



The National Institute for Pharmaceutical Technology & Education

Pharmaceutical Continuous Manufacturing: Knowledge Center Aims to Expand Information Access, Facilitate Innovation and Lower Barriers to PCM Adoption

Minneapolis, April 6, 2022 - The National Institute for Pharmaceutical Technology and Education (NIPTE) and U.S. Pharmacopeia (USP) today announced the initiation of a joint effort to create the Knowledge Center for Pharmaceutical Continuous Manufacturing (PCM) technology. The result will be a digital knowledge management resource for capturing, contextualizing, organizing, and updating rapidly expanding knowledge about PCM with the goal of facilitating innovation in PCM and lowering barriers to its adoption to help strengthen the medicines supply chain.

“PCM is one of the most promising manufacturing technology advancements in recent years,” explained Vadim J. Gurvich, Ph.D., MBA, Executive Director of NIPTE and Research Associate Professor at the University of Minnesota. “By enabling pharmaceutical manufacturing as an uninterrupted process in a single facility, PCM not only increases efficiency. It lowers costs, minimizes environmental footprints, and allows for a more rapid scale-up of production to meet surge demand in response to crises. The new Knowledge Center will provide industry, regulatory bodies, academia, and other stakeholders with rapid and comprehensive access to the latest, updated information to help accelerate the adoption of PCM, increase the resilience of the global medicines supply chain, and benefit patients.”

Although PCM has advanced substantially in recent years, most of the valuable technical information resides with private companies and academic publications across multiple platforms, such as scientific publications, dissertations, industrial reports, and trade publications. Moreover, scientific and technical presentations are rarely archived, and thus may not be easily accessible, if at all, by the scientific and technical community. The development of the new Knowledge Center will provide a central and comprehensive repository of PCM information accessible by all stakeholders.

“PCM is one way to increase domestic production of critical drugs and active pharmaceutical ingredients in the U.S. and other countries to help guard against acute supply chain disruptions,” said Ronald T. Piervincenzi, Ph.D., CEO of USP. “USP is collaborating with stakeholders to address PCM knowledge gaps, certify and validate related manufacturing processes, and explore where there is a need and opportunity to develop new quality standards. The Knowledge Center for PCM builds on all these efforts to help promote public trust in quality-assured medicines made with PCM.”

Funding support for the establishment of the knowledge management system for PCM is provided by the U.S. Food and Drug Administration through a U01 grant “Manufacturing Sector Research Initiative” awarded to NIPTE.

The Knowledge Center for PCM will include information curated by NIPTE and USP from research publications, presentations at technical forums, and regulatory communications currently scattered across multiple platforms or otherwise not easily accessible. The scope and structure of the information will be guided by the NIPTE Editorial Board to help ensure its focus on the latest and most relevant information for stakeholders. The Board consists of experts in technical areas of interest including active pharmaceutical

ingredients, solid dose products, process analytical technologies, process modeling, process control, and regulatory considerations. The collaboration will facilitate USP's ongoing expansion and evolution of this dynamic resource to help foster an active community of users.

The Knowledge Center for PCM online platform is anticipated to be fully operational and publicly accessible later this year.

About NIPTE

NIPTE is a non-profit academic organization that collaborates with industry, academia, and government to improve the way medicines are designed, developed, and manufactured to meet the needs of patients in the 21st century. It consists of Duquesne University, Illinois Institute of Technology, Long Island University, Purdue University, Rutgers University, Texas A&M University, University of Connecticut, University of Kansas, University of Kentucky, University of Maryland, University of Michigan, University of Minnesota, University of Mississippi, University of Puerto Rico, University of Rochester, University of Texas at Austin, Virginia Commonwealth University, and Indian Institute of Technology at Delhi. For more information, visit: www.nipte.org

About USP

USP is an independent scientific organization that collaborates with the world's top experts in health and science to develop quality resources and standards for medicines, dietary supplements and food ingredients. This includes actively collaborating with academic research centers, industry and regulators to help advance PCM standardization efforts. Through our resources, standards, advocacy and education, USP helps increase the availability of quality medicines, supplements and foods for billions of people worldwide. For more information, visit: www.usp.org

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