3rd Workshop focused on Global Harmonization of Specifications
September 14 – 15, 2022
Basel, Switzerland

The goal of this workshop is to help brainstorm opportunities to harmonize specification requirements globally.

A key component of a biologicals control strategy is the product specification. Current regulatory guidances include general principles regarding the product specification but provide limited detail about important aspects of its determination. This results in regional differences which may include: (1) which attributes should be on the product specification; (2) what test is used to measure an attribute; (3) differing views on the basis and determination of acceptance criteria, and (4) what level of control is needed for attributes which are not related to safety or efficacy.

Currently there are over 195 regional, country, and international regulating authorities. Diverse requirements for human and animal biologicals slow the approval and acceptance process and creates development, life-cycle management, and logistical challenges for global review, access, and distribution.

This workshop is designed to review and discuss potential options for harmonization. It is divided into 3 parts – Part 1 will include talks and discussion focused on the basis of the biologicals control strategy including patient-centric, clinically relevant specifications, identification of CQAs, use of prior knowledge, and how the control strategy relates to manufacturing consistency. Case studies illustrating risk-based approaches and/or regulatory collaborations which were successful will be included. Part 2 will include breakout sessions to maximize participant contributions, expanding on workshop principles and conclusions. Part 3 will be an extended panel session with global regulators, compendial officials, and industry representatives to discuss the challenges of regional legal and process differences which influence development and review of specifications.

This workshop compliments other activities and organizations working towards the goal of global harmonization and access of biologicals, with the difference that this will be focused solely on specifications. As such, this workshop is scheduled to precede the ICH Q6AB review and revision meeting of the ICH Quality Discussion Group scheduled for November, 2022. This group is hoping to update and harmonize Q6AB with more recent ICH guidelines which rely on scientific knowledge and risk management. A white paper outlining discussions, examples, and conclusions from the workshop will be published to help inform the ICH revision process.

Participants in this IABS workshop will gain understanding of the challenges and impediments to harmonization of specifications and help provide feedback and ideas through the Proceedings publication to the global biologicals community and guidance organizations.