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 (20 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

- **Recap of Day 1 and Introduction to Day 2 – ICH S7B Best Practice and Principles Q&As (15 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; Yu-Chung Chiao - TFDA, Chinese Taipei; Katsuyoshi Chiba - JPMA