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