Focus workshop agenda 20-22 May, 2019

Sunday 19 May

18:00 19:00 Complementary welcome reception

Monday 20 May

08:25 08:30 Welcome, aim of the meeting

08:30 10:00 Plenary session 1
Introduction, objective, background and scope of the Guideline
Comparison of draft ICH M10 with exisiting Guidance/Guidelines

08:30 09:30 Comparison of draft ICH M10 with exisiting Guidance/Guidelines
EMA/MHLW - presenter: Joanne Goodman (AstraZeneca)
NMPA(China) - presenter: Fan Jin (Covance, on behalf of the CBF)
FDA 2018 - presenter: Boris Gorovits (Pfizer, on behalf of the AAPS)

09:30 10:00 Scope of ICH M10 - learnings from EBF Strategy Meeting, ICH M3 (R2) and metabolite quantification
presenter: Philip Timmerman (EBF)

10:00 10:30 Coffee break

10:30 12:20 Plenary session 2
Did we consider the world around us?

10:30 10:35 Introduction in the session
presenter: Michaela Golob (Nuvisan)

10:35 10:50 3Rs and surrogate matrix
presenter: James Lawrence (Envigo)

10:50 11:10 Clinical vs. Preclinical
presenter: Eric Woolf (MSD)

11:10 11:25 Informed consent and GCP
presenter: Cecilia Arfvidsson (AstraZeneca)

11:25 11:40 The Value of Decision-based acceptance criteria!
presenter: Magnus Knutsson (Ferring)

11:40 12:20 Panel Discussion - including stakeholders from PK/TK and representatives of the UK-MHRA

12:20 12:40 Introduction to Tuesday workshops

General introduction: aim of the workshops Philip Timmerman, EBF
A. Dried Matrix Methods (introduction by Enaksha Wickremsinhe, Lilly)
B. New or Alternative Technologies (introduction by Scott Summerfield, GlaxoSmithKline)

C. Commercial and Diagnostic Kits (introduction by Arno Kromminga, Bioagilytix)

12:40 13:40 Lunch break

13:40 14:10 ICH M10: a global harmonised BMV Guideline
presenter: Brian Booth (CDER) (Video/TC-link)

14:10 15:40 Plenary session 3

General principles of method development/Validation, Partial and cross validation

14:10 14:20 Introduction in the session
presenter: Magnus Knutsson (Ferring)
14:20 14:40 Method Development
presenter: Marco Michi (Aptuit)
14:40 15:00 Full & Partial Validation - LBA and CHROM
presenter: Mark Arnold (Covance)
15:00 15:20 Cross validation
presenter: Tom Verhaeghe (Janssen R&D)
15:20 15:40 Panel discussion

15:40 16:10 Coffee break

16:10 18:00 Plenary session 4: common themes in stability assessment

16:10 16:20 Introduction in the session
presenter: Faye Vazvaei (MSD)
16:20 16:40 General Principles of Stability Testing
presenter: Stuart McDougall (Arcinova)
16:40 16:55 Benchtop and F/T
presenter: Tim Sangster (Charles River)
16:55 17:10 Blood stability testing
presenter: Johannes Stanta (Covance)
17:10 17:25 F/T and LT stability testing: intra- or extrapolation?
presenter: Susanne Pihl (Ascendis)
17:25 18:00 Day 1 closing panel discussion

Tuesday 21 May

08:30 10:00 Focussed parallel sessions (duration: 90 minutes approx.)
A. Dried Matrix Methods *(moderated by Enaksha Wickremsinhe, Lilly)*
B. New or Alternative Technologies *(moderated by Scott Summerfield , GlaxoSmithKline)*

C. Commercial and Diagnostic Kits *(moderated by Arno Kromminga , Bioagilytix)*

10:00 10:30 Coffee break

10:30 17:30 Tuesday Breakout sessions: Chromatography

Key Validation parameters for **chromatography assays** will be discussed. The sessions will include short or full presentations on selectivity, specificity, Matrix Effect, Cal curve, A&P, QCs, Carry-over, stability assessment, dilution integrity, reinjections and extraction recovery, Acceptance Criteria for an Analytical Run, calibration range reanalysis & reinjection of study samples, (re)integration of chromatograms - **some panel discussions may include input from PK/TK stakeholders.**

10:30 12:20 Breakout session 1: Chromatography

10:30	10:40	Introduction to the morning session *presenter: Magnus Knutsson (Ferring)*
10:40	11:00	Guideline paragraphs anticipated of not needing a discussion *presenter: Johannes Stanta (Covance)*
11:00	11:10	Considerations from the JBF for general requirements (with focus on Chromatographic assays) *presenter: Masanari Mabuchi (Mitsubishi Tanabe Pharma, on behalf of the JBF)*
11:10	11:30	Considerations on reference standards for chromatographic assays *presenter: Amanda Wilson (AstraZeneca)*
11:30	11:50	Haemolysed/hyperlipidaemic - matrix effects *presenter: Steve White (GlaxoSmithKline)*
11:50	12:20	Panel discussion

12:20 13:30 Lunch break

13:30 15:20 Breakout session 2: Chromatography

13:30	13:40	Introduction to the afternoon session *presenter: Johannes Stanta (Covance)*
13:40	14:00	Stability assessment: considerations on FDC *presenter: Eric Woolf (MSD)*
14:00	14:20	Considerations on specificity and selectivity for MS/MS assays *presenter: Tim Sangster (Charles River)*
14:20	14:30	Value of Dilution QC in batch analysis *presenter: Stuart McDougall (Arcinova)*
14:30	14:50	QC samples - considerations on geometric vs. arithmetic placement of the midQC *presenter: Peter van Amsterdam (Abbott Healthcare Products)*
14:50	15:20	Panel discussion

15:20 16:00 Coffee break

16:00 17:30 Breakout session 3: Chromatography

16:00	16:20	Considerations on re-injection *presenter: Amanda Wilson (AstraZeneca)*
16:20	16:40	Considerations from the JBF for requirements specific to chromatographic assays

presenter: Masanari Mabuchi (Mitsubishi Tanabe Pharma, on behalf of the JBF)

16:40 17:00 Documentation & Glossary - Specific to Chromatographic assays
presenter: Tom Verhaeghe (Janssen R&D)

17:00 17:30 Closing Panel discussion CHROM

10:30 17:30 <u>Tuesday Breakout session: Ligand Binding Assays</u>

Key Validation parameters for **LBA** will be discussed. The sessions will include short or full presentations on selectivity, specificity, Cal curve, A&P, QCs, Carry over, stability assessment, dilution linearity, Parallelism, Minimum Required Dilution, Free/total and Hook Effect, Acceptance Criteria for an Analytical Run, calibration range, reanalysis of study samples - **some panel discussions may include input from PK/TK stakeholders**.

10:30 12:20 <u>Breakout session 1: LBA</u>

10:30 10:40 Introduction to the session
presenter: <u>Robert Nelson</u> (Novimmune)

10:40 11:00 Guideline paragraphs anticipated of not needing a discussion
presenter: <u>Robert Nelson</u> (Novimmune)

11:00 11:20 Considerations for reference standards and key reagents
presenter: Johanna Mora (BMS)

11:20 11:40 Scientific aspects for the use of surrogate matrix in calibration, dilution and QC
presenter: <u>Roland Staack</u> (Roche)

11:40 11:50 Analytes that are also Endogenous Compounds - Focus on LBA
presenter: <u>Birgitte Buur Rasmussen</u> (Ferring)

11:50 12:20 Panel discussion

12:20 13:30 Lunch break

13:30 15:20 <u>Breakout session 2: LBA</u>

13:30 13:40 Introduction to the afternoon session
presenter: <u>Joanne Goodman</u> (AstraZeneca)

13:40 14:00 Stability assessments
presenter: <u>Michaele Golob</u> (Nuvisan)

14:00 14:20 Considerations on calibration range during validation & sample analysis
presenter: <u>Anna Laurén</u> (SVAR)

14:20 14:40 Specificity and Selectivity
presenter: <u>Wibke Lembke</u> (Janssen Biologics)

14:40 15:20 Panel discussion

15:20 16:00 Coffee break

16:00 17:30 <u>Breakout session 3: LBA</u>

16:00 16:20 Partial validation and/or Dilution linearity & Parallelism
presenter: Robert Nelson (Novimmune)
16:20 16:40 Documentation & glossary - Specific to LBA
presenter: Stephen Williams (Charles River)
16:40 17:30 Closing panel discussion LBA

Wednesday 22 May

08:30 09:50 Plenary session 4
ISR, general aspects of Documentation for Validation and Bioanalytical Reports and Glossary

08:30 08:50 ISR
presenter: Morten A. Kall (Lundbeck)
08:50 09:10 General aspects of Documentation & Glossary for Validation and Bioanalytical Report
presenter: Steve White (GlaxoSmithKline)
09:10 09:30 Repeat Analysis
presenter: Mark Arnold (Covance) and Boris Gorovits (Pfizer)
09:30 09:50 Panel dicsussion

09:50 10:20 Plenary session 5
FB from interactive discussions during workshops on day 2 (10 min each)
A. Dried Matrix Methods (feedback by Enaksha Wickremsinhe, Lilly)
B. New or Alternative Technologies (feedback by Scott Summerfield, GlaxoSmithKline)

C. Commercial and Diagnostic Kits (feedback by Arno Kromminga, Bioagilytix)

10:20 11:00 Coffee break

11:00 13:00 Summarising the 2 days – our FB to EWG & Wrap up
Panel, including Brian Booth (CDER) (Video/TC-link)

13:00 Adjourn