



International Alliance for
Biological Standardization

Basel, Switzerland

September 14-15, 2022

Globally Harmonized Specifications: Current State and Future Opportunities

Brainstorming opportunities to harmonize biological specifications globally.

Current regulatory guidance includes general principles regarding the product specification but provides limited detail about important aspects of its determination. Regional differences include:

- which attributes are included;
- what test is used to measure an attribute;
- what data to use when determining acceptance criteria, and
- how to control attributes which are not related to safety or efficacy.

In this workshop we will discuss the basis of a biologicals control strategy including patient-centric specifications, identification of CQAs, use of prior knowledge, and how the control strategy relates to manufacturing consistency. There will be breakout sessions to maximize participant contributions and an extended panel session with global regulators, compendial officials, and industry representatives to discuss the challenges of regional legal and process differences. To maximize impact, this workshop is scheduled to precede the ICH Q6AB review and revision meeting of the ICH Quality Discussion Group scheduled for November, 2022.

Participants will gain understanding of the challenges and impediments to harmonization of specifications, helping provide feedback and ideas to the global biologicals community and guidance organizations through publication of a white paper in the journal *Biologicals*

Scientific Committee:

- **Shawn Novick**, Co-Chair, IABS
- **Mats Welin**, Co-Chair, Swedish Medical Products Agency
- **Svein Rune Andersen**, Norwegian Medicines Agency
- **Kris Barnthouse**, Johnson & Johnson
- **Karoline Bechthold-Peters**, Novartis
- **Cristiana Campa**, GSK Vaccines
- **Andrew Chang**, Novonordisk
- **Markus Goese**, Roche
- **Melody Gossage**, Eli Lilly and Company
- **Emily Jing**, FDA - CDER
- **Mourad Mellal**, Catalent
- **Laurent Mallet**, EDQM
- **Barbra Rellahan**, Amgen
- **Tim Schofield**, IABS
- **Karin Sewerin**, BioPharmaLinx AB
- **Dean Smith**, Health Canada
- **Tami Wu**, Seagen

[Register here](#)



SCAN ME

Venue :

Kunstmuseum Basel
Fine Arts Museum Basel