



**USP Biologics and IFPMA Roundtable Agenda Performance Standards Development  
May 31, 2018  
Vienna, Austria - Renaissance Marriott Hotel**

**Executive Summary**

USP and International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) cosponsored a roundtable with analytical scientists and compendial representatives from eight major biopharmaceutical companies to discuss performance standards development. Performance standards are important to the industry as they support quality control, analytical development, process development and comparability of assays and materials between companies.

The objective of the roundtable was to identify, prioritize and develop an action plan for the collaborative development of biologics performance standards, with a focus to applications in the therapeutic protein areas. Participants shared ideas, raised important questions and concerns, and discussed potential approaches for the path forward. Notably, the group accomplished a major objective by identifying four areas for performance standards with the biggest potential impact and the highest probability of success. In addition to the tangible outcomes of the meeting, USP reaffirmed its ongoing commitment to partnering with its stakeholders in the development of performance standards.

**Definition of performance standards:**

Biologics ***performance standards*** are targeted at product families or classes. Performance standards are used to demonstrate analytical methods' effectiveness and process performance throughout the product lifecycle. A performance standard may or may not be tied to a monograph and will be accompanied by a separate dataset or application note.

**Key takeaways from participant discussions:**

- Participants recognize a clear value of performance standards, and an objective moving forward will be to develop a common understanding of how these standards are used.
- The role of performance standards in regulatory filings needs further discussion as standards are developed.
- USP's plans to develop performance standards are of interest to participants.
- The group discussed potential uses of performance standards and challenges with bioassays which will be explored further through next steps and ongoing expert discussions.
- An important factor in the use of standards is their applicability across laboratories.

**Prioritization Exercise:**

Participants built on the list of performance standards discussed at a previous performance standards roundtable to identify and prioritize those with the most potential benefit to the industry and highest probability of success to develop. The group reached a consensus on the following standards which they considered most feasible and beneficial to industry, while acknowledging that different subject matter experts might prioritize the list differently.

- FC receptor assay standard for monoclonal antibodies
- Mass Spec peptide standard
- Visible particulate standard
- Standards to support chromatographic column qualification

**Next steps include:**

- Additional focused discussions (roundtables/panels) to engage subject matter experts in the prioritized topics.
- A white paper on biologics performance standards will include the outcomes from the two roundtable discussions.
- Cooperation and collaboration to reach shared goals will be critical.
- USP's continued work to raise awareness of the future of biologics performance standards.

USP will continue to seek industry input, perspective, collaborative development opportunities, and material sponsorships for biologics performance standards. We look forward to further interactions and collaborations to help ensure that USP is delivering solutions that meet the needs of the biologics community.

For additional information on the USP biologics program, visit <https://biologics.usp.org/>.