

Sunday: 24 September 2017

18:00 20:00 Complementary cocktail reception

Monday: 25 September 2017

Unless otherwise indicated, all presenters will be presenting on behalf of the EBF

08:30	10:30	Introduction
08:30	08:45	Welcome, aim of the meeting, the ICH process Philip Timmerman
08:45	09:00	Issues in industry with current Guidance Jo Goodman
09:00	09:20	Regulatory reflections on the BMV Guideline/Guidance harmonization Noriko Katori (NIHS)
09:20	09:40	Take home message from the AAPS/EBF/JBF sister meeting Faye Vazvaei (on behalf of the AAPS)
09:40	10:00	What should be the scope of the guideline and why, including Philip Timmerman
10:00	10:30	Panel – Intake questions from the audience on meeting expectations
10:30	11:00	Coffee break
11:00	12:30	Plenary session: Accepting and reporting the final result
11:00	11:20	ISR: When why and how? Morten Kall
11:20	11:40	Best practices for reanalysis: from instrument failure to PK outliers Joe Stanta
11:40	12:00	Documentation and reporting: best practices proposed by the GBC Tom Verhaeghe (on behalf of the GBC)
12:00	12:30	Session close out panel discussion
12:30	13:30	Lunch
13:30	15:30	Plenary Session – Acceptance criteria for PK assays
13:30	13:40	Introduction: Chromatography, LBA or PK assays? Philip Timmerman
13:40	14:00	ICH M10 Harmonization: JBF point of view for general topics Hisanori Hara (Novartis, on behalf of the JBF)
14:00	14:20	Run acceptance criteria Steve White
14:20	14:40	Cross and partial validation Rachel Green
14:40	15:00	General principles on stability testing – what is a single source? Stuart Mc Dougall
15:00	15:30	Session close out panel discussion
15:30	16:00	Coffee Break
16:00	18:00	Plenary Session: Areas of common interest and cross-fertilization
16:00	16:15	Requirements for reference standards for NCE Amanda Wilson

16:15	16:30	Challenges and requirements for reference standards for NBE Marianne Scheel Fjording
16:30	16:45	Sense and nonsense of geomean or arithmetic mean discussion Peter van Amsterdam
16:45	17:00	Hemolysed & hyperlipidemic plasma – a real or perceived issue? Cecilia Sparr Eskilsson
17:00	17:15	Temperature stability testing, are both -20 and -70 needed? Timothy Sangster
17:15	18:00	Session close out panel discussion

Tuesday: 26 September 2017

08:30	12:30	Breakout Session – Stability testing for Chromatographic assays
08:30	09:00	Plenary Feedback from day 1 and day 1 evening discussions with
09:00	09:30	Comed stability testing for chromatographic assays Magnus Knutsson
09:30	10:00	Blood stability testing Achim Freisleben
10:00	10:30	ICH M10 Harmonization: JBF point of view for chromatographic assays Hisanori Hara (Novartis, on behalf of the JBF)
10:30	11:00	Coffee Break
11:00	11:30	Processed sample stability Amanda Wilson
11:30	12:00	Feedback from the AAPS/EBF/JBF meeting on above topics Eric Woolf (on behalf of the AAPS)
12:00	12:30	Session close out panel discussion
08:30	12:30	Breakout Session – Hot topics in LBA
08:30	09:00	Plenary Feedback from day 1 and day 1 evening discussions with
09:00	09:30	Selectivity and interference challenges for LBA Michaela Golob
09:30	10:00	Dilution linearity/parallelism Robert Nelson
10:00	10:30	Use of surrogate matrices in LBA PK assays Marianne Scheel Fjording
10:30	11:00	Coffee break
11:00	11:30	Critical reagents in LBA Susanne Pihl
11:30	12:00	Feedback from the AAPS/EBF/JBF meeting on above topics Heather Myler (on behalf of the AAPS)
12:00	12:30	Session close out panel discussion
12:30	13:30	Lunch
13:30	15:00	Breakout Session – Matrix effects, selectivity and interference testing

13:30	13:50	Selectivity and interference testing for chromatographic assays Magnus Knutsson
13:50	14:10	The essence of matrix effects for chromatographic assays Benno Ingelse
14:10	14:30	Feedback from the AAPS/EBF/JBF meeting on above topics Eric Woolf (on behalf of the AAPS)
14:30	15:00	Session close out panel discussion + unanswered question from the day 1 (focus on Chromatography)
13:30	15:00	Breakout Session – Regulatory ambiguities in LBA
13:30	14:00	Single vs duplicate analysis in LBA Pascal Delrat/Gerhard Paul
14:00	14:15	What should not be in the guideline? Jo Goodman
14:15	14:30	Feedback from the AAPS/EBF/JBF meeting on above topics Heather Myler (on behalf of the AAPS)
14:30	15:00	Session close out panel discussion + unanswered question from the day 1 (focus on LBA)
15:00	15:30	Coffee break
15:30	16:30	Summary of meeting and closing discussions
16:30	17:00	Next steps and adjourn (17:00)