



Performance and Raw Materials Standards

USP's biological standards support its mission of promoting public health. The early standards for biologics included in the *USP* covered antitoxin products, and evolved over time to a wide range of biological products including complex extracts, peptides, proteins, vaccines, blood products, cell, and tissue based products.

The development process for standards involves collaborating with practitioners, industry, and government agencies. It is important to highlight that the performance and raw materials standards to be generated in this context will be developed in collaboration with USP's stakeholders using the same quality systems used for product specific standards. Comments and queries should be addressed to [Fouad Atouf](#).

Don't Miss Out On These Opportunities!

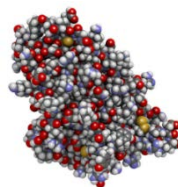
[USP's 7th Bioassay Workshop – Bioassay: A Lifecycle Approach](#), Sept 25–26, 2017 at USP Rockville, MD.

Bioassay Design, Development and Validation [Classroom](#) and [Live Webinar](#), September 27, 2017, 9:00 AM – 5:00 PM EDT, USP Rockville, MD

This one-day bioassay course will focus on the essential factors to be considered in the design, development, and validation of bioassays.

The course introduces related USP general chapters, terminology, bioassay life cycle, important tools and best practices, followed by a detailed discussion on the topics of design and development, robustness, validation, and post-validation. The course ends with an example of a USP pharmacopeial bioassay.

[4th USP Workshop on Synthetic Therapeutic Peptides: Regulations, Standards and Quality](#), November 6–7, 2017 at USP Rockville, MD.



Protein Reference Standards Released!

[Erythropoietin RS](#) now available for use with Epoetin Monograph!

CHO Genomic DNA and **E. coli Genomic DNA** Standards for Chapter <509> Residual DNA testing are in development. [Read on](#) for more information.



[Exenatide Reference Standard](#) joins the Exenatide impurities in your quality testing arsenal.

Triptorelin impurities are in development. Click [here](#) for details.

News in Blood Coagulants



Coagulation Factor VIIa Reference Standard approved, released soon and **Coagulation Factor VIIa for Bioassay** RS is *coming soon!* Read about this news and other Blood-Related information [here](#).



Check out the USP Biologics newsletters, tools and links [here](#).

Collaborative Testing Opportunities

Bivalirudin
Gonadorelin Acetate
Leuprolide Acetate
Albumin Human
Coagulation Factor VIIa for Bioassay

Contact [Dale Schmidt](#) for more information.

Biologics Contacts

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Explore the *NEW* [USP Biologics Webpages](#) for the latest ways we can help you throughout the product development lifecycle.