EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Programme

Expert Workshop on Setting Specifications for Biotech Products

9th September 2011, 9:00 – 17:00 (GMT)
European Medicines Agency, 7 Westferry Circus, Canary Wharf, London, E14 4HB, UK

Chair: Jean-Hugues Trouvin, Chairman of the CHMP Biologics Working Party

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8.30 – 9.00	**Registration**
9:00 – 9:10	**Welcome address** Jean-Hugues Trouvin (BWP Chairman)
9:10 – 9:20	**Introduction** Enda Moran (EBE, EuropaBio, Pfizer)

Session 1: What to Control

- **Defining Quality attributes:**
  - **Critical and non-critical**
  - **Tool**
  - **Applicability of Critical Quality Attributes (CQAs) to drug product? Drug substance, intermediates, starting and raw materials?**
- **Considerations in relation to:**
  - **Identity, purity, biological activity…**
  - **Characterisation studies**
  - **Development studies**
  - **Stability studies**

  etc…

Moderators: Brigitte Brake (BfArM), Simon Hotchin (EBE, Amgen)

9:20 – 9:40	**Presentation by an EU Regulator** Nanna Aaby Kruse (BWP, BMWP, Danish Medicines Agency)
9:40 – 10:00	**Presentation by Industry** Thomas Stangler (EGA, Sandoz)
10:00 – 10:20	**Discussion**

Session 2: Basis for Setting Acceptance Criteria

- **Aspects to consider**
  - **Historical data/prior knowledge**
  - **Number of batches**
  - **Development (clinical lots) vs consistency lots**
  - **Development assays vs validated assays**
  - **Ph. Eur. vs safety and consistency data**
- **Clinical exposure vs process capacity**

Moderators: Brigitte Brake (BfArM), Andreas Premstaller (EGA, Sandoz)

10:20 – 10:40	**Presentation by an EU Regulator** Mats Welin (BWP, Medical Products Agency)
10:40 – 11:00	**Presentation by Industry** Brian Withers (EBE, Abbott)
11:00 – 11:20	**Discussion**

11:20 – 11:50	**Coffee break**

Session 3: Statistical Considerations in Setting Acceptance Criteria

- **Statistical approaches / applications**
  - **When and why is one selected**
  - **Trending and internal limits for consistency control**
- **Sample size**
  - **Number of units**
  - **Volume**

Moderators: Lyudmil Antonov (BWP, BDA), Karin Sewerin (EBE, MedImmune)

11:50 – 12:10	**Presentation by an EU Regulator** Kai-Martin Hanschmann (Paul Ehrlich Institute)
12:10 – 12:30	**Presentation by Industry** Enda Moran (EuropaBio, Pfizer)
12:30 – 12:50	**Discussion**

12:50 – 14:00 **Lunch**

Session 4: How and Where to Control and What to Put in the File

- **Control strategy: testing vs validation vs procedural controls**
  - **In-process control/ Release/ Real-Time Release Testing/ Skip lot testing**
  - **Criteria**
    - **Range/ Limit/ Qualitative**
    - **Alert/ Action/ Reject**
- **Handling of CQAs/non CQAs in the file**
- **Risk management**
  - **Variability and Experience**
- **Regulatory agreement in relation to specifications - What would it look like**

Moderators: Mats Welin (BWP, Medical Products Agency), Ronald Imhoff (EBE, Janssen Biologics)

14.00 – 14:25	**Presentation by an EU Regulator** Kowid Ho (BWP, BMWP, Afssaps)
14.25 – 14:50	**Presentation by Industry** Karin Sewerin (EBE, MedImmune)

14:50 – 15:05 **Coffee break**

Questions and Discussion Moderators: Mats Welin (BWP, Medical Products Agency), Ronald Imhoff (EBE, Janssen Biologics) Panel: All Speakers and Moderators in Sessions	
15:05 – 16:45	Regulators/Industry

Closing Remarks	
16:45 – 17:00	Jean-Hugues Trouvin (BWP Chairman) Brian Withers (EBE, Abbott)

17:00 End of Workshop