



IV

Resolution

Year 1 Resolution Update: Access to Biologics

Resolution

USP will develop standards and other solutions to support innovation in the efficient development and manufacturing of quality biologics and advanced therapies to increase access to these medicines.

Alignment with USP's Mission

USP continues to prioritize its portfolio of standards based on impact, technology, and regulatory considerations, providing a pathway for quality-assured medicines, including biologics. The best practices and requirements delineated in the *USP* General Chapters, as well as the existing monographs, provide the expectations for quality peptides, therapeutic proteins, and vaccines, thereby allowing manufacturers, regulators, and other interested parties to test for quality at any point in the biologics product lifecycle. Furthermore, USP performance standards are intended to support the development of analytical methods and new manufacturing processes, with a goal of facilitating the development of biologics and biosimilars. The evolution and availability of public and transparent quality standards, and adherence to those standards, will build patient and healthcare practitioner confidence in biologics.

Year 1 Update

Key progress areas over the past fiscal year include:

Standards – USP's Biologics program includes development of standards to support analytical testing of peptides, proteins, advanced therapies, and raw materials.

- ▶ USP launched the first set of monoclonal antibody performance standards to support assessment of multiple analytical methods used to evaluate product quality attributes, including identity, post-translational modifications, and aggregation.
- ▶ USP announced a collaboration with the National Institute of Standards and Technology, and the National Institute for Innovation in Manufacturing Biopharmaceuticals to design and implement a multi-laboratory study to assess analytical tools applicable to gene therapies, which will support the development of standards.
- ▶ USP developed a new standard for methoxypolyethylene glycol aldehyde, a raw material used in the production of pegylated protein therapeutics. In addition to the physical standard, a method is provided to assess the quality of the material when used with the recently approved standard.

COVID-19 Vaccines – To respond to the pandemic, USP formed a Vaccine Advisory Group comprised of external subject matter experts who advise USP on matters related to COVID-19 vaccines. We developed and released four toolkits for assessing the quality of COVID-19 vaccines, covering general/compendial tests and quality tests for mRNA, viral vectored, and inactivated vaccines. The toolkits link quality attributes for vaccines with possible methods and supporting chapters in the *USP–NF*.

Asia-Pacific Economic Cooperation – To help advance patient access to innovative therapies, including biologics, the 21 economies in the Asia-Pacific Economic Cooperation (APEC) organization endorsed USP to become an APEC Center of Excellence for Advanced Therapies. As a Center of Excellence, USP will work with regulators across the region in trainings and other forums to build capacity.

Convenings – USP launched the cycle’s Biologics Stakeholders’ Forum and delivered a series of roundtables to gather insight on key biologics topics. These included genomics and precision medicine, and the quality of insulins. USP is also engaging with the biologics continuous manufacturing (CM) community to understand where there is need and opportunity to develop standards to

support CM for biologics. This engagement includes a recently completed roundtable and stakeholders’ forum.

Planned for Year 2

- ▶ USP is engaging with Expert Volunteers and global stakeholders to identify areas where new standards are needed. Current efforts include development of standards to support new therapeutic modalities, such as gene therapy and oligonucleotides, and emerging analytical techniques, such as the multi-attribute method.
- ▶ We are developing additional performance standards for monoclonal antibodies and vaccines, including standards for raw materials and impurities testing.
- ▶ Additional toolkits for other vaccine platforms relevant to COVID-19 are under development.
- ▶ We are continuing to modernize existing standards with a particular focus on replacing animal-based assays with in vitro assays.

Contact

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