## 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
10.00	11100	College Broak
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)
40.00		
12:00	12:30	Session close out panel discussion
12:00 12:30	12:30 13:30	Session close out panel discussion  Lunch
12:30	13:30	Lunch
12:30 13:30	13:30 15:30	Lunch Plenary Session – Acceptance criteria for PK assays
12:30	13:30	Lunch  Plenary Session – Acceptance criteria for PK assays Introduction: Chromatography, LBA or PK assays?
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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?
17:00	17:15	Cecilia Sparr Eskilsson Temperature stability testing, are both -20 and -70 needed?
17:15	18:00	Timothy Sangster Session close out panel discussion

## Tuesday: 26 September 2017

08:3012:30Breakout Session – Stability testing for Chromatographic assays09:0009:00Plenary Feedback from day 1 and day 1 evening discussions with09:3010:00Blood stability testing for chromatographic assays Magnus Knutsson10:0010:30ICH M10 Harmonization: JBF point of view for chromatographic assays Hisanori Hara (Novartis, on behalf of the JBF)10:3011:00Coffee Break11:3012:00Processed sample stability Amanda Wilson12:00Feedback from the AAPS/EBF/JBF meeting on above topics Eric Woolf (on behalf of the AAPS)12:0012:30Session close out panel discussion08:3012:30Breakout Session – Hot topics in LBA08:3009:00Plenary Feedback from day 1 and day 1 evening discussions with09:0009:30Selectivity and interference challenges for LBA Michaela Golob09:3010:00Dilution linearity/parallelism Robert Nelson10:0010:30Use of surrogate matrices in LBA PK assays Marianne Scheel Fjording10:3011:00Coffee break11:3012:00Feedback from the AAPS/EBF/JBF meeting on above topics Heather Myler (on behalf of the AAPS)12:0012:30Session close out panel discussion12:3013:30Lunch13:30Breakout Session – Matrix effects, selectivity and interference testing			
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	13:30	15:00	Breakout Session – Matrix effects, selectivity and interference testing

13:3	0 13:50	Selectivity and interference testing for chromatographic assays  Magnus Knutsson
13:5	0 14:10	The essence of matrix effects for chromatographic assays Benno Ingelse
14:1	0 14:30	Feedback from the AAPS/EBF/JBF meeting on above topics Eric Woolf (on behalf of the AAPS)
14:3	0 15:00	Session close out panel discussion + unanswered question from the day 1 (focus on Chromatography)
13:3	0 15:00	Breakout Session – Regulatory ambiguities in LBA
13:3	0 14:00	Single vs duplicate analysis in LBA Pascal Delrat/Gerhard Paul
14:0	0 14:15	What should not be in the guideline?  Jo Goodman
14:1	5 14:30	Feedback from the AAPS/EBF/JBF meeting on above topics Heather Myler (on behalf of the AAPS)
14:3	0 15:00	Session close out panel discussion + unanswered question from the day 1 (focus on LBA)
15:0	0 15:30	Coffee break
15:3	0 16:30	Summary of meeting and closing discussions
16:3	0 17:00	Next steps and adjourn (17:00)