Day 1 - Wednesday 21 NOV 2018

08:40 - 09:00 Welcome

09:00 - 10:40 Day 1-01: Cell & Gene Therapies

Session chair: Matthew Barfield (GlaxoSmithKline)

09:00 - 09:40 *Steve Hyde, Radcliffe Department of Medicine, University of Oxford*

Cell & Gene Therapy, Where are we and where are we going?

09:40 - 10:00 *Patrick Bennett, PPDi*

Exploring the Changing Bioanalytical Solutions in Gene and Cellular Therapies

10:00 - 10:20 *Fiona Campbell, Charles River*

When the Cell is the drug, challenges for Bioanalysis

10:20 - 10:40 *Michael Schwenkert, Bio-Rad*

Bioanalysis assays and tools for the development of CAR-T cell therapies

10:40 - 11:30 Coffee break

11:30 - 12:50 Day 1-02: Future Bioanalytical Landscape

Session chair: Magnus Knutsson (Ferring Pharmaceuticals)

11:30 - 11:50 *Philip Timmerman, EBF*

Future challenges for BioA

11:50 - 12:10 *Hisanori Hara, Novartis*

Acceptance criteria for method validation and sample analyses of a protein by LC-MS/MS

12:10 - 12:30 *Matthew Barfield, on behalf of the EBF*

Singlet or Duplicate analysis in LBA?

12:30 - 12:50 *Marianne Scheel Fjording, on behalf of the EBF*

EBF Biomarker Strategies – a new deal?

12:50 - 14:00 Lunch break

14:00 - 15:50 **Day 1-03: Regulatory Feedback on and/or interactions with FDA, MHRA, ICH**

Session chair: Steve White (GlaxoSmithKline)

In this session, we will discuss recent developments in the regulatory landscape. Invitations to HA representatives are in progress. Discussions will focus on (i) Industry experience with ambiguously interpreted chapters/paragraphs of Bioanalytical Guidelines, (ii) FB from industry and regulators to understand regulatory feedback, (iii) GcLP and recent data integrity guidelines or expectations, (iv) status update on ICH M10 (as appropriate) **and Feedback from regulatory discussions at the EBF Autumn Focus Workshop on Immunogenicity.**

contribution and themes - order and timing will be decided at the meeting

Sriram Subramaniam, FDA

Feedback on regulatry process

Jason Wakelin-Smith and Andrew Gray, MHRA

Data Integrity and GcLP: the essence of the Guidelines and sharing of findings during inspections

Jo Goodman, on behalf of the EBF

Updates on the Immunogencity Guidelines (EMA/FDA) and feedback from regulatory discussions from the recent EBF Autumn Focus Workshop

Philip Timmerman, EBF

ICH M10: Updates on the process and progress

15:50 - 16:40 **Coffee break - poster focus 1**

16:40 - 18:00 **Day 1-04 Auditorium: Practical application of HRMS**

Session chair: Johannes Stanta (Covance)

16:40 - 17:00 *Richard Snell, GlaxoSmithKline*

Jack of all Trades or Master of None? The Role of High Resolution Mass Spectrometry in Quantitative Bioanalytical Lab

17:00 - 17:20 *Chris Beaver, Syneos Health*

Assuring Quality and Consistency of Critical Reagents Using HRMS

17:20 - 17:40 *Ils Pijpers, Janssen R&D*

	High resolution quantification in preclinical studies: impact evaluation of different data processing software packages.
17:40 - 18:00	*Rob Wheller, LGC*
	Diversifying the bioanalytical toolkit for protein LC-MS: Improving selectivity with 2D-LC and HR-MS

16:40 - 18:00 **Day 1-04 Jupiter: Immunogenicity 1**

Session chair: Joanne Goodman (MedImmune)

16:40 - 17:00	*Barry van der Strate, on behalf of the EBF*
	Critical Reagents for ADA assays: an EBF perspective
17:00 - 17:20	*Nicoline Videbæk, Novo Nordisk*
	Careful handling of sample pre-treatment in an antibody analysis assay determines how drug tolerance and sensitivity may be improved
17:20 - 17:40	*Laura Coch, Envigo*
	Assay overkill:- Practical solutions for development and validation of fit-for-purpose pre-clinical immunogenicity assays
17:40 - 18:00	*Jessica St Charles, MPI Research*
	Challenges of Immunogenicity Testing for Fusion Protein Biotherapeutics

18:00 - 19:00 **Cocktail reception**

Day 2 - Thursday 22 NOV 2018

08:30 - 10:10 **Day 2-01 Auditorium: Biomarkers Strategies**

Session chair: Michaela Golob (Nuvisan)

08:30 - 08:50	*Steve Piccoli (GlaxoSmithKline)*
	Consensus Framework for Assay Validation for Biomarker Qualification
08:50 - 09:10	*Stephanie Traub, Cancer Research UK*
	Fit-for-purpose Biomarker validation of non-LBA assays and new technologies
09:10 - 09:30	*Marianne Scheel Fjording, Novo Nordisk*
	Is the Biomarker World more simple after – Gold, Silver, Bronze?
09:30 - 09:50	*Yoshinobu Yokota, SNBL on behalf of the JBF*
	Recommendations for regulated biomarker analysis using LBA kits
09:50 - 10:10	Panel Discussion

08:30 - 10:10 **Day 2-01 Jupiter: Sample Handling**

Session chair: Matthew Barfield (GlaxoSmithKline)

08:30 - 08:50 *Nico van de Merbel, PRA-HS*

Instability of biological matrices and its effect on bioanalytical method performance

08:50 - 09:10 *Sune Sporring, Novo Nordisk*

When in-vivo sample handling issues cannot be predicted using spiked samples.

09:10 - 09:30 *Annick de Vries, Sanquin*

Support PK and ADA of biologics using finger prick sampling; a real-life example of infliximab in IBD-patients

09:30 - 09:50 *Lisa Delahaye, Ghent University*

Volumetric absorptive microsampling as an alternative sampling strategy for cerebrospinal fluid

09:50 - 10:10 *Kevin Bateman, MSD*

Smart Trials: Assessment of At-Home Sampling and Digital Health Technologies in a Clinical Pilot Trial

10:10 - 11:00 **Coffee break - poster focus 2**

11:00 - 12:40 **Day 2-02 Auditorium: Scientific Validation/Fit for Purpose Round table**

Session chair: Philip Timmerman (EBF)

11:00 - 12:40 *Hans Stieltjes (Janssen R&D), Martine Broekema (PRA-HS), James Lawrence (Envigo), Steve White (GlaxoSmithKline), Timothy Sangster (Charles River), Morten Anders Kall (Lundbeck)*

Scientific Validation/Fit for Purpose Validation - Panel Discussion

In this session, a panel discussion will be held focusing on the key questions of practical implementation of Scientific Validation/Fit-for-Purpose. An expert panel of EBF leaders will prepare panel questions, give feedback on the hurdles and/or advantages they have seen based on their experience in the lab, with the end users of the data or with regulators. It is the intention to share the questions beforehand with all registered delegates in order to get maximum value from the session.

11:00 - 12:40 **Day 2-02 Jupiter: New Technologies: LBA**

Session chair: Robert Nelson (Novimmune)

11:00 - 11:20 *Mikko Hölttä, Astra Zeneca*

Pre-clinical bioanalytical strategies to support the hVEGF-A modified mRNA program (AZD8601)

11:20 - 11:40 *Uwe Wessels, Roche*

Application of the ProteinSimple ELLA platform for PK and ADA analysis in preclinical studies.

11:40 - 12:00 *Eva Vieser, Amgen*

High sensitive PK analysis of BiTE® molecules using SIMOA technology

12:00 - 12:20 *Kees Mulder, PRA-HS*

Implementation of an ultrasensitive Single Molecule Counting Immunoassay for determination of pharmacokinetics in a regulated environment

12:20 - 12:40 *Bernd Potthoff, Novartis*

Determination of a first in human dose at the minimum anticipated biological effect level with an in vitro receptor occupancy assay

12:40 - 14:00 **Lunch break**

14:00 - 15:30 In each of the short workshops, the EBF Open Symposium Organizing Committee together with the individual workshop moderators, has prepared discussions around themes relevant to our industry today. More details on the questions asked, anticipated deliverables for each of these workshops can be found on the conference website (program). The meeting rooms for the workshops will be posted in all areas of the venue.

WS 1: Technology Development

WS 2: e-Environment / Data Integrity - with contributions from Andrew Gray (MHRA) and Jason Wakelin-Smith (MHRA)

WS 3: Biomarkers

WS 4: Automation

WS 5: qPCR current application in bioanalysis– in collaboration with the JBF (incl. Asako Uchiyama, SNBL Japan presenting on behalf ot the JBF)

15:30 - 16:20 **Coffee break - poster focus 3**

16:20 - 18:00 **Day 2-03 Auditorium: LC-MS Technology Advances**

Session chair: Tim Sangster (Charles River)

16:20 - 16:40 *Pegah Jalili, Merck KGaA*

Optimization of Easy to Use Plate-based Immunoaffinity LC-MS/MS Workflow for Preclinical Monoclonal Antibody Quantification

16:40 - 17:00 *Jordane Biarc, Atlanbio*

Quantification of therapeutic antibodies in plasma for pre-clinical and clinical studies: Comparison of different technologies and protocols.

17:00 - 17:20 *Jon Bardsley, Thermo Fisher Scientific*

Simple solution for complex analysis; an assessment of Heat-stable trypsin for surrogate peptide quantitation and characterisation workflows

17:20 - 17:40 *Takashi Shimada, Shimadzu*

Validated bioanalysis for therapeutic antibodies by LC-MS: Fab-selective proteolysis nSMOL

17:40 - 18:00 *Jing Tu, PPDI*

Bioanalysis Rising Star Award Winner

16:20 - 18:00 **Day 2-03 Jupiter: Biomarker Applications**

Session chair: Marianne Scheel Fjording (Novo Nordisk)

16:20 - 16:40 *Yoshiaki Ohtsu, Astellas - on behalf of the JBF*

Biomarker calibration standards in ligand binding assays: Feedback from JBF

16:40 - 17:00 *Emmanuel Njumbe Ediage, Janssen R&D*

Scientific validation of an LC-MS/MS method for coproporphyrin I and III as endogenous biomarkers for transporter-mediated Drug-Drug Interactions

17:00 - 17:20 *James Beecroft, LGC*

Problems that arise during long term biomarker studies

17:20 - 17:40 *Michael Naughton, GlaxoSmithKline*

Assessment of Parallelism in Biomarker Support: Strategies for application and real-life data interpretation

17:40 - 18:00 *Laure Queyrel, Envigo*

To sensitivity or too sensitivity. Case studies on challenges and trends in bioanalytical assay sensitivity

18:00 - 19:00 **Cocktail reception**

Day 3 - Friday 23 NOV 2018

08:40 - 10:20 Day 3-01 Auditorium: LC-MS Technical Applications

Session chair: Cecilia Arfvidsson (Astra Zeneca)

08:40 - 09:00 *Organisers of the 5th EBF Young Scientist Symposium*

To Bioanalysis and Beyond!

09:00 - 09:20 *Omnia Ismaiel, PPDi*

LBA/LC–MS/MS methodology for Protein based therapeutics bioanalysis-Current and Evolving trends.

09:20 - 09:40 *Marco Michi, Aptuit*

Development of a hybrid assay for the quantification of a mAb drug in human serum at the low ng/mL levels.

09:40 - 10:00 *Jeroen Kooistra, Charles River*

Taking Insulin analysis to the next level, application of new science in advanced LC-MS based workflows.

10:00 - 10:20 *Ian Edwards, Waters*

Automated protein digestion: Does it add value?

08:40 - 10:20 Day 3-01 Jupiter: Immunogenicity 2

Session chair: Michaela Golob (Nuvisan)

08:40 - 09:00 *Lone Hummelshøj Landsy, Novo Nordisk*

Stability of anti-drug antibodies in human samples

09:00 - 09:20 *Rebecca O'Donnell, LGC*

The impact on biological variability when introducing improvements to assay sensitivity and drug tolerance for Immunogenicity assays

09:20 - 09:40 *Alexander Poehler, Roche*

Evaluation of potential biotin interference in immunogenicity testing

09:40 - 10:00 Lydia Michaut, Novartis

Determination the acceptance range of the titer positive control in clinical ADA assays: practical examples

10:00 - 10:20 *Nick White, MedImmune*

Just how low-a-level of ADA can you detect? And just because you can, does it mean you should?

10:20 - 11:00 **Coffee break - poster focus 4**

11:00 - 12:55 **Day 3-02 Auditorium: Practical Implementation of FDA 2018 BMV Guidance**

Session chair: Philip Timmerman (EBF)

In this session, we plan to focus on Industry's first experience of bringing the 2018-FDA BMV Guidance into practice. From a recent survey, EBF delegates will present their current experience or share the ambiguities they have on 6 themes areas. We have invited FDA- and US industry experts to help us implement the 2018-FDA Guidance as harmonized as possible.

EBF Case studies and/or survey results

Presentations from Sriram Subramaniam (CDER-FDA) and Lakshmi Amaravadi (Shire/ AAPS) Feedback from US Bioanalytical community

Order and timing of contributions will be decided by all presenters shortly prior the meeting

Case studies or survey results

Presentation from Sriram Subramaniam, CDER-FDA

Lakshmi Amaravadi (Shire/ AAPS)

Panel Discussion

12:55 - 13:00 **Plans for 2019 and Adjourn**