



Press release

IMMEDIATE RELEASE

06 December 2016

PSE and RCPE announce pharma Centre of Excellence

Combination of mechanistic modelling and experimentation boosts drug development and manufacturing

LONDON, 6 December 2016 --- Process Systems Enterprise (PSE), the Advanced Process Modelling company, and the Research Center for Pharmaceutical Engineering GmbH (RCPE), an independent R&D Centre specialised in Advanced Manufacturing Science and Pharmaceutical Engineering, today announced the formation of a Centre of Excellence (CoE) aimed at bringing combined model-based analytical technology and services to pharmaceutical manufacturers.

The CoE for Pharmaceutical Formulation & Manufacture provides a single-point service for material characterisation, predictive modelling and process optimisation. It aims to help pharmaceutical companies accelerate the development of drugs and their manufacturing processes, from R&D through tech transfer to commercial manufacturing. Further detail on the CoE and the services it provides to pharmaceutical drug development is also outlined [in this webinar](#).

The combined, integrated service will provide solutions that help pharma organisations to explore the formulation and manufacturing decision space rapidly and effectively using mechanistic modelling approaches. By combining models and experimental data to provide an accurate predictive capability for drug products and their manufacture the CoE will be able to help companies accelerate formulation decisions and design more effective and efficient manufacturing processes.

PSE provides the gPROMS FormulatedProducts modelling suite, which contains mechanistic models for drug substance manufacture, drug product manufacture and in-vitro/vivo product performance as well as specific capabilities for optimising product and process design. The company pioneered the emerging science of [Systems-based Pharmaceutics](#), and is the leader of the £20.4m digital design ADDoPT project.

RCPE performs cutting-edge research in process and product optimisation to help create competitive advantage through development of novel products and production processes, with a key focus being new drug delivery systems. The company has extensive experimental and processing facilities in Graz, Austria that include analytical science, material science, PAT and pharmaceutical engineering capabilities, and has significant experience in modelling and simulation of fluid and granular/powder systems.

Massimo Bresciani, Executive Director for Scientific Operations & BD of RCPE, says “we are very excited about the Centre of Excellence. It gives us a truly unique capability and allows us to provide the most modern set of integrated tools and services for product and process design and development. By using both parties’ experience we can, for example, help pharma companies speed up tech transfer and late phase filings”.

Sean Bermingham, VP for PSE’s Formulated Products Business says “the combination of mechanistic models and targeted experiments is a powerful approach that helps pharma companies accelerate drug substance and product development, quantify and manage risk, and design and scale-up robust manufacturing processes. We very much look forward to working with RCPE to provide a holistic service that covers all these aspects”.

Watch [this webinar](#) for more information on the CoE.

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About Process Systems Enterprise Ltd (PSE)

PSE (www.psenterprise.com) is the world's foremost provider of Advanced Process Modelling software and services to the process industries. Companies apply advanced process models to explore the process decision space rapidly and effectively, in order to reduce uncertainty and make better, faster and safer design and operating decisions.

PSE provides gPROMS family products built on its gPROMS® advanced modelling platform. These include the gPROMS FormulatedProducts modelling suite, which provides mechanistic models for active ingredient manufacture, formulation and product performance as well as specific capabilities for optimising solids and crystallization process design and operation. The company has pioneered the emerging science of Systems-based Pharmaceutics with Pfizer and other pharmaceutical companies, and is the leader of the £20.6m ADDoPT project, which involves Pfizer, AstraZeneca, GlaxoSmithKline and Bristol-Myers Squibb as well as several UK universities and SMEs in a knowledge-driven Digital Design and Control approach for drug products and their manufacturing processes.

Use of PSE's technology and services results in faster innovation, improved process and product designs, enhanced operations, reduced risk, more effective R&D and experimental campaigns and better capture and transfer of corporate knowledge across the organisation. Results are achieved with relatively low investment compared to alternative approaches, with rapid returns on investment.

PSE's global customer base of Fortune 500 process industry companies is served by operations in the UK, USA, Switzerland, Japan and Korea, and agencies in Abu Dhabi, China, Malaysia, Taiwan and Thailand. PSE is a spin-out of Imperial College London, and its software is used in over 200 universities around the world.

PSE is committed to defining, developing and driving the adoption of next-generation process modelling software and workflows. The company's own ability to innovate was recognised with the award of the prestigious Royal Academy of Engineering MacRobert Award for Engineering Innovation, the UK's highest engineering prize.

About RCPE

Together with the global players in the pharmaceutical industry, Research Center Pharmaceutical Engineering GmbH (RCPE) performs cutting-edge research in the field of process and product optimization.

Established as GmbH (Competence Center within the COMET Program) which shareholders are Technology University Graz, Karl-Franzens University Graz and Joanneum Research Institute Graz.

While maintaining a close relationship with academia, RCPE succeeded in becoming a company that provides both scientific excellence and leadership, with a highly professional management of HR, finances and business operations. As a private entity, RCPE offers its partners highly flexible business models that allow setting up particular teams and maximizing the cost efficiency.

RCPE focus is on the development of new drug delivery systems and on the associated production processes and their monitoring. The Center's excellent performance is due not only to its experienced interdisciplinary international team but to its location in close proximity to the universities of Graz. As a link between science and industry, RCPE carries out state-of-the-art business-oriented research

To that end, RCPE combines multidisciplinary expertise in process engineering, pharmaceutical science, chemistry, biotechnology, material science and nanotechnology. In close collaboration with national and international partners from the pharmaceutical, biopharmaceutical and diagnostic industries develops methods for design, optimization, scale-up and control of new manufacturing processes. To ensure excellent staff quality in the future, RCPE pursues targeted education and gender mainstreaming activities in the human resource development. Moreover, RCPE acts as an information centre and a knowledge exchange interface between science and industry.

Since 2008 RCPE has developed its own process and analytical laboratory with state-of-the-art equipment. The process facility as well as the analytics and Material Science laboratory is extensively equipped and comprise state-of-the-art equipment. Regular maintenance and certification of the equipment and extensive training of the employees guarantee top research results and performance. The Centre is ISO 9001 and 14001 certified.