Biologics

Fall Newsletter

USP´s 7th Bioassay Workshop - Bioassay: A Lifecycle Approach

USP´s 7th Bioassay Workshop, A Life Cycle Approach was held September 25-26, 2017 at USP in Rockville MD. The workshop focused on Life Cycle Management of bioassays and how the principles in the USP Bioassay chapters are applied throughout the life cycle of a bioassay. Statistical, industry and regulatory perspectives were presented for each stage of the Life Cycle Approach to Bioassays: Stage 1, Method Design and Development; Stage 2, Procedure Performance Qualification; and, Stage 3, Continued Procedure Performance Verification. Key concepts in Life cycle management of bioassays such as the Analytical Target Profile (ATP), risk management and control strategy were discussed in USP´s 7th Bioassay workshop. Software vendors participated in a round table to discuss the challenges of bioassay software in today´s dynamic laboratory environment. Attendees contributed insights into issues with implementing a life cycle approach in development of new drugs.

USP Biologics is developing new guidelines to help organizations prioritize risk and ensure raw material quality.

As raw materials are a large component of the biopharmaceutical supply chain and have potential to introduce adventitious agents, raw material qualification is extremely important. Read more about USP´s approach to assessing risks of raw and ancillary materials as well as qualification programs.

Higher Order Structure Stimuli Article Published in PF for

Order USP Coagulation Factor VIIa Reference Standard

Use USP´s Coagulation factor VIIa RS to establish system suitability for peptide mapping, degraded heavy chain and oxidized forms, and glycan analysis. Typical chromatograms provided for all three methods including peak identification of glycans.Click here to comment on the Eptacog Alfa Activated monograph, now in *Pharmacopeial Forum*.

Order Now!

Other recent F-Lots include PS NMR System Suitability Standard

Use this standard in conjunction with validated method in General Chapter <198> Nuclear Magnetic Resonance Spectroscopy Identity Testing of Bacterial Polysaccarides Used in Vaccine Manufacture, available for complimentary download here.

Comments

Characterization of higher order structure (HOS) is an important aspect of research and development for biologic drugs. During the development of a new protein-based biopharmaceutical, HOS characterization is a critical step because the protein HOS will play a key role in the function and safety of the drug product. As an outcome of the industry roundtable hosted by USP Biologics, USP has recently published a stimuli article on this topic which is currently open for comments in PF 43(6).

USP provides complimentary on-demand webinar covering Packaging System Quality

As a result of improvements in analytical techniques and industry best practices, USP is taking a closer look at standards associated with plastic, glass, and elastomeric materials used to package pharmaceutical products and the biocompatibility testing of these materials. USP´s complimentary, on-demand webcast will provide an overview of current revision efforts by USP to modernize its packaging material and packaging system standards. Click here for more information.

Learn *more* about USP's Biologics Standards

Visit Biologics at usp.org

or go directly to the

Blood-related Standards **or** **Vaccines** pages.

Empowering a healthy tomorrow