

## final agenda vo6APR2018

### Critical reagents for LBA

#### 13 MAY 2018

17:00 Registration desk opens  
18:00 – 19:00 Welcome reception – Altis Hotel

#### 14 MAY 2018

07:30 Registration desk opens  
08:45 – 09:00 Welcome and introduction  
09:00 – 10:30 **Session 1 – Critical reagents for PK assays: general & regulatory framework**  
09:00 – 09:15 Introduction to the session – *Susanne Pihl (on behalf of the EBF)*  
09:15 – 09:45 Update on the guidelines and current practice in industry  
*Michaela Golob (on behalf of the EBF)*  
09:45 – 10:15 The EBF decision tree on CR for PK assays, in perspective of current industry practices  
*Susanne Pihl (on behalf of the EBF)*  
10:15 – 10:30 Q&A

10:30 – 11:00 **Coffee break & networking**  
11:00 – 12:30 **Session 2 – Case studies on alternative approaches to manage critical reagents (PK assays)**  
11:00 – 11:20 Case study: The importance of quality critical reagents for the entire developmental life cycle of a biopharmaceutical: A PK Case Study  
*Andrew Mayer (GlaxoSmithKline)*  
11:20 – 11:40 Characterization of critical reagents – FB from the AAPS ADA community  
*Jonathan Haulenbeek (BMS, on behalf of the AAPS)*  
11:40 – 12:00 Critical reagents for PK assessment – How reagent characteristics can impact your result interpretation  
*Thomas Emrich (Roche Pharma Research and Early Development)*  
12:00 – 12:30 Expert panel discussion

12:30 – 13:30 **Lunch**  
13:30 – 15:00 **Session 3 – Critical reagents for immunogenicity assays – general & regulatory framework**  
13:30 – 13:45 Introduction to the session – *Birgit Jaitner (on behalf of the EBF)*  
13:45 – 14:05 Update on the guidelines and current practice in industry  
*Jo Goodman (on behalf of the EBF)*  
14:05 – 14:40 Recommendations on CR for immunogenicity assays, in perspective of current industry practices  
*Barry van der Strate (on behalf of the EBF)*  
14:40 – 15:00 Q&A

15:00 – 15:40 **Coffee break & networking**  
15:40 – 17:15 **Session 4 – Case studies on alternatives approaches to manage critical reagents (immunogenicity assays)**  
15:40 – 16:00 Qualification of new lots of critical reagents for IG assays: Some practical examples  
*Lydia Michaut (Novartis)*

16:00 – 16:20	Management of an ADA critical reagent issue during a clinical study support <i>Laurent Vermet (Sanofi)</i>
16:20 – 16:40	ADA Case study: Generation and characterization of critical reagents supporting immunogenicity assays: Case studies on how to navigate challenging drug modalities <i>Terri Caiazzo (Pfizer)</i>
16:40 – 17:15	Expert panel discussion
<b>17:15 – 17:30</b>	<b>Closing Questions &amp; Answers session</b> Panel of presenters answering delegate's pre-submitted questions
<b>17:30</b>	<b>Adjourn</b>