MULTINATIONAL RESEARCH CONSORTIUM TO ADVANCE NANOMEDICINE MANUFACTURING

Gattefossé, InProcess-LSP, Knauer, Microfluidics, Skyepharma, and the University of Graz join the RCPE-led European Consortium for Continuous Pharmaceutical Manufacturing (ECCPM) to jointly develop a modular, flexible toolkit to advance industrial-scale production of lipid nanoparticles.

The ECCPM, founded and led by the Research Center Pharmaceutical Engineering (RCPE), announces the establishment of NanoFacT, a joint-research consortium addressing the challenging scale-up of manufacturing processes for nanoparticle formulations. Throughout the next 36 months, the consortium will generate and disseminate fundamental knowledge by converging industry-leading capabilities in (pharmaceutical) engineering, material science, and innovative process analytical technologies to create a flexible, modular toolkit and manufacturing platform.

Over the past decades, nanomedicines and nanoparticles have emerged as promising therapeutic/diagnostic agents and powerful drug delivery tools. Still, the complexity of manufacturing processes has inevitably limited their actual impact. “We manufacture nanopharmaceuticals in time-consuming, difficult-to-control batch processes,” said Prof. Dr. Eva Roblegg, Key Researcher for NanoFacT, “The need to integrate previously isolated unit operations into seamless, GMP-compliant platforms is evident. Even more so, it is a prerequisite to keep pace with medical progress and provide patients with the best possible treatment.” The principal lack of understanding of process parameters and material attributes has made the transition from successful lab-scale synthesis to industrial-relevant production environments unnecessarily challenging.

The consortium partners aim to develop scalable and versatile continuous manufacturing platforms for nanopharmaceuticals. “We’re essentially enriching proven solutions with advanced analytical technologies and a rational, science-based approach to process and product design,” explains Dr. Carolin Tetyczka, one of NanoFacT’s Project Leaders. These new production platforms will allow the exact adjustment and monitoring of physicochemical properties, achieving better product quality with faster product release with beneficial process economics. Individual GMP-compliant and scalable processes (i.e., (high) shear mixing, Microfluidizer® Processing and impingement jet mixing) will be equipped with process analytical technologies, such as spatially resolved dynamic light scattering (SR-DLS) for inline particle size measurement, electrophoretic light scattering for zeta potential monitoring, inline viscosity measurements, and spectroscopic methods to ensure drug encapsulation and achieve product and process monitoring. We will attempt to link and centralize the control logic of individual units (e.g., pumps, actuators, and PAT tools). In addition, multidisciplinary approaches of Quality by Design (QbD) to determine process- and product-critical parameters will be established. Suitable individual processes will then be linked to create a proof-of-concept prototype of a flexible continuous production line at laboratory scale.

ABOUT ECCPM:

ECCPM was founded to address the challenges of transferring continuous manufacturing (CM) concepts from R&D to production scale. The consortium serves as a platform for companies and academic institutions to share knowledge and best practices and develop a collective vision of CM. We do this through regular, pre-competitive workshops and forums where we address the challenges we face when implementing new processes or developing new products.

ABOUT THE PARTNERS

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.
// www.rcpe.at

GATTEFOSSÉ
The Gattefossé Group is a community of employees, all driven by a dual mission: the performance of its products and the personalized support of its customers. Gattefossé develops, manufactures and sells pharmaceutical excipients and cosmetic ingredients of natural origin for the health and beauty industries worldwide, through its 12 affiliated companies and network of global agents and distributors in 80 countries. Specialist in lipid chemistry and plant extraction, Gattefossé offers recognized expertise in formulation using its 4 Technical Centers of Excellence in France, China, India and the United States. Environmental and social issues have always been part of the culture of this French family business, founded in Lyon in 1880. Today, Gattefossé relies on a purposeful CSR approach to build its innovation and development strategy.
// www.gattefosse.com

INPROCESS-LSP
InProcess-LSP, founded in 2014, is a highly innovative organization providing full Process Analytical Technology (PAT) method and instrument development services. With many years of academic and industrial experience, we offer a highly skilled and experienced team of scientists and process specialists. In 2019 InProcess-LSP commercialized the first and unique NanoFlowSizer technology. The NanoFlowSizer is a new innovative system for continuous, real-time and inline nanoparticle size characterization of colloidal systems, nanosuspensions, nanoemulsions and other dispersed nanoproducts in flow, without the need for sample treatment or dilution.
// www.inprocess-lsp.com

KNAUER
KNAUER Wissenschaftliche Geräte GmbH develops and produces laboratory instruments in Berlin, Germany since 1962. Best known for liquid chromatography systems and components, the company also played a vital role in the large-scale production of lipid nanoparticles for mRNA-Corona vaccines. KNAUER's IJM NanoProducer skids can produce LNP for a million doses per week. The IJM NanoScaler applies the same technology in lab-scale e.g. for pre-clinical research. Owner Alexandra Knauer manages the family-business together with Carsten Losch. Both are committed to sustainable and responsible corporate governance with a focus on users, the 180 employees and society.
// www.knauer.net

PUSHING BOUNDARIES CONTINUOUSLY

MICROFLUIDICS
Microfluidics International Corporation, the manufacturer of Microfluidizer® high shear fluid processors, is a leader in the design and production of laboratory and commercial processing equipment used in the production of micro- and nano-scale materials for pharmaceutical, biotech, chemical and diverse industries. Microfluidizer® technology enables some of the world's top companies to create superior products, develop intellectual property, improve process efficiency and capitalize on new revenue streams – setting the standard for nanoemulsion and nanoparticle applications. Since 2011, Microfluidics has been part of the IDEX Corporation and became part of the IDEX Material Processing Technologies (IDEX MPT) division.
// www.microfluidics-mpt.com

SKYEPHARMA
Skyepharma is an independent French pharmaceutical CDMO, 100% owned by its management team and Bpifrance. Skyepharma is an expert CDMO specialized in the formulation, development and manufacturing of complex oral solid forms (OSD), with a specific expertise and proprietary technologies on modified release products.Skyepharma is based in Saint-Quentin-Fallavier, France. The current factory, dedicated to its OSD activity, occupies 22,000m², on a 60,000m² piece of land. Skyepharma has decided to allocate a portion of the available land (more than 20,000m²) to establish its SkyeHub Bioproduction, an innovative model designed to offer clinical and commercial production capacities to biotech companies. This SkyeHub model includes the construction of dedicated buildings, with specifically designed surfaces and premises, together with transverse support services such as quality, maintenance, batch release, etc.
// www.skyepharma.fr

UNIVERSITY OF GRAZ
At the University of Graz, researchers and students work across a broad spectrum of fields to find solutions for tomorrow's world. The scientists address some of the key challenges of our society and are working to develop strategies for tackling them. How to respond to climate change, for example, and how to fight diseases of the metabolism and of old age – these and other important topics are studied through our innovative programmes. Students learn to apply their knowledge and findings effectively to help shape our future.
// www.uni-graz.at

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