The Role of Standards and Regulatory Sciencein the Characterization of Biopharmacueticals

December 2, 2014 University of Maryland School of Pharmacy

Number of Attendees: 46, 21Industry, 23 Academia and 2 Federal Government

Host: Waters Corporation

Lively discussion at end of program was an indication of the need for a development of standards and standard methodology in academic laboratories as well as the need for global harmonization within the pharmaceutical industry. Complexity of biotherapeutics complicates defining standards or reference material, as more complex biologics come to market the problem with intensify. Significant discussion on linkage of universal method to universal reference material rather than a standard. Surprisingly, the industry participants were very vocal on the changes that t hey would like to see in training that students receive prior to graduation.

Agenda:

The Case for Standards in Life Science Research
Leonard Freedman, Ph.D, Global Biological Standards Institute

Industry need for Standards
Darryl Davis, Ph.D. Principal Research Scientist, Janssen Research and Development

The NIST mAb: A Reference Material for Biopharmaceutical Method Evaluation
John Schiel, Ph.D., Research Chemist, National Institute of Standards and Technology

Modernizing USP Pancreatin Standards with Modern Identification Testing
Kevin Carrick, Ph.D., U.S. Pharmacopeial Convention

Developing the Skilled Workforce
Jeff Agar, Ph.D., Northeastern University Biopharmaceutical Analysis Training Laboratory,
Nathaniel Hentz, Ph.D., North Carolina State University Biomanufacturing Training and Education Center

Emerging Mass Spectrometry Applications for Biopharmaceutical Characterization
Justin Sperry, Ph.D, Analytical R&D, Pfizer Inc., St. Louis, MO

Analytical challenges of Antibody Drug Conjugates John Gebler, PhD., Waters

Round Table Discussion with Panel - Creation of Standards for Biologics
NIST, USP, Industry, GBSI, and Waters