

**NEWS ANNOUNCEMENT - FOR IMMEDIATE RELEASE**

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Cambridge / Graz / Lund

**Research Center
Pharmaceutical
Engineering**Inffeldgasse 13
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www.rcpe.at**New Partnership to Spearhead the Development of
Advanced Controls for Oral Solid Dosage Forms**

An international consortium founded by RCPE and supported by Pfizer, Gasporox, Teraview, and the University of Cambridge launches a project that aims to develop novel sensor and modeling approaches to accelerate the adoption of Real-Time Release Testing (RTRT) for dissolution in continuous production settings. The project, worth a total of €536,812, including equipment and in-kind contributions, has received support through the Austrian COMET Program.

The manufacture of pharmaceuticals is tightly regulated to assure patients and healthcare professionals of medicines' safety, efficacy, and quality. Current quality assurance and control processes rely heavily on in-process control measurements and labor-intensive testing of intermediates and finished products, leading to higher costs and longer cycle times. In the context of the industry's migration to continuous manufacturing practices, RTRT is the release of medicine only based on "in-process data". This could mean that less time-consuming laboratory testing is necessary. In fact, this could lead to more flexible supply chains, streamlined production, and ultimately better drug quality through enhanced statistical analysis.

The established project consortium addresses essential RTRT implementation gaps for disintegration and dissolution — two crucial indicators to bioavailability and efficacy that are difficult to monitor in-line. One key innovation is an advanced modeling environment that integrates process, soft and hard sensor measurements (GASMAS, Terahertz, and OCT) to predict dissolution performance non-invasively and comply with regulatory frameworks. The 36-month project includes two use cases for continuous, direct compaction and pellets coating using fluid bed coating. Experimental work will be conducted at the University of Cambridge, RCPE's facility in Graz, Austria, and across select Pfizer sites. The project is part of the European Consortium for Continuous Pharmaceutical Manufacturing (ECCPM). A platform that connects industrial and academic partners to share knowledge and best practices and develop a collective vision on the transformation towards continuous manufacturing.

Prof Dr. Johannes Khinast, Scientific Director & CEO of RCPE, said: "The expertise and capabilities in this consortium are an incredible asset to this exciting project. We are delighted to collaborate with these organizations. Developing data-driven, digitalized manufacturing platforms to reduce cost, risk, and advance sustainability in pharmaceutical manufacturing is key for efficient responses to global health challenges and improving medicine supply to patients."

Gasporox's CEO Dr. Lewander Xu comments: "The Gasporox GASMAS technology for porosity assessment is novel and this consortium with experts from institute, academia, and industry with end-users constitutes an ideal fit to together evaluate the groundbreaking non-destructive technology in-depth to understand its contribution to an efficient real-time testing."

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Dr. Don Arnone, CEO of TeraView Limited, states: “TeraView is excited about this project as it helps to move terahertz pulses application into the process environment with the pharmaceutical sector. TeraView is currently seeing interest in its TeraSolve from the Industry and will be working closely with the University of Cambridge in the development of the technique.”

Prof. Axel Zeitler, Professor of Microstructure Engineering, Department of Chemical Engineering and Biotechnology, University of Cambridge, added: “This project is an exciting opportunity for translating our research into fast and non-destructive sensing of the porosity in tablets to realistic use case scenarios. We can systematically challenge and develop our methods and concepts in partnership with industrial end users as well as instrument companies and bring these tools to industrial application.”

Tags:

RCPE, Pfizer, Gasporox, Teraview, University of Cambridge, Advanced control, pharmaceutical manufacturing, continuous manufacturing, Pharma 4.0, Dissolution, Drug Quality



Better use of data in novel modeling environments can accelerate release testing of tablets. © Markus Trinkel



OCT Sensor in-line setup measures coating thickness and uniformity. © RCPE



Gasporox's GPX measurement system for porosity analysis. © Gasporox SE



The TeraSolve porosity measurement tool. © TeraView Limited



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RCPE

The Research Center Pharmaceutical Engineering (RCPE) is a global leader in pharmaceutical process engineering. The center supports its partners in the development and manufacture of innovative medicines.

Our science enables tomorrow's medical discoveries and improves patients' lives worldwide. The experience and expertise of our multidisciplinary team and our unique capabilities in simulation, AI, (nano-)material science, process design & quality control, as well as process monitoring and quality assurance, redefine the boundaries of what is possible and provide cutting-edge, scientific solutions tailored to our partners' needs.

As a non-profit, private company owned by Graz University of Technology (65%), the University of Graz (20%), and Joanneum Research GmbH (15%), we combine outstanding science, business, and industry in an application-oriented approach.

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Pfizer

At Pfizer, we apply science and our global resources to bring therapies to people that extend and significantly improve their lives. We strive to set the standard for quality, safety and value in the discovery, development and manufacture of health care products, including innovative medicines and vaccines. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as one of the world's premier innovative biopharmaceutical companies, we collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 170 years, we have worked to make a difference for all who rely on us.

// www.pfizer.com

Gasporox AB (publ)

With a highly skilled team, extensive expertise, and innovation for laser-based quality inspection Gasporox offers world-class leading solutions that completes our customers offer and quality inspection needs. We provide non-destructive and non-intrusive products for headspace analysis and leak detection, automated in-line or, if you prefer, at-line inspection.

As a leading global provider of this technology, Gasporox continues to challenge today's methods with innovative solutions that pioneers the development of quality inspection within industry 4.0. Our products generate accurate, robust and efficient measurement data that helps our customers optimize their production and needs. The range of patented products include sensors for integration and benchtop systems that monitors pharmaceutical and food packaging processes. In addition to this, Gasporox has several fields of innovation. The Gasporox GPX Porosity technology represents a new approach to porosity analysis of pharmaceutical substrates such as ribbons and tablets.

// www.gasporox.se

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Teraview Limited

TeraView is the world's first and leading company solely focused on the application of terahertz light to provide solutions to customer issues. A spin out from the Toshiba Corporation and Cambridge University, TeraView has developed its proprietary technology across a number of markets. These include fault analysis and quality assurance for semiconductor chips used in mobile computing and communications, as well as non-destructive inspection of high value coatings used in the automotive, pharmaceutical, food and solar industries. With the largest number of systems in the field, as well as applications know-how made available to customers via a team of dedicated engineers using intellectual property and knowledge in peer-reviewed scientific publications, TeraView is uniquely placed to deliver the business benefits of terahertz to customers. Headquartered in Cambridge UK, sales and customer support are available throughout the Far East, North America and Europe either directly or through a network of distributors.

// www.teraview.com

University of Cambridge

The University of Cambridge is one of the world's top ten leading universities, with a rich history of radical thinking dating back to 1209. Its mission is to contribute to society through the pursuit of education, learning and research at the highest international levels of excellence.

The University comprises 31 autonomous Colleges and 150 departments, faculties and institutions. Its 24,450 student body includes more than 9,000 international students from 147 countries. In 2020, 70.6% of its new undergraduate students were from state schools and 21.6% from economically disadvantaged areas.

Cambridge research spans almost every discipline, from science, technology, engineering and medicine through to the arts, humanities and social sciences, with multi-disciplinary teams working to address major global challenges. Its researchers provide academic leadership, develop strategic partnerships and collaborate with colleagues worldwide.

The University sits at the heart of the 'Cambridge cluster', in which more than 5,300 knowledge-intensive firms employ more than 67,000 people and generate £18 billion in turnover. Cambridge has the highest number of patent applications per 100,000 residents in the UK.

// www.cam.ac.uk