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

June 23-25, 2025

Tokyo, Japan

ABSTRACT

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
Kelley **BURRIDGE –** CDER-FDA, USA
Andrew **CHANG –** Novo Nordisk, USA
Melody **GOSSAGE –** Lilly, USA
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Akiko **ISHII –** National Institute of Health Sciences, Japan
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Bart **VAN MONTFORT –** Johnson & Johnson, Netherlands
Dean **SMITH –** Health Canada, Canada
Emily **XIANGHONG –** CDER-FDA, USA

ORGANIZING COMMITTEE

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Dean **SMITH**, Health Canada, Canada
Yoji **SATO -** Co-Chair, National Institute of Health Sciences, Japan
Madinina **COX,** IABS Secretariat, France

PROVISIONAL AGENDA

Monday 23 of June, 2025

8.30-9.00am *Registration and Welcome Coffee*

9.00-9.15am **Welcome address**
Yoji Sato (NIHS, Japan) and Shawn Novick (IABS)

KEYNOTE SESSION

9.15-10.00am **Dr. Masayo Takahashi**

10.00-10.30am *Morning Coffee-Break*

SESSION 1 - Common/general Principles of using the Patient Centric or Enhanced approach to setting specifications for a product, including modality considerations

Moderator: Dean Smith, Health Canada & Cristiana Campa, GSK, Italy

10.30-11.00am **Summary of outcomes and key messages from previous GHS meeting**
Phil KRAUSE, USA

11.00-11.30am **ICH Q6 review status**
Ingrid MARKOVIC, ICH Q6 Regulatory Chair, USFDA, USA (Virtual)
Akiko ISHII-WATABE, ICH Q6 EWG, NIHS, Japan

11.30-12.00pm **Industry perspective on ICH Q6 review, with focus on Japan/ Asia region opportunities**
Takahiro YAMAGUCHI, ICH EWG member for JPMA, Japan

12.00-2.00pm *Lunch* - **POSTER SESSION**

SESSION 2 - Using traditional and enhanced approaches to setting specifications and the impact on life-cycle management

Moderator: Andrew Chang, Novo Nordisk, USA & Bart van Monfort, Johnson & Johnson, Netherlands

2:00-2.30pm **Justification of Specifications**
Rafeek SHOKRY, EDA, Egypt

2.30-3.00pm **Specification Consideration for CGT Products**
Kaushik SARKAR, Novo Nordisk A/S, Denmark

3.00-3.30pm **Use Post-Approval Change Management Protocol for Specifications Lifecycle Management of CGT Products**
Peter MILLILI, Janssen, USA

3.30-4.00pm *Afternoon Coffee-Break*

SESSION 3 – Panel discussion

4.00-5.15pm Phil KRAUSE, USA
Ingrid MARKOVIC, ICH Q6 Regulatory Chair, USFDA, USA (Virtual)
Akiko ISHII-WATABE, NIHS, Japan
Takahiro YAMAGUCHI, ICH EWG member for JPMA, Japan
Rafeek SHOKRY, EDA, EgyptKaushik Sarkar, Novonordisk, Denmark
Peter MILLILI, Janssen, USA
Andrew CHANG, Novo Nordisk, USA

Tuesday 24 of June, 2025

8.00-8.30am *Registration and Welcome Coffee*

8.30-8.45am **Welcome address**

SESSION 4 - Case studies: Can the enhanced approach be successful? How do we justify ranges and what is the feedback encountered?

Moderator: Robin Levis, CBER-FDA, USA & Gerald Gellermann, Novartis, Switzerland

8.45-12.00pm **Case studies: Can the enhanced approach be successful? How do we justify ranges and what is the feedback encountered? – Part 1**

- **Science and Risk-based approaches to Specifications: Application to rapid development of Antibody-drug conjugates**
  Keiko FUNATO, GSK

2 speakers TBD (GSK, Lilly, Amgen)

10.30-11.00am *Morning Coffee-Break*

11.00-12.00pm **Case studies: Can the enhanced approach be successful? How do we justify ranges and what is the feedback encountered? – Part 2**

2 speakers TBD

SESSION 5 – Panel discussion

12-1.30pm **Speakers from Session 3**

1.30-2.30pm *Lunch break*

SESSION 6 - Focus on Global landscape – one speaker and extended regulatory panel (ICH, ISO, Recognition, Reliance, Pharmacopoeias, etc..)

Moderator: Shawn Novick, IABS, USA & Akiko Ishii-Watabee, National Institute of Health Sciences, Japan

2.30-3.45pm **Current global guidance, including Pharmacopoeia**

Emmanuelle CHARTON, EDQM, France
M KALAIVANI India pharmacopeia (Virtual)
Minkyung KIM, USP, Asia
TBD

3.45-4.15pm *Afternoon Coffee-Break*

SESSION 7 - Break Out (Part 1)

4.15-5.30pm **When is it appropriate to tighten or broaden specification ranges? What experiences have we encountered? Is this different depending upon the modality/risk/benefit?**

- **Vaccines**
  Moderator: Cristiana Campa, GSK, Italy
- **Biotherapeutics**
  Moderator: Shawn Novick, IABS, USA
- **Cell & Gene Therapy**
  Moderator: Bart Van Montfort, Johnson & Johnson, Netherlands
- **Online Break Out**

5.30pm *End of day*

Wednesday 25 of June, 2025

8.00-8.30am	*Registration and Welcome Coffee*
8.30-8.45am	**Welcome address**

SESSION 8 - Break Out (Part 2)

8.45-10.00am	**Break Out Session Summary** **Panel Discussion**
10.00-10.30am	*Morning Coffee-Break*

SESSION 9 – Panel discussion

10.30-11.45am	**Regulators and Industry: What is the path forward? What actions are occurring globally to allow for 'one product-one specification/quality standard'?**

Summary and Conclusions

11.45am-12.15pm	Meeting review & summary
12.15pm	Closing remarks