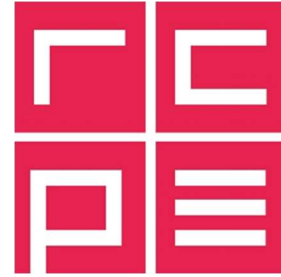


**RCPE
RESEARCH CENTER
PHARMACEUTICAL
ENGINEERING**

Programme: COMET – Competence
Centers for Excellent Technologies

Programme line: COMET-Centre K1

Type of project: NonK



RCPE AWARDED TWO FDA CONTRACTS FOR NEXT-GENERATION PHARMA TECHNOLOGY

THE INTEGRATION OF DIGITAL TECHNOLOGIES IN PHARMACEUTICAL
MANUFACTURING PROCESSES WILL ACCELERATE PRODUCTION SIGNIFICANTLY.

The Research Center Pharmaceutical Engineering GmbH (RCPE), a COMET K1 Center and owned by Graz University of Technology (65%), University of Graz (20%) and Joanneum Research (15%), has been awarded FDA funding for two projects commencing in 2020. The projects will focus on utilizing 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.

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.

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.

Dr. Thomas Klein, RCPE CEO/Business Director, commented: “We are delighted that the FDA has recognized the potential our projects offer for the industry and patients worldwide. The expertise and

SUCCESS STORY

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.”

Impact and effects

Integrating OCT 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, minimize environmental impact and allow life-changing medicines to reach patients more rapidly.

The simulation platform will model products, processes and conditions to enable earlier evaluation, as well as optimization 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.



©Lichtmeister Photography, over 150 researchers in Graz work on future technologies for manufacturing

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.”

Project coordination (Story)

Constantin Schmidt, MA, MA
Head of Marketing & PR
Research Center Pharmaceutical Engineering

T +43 (0) 316 873 35915
Constantin.schmidt@rcpe.at

RCPE

Research Center Pharmaceutical Engineering

Inffeldgasse 13
8010 Graz
T +43 (0) 316 873 30901
office@rcpe.at
www.rcpe.at

Project partner

- MSD, USA
- Pfizer, USA

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