USP Biologics Newsletter

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Standards – Residual DNA

This month we are highlighting our Reference Standards for measurement of residual host cell DNA: two USP Reference Standards for residual DNA: CHO genomic DNA and E. coli genomic DNA

Residual host cell DNA must be minimized as much as possible during production of therapeutic proteins. The removal or reduction of host cell DNA is, therefore, mandatory for biopharmaceuticals, requiring accurate and sensitive tests to quantify such impurities and to meet guidelines established by regulatory agencies.

Now available – Two highly characterized Reference Standards for residual host cell DNA: CHO genomic DNA and E. coli genomic DNA with the following benefits:

- highly sensitive and specific residual genomic DNA measurement method
- optional protein extraction procedure to minimize sample matrix effects
- no kit required
- primer and probe sequences provided
- flexibility in labeling oligonucleotides

Additionally, USP General Chapter <509> Residual DNA Testing that features:

- a publicly available, validated method to detect residual genomic DNA
- confirmed primer and probe sequences that provide flexibility in choice of labeling reagents

Provide Your Input to Inform New USP Standards for Biologics!

Complete this brief online survey.

USP is developing standards that support specific assays or technologies and that are applicable across a class or multiple classes of biotherapeutics.

Standards for mass spectrometry applications have been identified as an industry need. MAM/peptide mapping is one area USP is pursuing. USP would like to better understand the methods and software that are currently being used in industry and the most critical modifications to monitor in a MAM study in order to best align our work with industry needs. USP is also interested in gathering feedback on the utility of a pre-digested mAb standard and an intact mAb standard for mass spectrometry applications.

Your response to this survey will be greatly appreciated and will help shape the development of USP standards for Biologics.

USP in the News

FDA's "Show Me The Data" A Recipe For Tailored Biosimilar Development?

In the first of two interviews, Fouad Atouf, the VP of global biologics, science and standards, for U.S. Pharmacopeia (USP), Atouf highlights the challenges

presented by the FDA's newest guidance.

USP Workshops

USP Peptide/Oligonucleotide Workshop
November 4-5 (in Rockville, MD)

This workshop continues USP's efforts to inform public standard setting for therapeutic peptides and peptide vaccines while introducing similar considerations for therapeutic oligonucleotides.

Key Session Topics:

- Challenges in measurement and specification setting, particularly for impurities
- Innovative analytical and manufacturing technologies
- Immunogenicity
- Bioassays for complex products
- Peptide vaccines: analytical and regulatory strategies
- Oligonucleotide products
- Peptide and oligonucleotide standards
- Regulatory expectations for peptides and oligonucleotides
- Raw materials
- Manufacturing and control strategies

For more information, including the agenda and registration, visit the USP Peptide/Oligonucleotide Workshop information page.

USP at Conferences

USP at Cell and Gene Meeting on the Mesa

In October, USP Biologics will attend and present at the 2019 Cell and Gene Meeting on the Mesa in Carlsbad, CA. The Cell & Gene Meeting on the Mesa is the sector's foremost annual conference bringing together senior executives and top decision-makers in the industry to advance cutting-edge research into cures. Tackling the commercialization hurdles facing the cell and gene therapy sector today, this meeting covers a wide range of topics from clinical trial design to alternative payment models to scale-up and supply chain platforms

for advanced therapies.

For more information, visit USP Biologics.

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