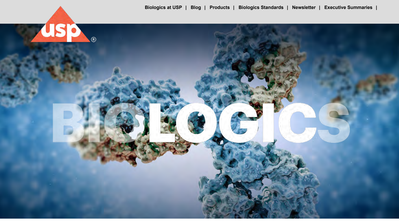


USP continues to lead the way in biologics with new Reference Standards, education opportunities and global outreach. Read all about our efforts to advance the field in this newsletter.

In this issue:

Standards

This month we are highlighting our IgG standard

A common analytical challenge associated with monoclonal antibody products is ascertaining if a specific method can resolve relevant product variants.

The USP monoclonal IgG system suitability standard was developed to address this issue by using a variety of analytical methods confirmed in an international round robin study, and extensive characterization of a monoclonal antibody material at six collaborative labs.

Manufacturers can use this standard to assess the performance of methods that measure molecular variants, purity, and oligosaccharides for monoclonal antibody therapeutics.

Learn more and order

USP Education Events

USP Workshops in China

USP China invites experts and leaders, both domestic and overseas, from regulatory agencies, manufacturing industry, research and development, CRO/CDMO, academic institutions and other standard-setting organizations, to present and discuss perspectives on current landscapes and future opportunities of biologics drugs, GMP manufacturing and regulations, state-of-the-art technologies for biologics quality, updates on biologics standards, and analytical technologies and quality standards for impurities.

A total of six sessions covering recombinant protein and synthetic peptides are listed below. Sessions 1-4 were designed for recombinant protein while sessions 5-6 were designed for synthetic peptides.

Session 1: Regulation expectations for biologics
Session 2: Analytical methodology for biologics characterization
Session 3: Quality Control and Role of International and Pharmacopeials Standards
Session 4: GMP requirements and Manufacture control for recombinant protein
Session 5: Impurity Study of Synthetic Peptide
Session 6: GMP requirements and Manufacture control for synthetic peptide

To register, please contact Dr. Yi Huang, yxh@usp.org or +1 (812) 121-5268.

Future of Endotoxins and Pyrogen Testing: Reference Standards and Procedures Workshop

June 10-11 • Rockville, MD
Be a part of the discussion that will begin to address the challenges that we face as we consider the future of Endotoxin and Pyrogen Testing.

The USP Microbiology Expert Committee has developed this workshop to enable open objective discussions of practical and science-based issues evolving in endotoxin and pyrogen testing. The purpose of this workshop is to consider new reference endotoxin standards and the requirements for the revision of new endotoxins test methods in the near future.

Objectives

- Engage stakeholders and provide background on USP's effort to consider the development of a new reference standard for endotoxins and its potential applications in overcoming test interferences and depyrogenation.
- Discuss experimental design for spike recovery studies and how they can be made more representative of product manufacturing conditions.
- Examine the implementation alternate test methods for endotoxin testing
- Review current challenges and strategies for use of alternate in vitro methods and reference standards for pyrogen testing.

Sign up today

Additional education opportunities from USP

Bioassays: September 18-19 > REGISTER
Peptides: November 4-8 > REGISTER

USP at conferences

USP at WCBP

In January, USP Biologics attended the WCBP Symposium in Washington, DC. The conference was created to address issues at the interface of analytical development and global regulatory for biotechnology-derived health intervention products. The theme of this year's conference was: Patient-centric CMC development: Rigor & speed with purpose. The goal of this Symposium series is to provide a forum for discussing the latest bioanalytical methods and their practical application to biotechnology pharmaceuticals and other health related products. Both state-of-the-art innovations as well as conventional technologies addressing research and routine testing applications were covered.

USP at ASCGT

USP will be hosting an opening reception in the Columbia Room on Monday, April 29 from 5:00 pm–6:00 pm at the Annual ASCGT Conference in Washington, DC. Visit our table to learn more about our updated chapters on cell and gene therapy.

Learn about **USP Standards for Cell and Gene Therapy** from Jim Richardson, Ph.D., Senior Science and Standards Liaison– Biologics, USP during the poster session in the Columbia Room on Monday, April 29 from 5:00 pm–6:00 pm.

Attend **USP Approaches to Standards for Cell and Gene Therapies** presented by Fouad Atouf, Ph.D., Vice President, Science–Global Biologics, USP in the Lincoln Room on Tuesday, April 30 from 8:00 am–10:00 am.

USP at TIDES

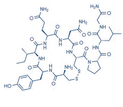
May 20-23 • Manchester Grand Hyatt San Diego – San Diego, CA
Visit us at Booth # 323 and learn about our latest peptides standards for biologics.

Past event highlights

USP's team wins best poster award

"Survey of Peptide Quantification Methods and Comparison of their Reproducibility: A Case Study Using Oxytocin" is a winner! A huge congratulations to the team led by Dr. Trish Li and Dr. Ram Bhavaraju. The poster presented by Dr. Fouad Atouf, USP's VP of Science - Global Biologics, won the best poster award at this week's International Symposium on Pharmaceutical Reference Standards in France. > Read the poster.

Survey of peptide quantification methods and comparison of their reproducibility: A case study using oxytocin



Abstract
USP's peptide reference standards content is typically determined using an HPLC assay against an external standard for which the purity was determined by a mass balance approach. To explore the use of other analytical methods, the USP Biologics Department conducted a multi-laboratory collaborative study. The study determined the inter-laboratory variability for peptide quantitation using the following methods: HPLC assay, quantitative nuclear magnetic resonance (qNMR) spectroscopy, or amino acid analysis (AAA). The three methods were compared with regard to their suitability for quantitation of the nonapeptide oxytocin. In this study, the HPLC assay method using the same peptide bulk material as the standard showed the lowest inter-lab variability. The coefficient of variation (%CV) was calculated without counting the uncertainty associated with the purity assignment of the standard with mass balance. The proton qNMR method is a direct measurement of the peptide against an internal standard, which is not difficult to perform under common laboratory conditions. Because of the simpler operation and shorter analytical time, qNMR as a primary method for peptide reference standard value assignment deserves further exploration.

Download complete article

USP India Biologics - Roundtable on Biological Standards

February 4, 2019 • Hotel Westin – Hyderabad, India
Scientific leaders from biopharmaceutical companies, regulatory agencies, and academia from India and South Korea came together for a roundtable focused on key quality challenges that the Biopharma industry faces as pertains to analytical methods and technologies for therapeutic proteins. The participants discussed the types of standards that would alleviate analytical performance of their methods and shared perspectives representing industry and regulators through their product development and regulatory experiences.

Potential standards for analyzing key quality attributes of therapeutic proteins were listed and discussed. A prioritization exercise was done, and specific standards identified were rated based on potential impact and probability/feasibility of successful standard development by USP. The prioritization exercise was a culmination of views from Industry, Academia and Regulatory, hence reflecting a comprehensive outcome from all stakeholders.

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