfizer, RCPE will use the FDA funding to investigate the use of optical coherence tomography (OCT) for real-time monitoring and control of the drug tablet coating process. Integrating this technology with AI and machine learning approaches may enable researchers to effectively prevent errors in tablet coating before they occur. This can help to increase efficiency, minimise environmental impact and allow life-changing medicines to reach patients more rapidly.

In addition, RCPE will also partner with MSD, Pfizer and other collaborators to pioneer the use of digital simulation tools in drug product manufacturing and process development. Building on previous work, this project will focus on the development of a digital twin-based platform to virtually explore drug production control strategies. The platform will model products, processes and conditions to enable earlier evaluation, as well as optimisation and scale up, without the need for extensive lab-based experiments. Adopting digital simulations is therefore anticipated to reduce not only drug development and manufacturing time, but also energy consumption and carbon footprint for next-generation pharmaceutical production.

Having been awarded funding by the FDA for these two projects, RCPE is now well positioned to achieve its vision of enhancing pharmaceutical product development through technological innovation in order to improve patient access to medicine.



Prof. Johannes Khinast, RCPE CEO/Scientific Director, said: *“We are incredibly proud to have been awarded two FDA contracts in a single year. It is a fantastic endorsement of our pioneering approach to solving drug manufacturing challenges. Having achieved this important milestone, we look forward to working with our partners to improve their manufacturing technology, ultimately benefitting patients around the globe.”*

Dr. Thomas Klein, RCPE CEO/Business Director, commented: *“We are delighted that the FDA has recognised the potential our projects offer for the industry and patients worldwide. The expertise and commitment of our multidisciplinary team have been instrumental in achieving our current success. We are excited to further build on our legacy of innovation as we work to transform pharma product development through the power of new technologies.”*

TAGS

FDA, RCPE, MSD, Pfizer, pharma, pharmaceutical manufacturing, process control, optical coherence tomography, real-time monitoring, tablet coating, digital simulation, digital twin, AI, machine learning



Headquarter RCPE GmbH – Graz, Austria
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Dr. Klein and Prof. Khinast, CEOs of RCPE
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The Research Center for Pharmaceutical Engineering GmbH (RCPE) 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 Centres 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).