The Scientific challenge: who will be driving innovation in the future?

Clare Kingsley

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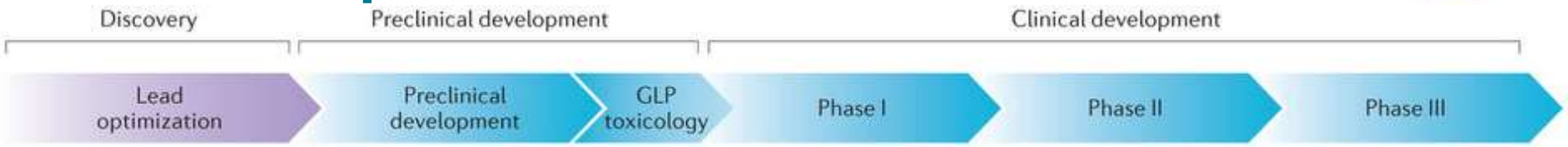
The boundaries are changing

- The relationship between CROs and Pharmaceutical companies are changing towards partnership

- There is an increase in the number of high quality CROs offering full service vs niche services

- In some cases there is a shift towards ‘virtual pharma’

Driving Science in Drug Development in Partnership



- In a survey carried out by The Economist* 49% of respondents said that 'talented and experienced scientists were the most significant factor when selecting a CRO'
  - 'expertise in specific areas of drug development is important in CRO selection'
  - 'CROs being seen as innovators and not just to cut costs'
  - 'it is up to the CRO industry to put forward a broader value proposition'
- Other key factors:
  - Outsourcing is happening *earlier* in the drug development pipeline
  - *Cultural fit* is important in building the right partnerships
  - The relationship with technology suppliers and academia are important
- The model to drive innovation has shifted and is now being driven through partnerships to evaluate new technologies and advance the science

* **Finding Alignment** Opportunities and Obstacles in the Pharma/CRO Relationship 2012

Innovations in Bioanalysis- DBS and Microsampling

- Science through partnership between Pharma companies and CROs

RESEARCH ARTICLE
MINI FOCUS ISSUE: DRIED BLOOD SPOTS

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The effect of hematocrit on bioanalysis of DBS: results from the EBF DBS-microsampling consortium

Background: The European Bioanalysis Forum dried blood spots (DBS)/microsampling consortium is reporting back from the experiments they performed on further documenting the potential hurdles of the DBS technology. This paper is focused on the impact of hematocrit changes on DBS analyses. **Results:** The hematocrit can have an effect on the size of the blood spot, on spot homogeneity and on extraction recovery in a compound-dependent manner. The extraction recovery can change upon aging in an hematocrit-dependent way. Different card materials can give different outcomes. **Conclusions:** The results from the conducted experiments show that the issues of DBS in regulated bioanalysis are real and that the technology will need improvements to be ready for use as a general tool for regulated bioanalysis.

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Innovations in Bioanalysis- Large molecules by LC-MS

High-sensitivity quantitation of a Nanobody® in plasma by single-cartridge multidimensional SPE and ultra-performance LC–MS/MS

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Background: A major challenge in protein quantitation based on enzymatic digestion of complex biological samples and subsequent LC–MS/MS analysis of a signature peptide is dealing with the high complexity of the matrix after digestion, which can reduce sensitivity considera
SPE, sufficient selectivity was i
down to 10.0 ng/ml (~0.3 nM).
was used as the internal stanc
rabbit plasma. **Conclusion:** The
selective LC–MS/MS quantitatio
When appropriate precautions
economical alternative to custor

Development of a high-throughput UHPLC–MS/MS (SRM) method for the quantitation of endogenous glucagon from human plasma

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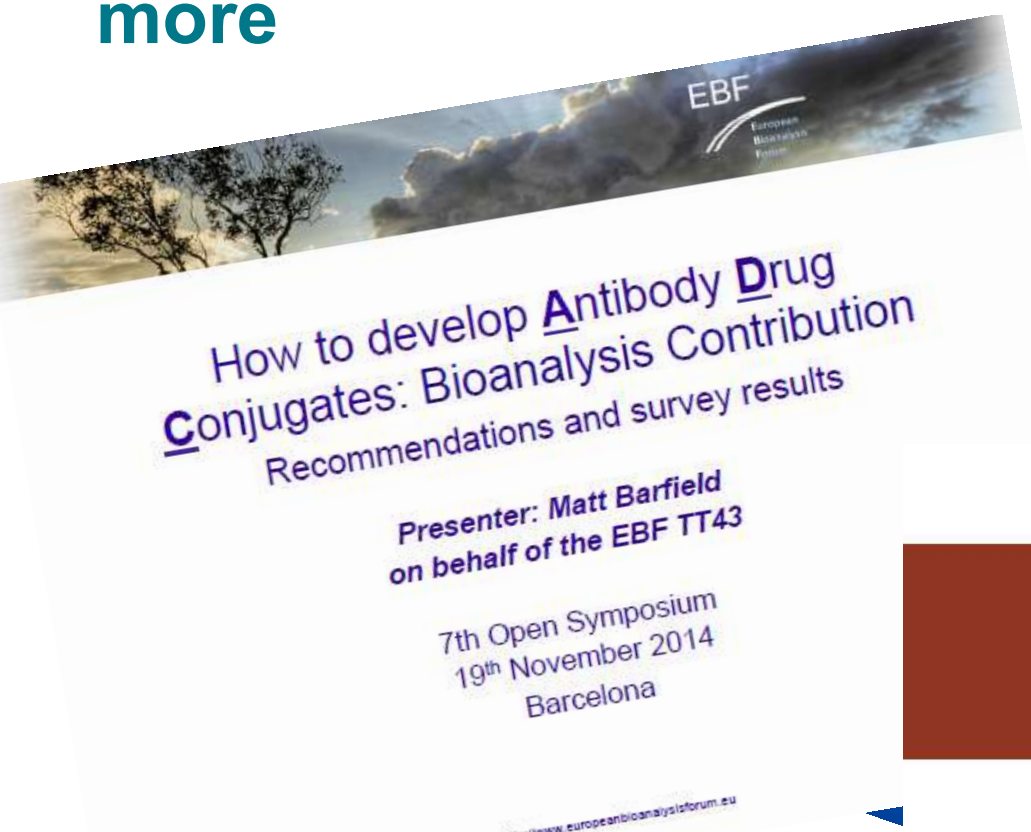
Background: Published LC–MS/MS methods are not sensitive enough to quantify endogenous levels of glucagon. **Results:** An ultra high performance liquid chromatography-MS/MS (SRM) method for the quantitation of endogenous levels glucagon was successfully developed and qualified. A novel 2D extraction procedure was used to reduce matrix suppression, background noise and interferences. Glucagon levels in samples from healthy volunteers were found to agree with radioimmunoassay (RIA) derived literature values. Bland–Altman analysis showed a concentration-dependent positive bias of the LC/MS–MS assay versus an RIA. Both assays produced similar pharmacokinetic profiles, both of which were feasible considering the nature of the study. **Conclusion:** Our method is the first peer reviewed LC–MS/MS method for the quantitation of endogenous levels of glucagon, and offers a viable alternative to RIA-based approaches.

Innovations in Bioanalysis- ADC and more



- Topic teams within the EBF, research within CROs as well as traditional research from within Pharmaceutical companies is driving the way forwards

Who will be driving innovation of the future?

Most exciting opportunities

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