To Bioanalysis and Beyond!

Presenters: Michele Protti and Toon Babylon
on behalf of EBF YSS

EBF 11th Open Symposium
Raise the Anchor – Set Sail for Science
23 Nov 2018 - Barcelona, Spain
Outline

1) What is the YSS?

2) Highlights from YSS 2018

3) What can you expect in 2019?

4) What we need you to do?
1) What is the YSS?

**Young Scientist Symposium**

Early career bioanalytical scientists (typically <35 or <5 years in bioanalysis) from industry (Pharma/CROs) or academia

As a part of the EBF we also aim to:

- Share, discuss, optimize and seek alignment on a broad array of BioA topics (including science, procedures, business tools, technology, and regulatory issues)

Within the EBF:

- We contribute to the aim of recommending or influencing opinions/procedures towards our members, business partners, regulatory bodies and any other stakeholders
- Going forward, EBF is providing guidance and recommendations to the European and Global bioanalytical community
- Provide development opportunities for EU based scientist by joining cross company collaborations and contributions to peer reviewed journals, international meetings and symposia
1) What is the YSS?

Previous YSS meetings:

1st YSS 2014 (Barcelona, Spain):
“Unleashing the Future”
- [hyperlink to program](#)

2nd YSS 2015 (Barcelona, Spain):
“Future of Bioanalysis… A Bridge between Industry and Academia”
- [hyperlink to program](#)

3rd YSS 2016 (Barcelona, Spain):
“In Unity Lies Power; Building a Better Bioanalytical World Together”
- [hyperlink to program](#)
2) Highlights from YSS 2018


The 4th YSS was the first one organized as a stand-alone meeting, delivering on promise, quality and engagement.

1. “Het Pand” was chosen as venue to further visualize the growing connectivity between the EBF and academia.
2. The OC consisted of a strong representation from the EBF young scientist community and academic centres.
3. The meeting was fully booked with attendance from 65 young scientists, coming from both academia and industry.
2) Highlights from YSS 2018

Objectives:

- A chance to network with others from different backgrounds and interests
- Openly discuss two hot topics of today’s and tomorrow’s bioanalytical work…

Theme 1:
Are we doing too much validation?

Theme 2:
Is automation helping us as we hoped?

How do you like it cooked?
Rare or Well done?
Theme 1: Are we doing too much validation?

- Is it a tick box exercise? Or is it adding value (non-GLP being validated to GLP standard)?
- Fit for purpose methods?
- Scientific considerations need to be made upfront (stability, recovery, cross validation between different analysts, automated steps)
- Sometimes full validation is easier than retrospective validation

Are young scientists in a position to question processes in their workplace/ of the regulators?

- Client-dependent; CRO does what the client asks for. No questions asked.
- Scared of not adhering to the guidelines
- A requirement for meetings with regulators to present and discuss data

- Young Scientists need to drive the change to the validation process, as ultimately they will be the ones to follow any new regulations and guidelines
Theme 2: Is automation helping us as we hoped?

Pros
- Faster
- Less-labour intensive
- High-throughput
- Robustness
- Improve Data Integrity
- Accuracy & Precision
- Reduce Human Error
- Reproducible

Cons
- Expensive
- Validation & Training Required
- Maintenance
- Client-dependant
- Long lead time
- Break downs
- Extensive troubleshooting
- Reduced flexibility

Regulatory agencies’ expectation with regards to automation in validation?
- Comparable or even better performance is expected
- Every step is traceable, data integrity

➢ Expectation was that automation would play a major role in future bioanalytical work and its increasing usage would potentially result in further guidance from regulatory agencies.
1. Alternative sampling having an impact

- Many advantages
  + Ease of sampling
  + Minimally invasive collection
  + Small sample volume
- Dried Blood Spots (DBS).
  - Although DBS suffers from haematocrit issue, it still remains one of the most commonly used alternative sampling strategies
- Different bioanalytical areas, ranging from preclinical animal study units, to therapeutic drug monitoring and forensic toxicology, have taken to microsampling.
- Volumetric Absorptive MicroSampling (VAMS) and Dried Plasma Spots (DPS) maintain the benefits of DBS but eliminate haematocrit bias

➢ There is a continued interest of the young scientist community in microsampling technology
2) Highlights from YSS 2018 – Day 2

2. Overcoming bioanalytical issues

- Often unknowingly, young scientists are at an advantage
  - Fresh approach and new perspectives
  - Unclouded by previous experience

- Presentations highlighted issues due to the diversity of drug entities, biomarkers, methods and instruments in use
  - Method development via LC-MS/MS to quantitate multiple target analytes
  - Problematic analytes (highly polar, hydrophilic, poorly adsorbed) on LC-MS/MS
  - Importance of extraction solvent affecting recovery

- Session provided an insight into a variety of bioanalytical challenges, overall fuelling stimulating concepts for thought in the young scientist community.
3. MMM - Matrices, Molecules and Methods

- Developing and validating methods for
  - Endogenous compounds (use of surrogate matrices)
  - Biomarkers
  - Neutralising antibodies against therapeutic fusion proteins

- New ways and best practices of combining workflows from Large and Small molecule approaches.
  - Hybrid immunocapture-LC-MS/MS

- New methodologies
  - Determination of drug-to-antibody ratio (DAR) for ADCs
  - Single molecule Counting Immunoassay platform
3) What can you expect in 2019?

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
3) What can you expect in 2019?

Location

- The 5th YSS will be hosted by Università di Bologna. Founded in 1088 it is the oldest European university in continuous operation.
- Bologna’s well-preserved historic centre boasts a wealth of ancient architecture, towers and piazzas

Venue

- The Symposium will be held in Oratorio di San Filippo Neri, a restored late-Baroque religious building.
- Located in the centre of Bologna, it is easily accessible…
  - From Bologna Airport → 30 minutes by bus, or 20 minutes by taxi)
  - From Bologna central train station → a 15 minute walk through the picturesque city.
3) What can you expect in 2019? – Day 1

What is the impact of the recent release of the FDA BMV Guidance and/or the ICH M10 harmonisation guideline at our doorsteps?

Why have we chosen this topic?
- It is Young Scientists who have to apply these regulations to their everyday work, moving forward
- Updates to regulations and harmonisation of regulations shape their careers → They are entitled to an opinion
- An open discussion amongst peers should help with individual’s understanding of the importance of the updates, and the importance of harmonisation across the industry
- The outcome of these discussions may be used to provide young scientist industry feedback to the ICH M10 Guideline at the public consultation period.
3) What can you expect in 2019? – Day 1

*What is the impact of the recent release of the FDA BMV Guidance and/or the ICH M10 harmonisation guideline at our doorsteps?*

In detail we will discuss the following (and more) -

- How do you feel modern guidelines can support good science?
- Is this increasing the workload of young scientists?
- Can young scientists deviate from these guidelines, provided scientific justification?
- What are the ambiguities with in-house procedures?
- How can we bridge these guidelines into practice?
- How did your lab adopt?
3) What can you expect in 2019? – Day 2

Plenary sessions:

Theme 1: Quantification of proteins/peptides/protein biomarkers

Theme 2: Advancements in clinical/medical bioanalysis
3) What can you expect in 2019? – Day 2

Theme 1: **Quantification of proteins/peptides/protein biomarkers**

Are we implementing new technologies?

- High sensitivity LBA platforms
  - Affinity Capture and purification instruments e.g. Thermo Scientific KingFisher Flex
  - Singulex technology

Increasing interest in the simultaneous measurement of many proteins in experimental samples, leading to…

- Multiplexing technologies
  - Magnetic Beads
  - Biochips

High-Resolution Mass Spectrometry (HRMS) – Exact masses are measured, instead of nominal masses

- TOFMS, Q-TOF, Orbitraps, TripleTOF
3) What can you expect in 2019? – Day 2

Theme 1: Quantification of proteins/peptides/protein biomarkers

Recent developments, successes and challenges in the lab
- Assay troubleshooting
- Fit for purpose assay development
  - Standardising assay methods to work across multiple drug products
  - Implementing more efficient techniques e.g. multi-analyte methods
- Assay interference
- Using automated liquid handlers (e.g. Bravo, Evo, D300)
- Automation
3) What can you expect in 2019? – Day 2

Theme 2: Advancements in clinical/medical bioanalysis

Technology developments, challenges and opportunities in Drugs of abuse testing/TDM/home sampling
- DoA and alcohol testing in forensic, workplace, DUI frameworks
  - New strategies for classic DoA
  - Tackling NPS emergency
- Therapeutic Drug Monitoring
  - Towards home sampling of non-hospitalised patients
  - Implementing versatile methodologies in routine analysis
- Novel sampling and pretreatment approaches
  - The smaller, the better? Insights into microsampling
  - Focused bridging studies for novel analytical strategies
3) What can you expect in 2019? – Day 2

Theme 2: **Advancements in clinical/medical bioanalysis**

New developments and reagent characterization of LBA assay
- The number of critical reagents in use is ever increasing
  - Traditionally antibodies, engineered proteins, and conjugates
  - Now includes chemically synthesized molecules and complex biologics
- Going beyond concentration as an assessment
  - Pursuing binding activity/kinetics, aggregation level, molecular weight
  - Where do we draw the line?
- Moving towards targeted labelling
  - Reducing heterogeneous nature of labelled reagents
  - Preventing blockage of target binding epitope
4) What we need you to do?

1. To spread the words and promote the EBF YSS amongst your colleagues!
2. To prepare abstracts for poster and oral presentations
3. To convince your managers that attending the 5th YSS will
   - Extend your bioanalytical expertise
   - Improve your presentation skills
   - Extend your network in the bioanalytical community
   - Harvest alternative solutions on day-to-day issues in the lab

EBF YSS standalone website since Sep 2017!

http://yss.e-b-f.eu
Abstract submission open

EBF 5th YSS:
In collaboration with the University of Bologna

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Oratorio di San Filippo Neri
21-22 March 2019, Bologna, Italy

REGISTER NOW

GENERAL PROGRAM SPEAKERS AND POSTERS TRAVEL AND LODGING PREVIOUS MEETINGS

Speakers & Posters

Submit an abstract

You are invited to submit your abstract for a podium presentation or poster reflecting your research, experiences and interests and fitting the proposed themes of the plenary session on March 22nd.

- Oral presentations: Submit abstract before November 26th, 2018 using this form
- Posters: Submit abstract before January 25th, 2019 using this form
Meeting Organisation:

- Jörg Faber (A&M Labor)
- Chris Fox (MedImmune)
- 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)

* Godknows Hlatshwayo (Medimmune) was a former member of the OC during agenda planning. He has now left to pastures new.

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.