Resolution VI: Standards for Biological Medicines

USP will promote alignment with stakeholders to develop quality standards for biological medicines, ensuring that innovation and availability are facilitated and complemented.

USP’s Biologics program is positioned to be the leading choice for scientists in research and development at biologics manufacturers that have the need for standards, tools and education that define quality, increase predictability and consistency of processes, and streamline regulatory approvals. USP Biologics is backed by rigorous science and the expertise of independent volunteer experts from leading industry, academia and regulatory organizations.

The strategy focuses on the development and release of standards that address industry challenges and fulfill the needs of key stakeholders globally. Prioritization of the pipeline takes into consideration several factors, including consensus, feasibility, collaborative opportunities and impact on global public health.

Here are a few ways we are demonstrating our commitment to biologics standards.

In 2019, USP Biologics continued to elevate its commitment to biologics through an increased presence at conferences, including poster sessions and platform presentations. Additional educational offerings were made available, including workshops and webinars that specifically addressed quality challenges in biologic product development.

We conducted multiple roundtable meetings with industry and regulatory agencies. As a result, USP, with input from participants, identified and prioritized standards to benefit global biologics development.

In addition, the USP website features an updated section dedicated to biologics that includes relevant information and publicly available resources. Information contained on the site includes product release announcements; access to downloadable studies, posters, chapters and white papers; opt-in access to a bimonthly newsletter; and access to the company store with a catalog of available standards.

The Biologics program aims to be a leading provider of quality standards, education and resources that help ensure patients receive quality biologic therapies.

Key Accomplishments

- Made considerable progress on the implementation of the new biologics strategy
- Engaged stakeholders who played an integral role in further defining and refining the biologic pipeline
- Released or replaced 24 physical reference standards
- Submitted a total of 37 new and revised monographs and general chapters
- Continued to increase opportunities for collaboration through membership in multiple biologic consortiums, including the National Institute for Innovation in Manufacturing Biopharmaceuticals and BioPhorum