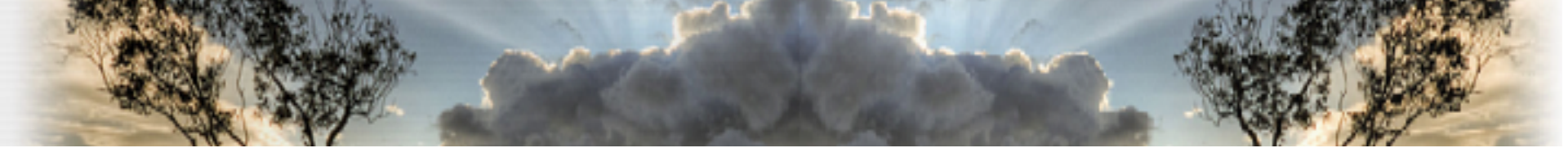

Breakout Sessions 2 and 3: LBA

Joanne Goodman, on behalf of the EBF

Ligand Binding Assays (LBA)

- Previously LBA may have been viewed as the ‘poor relative’ in terms of regulatory guidelines
  - MHLW being the exception with a completely separate guideline
  - Otherwise chromatography language has been adapted

- ICH M10 brings a dedicated LBA part of the guidance which is welcomed
  - Cross referencing to chromatography sections is ***almost*** removed
  - Hopefully removes some ambiguity

However ….

- Despite dedicated sections for LBA, there may still have some areas of "*chromatography creep*"
  - e.g. calibration curve range
- Other areas treat LBA differently to chromatography
  - e.g. stability
- In the next 2 sessions, we will continue to discuss the items that have been identified by the EBF community as worthy of discussion for LBA

13:30	**15:20**	**Breakout session 2: LBA**
13:30	13:40	Introduction to the afternoon session *presenter: Joanne Goodman (AstraZeneca)*
13:40	14:00	Stability assessments *presenter: Michaele Golob (Nuvisan)*
14:00	14:20	Considerations on calibration range during validation & sample analysis *presenter: Anna Laurén (SVAR)*
14:20	14:40	Specificity and Selectivity *presenter: Wibke Lembke (Janssen Biologics)*
14:40	15:20	Panel discussion
15:20	**16:00**	**Coffee break**
16:00	**17:30**	**Breakout session 3: LBA**
16:00	16:20	Partial validation and/or Dilution linearity & Parallelism *presenter: Robert Nelson (Novimmune)*
16:20	16:40	Documentation & glossary – Specific to LBA *presenter: Stephen Williams (Charles River)*
16:40	17:30	Closing panel discussion LBA