USP Biologics Newsletter

In this Edition

Standards

In this edition, we are highlighting two USP Biologics Reference Standards (RS): **Filgrastim for Bioassay RS** (newly released standard) and **Monoclonal IgG System Suitability RS** (the first of several monoclonal antibody standards for multiple analytical methods).

USP Filgrastim for Bioassay

The USP Filgrastim for Bioassay RS helps manufacturers ensure that potency measurements are reliable and aligned globally.

Key Features of the USP Filgrastim for Bioassay RS include:

- Potency assigned relative to the WHO 2nd IS for Filgrastim
- Convenient format for use with the cell-based bioassay in the USP Filgrastim monograph
- Rigorously evaluated and tested in 7 collaborating laboratories
- Each ampule contains 96,815 IU of biological activity in a lyophilized format for added stability

The USP **Filgrastim for Bioassay RS is now available for purchase** (as catalog #1270468) in the USP Store.

For more information and/or to receive email updates, please visit our Filgrastim for Bioassay webpage.

USP Monoclonal IgG System Suitability RS

The USP Monoclonal IgG System Suitability RS was developed to ensure consistency and reproducibility of your analytical methods. When characterizing monoclonal antibody products it is important to be sure that your method has the resolution, sensitivity, and specificity needed to achieve your measurement goals. The first USP Monoclonal IgG System Suitability RS was designed to support common monoclonal antibody platform methods contained within USP general chapter <129> *Analytical Procedures for Recombinant Therapeutic Monoclonal Antibodies* measuring aggregates, fragments, and glycans. To support these uses, USP conducted an international round robin study followed by extensive characterization of the RS in six collaborative labs.

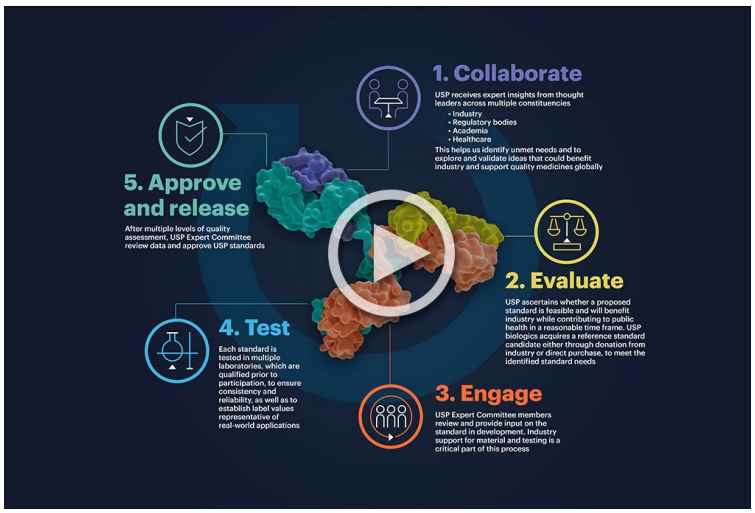
Manufacturers can use this standard to assess the performance of either the chapter <129> methods or their own in-house methods that measure molecular variants, purity, and oligosaccharides of monoclonal antibody therapeutics.

USP's *first* Monoclonal IgG System Suitability RS is now available for purchase (catalog # 1445550) in the USP Store.

More USP monoclonal antibody RS's are coming soon… To learn more and/or be notified when new standards are available, please visit our Monoclonal Antibody System Suitability Standard webpage.

USP Biologics: *The Difference is in Our Process*

Our commitment to quality begins with our process. USP uses a rigorous, comprehensive, and consistent process to identify and develop standards that support characterization biologics.



Our process includes the following steps:

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.
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.
5. **Approve and release:** After multiple levels of quality assessment, USP Expert Committees review data and approve USP standards.

Learn more about our USP Biologics development process by visiting our Biologics Process webpage.

USP in the News

USP Views Early Broad Stakeholder Engagement as Essential in Developing Performance-Based Standards for Biologics

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USP views expanded early engagement with key stakeholders through workshops, roundtable meetings/studies, and relevant articles as an essential component in advancing performance-based standards for biologic products. As biologics treatments evolve, so does USP in our approach to developing new standards. Hear more from USP's Dr. Fouad Atouf's talk at the recent Pharmacopeial Interest Group meeting at the PDA/FDA conference featured in IPQ's story covering the latest on USP's novel approaches to standards development for biologics.

Quality: A Standard Expectation at USP

Society demands and has become accustomed to speed and convenience but not at the cost of quality. This is particularly notable in the area of medicines which represents the pinnacle for our demand for quality. USP has a long-standing heritage and commitment to developing standards that ensure quality medicines are available globally.

"We are all consumers at some point, and we all demand quality products.", writes Meyer Gladstone, Senior Director, USP Biologics Strategic Marketing & Program Operations. In his recently released article, Meyer shares a customer-centric USP Biologics perspective on the need for uncompromising commitment to quality. For example, did you know?... USP collaborates with independent expert volunteers from industry and regulatory agencies to review data and make recommendations on approving standards to be released and made available… Or, that USP provides a customer service team – that includes the scientist who led the standard development – to address a wide range of technical questions regarding reference standards.

Read more from Meyer Gladstone on a commitment to quality in his article Quality: A Standard Expectation.

USP Workshops and Forums

USP Biologics Stakeholder Forum
January 10, 2020 @ 9:00 AM – 5:00 PM
Omni San Francisco Hotel (San Francisco, CA)
Forum is free of charge, but advance registration is required.

Overview: USP will host a Biologics Stakeholder Forum on Friday, January 10, 2020 to provide a collaborative framework for representatives of biologics manufacturers, associations, regulators, and other groups to engage with USP on addressing challenges that occur throughout the development lifecycle that relate to quality standards, tools, and training. The Forum will also serve as a venue for USP staff and volunteers to inform USP Biologics stakeholders of USP initiatives, work in progress, and opportunities to support development of new standards. Dr. Ron Piervincenzi, the CEO of USP, will also be present to share his vision on standards for biopharmaceutical innovation and to answer questions from participants.

Objectives

- To educate USP Biologics' stakeholders on the current strategy and learn about standards in development
- To gather subject matter experts on multi-attribute monitoring (MAM) and to hear case studies from 1 FDA and 2 industry experts about its use in characterization of biologics and opportunities for release testing
- To discuss challenges around implementing these approaches in a GMP environment and to identify standards that might support these innovative approaches supporting quality and efficient testing

Those who should participate include subject matter experts in MAM, Biologics manufacturers, contract research organizations, regulators, and suppliers, whether members of a trade organization or independent.

For more information and to complete the required advance registration, please visit our USP Biologics Stakeholder Forum information page.

CMC for Gene Therapy: Regulations, Standards and Quality
Feb. 18-19, 2020 (USP Meeting Center, Rockville, MD)

Overview: This workshop will include presentations, case studies and panel discussions from subject matter experts in manufacturing, regulation, process development, and analysis of gene therapy products, intermediates, and raw materials.

Reasons to attend the Workshop include:

- To better understand USP's standards in development for gene therapy products
- To learn about new gene therapy targets and novel advances in manufacturing, purification technologies, analytical methods strategies and bioassay
- To learn regulatory expectations for gene therapies
- To provide feedback to USP, regulators, and other workshop participants on challenges and potential solutions to help advance this field
- To network with other manufacturers, scientists, and regulators in this area

For more information, advance registration and/or Call for Abstracts, please visit the CMC for Gene Therapy Workshop information page. Discounted early bird rates are available until January 20th so register soon!

USP at Conferences

PepTalk – The Protein Science Week
January 21 - 24, 2020 (at Hilton San Diego Bayfront, San Diego, CA)

Wednesday, January 22, 2020 at 8:20 am. Dr. Jim Richardson, Senior Science and Standards Liaison, in USP's Global Biologics department will present "USP Standards for Gene Therapy" within the Gene Therapy Analytics

and Manufacturing track. His presentation will provide updated information on existing USP Standards relevant for developers of Gene Therapies, such as Chapter <1047> Gene Therapy Products as well as Chapter <1043> Ancillary Materials for Cell, Gene, and Tissue-Engineered Products. It will also cover USP's development of new physical reference materials to aid developers of Gene Therapies.

You can view the Gene Therapy Analytics and Manufacturing program agenda for more details.

Thursday, January 23, 2020 at 9:00 am. Dr. Jim Richardson will present an additional talk on "USP Standards Development for Cell Therapies" within the Cell Therapy Analytics and Manufacturing track. - This presentation will provide updated information on existing USP Standards relevant to developers of Cell Therapies, such as Chapter <1046> Cell and Gene Therapy Products, as well as Chapter <1043> Ancillary Materials for Cell-, Gene-, and Tissue-Engineered Products. It will also cover USP's development of new physical reference materials to aid developers of Cell Therapies.

You can view the Cell Therapy Analytics and Manufacturing program agenda for more details.

Dr. Huiping Tu will present a poster titled "Development of Standards for Cation exchange chromatography Column Qualification" at Peptalk.

WCBP 2020 (Well Characterized Biotechnology Pharmaceuticals)
January 28-30, 2020 (The Mayflower Hotel, Washington, DC)

WCBP (Well Characterized Biotechnology Pharmaceuticals) will hold its 24th Symposium on the Interface of Regulatory & Analytical Sciences for Biotechnology Health Products.

USP staff will be available to answer questions and share new information on new biologics initiatives and standards in development at booth #24.

To learn more about the conference and to register see the WCBP 2020 web

page. To arrange in advance to meet with staff at the conference please email BioTech@usp.org.

Workshop: Analytical Methods to Support Vaccine Quality
Monday, April 6, 2020 @ 10:00 AM (at the World Vaccine Congress in Washington, DC)

Overview: USP Biologics will gather stakeholders to learn about novel methods and to discuss opportunities to advance these methods in both pharmaceutical QC labs as well as global control laboratories.The workshop will include talks as well as an expert panel to debate these topics and address questions from the audience.

Workshop participants and remarks to include various industry, regulatory and scientific leaders, including USP's Dr. Maura Kibbey, Senior Scientific Fellow.

For more workshop details, please visit the Analytical Methods to Support Vaccine Quality workshop information page.

Our mailing address is:

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Rockville, MD 20852-1790