



WORKSHOP

Towards harmonised implementation of the ICH M10 Guideline

15 November 2022 - Barcelona (Spain)

08:30	09:00	Welcome - The route to ICH M10 (plenary session)
09:00	10:15	Chapters 1 & 2 (plenary session) <i>Session moderator: Matthew Barfield, on behalf of the EBF</i> <i>Session includes a presentation from the JBF (Takashi Miyayama, Chugai Pharmaceutical Co)</i>
10:15	11:00	Coffee break
11:00	13:00	Chapter 3 - Chromatography (breakout session) <i>Session moderator: Stuart Mc Dougall and Iain Love, on behalf of the EBF</i> <i>Session includes a presentation from the AAPS (Eric Woolf, MSD)</i>
11:00	13:00	Chapter 4 - LBA (breakout session) <i>Session moderator: Michaela Golob, Anna Laurén and Robert Nelson, on behalf of the EBF</i>
13:00	14:00	Lunch break
14:00	14:30	Chapter 5 - ISR (plenary session) <i>Session moderator: Morten Kall, on behalf of the EBF</i>
14:30	14:40	Short logistic break
14:40	16:00	Chapter 6 - Partial and Cross Validation (plenary session) <i>Session moderators: Tom Verhaeghe and Gwenda Pynaert, on behalf of the EBF</i>
16:00	16:30	Coffee break
16:30	17:30	Chapter 8 - Documentation (plenary session) <i>Session moderators: Luca Ferrari on behalf of the EBF</i>
17:30	18:15	Chapter 7- Additional Considerations - general topics (plenary session) <i>Session moderator: Iain Love and Anna Laurén, on behalf of the EBF</i>
18:15	18:30	Short logistic break
18:30	19:00	Chapter 7 - Additional Considerations - Chromatography (breakout session) <i>Session moderator: Iain Love, on behalf of the EBF</i>
18:30	19:00	Chapter 7 - Additional Considerations - LBA (breakout session) <i>Session moderators: Anna Laurén, on behalf of the EBF</i>
19:00		End of the Workshop
Slides		Summary slides from the Workshop as presented at the 15th OS
Slides		Public comments submitted to EMA by the EBF during public consultation in 2019

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)