Large-molecule therapeutic agents, often monoclonal antibodies, antibody-drug conjugates, and fusion proteins, have assumed a higher profile in pharmaceutical research and development in recent years, and there is no reason to think that this trend will end any time soon. The discussion comes from the point of view of a scientist from a contract R&D/contract manufacturing organization that handles both large and small molecules at various stages of
development, with responsibilities ranging from analytical method development and validation to formulation and process development of injectable dosage forms. We encourage our scientists to develop both deep expertise in a particular area of interest to them, but also to develop a broad understanding and the ability to converse intelligently with scientists and engineers involved in such areas as biophysical characterization of proteins, physical and chemical stability assessment, unit operations in manufacture of injectable products, as well as unit operations in the production of a large molecule bulk drug substance. Scientists should be encouraged to view the development process as a continuum, with no sharp dividing lines. We view university faculty as critical partners, both in the development of deep and relatively narrow expertise, as well as developing a “big view” of our scientific and technical world.

Dr. Nathaniel Milton

Research Advisor in Biopharmaceutical Product Development, Retired from Eli Lilly

Nathaniel (Nate) Milton Ph.D., RPh received his B.S. in Pharmacy ('89) and Ph.D. in Industrial and Physical Pharmacy ('95) from Purdue University. He retired from Eli Lilly and Company after 28 years of service where his last role was as a Research Advisor in Biopharmaceutical Product Development. In this role, Dr. Milton led formulation development teams responsible for developing small and large molecule (proteins, peptides, and insulins) parenteral formulations, supporting technology transfer to clinical trial and commercial manufacturing facilities, and establishing processes for sterile extemporaneous compounding to enable early phase clinical trials.

Dr. Milton recently joined Exelead Biopharmaceuticals as a Senior Scientist providing technical support to manufacturing, quality control, and product development. His memberships and professional affiliations include Purdue’s College of Pharmacy Diversity and Inclusion Committee, the Dean's Advisory Council, and he is an Adjunct Faculty member. Dr. Milton also volunteers at the Rophe Free Clinic in Indianapolis where he practices community pharmacy and mentors pharmacy interns.

The Influence of Biotechnology on Industrial Pharmacy and Health Outcomes

The presentation is a broad review of trends in the health care industry, the development of new drug products, and changes in the pharmaceutical business. The influence of biotechnology, personalized medicine, advances in drug delivery technology, and parenteral manufacturing and their impact on the practice of industrial and physical pharmacy will be discussed.
Dr. Chetan Pujara is Vice President in Global R&D at Allergan plc, Irvine, CA. His organization designs and develops dosage forms and drug-device combination products intended for clinical trials and commercialization. In this role, he oversees formulation & manufacturing process development, analytical & microbiology development, packaging development, clinical supplies manufacture and GMP lab systems operations departments.

Evolving trends in patient-centric dosage form design and development

Dr. William Randolph

Vice President, Global Technology Services, Johnson & Johnson
The Future of the Pharmaceutical Supply Chain: Janssen's view on what it means for the Pharmaceutical Scientist of 2035?

In this discussion I will attempt to provide insights into what Janssen Pharmaceuticals currently sees as the future of the Pharmaceutical business. We see this future as a combination of not only the amazing new age technologies and therapies we are currently developing or investing in, but also the mega trends that we see impacting our business and what these together mean to our supply chain but more specifically to our pharmaceutical technical organization and its resources. We will discuss our thoughts on the direction of the industry and how we plan to cope with those changes. Our intent is to provoke thought of what the overall future of the industry is looking like therefore laying the groundwork, so we can debate how best to prepare the Pharmaceutical Scientists of 2035 and beyond.

Wurster's research has largely focused on interactions occurring across interfaces. He is the author or co-author of over 200 peer-reviewed abstracts and research articles, and he has served as major professor for 34 past and current Ph.D. students.

Wurster is currently serving a three-year term as President Elect (2018), President (2019), and Past President (2020) of the American Association of Pharmaceutical Scientists (AAPS). He is an AAPS Fellow (1998) and the recipient of an AAPS Research Achievement Award in Manufacturing Science and Engineering (2009). He was named a Distinguished Alumnus of the Purdue University College of Pharmacy in 2015, and, in 2017, he was presented with the Ralph Shangraw Memorial Award by the IPEC Foundation. In 2018, he received the David J. W. Grant NIPTE Distinguished Scholar Award in Basic Pharmaceutics.

Title: Considerations in the Design of Graduate Programs
Dr. David Engers, Ph.D. is currently a director at the Purdue GMP Center (PGC). Dr. Engers has over 20 years of technical and leadership experience including development and innovation of technologies to improve oral bioavailability of poorly water-soluble compounds, technology transfer, scale-up, qualification of products and processes, high-potency formulations, and leading initiatives to accelerate the delivery of Phase I clinical supplies.

Dr. Engers has presented and/or published on topics in solid state chemistry, evergreening strategies, pharmaceutical unit operations, triboelectrification, and intellectual property strategies, including invited lectures at the United States Patent and Trademark Office and the Canadian Intellectual Property Office. He is an inventor on 14 issued patents in crystalline forms, amorphous solid dispersions, and nanocrystalline technology. Dr. Engers currently serves as an adjunct professor in the Department of Industrial and Physical Pharmacy at Purdue University and as a scientific advisor to the Editors for the Journal of Pharmaceutical Sciences.

Dr. Engers received his BSE in chemical engineering from the University of Michigan, Ann Arbor and his PhD in pharmaceutics from Purdue University, where he worked with Professor Kenneth R. Morris to advance the understanding of molecular anisotropy in the maintenance of local structure in amorphous materials.

**Director at Purdue GMP Center (PGC)**

**Moderator of Panel Discussions**