Globally Harmonized Specifications: Current State and Future Opportunities
January 10-12, 2023
Basel, Switzerland

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, importance of CQAs, use of prior knowledge, potential flexibilities created as the world managed Covid-19, and how the control strategy relates to manufacturing consistency and assurance that the product will meet product quality expectations. 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 an ICH Q 6AB review and revision evaluation, currently scheduled to occur in late 2023. Participants will gain understanding of the challenges and impediments to harmonization of specifications and help provide feedback and ideas to the global Biologicals community and guidance organizations through the Proceedings publication.

Scientific / Organizing Committee

Shawn **NOVICK**	Co-Chair, IABS
Mats **WELIN**	Co-Chair, Swedish Medical Products Agency
Svein Rune **ANDERSEN**	Norwegian Medicines Agency
Karoline **BECHTHOLD-PETERS**	Novartis
Cristiana **CAMPA**	GSK Vaccines
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Tim **SCHOFIELD**	IABS
Karin **SEWERIN**	BioPharmaLinx AB
Dean **SMITH**	Health Canada
Tami **WU**	Seagen

DAY 1 – TUESDAY, JANUARY 10, 2023

8:00 AM	Registration & Welcome Coffee
9:00 AM	Welcome
9:15 AM	Keynote Meeting the Challenge of Patient-Centric Specifications **Philip KRAUSE,** Chair: WHO Covid Vaccines Research Expert Group
10:00 AM	Summary from the 2019 2nd IABS Global Harmonization of Specifications Workshop **Tim SCHOFIELD**, IABS, U.S.A.
10:30	Break

Session 1 – Framework

The opening sessions 1A and 1B of this workshop will set the framework for globally harmonized specification discussions, offering perspectives from both Regulators and Industry. Concrete propositions will be shared to define scientifically sound specifications and promote harmonization over multiple regions. The presentations will include patient- centric approaches, strategies for specifications setting in accelerated scenarios, as well as learnings from the COVID-19 pandemic. In addition, current regulatory context for specification setting will be discussed, including recent proposals to revise ICH Q6, and the EMA Toolbox guidance on scientific elements and regulatory tools to support quality data packages for unmet medical needs. Principles and proposals will be applicable to other modalities however mostly based on experience in biotherapeutics and vaccines.

Chairpersons: Emily JING, FDA – CDER; Andrew CHANG, Novo Nordisk
NOTE: All titles represent the focus of each talk. The final titles have not yet been confirmed.

10:55-11:00	Session 1 intro
11:00 AM	Industry Challenges and Successes in Harmonizing Specifications Over Multiple Regulatory Regions **Carol KRANTZ,** Seagen, U.S.A.
11:30 AM	ICH Quality Discussion Group Vision for ICH Q6 Moderation **Roger NOSAL,** Rapporteur for ICH Quality Discussion Group
12:00 PM	Clinical interface with CMC and Specifications – Patient Centric Specifications **Elena FRAGAPANE; Marianna AGGRAVI**, GSK Vaccines, Italy
12:30 PM	Lunch
1:15 PM	Poster Session

Session 2 – Framework (continued)

Chairpersons: Cristiana CAMPA, GSK Vaccines; Tim Schofield, IABS, U.S.A.

1:50 PM	**Session 2 Introduction**
2:00 PM	What Was Gained / Lost with the Harmonization of Specifications for the Covid 19 Vaccine **Dean SMITH,** Health Canada

2:30 PM	Towards Globally Accepted Specifications of Pharmaceutical Products: A Summary of the Current State **Ximeng DOW,** MSD, U.S.A.
3:00 PM	Specifications - Too Wide or Too Narrow? The Age-old Debate Between Regulators and Industry, and How We Can Move Forward **Sean BARRY,** Health Products Regulatory Authority (HPRA), Ireland
3:30 PM	Break
4:00 PM	Panel Discussion moderated by **Andrew CHANG** and **Cristiana CAMPA**: All Speakers from Sessions 1 and 2
5:15 PM	End Day 1
5:30 PM	Reception : Posters

DAY 2 – WEDNESDAY, JANUARY 11, 2023

9:00 AM	Welcome to Day 2

Session 3 – Regulatory Panel Session

The ICH has approved a review and update to ICH Q6 A and B to align this 1999 guideline with concepts introduced in ICH Q8-14, such as risk evaluations, patient centric considerations, and a focus on QTPP and CQAs. Sessions 1 and 2 of this meeting have delved into the current landscape of setting specifications and provided ideas and tools which may be incorporated into a revised ICH Q6. This regulatory panel discussion will provide an opportunity to hear from regulators from different jurisdictions on their perspectives of ICH Q6 revision, how the proposals discussed in sessions 1 and 2 of this workshop can be integrated into their regional approval matrix, and what actions, either within their respective agencies, between agencies, and/or between their agency and dossier sponsors, would facilitate harmonization of a product specification between multiple regions.

9:15 AM	Regulatory Panel Session **Chairperson**: **Marion GRUBER**, IAVI CEMED (**Danay MORA PASCUAL**); China CDE (Invited); FDA-CBER (**Robin LEVIS);** Health Canada (**Jayda SIGGERS**); MHRA (**Leonard BOTH);** PEI (**Isabelle BEKEREDJIAN-DING**); MHLW/PMDA (**Akiko ISHII-WATABE**); TITCK (**F. Handan ÖZTUNCA**)
10:45 AM	Break

Session 4 – Case Studies

While, ideally ICH Q6 would define expectations for development of globally harmonized specifications, the goal of a globally harmonize specification has not been realized for most biotechnology products due to conflicting aspects to be taken into account in establishing acceptance limits. This session provides examples where inconsistency between expectations of major regulatory regions has resulted in regional specification variants, and the impact having regional differences has had, including shorter expiry periods and rejection of batches that met quality expectations in other regions. While still a challenging area, there have been successes in developing a globally harmonized specification and the session will also provide examples of such successes and how they were achieved.

Chairpersons: Laurent MALLET, EDQM**; Tammy WU,** Seagen

11:10	Session 4 Introduction
11:15 AM	A Journey Toward Biologics Product Specification Harmonization: Look Back & Look Ahead **Yingmei YANG** (MSD)

11:45 AM	Switching From In vivo to In vitro Potency: 2 Case Studies for Setting New Potency Acceptance Criteria **Patrice RIOU**, Sanofi
12:15 PM	Patient-Centric Drug Specifications: Monoclonal Antibody Therapeutic Case Studies **Andrew Lennard,** Amgen
12:45 PM	Lunch
2:00 PM	Harmonizing Specifications for Drug-device Combinations / Devices **Manfred MAEDER,** Novartis
2:30 PM	Panel Discussion moderated by **Laurent MALLET** and **Tami WU** Panelists: **Yingmei YANG,** MSD**; Patrice RIOU**, Sanofi; **Andrew LENNARD**, Amgen; **Manfred MAEDER,** Novartis**; Jayda SIGGERS** (Health Canada)
3:15 PM	Break
3:45 PM	**Breakout Sessions for Vaccines and BioTherapeutics:** **Discuss Global and Modality Specific Challenges** **Chairpersons:** **Shawn NOVICK,** IABS **Karoline BECHTHOLD-PETERS,** Novartis **Dean SMITH,** Health Canada **Mourad MELLAL,** Catalent Two breakout sessions to address global harmonization challenges and solutions. Breakout groups to address questions in common with all modalities and modality specific challenges
5:15 PM	**End Day 2**

DAY 3 – THURSDAY, JANUARY 12, 2023

Breakout Session ReCap // Session 5: Industry - Regulatory Extended Panel Discussion

8:30 AM	Welcome
8:45 AM	Breakout Session recap / Panel
9:45 AM	Break
10:15 AM	**Industry / Regulatory Extended Panel Discussion** **Moderator**: **Marion GRUBER,** IAVI **Panelists:** **Koen BRUSSELMANS,** EMA; **Kelley BURRIDGE,** FDA, OBP; **Cristiana CAMPA,** GSK Vaccines; **Andrew CHANG,** Novo Nordisk; **Emmanuelle CHARTON,** EDQM; **Philip KRAUSE**, WHO; **Juliana KRETSINGER,** Lilly; **Dean SMITH,** Health Canada
11:30 AM	Meeting review / summary
12:00 PM	Invitation to next meeting
12:15 PM	End of meeting