EBF 3rd Open Conference "From Challenges to Solutions"

Day 0 - 30 NOVEMBER 2010

14:00	20:00	Registration Desk Open

Day 1 - 1 DECEMBER 2010

08.30		Welcome
08.40	10.30	**Bioanalysis – Thinking Outside the "Commodity" Box** Aims and Objectives of the session: This session is intended to showcase why bioanalysts and bioanalytical groups should be considered as more than simply a commodity within an organisation. Bioanalysis is more than a black box where samples go in one end and results come out of the other. The knowledge and expertise within bioanalytical communities is a valuable resource which can significantly enhance the drug discovery & development process and decision making. Speakers are invited for this session to present where novel approaches, emerging technologies or provision of expertise have solved or can address complex project issues beyond the routine provision of TK/PK data. The session intends to host 4 speakers (20 – 30 min each, including Q&A) with an opportunity for the audience to provide input and share thoughts and insights at the end of each presentation.
10.30	11.00	Coffee Break
11.00	12.30	**Practical Solutions to Bioanalytical Challenges** Aims and Objectives of the session: In this session, four focussed presentations (15 minutes each) are invited on blood, plasma and serum chemistry in relation to bioanalytical challenges, the relevance to bioanalytical behaviour analytes in these matrices and their associated stabilities. The presentations will be followed by a panel discussion
12.30	13.30	Lunch and poster session
13.30	16.00	**Towards Global Harmonization** Aims and Objectives of the session: In this session, a status update will be given on global harmonization of Bioanalysis guidelines. Regulatory and industry representatives will provide feedback and discuss on the path forward. The session intends to host 6 presentations and will be followed by a panel discussion in which the audience is invited to provide input and share thoughts and insights.
16.00	16.30	Coffee Break
16.30	18.00	**Pt Sponsor session I** Aims and Objectives of the session: In this session, the Pt sponsors are invited to share cutting edge technology and scientific developments from within their company. Each Pt sponsor will have a 20-25 min slot (30 min - including Q&A). **Conference Reception I** Enjoy a few drinks and savor traditional food and snacks during this great networking opportunity

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Day 2 - 2 DECEMBER 2010

08.30	10.00		**Pt Sponsor session II** Aims and Objectives of the session: In this session, the Pt sponsors are invited to share cutting edge technology and scientific developments from within their company. Each Pt sponsor will have a 20-25 min slot (30 min - including Q&A).
10.00	10.30		Coffee Break
10.30	12.30		**Technologies and Comparison of Assay Platforms** Aims and Objectives of the session: The session will focus on one-to-one comparison of assay platforms for the determination of large molecules with ligand binding assays and hyphenated mass spectrometric techniques. In addition, applications of technologies like Multiplexing, ECL, Biacore, alphaLISA and automation will be discussed.
12.30	14.00		Lunch and poster session
14.00	17.30		**Breakout sessions I - III**
14.00	15.30	I	**Reconnect on Dried Blood Spots** Aims and Objectives of the session: EBF will give feedback on the June 2010 focus meeting on Dried Blood Spots and present their plans. Two additional presentations are invited with focus on new developments or new insights on the technique. Contributions on applications of DBS are invited to submit a poster.
		IIA	**Guideline on "Assay Development for Immunogenicity Testing of Therapeutic Proteins" and Related Topics** Aims and Objectives of the session: A consolidated response on FDA's draft guideline on "Assay Development for Immunogenicity Testing of Therapeutic Proteins" was submitted to the Agency by EBF Interest Group Marcomolecules (EBF-IGM) as well as by AAPS Ligand Binding Assay Bioanalytical Focus Group (AAPS LBABFG). In this session, based on the consolidated responses, regulatory requirements, current scientific knowledge and experiences from daily work will be discussed taking into account the establishment of the screening and confirmatory cutpoint and possible implications of immunogenicity on the pharmacokinetics. The second part of the session will focus on Neutralizing assays strategies and integrated PK/PD analysis.
15.30	16.00		Coffee Break
16.00	17.30	III	**Practical Solutions to Bioanalytical Challenges** Matrix Effects - breakout session: Aims and Objectives of the session: In this session, key speakers will be invited to present and elaborate on the influence of such topics as choice of anti-coagulant, counter-ions, hyperlipidaemic samples and haemolysed samples on bioanalytical results. The variability of IS response, the impact on results and possible acceptance criteria will be discussed. Speakers are invited to share their case study examples with the audience. The presentations will be followed by a panel discussion.
		IIB	**Guideline on "Assay Development for Immunogenicity Testing of Therapeutic Proteins" and Related Topics** continuation from break out session 14.00-15.30 **Conference Reception II** Enjoy a few drinks and savor traditional food and snacks during this great networking opportunity

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Day 3 - 3 DECEMBER 2010

08.30	09.30	**EBF Feedback** Aims and Objectives of the session: In this session, EBF members will give feedback on discussions and surveys organized in the EBF community. At the same time, EBF anticipates to get input for topics and issues that the audience would like to be discussed in the broader EBF community. The session will host 2 speakers.
09.30	10.00	Coffee Break
10.00	12.00	**Finding the Right Level** Aims and Objectives of the session: As bioanalyst we are not only facing the challenge of finding the right level of drug substance in biological matrices, but also finding the right level in processes related to our business, e.g. how and to which degree to investigate and document anomalous results within regulated bioanalysis and at the same time balance compliance while considering science. The aim of this session will be share experiences with the aspects mentioned and to discuss and try to find a common understanding how to handle these topics within regulated bioanalysis. The session intends to host 4 presentations (15-20 minutes each) and will be followed by a panel discussion in which the audience is invited to provide input and share thoughts and insights.
12.00	14.00	**Biomarkers** Aims and Objectives of the session: The session will focus on the validation of biomarker assays. We will discuss the extension of validation needed to fit different purposes like exploratory. investigations, PK/PD evaluation, support of safety parameter. The validation of commercially available kit will also be included.
14.00		**Meeting Closeout**