

ICH E14/S7B Webinar

October 15 and 16, 2020 (8:00-10:30 am US EDT [UTC-4])

New Approaches for an Integrated Nonclinical-Clinical QT/Proarrhythmic Risk Assessment

Presentation and Discussion from the International Council for Harmonisation (ICH) E14/S7B Implementation Working Group on the Recently Released Draft Q&As to ICH E14 and S7B

Day 1 Agenda

- **Background, Motivation for and Overview of the New Q&As for ICH E14 and S7B (15 min)**
 - David Strauss - FDA, United States
- **Revised E14 Q&As and Presentation of Examples to Highlight the Impact of Nonclinical Data on Clinical Development and Interpretation (30 min)**
 - Christine Garnett - FDA, United States
- **S7B Integrated Risk Assessment Q&As (20 min)**
 - Zhihua Li - FDA, United States
- **Considerations for an Integrated Nonclinical-Clinical Risk Assessment (20 min)**
 - Jean-Pierre Valentin - EFPIA
- **Discussion of Questions Received by Comment Box and Next Steps (50 min)**
 - Facilitators: David Strauss - FDA, United States and Derek Leishman, PhRMA
 - **All Speakers** and Flora Musuamba – EC, Europe; Colette Strnadova - Health Canada, Canada; Charles Benson - EFPIA

Day 2 Agenda

- **Introduction to Technical S7B Q&As (5 min)**
 - Derek Leishman - PhRMA
- **Best Practice Considerations for In vitro Studies Q&As (30 min)**
 - Wendy Wu – FDA, United States and Gary Gintant - PhRMA
- **Best Practice Considerations for In vivo QT Studies Q&As (20 min)**
 - Satoshi Tsunoda - MHLW/PMDA, Japan
- **Principles of Proarrhythmia Models Q&As (20 min)**
 - Takashi Yoshinaga, JPMA
- **Discussion of Questions Received by Comment Box and Next Steps (50 min)**
 - Facilitators: Derek Leishman - PhRMA and David Strauss – FDA, United States
 - **All Speakers** and Xiaomin Hu – NMPA, China; Eva Rached – Swissmedic, Switzerland; and Yu-Chung Chiao – TFDA, Chinese Taipei

List of ICH Members participating in the E14/S7B Implementation Working Group

[EC, Europe](#)

[FDA, United States](#)

[Health Canada, Canada](#)

[MHLW/PMDA, Japan](#)

[NMPA, China](#)

[Swissmedic, Switzerland](#)

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