Workshop on
Global Harmonization of Specification:
Implementing A Patient-Centric, Enhanced 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 the 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 what has been called patient-centric product specifications and is now being referred to as 'enhanced' approaches to setting specifications. This approach further aligns specification setting with development knowledge and risk-based decision making, considering the role of the release specification in the overall quality control strategy. The meeting will discuss 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 enhanced, risk-based 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 the enhanced approach to setting 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.

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

Monday 23 of June, 2025

8.00-8.30am — *Registration and Welcome Coffee*

8.30-8.45am — **Welcome address**
Shawn Novick, IABS, Co-Chair
Yoji Sato, NIHS, Co-Chair

KEYNOTE SESSION

8.45-9.25am (40')
Strategy for Retinal Cell Therapy
Masayo Takahashi

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

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

9:25-10.05am (40')
Summary of outcomes and key messages from previous GHS meeting
Phil KRAUSE, USA

10:05-10.30am (25')
Coffee-Break

10.30-11:00am (30')
ICH Q6 review status
Akiko ISHII-WATABE, ICH Q6 EWG, NIHS, Japan

11:00-11.30am (30')
Industry perspective on ICH Q6 review, with focus on Japan/Asia region opportunities
Takahiro YAMAGUCHI, ICH EWG member for JPMA, Japan (Virtual)

11:30am-12.15pm (45')
Panel Discussion
Phil KRAUSE, USA
Akiko ISHII-WATABE, ICH Q6 EWG, NIHS, Japan
Andrew CHANG, Novo Nordisk, USA
Horacio PAPPA, US Pharmacopeia, USA
Takahiro YAMAGUCHI, ICH EWG member for JPMA, Japan (Virtual)

12.15-1.45pm — *Lunch break* - **POSTER SESSION**

SESSION 2 - Case studies: Can the enhanced approach be successful? How do we justify ranges and what is the feedback encountered?

Moderators: Robin Levis, CBER-FDA, USA, Gerald Gellermann, Novartis, Switzerland & Jayda Siggers, Health Canada, Canada

In this session different case studies will be presented to illustrate ways to an enhanced product understanding. The product understanding builds the basis for the definition of product limits that ensure safety and efficacy. The case studies will also focus on illustrating how the generated knowledge on the potentially critical and non-critical attributes can be used for process consistency monitoring or as product-specifications in an overall control strategy to ensure pharmaceutical quality.

1.45-2.10pm 25′	Science and Risk-based approaches to Specifications: Application to rapid development of Antibody-drug conjugates **Keiko FUNATO**, GSK, Japan
2.10-2.35pm 25′	Vaccines are Biologicals with Unique Specificities **Bénédicte MOUTERDE & Patrice RIOU**, Sanofi, France
2.35-3.00pm 25′	How uncertainties for complex biologics can be addressed in an enhanced versus conventional approach **Gerald GELLERMANN**, Novartis, Switzerland
3.00-3.25pm 25′	A Clinical Impact of Attributes (CIA) Approach for developing clinically relevant specifications for biologics **Marisa JOUBERT**, AMGEN, USA
3.25-3.50pm 25′	Challenges in Product Specifications with Asian Regulatory Authorities: A Case Study **Vanessa AUQUIER,** UCB, Belgium
3.50-4.15pm 25′	*Coffee-Break*
4.15-5.20pm 65′	**Panel Discussion** **Keiko FUNATO**, GSK, Japan **Bénédicte MOUTERDE,** Sanofi, France **Gerald GELLERMANN**, Novartis, Switzerland **Marisa JOUBERT**, AMGEN, USA **Jayda SIGGERS**, Health Canada, Canada **Vanessa AUQUIER,** UCB, Belgium
5.20-5.30pm	Wrap-up

Tuesday 24 of June, 2025

8.00-8.15am *Registration and Welcome Coffee*

8.15-8.20am **Welcome address**

SESSION 3 - Opportunities and challenges for global harmonization of product specifications with multiple pharmacopoeia in a global landscape.

Moderator: Dean Smith, Health Canada & Akiko Ishii-Watabe, National Institute of Health Sciences, Japan

8.20-8.45am
25'
Global landscape of specifications: a European Pharmacopoeia perspective
Emmanuelle CHARTON, EDQM, France

8.45-9.10am
25'
Setting Specifications: Impact of Regulatory Harmonization
Patrice RIOU & **Bénédicte MOUTERDE**, Sanofi, Global

9.10-10.30am
80'
Panel Discussion
Emmanuelle CHARTON, EDQM, France
Anuradha GUPTA, India Pharmacopeia, India (likely in-person or perhaps virtual, TBD)
Patrice RIOU, Sanofi, Global
Bénédicte MOUTERDE, Sanofi, Global
Minkyung KIM, US Pharmacopeia, South Korea (Virtual)
Hiroko SHIBATA, NIHS, Japanese Pharmacopoeia, Japan
Sirichair KRABESRI, Thai Pharmacopeia, Thailand (Virtual) - TBC
Sasiwimon PATASEMA, Thai Pharmacopeia, Thailand (Virtual) - TBC
Jayoung KIM, Korean Pharmacopeia (Virtual)

10.30-11.00am
30'
Coffee-Break

SESSION 4 - Considerations for Cell and Gene Therapy Products and their Impact on Lifecycle Management

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

11.00-11.30am
30'
Strategies for Defining Specifications in Autologous Cell Therapy Products
Daisy NIE, Novartis, USA (Virtual)

11.30am-12.00pm
30'

Specification consideration for CGT products and role of analytics: Challenges and Opportunities
Kaushik SARKAR, Novo Nordisk A/S, Denmark

12.00-1.15pm
75'

Lunch break

1.15-1.45pm
30'

QbD-based CGT products manufacturing and lifecycle management
Shin KAWAMATA, Cyto-Facto, Japan

1.45-2.30pm
45'

Panel Discussion
Shin KAWAMATA, Cyto-Facto, Japan
Kaushik SARKAR, Novo Nordisk A/S, Denmark
Daisy NIE, Novartis, USA (Virtual)
Yoji SATO, NIHS, Japan

2.30-3.00pm

Coffee-Break

SESSION 5 - Break Out (Part 1)

3.00-5.00pm

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: Dean Smith, Health Canada, Canada
- **Biotherapeutics**
  Moderator: Shawn Novick, IABS, USA
- **Cell & Gene Therapy**
  Moderator: Bart Van Montfort, Johnson & Johnson, Netherlands
- **Online Break Out**
  Moderator: Cristiana Campa, GSK, Italy & Robin Levis, CBER-FDA, USA

5.00-5.15pm

Wrap-Up

Wednesday 25 of June, 2025

8.00-8.40am	*Registration and Welcome Coffee*
8.40-8.45am	**Welcome address**

SESSION 6 - Break Out (Part 2)

8.45-10.00am	**Break Out Session Summary** **Panel Discussion**
10.00-10.30am	*Coffee-Break*
10:30-11:45am	**SESSION 7 – Panel discussion** **Regulators and Industry: What is the path forward? What actions are occurring globally to allow for 'one product-one specification/quality standard'?**
11.45am-12.15pm	**Meeting review & Summary**
12.15pm	**Closing remarks**