

## Sanofi joins Systems-based Pharmaceutics Alliance

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## Development, adoption and acceptance of a framework for drug performance and manufacture

LONDON, 11 December 2019 --- The Systems-based Pharmaceutics Alliance welcomes Sanofi S.A. as its newest member.

The Alliance further comprises leading pharma companies Eli Lilly and Company, GlaxoSmithKline Research & Development Limited, Pfizer Inc. and F. Hoffmann-La Roche Ltd., and supplier of mechanistic modelling software, Process Systems Enterprise Ltd.

The Alliance is aimed at developing an integrated and interconnected systems-based mechanistic modelling framework based on available knowledge regarding drug substance manufacturing, drug product manufacturing, oral absorption and pharmacokinetics.

Ross Blundell at Sanofi (Head of Small Molecule Oral platform, Montpellier, France) says "We are pleased to be part of this exciting Alliance, which has the potential to change the way that drugs are developed and to accelerate the availability of important medicines for patients".

Sean Bermingham of PSE (Head of PSE Formulated Products and Director of the Alliance) adds "We are excited to have Sanofi join the pre-competitive activities of the Alliance aimed at developing the systems-based framework and encouraging its industry adoption and regulatory acceptance."

PSE's gPROMS FormulatedProducts was and continues to be developed under guidance of the Alliance.

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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 within digital design and digital operations initiatives to explore the process decision space rapidly and effectively. This helps them to reduce uncertainty and make better, faster and safer formulation, process and product design and operating decisions based on deep scientific and process knowledge.

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. PSE is committed to defining, developing and driving the adoption of next-generation process modelling software and workflows, and works in close collaboration with its major customers and selected R&D organisations to achieve this.

PSE's global customer base of Fortune 500 process industry companies and some 200 universities is served by operations in the UK, USA, UAE, Japan and Korea, and agencies in China and Taiwan.

**About gPROMS FormulatedProducts** Built on PSE's gPROMS® advanced process modelling platform, gPROMS FormulatedProducts provides state-of-the-art digital design and operation capabilities to food, agrochemical and consumer product industries, enabling model-based design and optimisation of process operations such as reaction, crystallization, wet and dry milling, spray drying, wet and dry granulation, blending and tabletting. Additionally, it enables pharmaceutical companies to optimise the formulation and manufacture of drug substances and drug products using mechanistic models of materials and unit operations, and provides detailed analysis of in-vivo drug product performance