Objectives for Today's Biologics Stakeholder Forum

Edward Chess, Ph.D.
USP Biologics Stakeholder Forum
Planning Committee Chair

The standard of trust

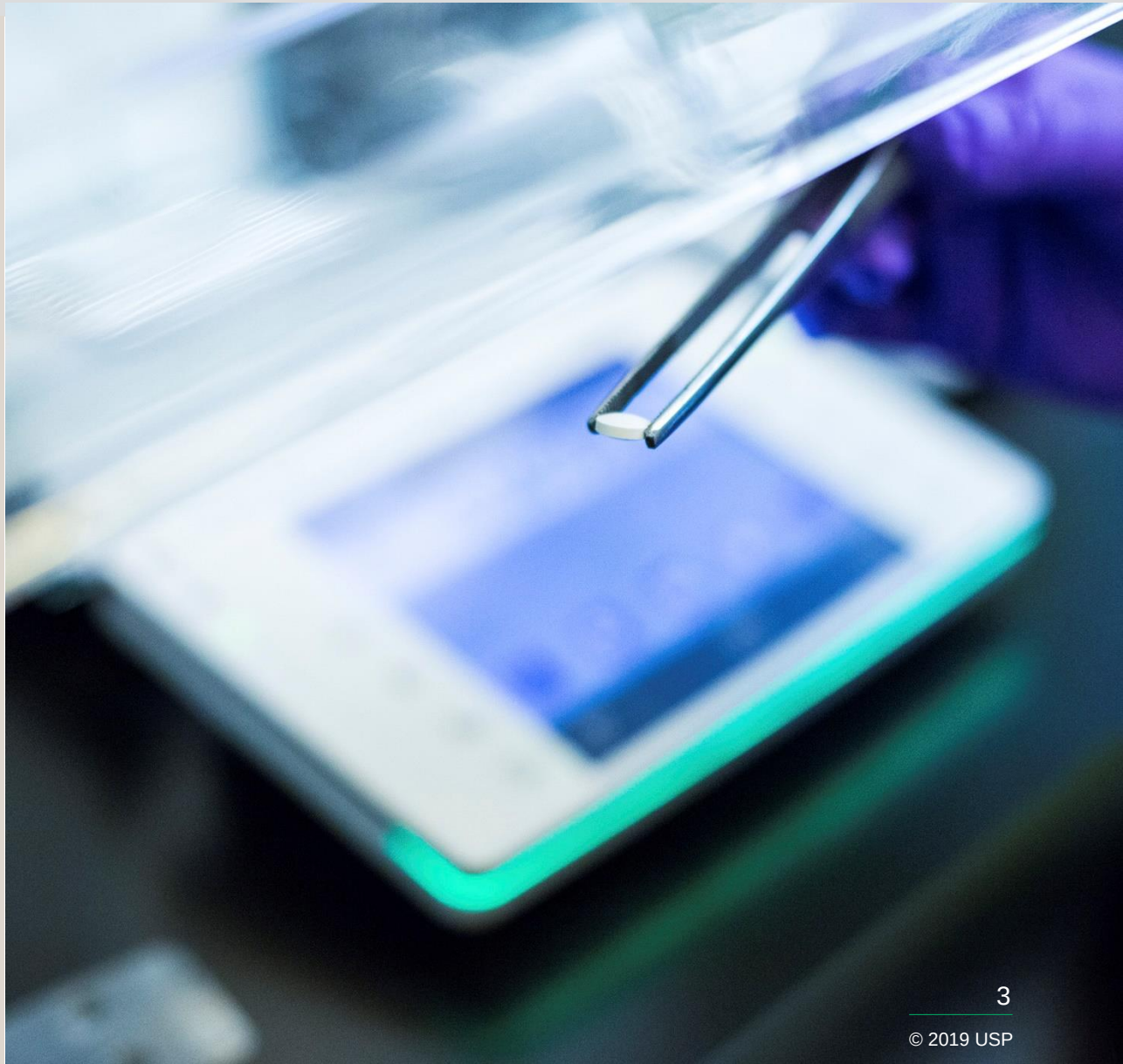
Biologics Stakeholder Forum (SF) charter

The goals of the Biologics Stakeholder Forum are:

1. To learn the needs of biologics stakeholders that may intersect with USP's core capabilities.
2. To share new information with the stakeholders and obtain feedback.
3. To recruit volunteers to support USP's Council of Experts.
4. To identify subject matter experts who can provide guidance or resources to support the execution of USP's biologics strategy.

2022 Biologics SF planning committee

- Ed Chess, Chair, Consultant, USA
- Linda Narhi, Consultant, USA
- Ben Clarke, USP
- Gael Debauve, UCB, Belgium
- Lauren Drouin, LogicBio Therapeutics, USA
- Marcus Haindl, Roche Diagnostics, Germany
- Maura Kibbey, USP
- Kik-Seong (KS) Lim, Metagenomi, USA
- Jacqueline D. Starkes, USP
- Nathan Weinstock, Biogen, USA



Multi Attribute Methods for Biologics

Topics & Speakers

- Development and Application of a Multi-Attribute Method (MAM)
  - Jette Wypych, Ph.D., Amgen
- Enhancing Biotherapeutic Process and Product Knowledge with the Multi-Attribute Method (MAM)
  - Andrew Dawdy, Ph.D., Pfizer
- Quality Considerations for the Multi-Attribute method (MAM)
  - Sarah Rogstad, Ph.D., FDA
- USP Standard to Support Multi-Attribute Methods (MAM) and Mass Spectrometry,
  - Diane McCarthy, Ph.D., USP

First Biologics SF, Jan 10, 2020

Discussion and Outcomes

- Recommendations from breakout sessions
  - There is a need for best practices for MAM and attendees supported developing a general chapter on best practices for MAM
  - Physical standards will be useful, with particular interest in matched sets of intact and pre-digested mAbs
- Outcome
  - MAM Expert Panel has drafted a general chapter on best practices (targeting PF49(4))
  - Digested USP mAb001, 002, 003 standards in development with external partner
- Other MAM activities
  - Collaborations to assess MAM – focus on sample preparation and tech transfer
  - USP MAM Exchange Online Community - join at mam.usp.org

Innovative Analytical and Digital Solutions to Advance Biomanufacturing and Product Quality

Topics & Speakers

Day 1 Analytical Day

- CHO Cell Process Monitoring of Quality Attributes using Raman Spectroscopy at Manufacturing Scale
  - Caitlin O'Mahony Hartnett, Ph.D., Scientist, Janssen Sciences Ireland
- In-line Viral Inactivation: Monitoring Key Process Parameters to Ensure Effectiveness
  - Michael Phillips, Ph.D., Director-Bioprocess Development, MilliporeSigma
- Enabling Real Time Release Testing (RTRT) with Multi-Attribute Methods
  - Galahad Deperalta, Ph.D., Senior Scientist and Innovation Group Leader, Analytical Development and Quality Control, Genentech

Innovative Analytical and Digital Solutions to Advance Biomanufacturing and Product Quality

Topics & Speakers

Day 2 Digital Day

- **How can in silico Models be Accepted in lieu of Lab Experiments and Manufacturing Runs?**
  - Marcus Fiadeiro, Associate Director, Purification Development, Sanofi
  - Siddhartha Jain, Ph.D., Director, MSAT Digital, Sanofi
- **The Potential of Hybrid Process Modeling and Digital Twins to Master the Goals of Industry 4.0 in Bioprocessing**
  - Michael Sokolov, Ph.D., COO and Co-Founder of DataHow AG
- **Advanced Technology for Manufacturing Process Control**
  - Riley Myers, Ph.D., Emerging Technology Team/OPQ and Lead Biologist, Office of Biotechnology Products, CDER, US FDA

Second Biologics SF, Aug 10 & 12, 2021

Discussion and Outcomes

- Recommendations from breakout sessions
  - USP to focus on analytical solutions as digital solutions are not yet mature enough for standardization
  - Host a roundtable on PAT for biomanufacturing
- Outcome
  - USP Roundtable on Implementation of At-Line and In-Line Analytical Tools for Biomanufacturing Process Development and Monitoring held Feb 24, 2022
    - USP to compile the ideas shared by the experts into a technical article outlining challenges and proposals to address those challenges
  - Creation of In-line/At-line Monitoring and Real-time Release Testing Expert Panel to draft a chapter on best practices
    - Call for Candidates for Expert Panel membership open now!

USP Biologics Stakeholder Forum Webinar

NOTICE TO PARTICIPANTS:

- During the main meeting, virtual attendees were muted. Please ask questions or make comments at any time by using the Q&A feature.
- Questions will be collated for the Q&A/Panel discussion after all the speakers have presented.
- Questions may be initially posed for one speaker, but other speakers are also free to join in and provide answers
- Today's event will be recorded strictly for note-taking purposes and destroyed afterward.
- You will receive a satisfaction survey after today's event. Please send us your input!

Questions VIA the Q&A Feature:

- Open the Q&A function by clicking on the 3 dots at the bottom of the screen and then clicking on Q&A.
- All questions/comments should be sent to "everyone."

Questions during the afternoon moderated session:

- Attendees in person should use the microphones near them to ask or respond to questions from the moderator. Virtual attendees can submit questions via the Q&A feature, and a USP staff member will read your question to the moderator when possible.

Third Biologics SF, Oct 26, 2022

Collaborating to Solve CMC Challenges and Support Efficient Development of Lentiviral-Mediated CAR T Cell Therapies

8:45 a.m. – 9:15 a.m.	**Registration and Information** Meeting Center Foyer
9:15 a.m. – 9:30 a.m.	**USP Welcome and Opening Remarks** Speaker: Maura Kibbey, Ph.D., Director, Biologics Marketing, USP
9:30 a.m. – 9:40 a.m.	**Introduction and Objectives for today's Biologics Stakeholder Forum** Moderator: Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair
9:40 a.m. – 10:05 a.m.	**USP standards to support the development of cell and gene therapy products** Speaker: Ben Clarke, Ph.D., Senior Scientist II, Global Biologics, USP
10:05 a.m. – 10:30 a.m.	**Regulatory Considerations for the Development of Potency Assays during CAR T Cell Development** Speaker: Andrew Timmons, Ph.D., Biologist, U.S. Food and Drug Administration (FDA)

Third Biologics SF, Oct 26, 2022

Collaborating to Solve CMC Challenges and Support Efficient Development of Lentiviral-Mediated CAR T Cell Therapies

10:30 a.m. – 10:55 a.m.	**Approaches to Potency Testing for Chimeric Antigen Receptor T Cells** Speaker: Shree Joshi, Senior Scientist, BioTD, Analytical Development, Janssen Pharmaceutical
10:55 a.m. – 11:10 a.m.	**Morning Break**
11:10 a.m. – 11:35 a.m.	**Implementation of QbD principles in potency assay development and overcoming challenges on the road to commercialization** Speaker: Kim Nguyen, Ph.D., Head of Product Attribute Sciences, Kite Pharma
11:35 a.m. – 12:00 p.m.	**Q&A Panel Discussion** Moderator: Edward Chess, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Chair Panelists: Fouad Atouf, Ben Clarke, Andrew Timmons, and Shree Joshi
12:00 p.m. – 1:00 p.m.	**Lunch and networking break for in-person attendees**

Third Biologics SF, Oct 26, 2022

Collaborating to Solve CMC Challenges and Support Efficient Development of Lentiviral-Mediated CAR T Cell Therapies

1:00 p.m. – 4:30 p.m.	**Moderated Discussion** Moderator: Kok-Seong (KS) Lim, Ph.D., Senior Director of Analytical Sciences, Metagenomi • Biological activity and potency • Safety (replication-competent virus, integration, etc.)
2:30 p.m. – 2:45 p.m.	**Afternoon Break**
4:30 p.m. – 5:00 p.m.	**Next steps and closing remarks** Speaker: Linda Narhi, Ph.D., USP Biologics Stakeholder Forum Planning Committee, Vice-Chair

Your moderators

- Ed Chess, Ph.D., Consultant
- Linda Narhi, Ph.D., Consultant
- KS Lim, Ph.D., Metagenomi

Thank You

Empowering a healthy tomorrow