
DSM Press Release



DSM Pharmaceutical Products
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DSM and the FDA Join Together for Innovative Partnership in PAT

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DSM Pharmaceuticals Inc. and the Food and Drug Administration (FDA) have recently signed an agreement to collaborate on a project involving Statistical Quality by Design Methodology during Pharmaceutical Manufacturing. Dr. Barry Gujral of DSM and Dr. Maziar Kakhi of the FDA will jointly work to build mathematical models using Quality by Design, Statistical Process Control, Design Space and Risk Analysis methodologies. The goal of this project is to recommend changes that support the Pharmaceutical Manufacturing sector's focus on proactively managing manufacturing processes. This will further enable the Pharmaceutical sector to reduce waste, enhance efficiency and manufacture drugs with improved consistency and quality.

The project is in line with the Process Analytical Technology Initiative the FDA released in September 2004 to bring more innovations in Pharmaceutical Manufacturing. *"This initiative with the FDA is a big step toward developing more innovative processes in the manufacturing of pharmaceuticals and will benefit current and future customers by improving efficiencies in the manufacturing process,"* says Terry Novak, President and Business Unit Director for DSM Pharmaceuticals Inc.

About DSM Pharmaceuticals Inc.

DSM Pharmaceuticals, Inc. a business unit of DSM Pharmaceutical Products, is a global provider of custom manufacturing services to the pharmaceutical and biopharmaceutical industries. Our breadth of manufacturing services include the areas of steriles, orals and topicals, including dose form manufacturing, scheduled drugs, clinical manufacturing, fill finish manufacturing, and lyophilization services.

About DSM Pharmaceutical Products

DSM Pharmaceutical Products is a global provider of high quality custom contract manufacturing services to the pharmaceutical and biopharmaceutical industries. DSM Pharmaceutical Products provides contract manufacturing services including: advanced intermediates, active ingredients (API's), amino acids and derivatives, mammalian cell culture production (fed-batch and perfusion) of monoclonal antibodies, proteins, vaccines, finished dose manufacturing of solid dose, scheduled drugs, liquids, aseptic liquid and lyophilized products.

From clinical to commercial services, DSM focuses the right resources on providing the highest level of service and quality while applying innovative solutions to satisfy customers' unique manufacturing and development needs.

About DSM

DSM creates innovative products and services in Life Sciences and Materials Sciences, contributing to the quality of life. DSM's products and services are used globally in a wide range of markets and applications, supporting a healthier, more sustainable and enjoyable way of living. End markets include human and animal nutrition and health, personal care, pharmaceuticals, automotive, coatings and paint, electrics & electronics, life protection and housing. The company strategy, [Vision 2010 – Building on Strengths](#), focuses on accelerating profitable and innovative growth of the company's specialties portfolio. The key drivers of this strategy are market-driven growth and innovation, an increased presence in emerging economies and operational excellence. DSM has annual sales of almost EUR 9 billion and employs some 22,000 people worldwide. The company is headquartered in the Netherlands, with [locations](#) in Europe, Asia, the Americas, Africa and Australia. More information on DSM can be found at www.dsm.com.

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Forward-looking statements

This press release contains forward-looking statements. These statements are based on current expectations, estimates and projections of DSM management and information currently available to the company. The statements involve certain risks and uncertainties that are difficult to predict and therefore DSM does not guarantee that its expectations will be realized. Furthermore, DSM has no obligation to update the statements contained in this press release.