

**USP Biologics and Biotechnology Innovation Organization (BIO) Roundtable On  
Performance Standards Development  
October 24, 2017  
USP Rockville Campus**

**Executive Summary**

Scientists from leading pharmaceutical companies came together for a one-day roundtable to discuss performance standards development for biologic medicines. The roundtable was co-sponsored with BIO and held at USP. The objective was to stimulate discussion and gather industry perspectives on ways that performance standards could help address the challenges companies face throughout the product development lifecycle. The development and availability of these standards will be beneficial in a variety of potential applications. Participants shared ideas, raised important questions and concerns, and discussed potential approaches for the path forward. Specifically, USP sought to identify and prioritize performance standards for possible development. The group accomplished a major objective by compiling a list of specific performance standards and then prioritizing these standards based on potential impact and probability of success. In addition to the tangible outcomes of the meeting, USP reaffirmed its ongoing commitment to partnering with industry.

**Defining a performance standard:**

Biologics performance standards are reference standards (physical specimens) which support biologics analytical testing throughout the product lifecycle. Performance standards are used to ensure and demonstrate methods effectiveness and process performance for the various steps in investigative work, process development, or manufacturing. These standards are broadly applicable across product families or classes, as opposed to only being applicable to a specific drug substance or drug product.

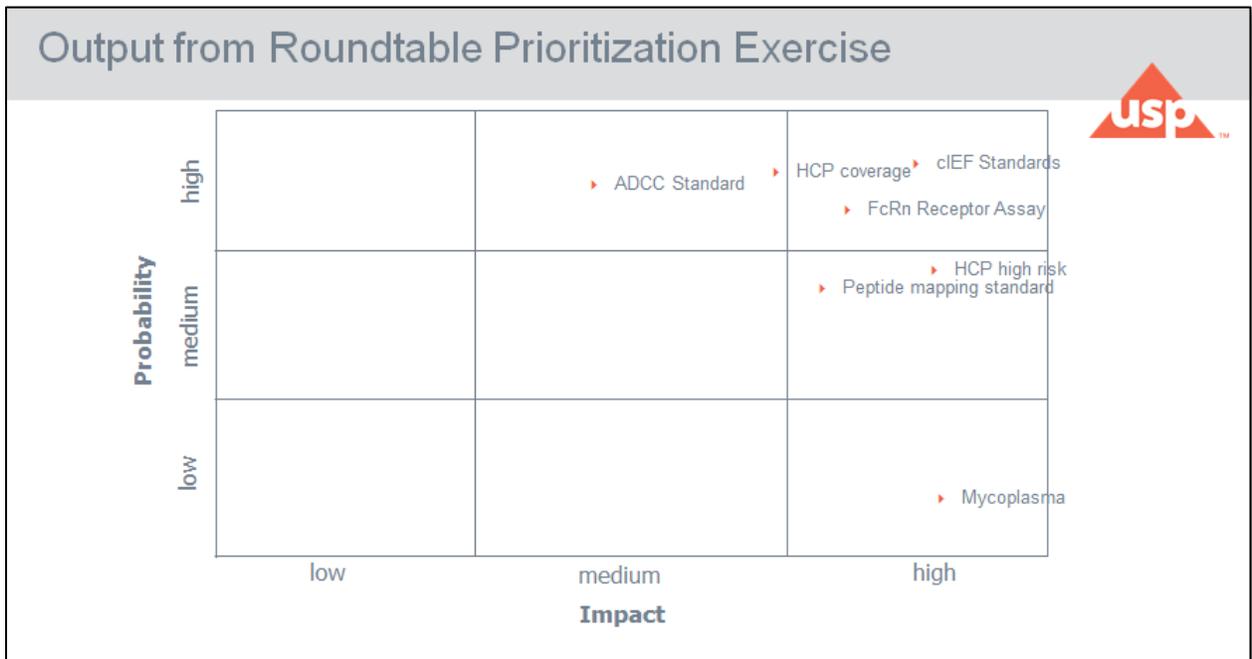
**Major themes from the roundtable:**

- The overriding goal is patient safety, and immunogenicity is a very challenging issue.
- Industry is concerned about ongoing availability/stability of potential performance standards.
- Companies want to know if they will be required to use USP performance standards.
- How simple or complex should the performance standards be?
- Performance standards could have various potential uses and applications:
  - To QC your method (this is the main purpose)
  - To qualify columns
  - For uses beyond the active pharmaceutical ingredient (API)
  - For uses beyond analytical methods
  - For host cell proteins (HCP) coverage

**Prioritization of performance standards:**

- There are many potential performance standards, which need to be prioritized:
  - Roundtable participants completed a prioritization exercise.
  - Performance standards were categorized (graphed) based on low/medium/high impact and probability of success.

Prioritization Criteria Definitions	
Probability	<ul style="list-style-type: none"> <li>• Availability of material</li> <li>• Fits into capabilities of USP</li> <li>• Ability to collaborate on development</li> </ul>
Impact	<ul style="list-style-type: none"> <li>• Broadly applicable across industry and products</li> <li>• High demand</li> <li>• Addresses unmet need</li> </ul>



- Key points for the path forward include:
  - HCPs as an example of major issues to be addressed.
  - Cell culture media and high risk raw materials with implications on critical quality attributes (CQAs) are promising areas to pursue.
  - Cooperation and collaboration will be critical for reaching shared goals.

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 as it will help ensure that USP is delivering on the needs of the biologics community.