USP Biologics Open Forum:
April 28, 2021, 11am - 12pm EDT

Shaping Tomorrow’s Solutions to Today’s Biologics Quality Challenges:

Update on USP’s Work Supporting Multi-Attribute Methods for Biologics
USP Welcome and Opening Remarks

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Agenda

- USP Welcome and Opening Remarks
- 2020 Stakeholder Forum Overview and USP Multi-Attribute Method Expert Panel
- Update on MAM Laboratory Studies and Future Plans
- Open Discussion with Questions from the Audience
- Final Remarks/Next Steps
“The value of the Pharmacopoeia depends upon the fidelity with which it conforms to the best state of medical knowledge of the day.”
- Jacob Bigelow, MD, 1808
For quality standards to be impactful, they must be...

- **Aligned with**
  Public health and patient safety priorities

- **Adapted & Improved**
  For technology and evolution of healthcare

- **Measured by**
  Public health impact indicators

- **Developed by**
  Independent experts

- **Practical for**
  - Users of the standard
  - Enforcers of the standard

- **Informed by**
  Real world implications for patients and practitioners
USP 2020-2025 Expert Committees

**Biologics**

- Biologics Monographs 1 - Peptides & Oligonucleotides
  - Michael De Felippis
- Biologics Monographs 2 - Proteins
  - Wendy Saffell-Clemmer
- Biologics Monographs 3 - Complex Biologics & Vaccines
  - Earl Zabackis
- Biologics Monographs 4 - Antibiotics
  - Matthew Borer
- Biologics Monographs 5 - Advanced Therapies
  - Mehrshid Alai

**Small Molecules**

- Small Molecules 1
  - Mary Seibel
- Small Molecules 2
  - Justin Pennington
- Small Molecules 3
  - Eric Kessler
- Small Molecules 4
  - Kim Huyhn-Ba
- Small Molecules 5
  - Amy Karren
- Over-the-Counter (OTC) Methods & Approaches
  - Raphael Ornaf

**Excipients**

- Simple Excipients
  - Eric Munson
- Complex Excipients
  - Otilia Koo
- Excipients Test Methods
  - Chris Moreton

**General Chapters**

- General Chapters - Dosage Forms
  - Martin Coffey
- General Chapters - Chemical Analysis
  - Nancy Lewen
- General Chapters - Microbiology
  - Donald Singer
- General Chapters - Packaging & Distribution
  - Renaud Janssen
- General Chapters - Measurement & Data Quality
  - Jane Weitzel
- General Chapters - Statistics
  - Charles Tan
- General Chapters - Physical Analysis
  - Xiaorong He

**Healthcare Quality & Safety**

- Nomenclature & Labeling
  - Stephanie Crawford
- Healthcare Safety & Quality
  - Melody Ryan
- Compounding
  - Brenda Jensen
- Healthcare Information & Technology
  - Jeanne Tuttle

**Dietary Supplements & Herbal Medicines**

- Botanical Dietary Supplements & Herbal Medicines
  - Robin Marles
- Non-botanical Dietary Supplements
  - Guido F Pauli
- Dietary Supplements Admission Evaluation & Labeling
  - Tierona Low Dog
- Food Ingredients
  - Jon DeVries
USP Biologics is expanding standards development to support testing throughout the product lifecycle and beyond

- Early engagement of stakeholders to identify common bottlenecks and identify solutions
- Focus on analytical tools and alignment with global norms
- Support raw materials qualification and biomanufacturing
- Address complementary tests, technologies, and tools that impact product and patients
Collaboration is key to standards relevance

- Early engagement of stakeholders (industry, regulators, academia, other pharmacopeias)
- Industry roundtables to discuss needs, challenges, potential standards, next steps
- Ongoing engagement with global partners, e.g.
  - APEC Regulatory Harmonization Steering Committee and associated centers of excellence
- Collaboration with industry groups, and standards setting organizations
  - BioPhorum
  - National Institute for Innovation in Manufacturing Biopharmaceuticals
  - National Institute of Standards and Technology
  - Standards Coordinating Body
Thank You

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Stay Connected
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