

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



Celebrating 200 years since our founding in 1820

“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...



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 Zablackis

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 Huynh-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, Food Ingredients



Botanical Dietary Supplements & Herbal Medicines

Robin Marles

Non-botanical Dietary Supplements

Guido F Pauli

Dietary Supplements Admission Evaluation & Labeling

Tieraona Low Dog

Food Ingredients

Jon DeVries

Enabling a culture of quality



- ▶ 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 centres 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



Empowering a healthy tomorrow

Stay Connected

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