Welcome and Introduction

EBF 3rd Focus Meeting:

"Hatching"

Emerging Technologies approaching the Regulated Bioanalysis Laboratory

EBF 3rd Focus Meeting

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Sheraton
Brussels, Belgium
12-13 June 2012

Bioanalysis

NUVISAN Pharma Services

QPS helps you navigate

GE Healthcare

SGS

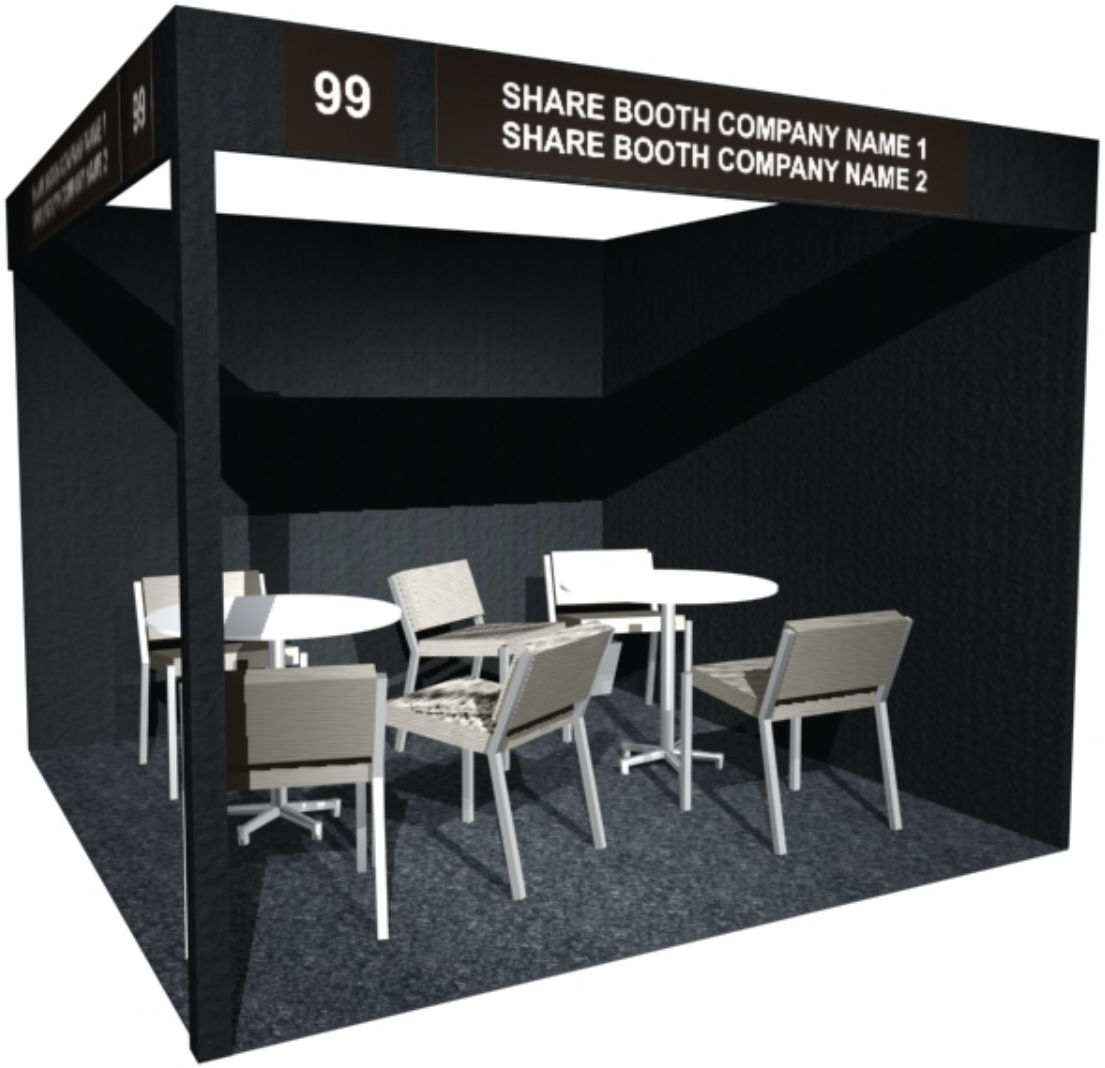
Thermo SCIENTIFIC

Unilabs
Bioanalytical Solutions · York · Sandwich · Copenhagen

Waters
THE SCIENCE OF WHAT'S POSSIBLE.™

COVANCE

AB SCIEX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SHARE BOOTH COMPANY NAME 1
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Why this Meeting?

- Is there life after LC-MS/MS and ELISA?
- Innovation
- Regulations
- Risk averseness

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Is there life after LC-MS/MS and ELISA?

- First ideas of this meeting sparked from the discussions in Topic Team 9: “Alternative techniques to LC-MS”
- This ideas rapidely evolved and broadened into the theme of Focus meeting 3

Is this really a Focus Meeting – “EBF Style”?

- 1st Focus on DBS
- 2nd Focus on peptide/proteins with LC-MS
- 3rd Focus meeting on 10+ technolgies....is this de-focus? NO
  - So, Is this really a Focus Meeting: **YES** - common denominator: technolgies for which the industry is either unclear or hesitant to implement in a regulated BA enviroment or is looking for the value addition in this space

Innovation:

- times have never been more exciting in bioanalysis

- LC: miniaturization
- LC-MS: new hyphenation
- MS(/MS): new and more diverse mass analyzers
- LBA/cell based: multiple new platforms allowing higher throughput and enhanced selectivity or sensitivity

Explosion of new possibilities

- New disease targets
- More diverse chemical portfolios
- Peptides, mAbs,
- Exciting line extensions of existing drugs
- Biomarkers

Explosion of new requests

Regulations:

- times have never been more dynamic in bioanalysis
  - New Guidelines are coming around the globe
    - EMA
    - ANVISA
    - Japan (upcoming)
    - FDA (update anticipated soon)
    - SFDA?
    - New insights on GLP or GCLP in Bioanalysis
    - Bioequivalence updates
    - Guidelines in adjacent discipline (DMPK, Toxicology, Clinical)
  - Bioanalysis is becoming a global sport
    - Labs performing (regulated) bioanalysis in all regions
  - Increased frequency and broadened focus of regulatory inspections

Risk averseness:

- regulated industry is increasingly reluctant to adopt new technologies in a regulated environment
  - Cost may be significant
  - Impact on programs in development not fully understood
  - Are guidelines not inviting enough to do so?
    - AMS, DBS, HR-MS?
  - Is industry risk averse? Are regulators pushing back? Or a combination of both..
  - When does “emerging technology” become “established technology”?
  - What role can vendors play?

So, enough to reflect on….

Enjoy the scientific journey our presenters offer you.

But before we start…think about following questions throughout the conference…they will be the background of our panel discussion tomorrow.

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We will have a panel discussion on the theme of the conference tomorrow

A few questions to think of

Was it easier to implement new technologies in reg. BA in the past?

- If so, give some examples, What helped?

Is it more difficult now? If so, what changed?

Which attitude is key in preventing rapid implementing of new technologies in regulated bioanalysis?

- Regulations:
  - (e.g. GLP, 21 CFR Part 11, BA guidelines, BE guidelines, GCP, other
- Regulators?
- Vendors? Are they aware of our struggle?
- We? Are we perhaps creating the hurdle ourselves?
  - E.g. by not being proactive enough to share in industry
  - E.g. by not being proactive enough to discuss with regulators

Do we know technologies whose full potential cannot be used because regulations stand in the way? ..or because we stand in the way?

(How) Can we stimulate new technologies to be used to their fullest potential?

- By being more proactive enough to share in industry
- By being proactive enough to involve or discuss with regulators earlier?

These questions will be put on a flipchart for all of you to reflect and comment on in preparation of tomorrow's panel discussion