

# **EBF TT-09 : Alternatives to LC-MS/MS**

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on behalf of the EBF (TT-09)

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# History

How a wild idea from 2011- Strategy Meeting becomes an interesting project:

- Discussion during identification of Topic Team topics
  - Are we on top of things?
  - Do we know what is being developed for us?
  - Do we know how technology developments will influence our thinking in 5 years from now?
  - Let's have a team on that....
- Needless to say, and in the best EBF spirit, “we volunteered” the person thinking of this wild idea to be the Team Lead...

# Small molecule Historical Perspective

- 70's: moving away from TLC
- 80's: moving away from immunoassays into chromatography
- Late 80's: techniques in small molecule bioanalysis were LC/UV, LC/Flu, GC, GC/MS = healthy mix
- 90's moving away from above into LC-MS/MS
- Late 90's: techniques in small molecule bioanalysis LC/UV, some GC/MS and LC-MS/MS = good mix
- Early 00's - #1 technique in small molecule bioanalysis was LC-MS/MS
- Late 00's: Reign of LC-MS/MS continued, but with exponential LC and MS improvements – speed and separation power
- Early 10's: continuation of late 00's ? Certainly broadening areas of applications of large molecules in LC-MS/MS
- Late 10's: more of the same?..... where do we want to be?

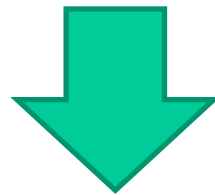
# Objectives

Do we want to sit back and visit Madame Zora occasionally



## Or influence....

- Identify and present unresolved Bioanalytical Challenges?
- Do we know Novel techniques which provide additional information to complement present lab techniques?
- Are we using these yet?



Let's think laterally about possible new techniques



# Strategy

- Would like to open up/host a discussion around new and emerging technology in bioanalysis
  - Novel analytical techniques
  - Older techniques with novel, non-conventional solutions for current project challenges
  - How to ensure these new approaches find their way into regulated laboratories
- Open to New Techniques for both Small and Large Molecule Analysis
- Include input from academic labs / research institutes as well as EBF member companies

# Out of Scope

- We recognise that some EBF members / academic groups may not be completely comfortable
  - E.g. Potential IP issues
- It is not our intention to open up discussion topics of potential concern
- With input from vendors being critical, we should be mindful EBF cannot engage in a single vendor relationship on product development



# Status today

- We are:
  - gaining consensus from EBF member companies to move forward with this topic
- From there, we intend to:
  - identify other recognised academic and research institutes with contributions to make in this area
  - compile a prioritised list of novel technologies/applications for further discussion within EBF and at scientific conference



Can we manage this?

Not sure, but at least, we want to try to be in the forefront of the discussions

It's always good to be near to or in the driver's seat



# Synergies

- EBF Focus Meeting:
  - 12-13 June 2012, Brussels
  - Emerging Technologies and their Applications in the Regulated Bioanalysis Laboratory
- More active participation to scientific conferences
- Input in GBC Harmonization Team 10

# Roles and Responsibilities

- Would require input from multiple stakeholders – EBF members / Academic Labs / Regulators / Large and Small Molecule Experts/(vendors?)
- Primary Responsibility :
  - EBF TT-09 members – current membership
    - o Richard Abbott (Shire, lead)
    - o Olivier Heudi (Novartis)
    - o Stephanie Fischman (Abbott)
    - o Ben Gordon (for Servier)
    - o Brigitte Buscher (TNO Triskelion)
    - o Philip Timmerman (Sponsor)