

USP Biologics: The difference is in our process

Commitment and collaboration ensure quality at every step

USP Biologics is addressing today's product development challenges with an ever-expanding portfolio of standards. Our primary focus is development of standards that support analytical testing across many biologics.

- Our rigorous development process ensures reliability and consistency
- Results from our multi-lab testing strategy provide users with confidence that results reflect current analytical capabilities
- **Our customer support team is available to address your questions. Should additional technical support be necessary, the scientist involved in the development of the standard is committed to responding personally to every question in a timely manner.**

5. Approve and release

After multiple levels of quality assessment, USP Expert Committee review data and approve USP standards

4. Test

Each standard is tested in multiple laboratories, which are qualified prior to participation, to ensure consistency and reliability, as well as to establish label values representative of real-world applications

1. Collaborate

USP receives expert insights from thought leaders across multiple constituencies

- Industry
- Regulatory bodies
- Academia
- Healthcare

This helps us identify unmet needs and to explore and validate ideas that could benefit industry and support quality medicines globally

2. Evaluate

USP ascertains whether a proposed standard is feasible and will benefit industry while contributing to public health in a reasonable time frame. USP biologics acquires a reference standard candidate either through donation from industry or direct purchase, to meet the identified standard needs

3. Engage

USP Expert Committee members review and provide input on the standard in development. Industry support for material and testing is a critical part of this process