

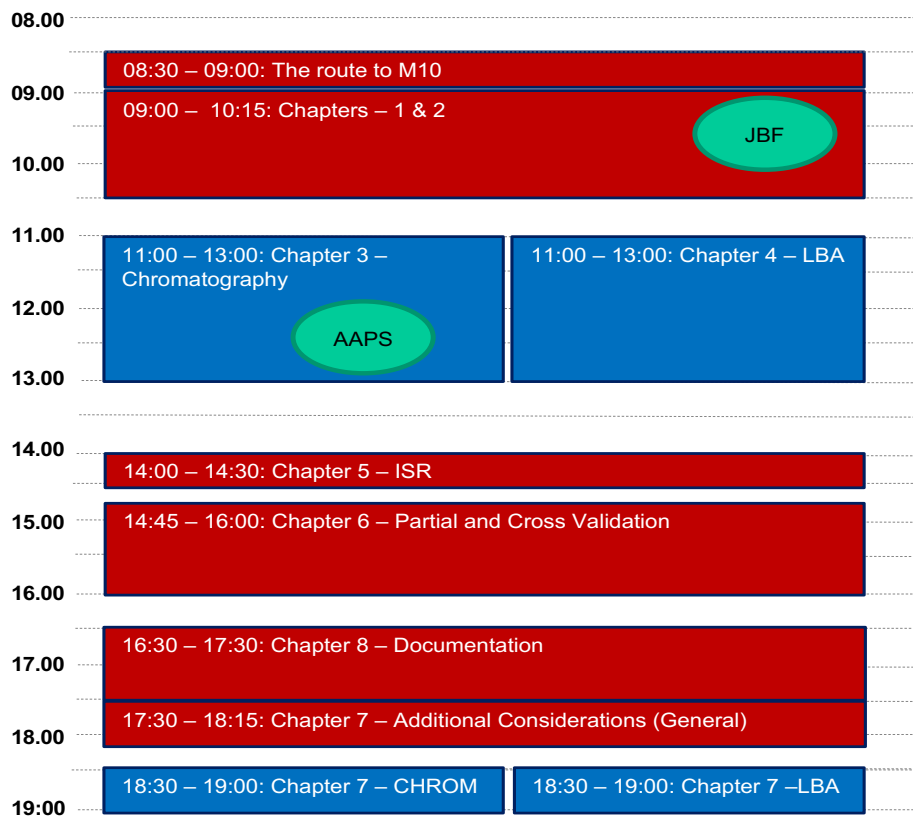


## WORKSHOP

# Towards harmonised implementation of the ICH M10 Guideline

15 November 2022 - Barcelona (Spain)

### Program @ a glance



### Details of the sessions

#### 08:30 09:00 Welcome - The route to ICH M10 (plenary session)

For each of the sessions, the intended flow will be:

- Short introduction on what is new or what has changed
- Panel discussion building on pre-submitted questions (from pre-meeting surveys in EBF and to delegates) on areas of (new/continued) ambiguity
- Additional questions from the audience

Albeit they will exist, please consider that the workshop is not intended to voice disagreements with the Guideline. Our goal and focus are harmonised interpretation and implementation (recommendations) for industry and regulators through open discussions.

Timing of the sessions is indicative and may be changed based on the need for shorter or longer discussions

For each of the sessions, the EBF has invited panelists to provide their or the community's expert view.

- 09:00 10:15 Chapters 1 & 2 (plenary session)**  
**Session moderator: Matthew Barfield, on behalf of the EBF**  
*Session includes a presentation from the JBF (Takashi Miyayama, Chugai Pharmaceutical Co)*
- 10:15 11:00 Coffee break
- 11:00 13:00 Chapter 3 - Chromatography (breakout session)**  
**Session moderator: Stuart Mc Dougall and Iain Love, on behalf of the EBF**  
  
*Session includes a presentation from the AAPS (Eric Woolf, MSD)*
- Chapter 4 - LBA (breakout session)**  
**Session moderator: Michaela Golob, Anna Laurén and Robert Nelson, on behalf of the EBF**
- 13:00 14:00 Lunch break
- 14:00 14:30 Chapter 5 - ISR (plenary session)**  
**Session moderator: Morten Kall, on behalf of the EBF**
- 14:30 14:40 Short logistic break
- 14:40 16:00 Chapter 6 - Partial and Cross Validation (plenary session)**  
**Session moderators: Tom Verhaeghe and Gwenda Pynaert, on behalf of the EBF**
- 16:00 16:30 Coffee break
- 16:30 17:30 Chapter 8 - Documentation (plenary session)**  
**Session moderators: Luca Ferrari on behalf of the EBF**
- 17:30 18:15 Chapter 7- Additional Considerations - general topics (plenary session)**  
**Session moderator: Iain Love and Anna Laurén, on behalf of the EBF**
- 18:15 18:30 Short logistic break
- 18:30 19:00 Chapter 7 - Additional Considerations - Chromatography (breakout session)**  
**Session moderator: Iain Love, on behalf of the EBF**  
  
**Chapter 7 - Additional Considerations - LBA (breakout session)**  
**Session moderators: Anna Laurén, on behalf of the EBF**
- 19:00 End of the Workshop**

**Meeting organisation:** Matthew Barfield (F. Hoffmann – La Roche), Kyra Cowan (Merck KGaA), Michaela Golob (Nuvisan), Jo Goodman (AstraZeneca), Robert Nelson (Labcorp), Steve White (GSK) and Philip Timmerman (EBF)