International Alliance for Biological Standardization

Nagai Memorial Hall of the Pharmaceutical Society of Japan, Tokyo

June 23-25, 2025

IABS Workshop on Global Harmonization of Specification: Implementing A Patient-Centric Control Strategy

A key component for a biologicals control strategy to ensure safety and efficacy is the product specification. Current regulatory guidelines include general principles regarding establishing specifications, with a focus on analytical technologies used for batch release and stability testing, but provide limited detail about science and the use of risk-based approaches to define a product specification. This creates regional differences in regulatory requirements and their interpretations, which increases complexity of product supply chain, and decreases patient access in global distribution.

In the fourth IABS workshop focused on global harmonization of specifications, we expand further the discussion on patient-centric product specifications, the role of the release specification in the overall quality control strategy, potential specific considerations for different product modalities (e.g., vaccines, biotherapeutics, and cell/gene therapies), lifecycle management, and the global regulatory landscape on specification requirements. Case studies and tools used to support patient-centric specifications will be shared and discussed. In addition, a key question relevant to all product modalities will be, in the absence of safety and efficacy issues with a marketed product, is there scientific justification for tightening a specification based on increased manufacturing consistency?

This workshop compliments other activities and organizations working towards the goal of global harmonization and improving access of biologicals.

Participants in this IABS workshop will gain understanding of the challenges and opportunities to global harmonization of specifications through the discussion of tools and solid examples where patient-centric specifications – i.e. specifications which help ensure safety and efficacy of the drug product by using risk management, process knowledge, and analytical understanding – were successful in preparing and receiving approval for a biologic.

Scientific Committee:

- **Shawn Novick** - Co-Chair, IABS, USA
- **Yoji Sato** - Co-Chair, National Institute of Health Sciences, Japan
- **Kelley Burridge** - CDER-FDA, USA
- **Cristiana Campa** - GSK, Italy
- **Andrew Chang** - Novo Nordisk, USA
- **Gerald Gellermann** - Novartis, Switzerland
- **Melody Gossage** - Lilly, USA
- **Akiko Ishii** - National Institute of Health Sciences, Japan
- **Michael Jordan** - MSD, Ireland
- **John Kim** - Bill & Melinda Gates Medical Research Institute, USA
- **Andrew Lennard** - Amgen, UK
- **Robin Levis** - CBER-FDA, USA
- **Mourad Mellal** - Catalent, Belgium
- **Bart van Montfort** - Johnson & Johnson, Netherlands
- **Akira Sakurai** - PMDA, Japan
- **Dean Smith** - Health Canada, Canada
- **Cecilia Tami** - Genentech, USA
- **Emily Xianghong** - CDER-FDA, USA
- **Satoshi Yasuda** - National Institute of Health Sciences, Japan

Venue:
Nagai Memorial Hall of the
Pharmaceutical Society of Japan
12-15, 2-chome, Shibuya,
Shibuya Ward, Tokyo

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