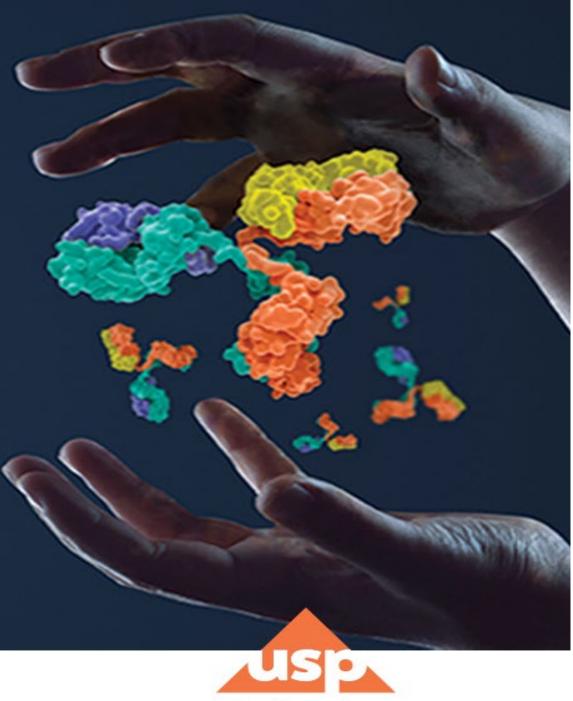
USP Biologics Open Forum: April 28, 2021, 11am - 12pm EDT

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

Update on USP's Work Supporting Multi-Attribute Methods for Biologics



Biologios

USP Welcome and Opening Remarks

Fouad Atouf, Ph.D. Vice President–Science, Global Biologics, USP



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. Que to the second of the second o

Adapted & Improved

For technology and evolution of healthcare

Measured by Public health impact indicators

Practical for

- Users of the standard
- Enforcers of the standard

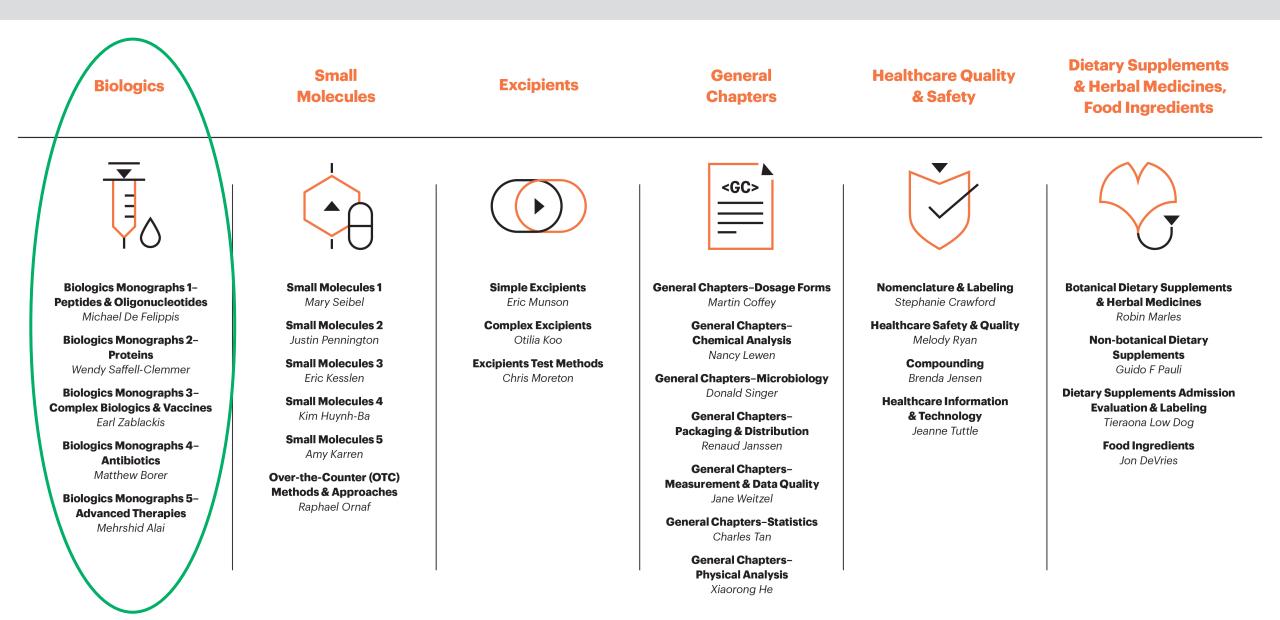
Informed by

Real world implications for patients and practitioners

5 © 2019 USP

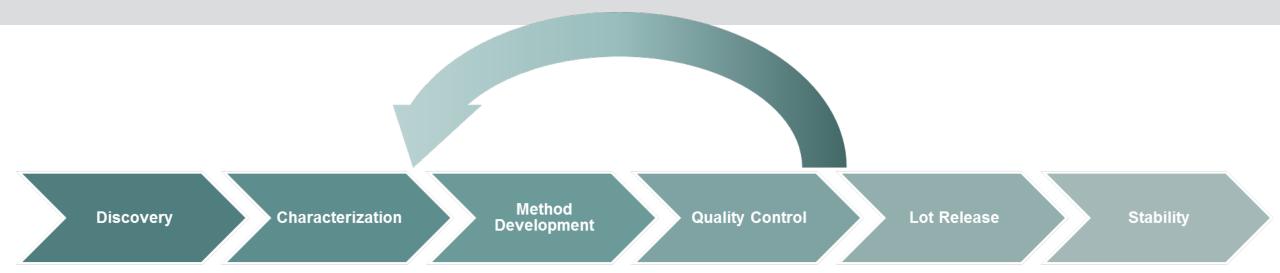
USP 2020-2025 Expert Committees





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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Empowering a healthy tomorrow