CALL FOR POSTER PRESENTATIONS

The **Globally Harmonized Specifications: Current State and Future Opportunities Workshop,** will be held on January 10-12, 2023 at the Kuntsmuseum in Basel, Switzerland.

Meeting Abstract: 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, 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. 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.

ABSTRACT SUBMISSION for POSTER PRESENTATION
Submission deadline: 02 DEC 2022.
Please send your abstract to : abbie.charlet@iabs.org

Please submit an abstract (in English) not more than 300 words (excluding title, authors, and affiliation). Papers expanding upon Poster concepts may be published in a special edition of the IABS peer reviewed journal *Biologicals*

The following topic suggestions related to Globally Harmonized Specifications are provided below, but other related topics will be considered:

Harmonization of Pharmacopoeias
Risk Assessments and Patient Centric Specifications
Tools to Aide Harmonization
Specifications for Cell and Gene Therapy Products
Platform Specifications
Integration of ICH Q6 B with Concepts in ICH Q8-14