IBBR Participates in NIIMBL-Supported Biomanufacturing Reagent Purification Project

IBBR Emeritus Fellow, Dr. Phil Bryan, and IBBR Fellow, Dr. Eric Toth, Receive NIIMBL Award

February 18, 2019 -- Many new drugs are biotherapeutics – proteins used to treat disease through specific and powerful activities within the human body. In fact, according to a March 2018 Genetic Engineering & Biotechnology News report, seven of the top ten drugs by sales in 2017 fell into this category. Therapeutic proteins are produced by living cells, and biomanufacturing processes require specialized biological reagents to regulate cell growth and protein production. Purification and standardization of reagents is crucial for end product consistency and reducing the risk of contamination, but can be labor intensive and is often the most expensive part of the process of manufacturing protein biotherapeutics. A new award from the National Institute for Innovation in Manufacturing Biopharmaceuticals (NIIMBL) will support collaborative work on a platform for producing reliable, cost-effective reagents.

NIIMBL is an industry-led, public-private partnership. It is funded through a $70M cooperative agreement with the National Institute of Standards and Technology (NIST) in the U.S. Department of Commerce and leverages an additional $129 million in commitments from industry, academic institutions, non-profit organizations, and state governments. An important element of NIIMBL’s mission is to accelerate
biopharmaceutical manufacturing innovation. Last month, NIIMBL announced technical and workforce awards for collaborative projects in twelve priority topic areas approved by key industry members, including one to Potomac Affinity Proteins (PAP) and the University of Maryland. PAP was founded by Dr. Phil Bryan, IBBR Fellow Emeritus, who will serve as project lead. IBBR Fellow Dr. Eric Toth will head up the University of Maryland participant project team. This is the first NIIMBL award for both PAP and IBBR.

The $300K award will be used to develop consistent, low-cost, cytokine and growth factor reagents for cell therapy applications. The project involves scaling up and standardizing a PAP-developed purification process. Scaling up is not always straightforward, and often requires many rounds of trial and error. The Toth laboratory, working in conjunction with IBBR Director Dr. Thomas Fuerst’s group, will characterize structure and function of the reagents to inform the iterative scale-up process at PAP. “Even the slightest change of the reagent during the purification process can alter its structure and function,” observes Dr. Toth. “These are large, complex biomolecules, and ensuring that the reagents look and perform as expected is critical.”

“Characterization of complex protein structures is one of IBBR’s foundational research platforms and core strengths,” notes Dr. Fuerst. “We are grateful for the support from NIIMBL as we use fundamental understanding of biomolecular structure-function relationships to advance important biomanufacturing applications, particularly those related to FDA-regulated biologics.”

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