

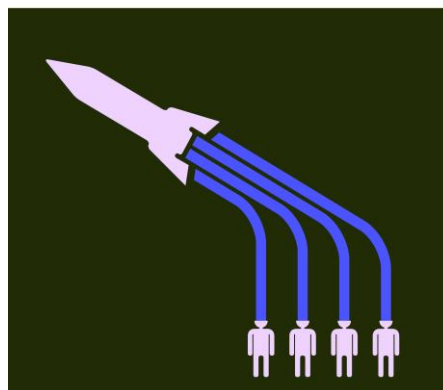
5th EBF YSS

In collaboration with the University of Bologna

To Bioanalysis and Beyond!

Oratorio di San Filippo Neri

Via Manzoni 5 – Bologna, Italy
21-22 March 2019



Thursday 21 March 2019

16:00 Welcome – Registration Opens

17:00 19:00 **Science Café: “Regulations – The Future is Ours”**

During the Science Café, we will focus on 4 themes related to interpretation and implementation of the recent FDA BMV Guidance. At different tables, each moderated by the organising committee, we will provide the opportunity to exchange views and opinions on:

Theme 1: Biomarkers/Endogenous compounds

(moderated by Tessa McDonald & Jörg Faber)

Theme 2: Fit for Purpose

(moderated by Lisa Delahaye & Alexandra Vantcheva)

Theme 3: Dried Blood Spot / Micro-sampling

(moderated by Farjana Mahammed & Michele Protti)

Theme 4: ISR

(moderated by Chris Fox & Mathias Salger)

Coordination: Toon Babylon

19:00 20:00 Complementary Cocktail Reception



Meeting Organisation: Jörg Faber (A&M Labor), Chris Fox (AstraZeneca), Farjana Mahammed (GlaxoSmithKline), Tessa McDonald (York Bioanalytical solutions); Toon Babylon (UCB Biopharma), Mathias Salger (Nuvisan); Alexandra Vantcheva (comac-medical), Lisa Delahaye (Ghent University), Michele Protti (Bologna University)

Meeting management: Philip Timmerman (EBF), Laura Mercolini (Bologna University)

The YSS is organized as a non-profit event by the EBF vzw. The organization is independent from all EBF member companies

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Friday 22 March 2019

- 09:00 09:05 Welcome and Introduction**
Laura Mercolini (Unibo) – Michele Protti (Unibo)
- 09:05 09:45 Feedback from the Science Café**
Chair: Mathias Salger (Nuvisan) – Tessa McDonald (Unilabs York Bio)
- 09:45 11:20 Session 1: Let's Continue Small**
Chair: Michele Protti (Unibo) – Farjana Mahammed (GlaxoSmithKline)
- 09:45 09:50 **Farjana Mahammed (GlaxoSmithKline)**
Introduction to the morning session
- 09:50 10:05 **Lisa Delahaye (U-Ghent)**
Volumetric absorptive microsampling as an alternative tool for adduct-based monitoring of paracetamol toxicity
- 10:05 10:20 **Michele Protti (Unibo)**
Bringing microsampling to the clinical practice: bioanalytical outcomes from a 4-year workplace alcohol consumption monitoring project
- 10:20 10:35 **Matthijs Pijnappel (Recipharm)**
Head-to-head comparison of Dried Blood Spots and traditional plasma PK sampling in a clinical trial
- 10:35 10:50 **Ian Dawson (Covance)**
Considerations for the use of volumetric adsorption micro sampling (VAMS) devices for a clinical bioanalytical assay
- 10:50 11:20 **Panel Discussion**
Future Avenues for Small Volume Sampling in the Clinic.
- 11:20 12:00 Coffee Break and Poster Viewing**
- 12:00 12:50 Session 2: From Applications to Lunch**
Chairs: Joerg Faber (A&M Labor) – Chris Fox (AstraZeneca)
- 12:00 12:10 **Jessica Knox (Charles River)**
Adapting to new guidance on the performance of in-vitro Bioanalysis
- 12:10 12:20 **Chris Nortcliffe (Sciex)**
Ultra-sensitive Quantification of Monoclonal antibodies and ADCs in Mouse Plasma using Micro LC-MS/MS methods.
- 12:20 12:30 **Quentin Enjalbert (ANAQUANT)**
LC-HRMS approach to identify and quantitate potential markers for pre-clinical and clinical applications in heterogeneous samples
- 12:30 12:40 **Sophia Christou (LGC)**
The role of bioanalytical CRO's in therapeutic drug monitoring
- 12:40 12:50 **Annelies Cannaert (U-Ghent)**
Alternative screening tools for the detection of novel psychoactive substances using an activity-based approach

- 12:50 13:10 Hungry? Not yet...: 20 min poster pitch**
Chair: Lisa Delahaye (U-Ghent) – Chris Fox (AstraZeneca)
- 13:10 14:10 Lunch break – Poster viewing**
- 14:10 15:25 Session 3: Platform 9^{3/4}**
Chairs: Alexandra Vantcheva (Comac Medical) – Tessa McDonald (Unilabs York Bio)
- 14:10 14:25 **Katja Zeiser (Nuvisan)**
MSD Assay Development – promises and issues
- 14:25 14:40 **Toon Babylon (UCB Pharma)**
Bridging a classic serum PK assay to Cerebrospinal Fluid: challenges in using surrogate matrices and semi-automation during assay development and validation
- 14:40 14:55 **Sarah Collomb (Novimmune)**
Comparison of Gyrolab™ and MSD® platforms for development of an anti-drug antibody assay
- 14:55 15:10 **Christopher Fox (AstraZeneca)**
Direct comparison between methods for the detection of PCSK9 on the Gyrolab and the ELLA instruments
- 15:10 15:25 **Florian Neff (Roche)**
Exploring ELLA technology for pre-clinical drug quantification and immunogenicity assessment
- 15:25 16:00 Coffee break**
- 16:00 16:05 Announcement 2019 YSS Best Poster Prize**
- 16:05 17:25 Session 4: Don't Leave Yet, There's More...**
Session chairs: Lisa Delahaye (U-Ghent) – Toon Babylon (UCB Pharma)
- 16:05 16:25 **Jenny Baker (LGC)**
Characterisation of RED devices: A glimpse into the challenges of protein binding in the bioanalysis area of drug development
- 16:25 16:45 **Alexandra Vantcheva (Comac Medical)**
The importance of selecting a method-appropriate internal standard for the quantitative determination of a recombinant polypeptide using a LC-MS/MS technique
- 16:45 17:05 **Matthew Sciscione (Syneos Health)**
Assuring Quality and Consistency of Critical Reagents
- 17:05 17:25 **Laure Queyrel (Envigo)**
On the road to simplified and fit for purpose immunogenicity assays to support pre-clinical studies
- 17:25 17:30 Closing Remarks and Adjourn**