# Press release



#### **IMMEDIATE RELEASE**

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# PSE releases gPROMS FormulatedProducts modelling platform

## Integrated mechanistic modelling from formulation to product performance

LONDON, 16 June 2017 --- Process Systems Enterprise (PSE), the Advanced Process Modelling company, today launched its new gPROMS FormulatedProducts modelling platform for the integrated digital design of robust formulated products and their manufacturing processes.

Developed in close collaboration with leading pharmaceutical, agrochemical, consumer products and food organisations, gPROMS FormulatedProducts deploys a mechanistic modelling approach to enable scientists and engineers to screen formulations with complex phase structures for quality attributes, determine whether they can be manufactured robustly, and comprehensively explore the design space for the whole formulation and manufacturing chain.

In particular, the platform helps pharmaceutical companies optimise the formulation and manufacture of drug substances and drug products using mechanistic models of material, unit operations and product performance. This enables them to screen new formulations faster against quality attributes including in vivo performance and manufacturability. It also accelerates tech transfer whilst reducing risk and improving R&D efficiency, and facilitates better capture and transfer of corporate knowledge across the organisation.

Sean Bermingham, head of PSE Formulated Products says, "gPROMS FormulatedProducts uniquely meets the needs of the pharmaceutical, agrochemical, consumer products and food organisations when it comes to accelerating innovation, improving product and manufacturing process robustness, and reducing time-to-market."

Built on PSE's state-of-the art gPROMS® modelling platform, gPROMS FormulatedProducts includes extensive libraries of mechanistic models for operations such as reaction, crystallization, wet and dry milling, spray drying, wet and dry granulation, blending and tabletting. It also provides databases and calculation methods for physical properties, material properties, equipment and physiology.

Data from batch and continuous experiments can be used to calibrate the manufacture and product models. The gPROMS platform's unique Global System Analysis capability can then be applied to perform a comprehensive assessment of the impact of input variability and model uncertainty on critical quality attributes (CQAs), allowing the screening and ranking of formulation and manufacturing process alternatives.

Bermingham adds "We have benefited enormously from the feedback we received from PSE's Formulated Products Advisory Board as well as the input from the Systems-based Pharmaceutics Alliance and our industrial and academic partners in major R&D collaborations such as ADDoPT, C-SOPS, CMAC, D3P and REMEDIES. This has resulted in a tool based on state-of-the-art science that can address practical challenges".

#### Contact

Kate Burness +44-20-8563-0888, k.burness@psenterprise.com

Editors: http://www.psenterprise.com/news/pr170616

### **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 formulation, process and product 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. PSE has also recently established two Centres of Excellence, with pharmaceuticals R&D centre RCPE for Pharmaceutical Formulation & Manufacture and with food & nutrition contract research organisation NIZO for Food Product & Process Modelling respectively.

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. The unique advantages that PSE tools bring are the combination of high-fidelity models, powerful mathematical optimisation and global system analysis capabilities, and an equation-oriented framework capable of rapid and robust solution of complex problems.

PSE's global customer base of Fortune 500 process industry companies is served by operations in the UK, USA, Japan and Korea, and agencies in China, 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.