A CLOSER LOOK AT THE NEW ICH E14/S7B Q&A'S AND TRAINING MATERIALS

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On-Demand Course Content

Overview of the ICH E14/7B Q&A Training Materials

Introduction - *David Strauss, FDA, United States*
Integrated Risk Assessment - *Zhihua Li, FDA, United States*
In Vitro - Derek Leishman, Lilly
In Vivo - Hugo Vargas, Amgen
Conclusions - *David Strauss, FDA, United States*

Case Studies and Scenarios for 5.1

Moderator: Christine Garnett, FDA, United States
Speakers - Corina Dota, EFPIA & Wendy Wu, FDA, United States
Topics covered: E14 Pathways and New Options, Clinical Scenarios, Integrated Nonclinical Data (*in vitro* & *in vivo*)

Case Studies and Scenarios for 6.1

Moderator: Christine Garnett, FDA, United States
Speakers - Hugo Vargas, Amgen & Flora Musuamba Tshinanu, FAGG-AFMPS, Europe
Topics covered: E14 Pathways and New Options, Clinical Scenarios, Integrated Nonclinical Data (*in vitro* & *in vivo*)
Summary of integrated risk data

Training Goals

1. Recognize when nonclinical data may be used in the regulatory QT assessment, including understanding the difference between 5.1 and 6.1.
2. Recognize quality hERG and *in vivo* studies:
   a. Are the studies of reasonable quality with the appropriate quality measures?
   b. Is the study consistent with the performing lab's experience with reference agents?
3. Gain familiarity with clinical exposure definitions and how margins are defined to understand the hERG and *in vivo* margin.
4. Recognize a double-negative nonclinical package.
5. Understand what information is needed to justify the integrated QTc risk assessment.
6. Understand that there can be mitigation around some of the nonclinical study features.
7. Understand timing of various assays and how to progress to clinic.
8. Understand the flexibility of these guidelines and what alternatives may be implemented.