

USP Biologics Stakeholder Forum Executive Summary

January 10, 2020 — The United States Pharmacopeial Convention (USP) held its inaugural Biologics Stakeholder Forum (SF) in San Francisco, CA. The SF was created to bring together leaders from industry, regulatory bodies, and USP to discuss ways to spur innovation while also supporting quality of biologics. Each year, a face-to-face meeting of the SF will be held to update biologics stakeholders on USP activities and to collaborate on strategies to solve issues associated with a particular hot topic facing this sector. The hot topic of the first meeting of this series brought together stakeholders to discuss multi-attribute methods (MAM) which enable simultaneous monitoring of multiple product attributes in a single assay. MAM conducted with mass spectrometry detection provides very specific and accurate measurements with much more information than traditional procedures. USP held this meeting to obtain feedback from industry and the U.S. Food and Drug Administration (FDA) regarding current applications, challenges, and quality considerations for MAM.

In the first session, USP's CEO, Dr. Ron Piervincenzi, and VP of Science-Global Biologics, Dr. Fouad Atouf, summarized USP's history of biologics standards and its Biologics strategy moving forward. USP is tailoring its approach to address the needs of its stakeholders by developing broadly applicable standards, focusing on emerging assays and technologies, and engaging and collaborating with industry and regulators. USP is committed to reducing uncertainty and variability in biotherapeutic development to increase the potential for innovation. An important and useful standard is a standard that will advance technology across products.

The second session provided an opportunity for attendees to hear about two different approaches from Dr. Jette Wypych, Director of Process Development at Amgen and Dr. Andrew Dawdy, who spoke on behalf of Pfizer's MAM Team, regarding the development of MAM as a tool for development, characterization, and release of biologics. It is common to have dozen of tests supporting release of drug substance and drug products for a large molecule like a monoclonal antibody (MAb). Many of these tests are resource intensive, complex, and require multiple instruments. MAM provides an opportunity to significantly reduce the number of methods required for drug characterization, development, and release; build a repository of information for future innovation; and expedite innovation in biologics development. However, before MAM can be implemented as a quality control release test, numerous concerns must be addressed before adoption in a GMP environment. Presenters emphasized the importance of robust data collection and described the current challenges, areas for optimization, and future applications of MAM.

Next, Dr. Sarah Rogstad from FDA's Emerging Technology Team provided a summary of important quality considerations for MAM, including risk assessment, method validation, new peak detection, and method comparison. Dr. Rogstad also shared data on MAM capabilities using rituximab as a model protein.

Dr. Diane McCarthy, Senior Manager in the USP Biologics department, presented an update on USP's performance standards under development. USP is already working on MAb-based performance standards that may help ensure the sensitivity of MAM-based methods and support transfer of methods across laboratories. She also described other standards in development for identification and quantification of host cell proteins and cell culture media components.

The meeting also included an open floor for audience members to share their MAM data and observations. Presentations focused on evaluating claims of MAM, additional attribute considerations for MAM, and insights from a recent National Institute of Standards and Technology round robin study.

Following the presentations, attendees divided into two breakout sessions and discussed technical aspects and potential areas for standardizing MAM.

Throughout the meeting, attendees engaged in robust discussion, identifying current challenges, important quality considerations, and future opportunities for MAM. USP plans to form a new USP Expert Panel dedicated to development of an informational chapter containing best practices for adopting MAM for characterization of biologics. This Expert Panel will also serve as a sounding board for USP's Biologics scientists to deliver the most useful performance standards to support the robustness of these measurements. To find out more about volunteering on a USP Expert Committee or Panel, please contact USPBiologics@usp.org.

In the spring of 2021 USP will hold its second annual Biologics Stakeholder Forum in Boston, MA. The Steering Committee is currently collecting ideas for the next hot topic. Stakeholders are encouraged to submit suggestions for the next meeting by emailing USPBiologics@usp.org.