The EMA Guideline on bioanalytical method validation

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Disclaimer

• The views expressed in this presentation are mine and may not represent those of either EMA, the PKWP, or Afssaps
History

- Concept paper Dec. 2008
- Consultation period till 31 May 2010
- Final guideline adopted July 2011
- Into effect 01 February 2012
Consultation period

- Comments received from > 50 sources
- Informal and formal contacts with FDA, under confidentiality agreements
- Discussions at workshops, meetings…
  - EBF/EUFEP, Brussels, April 2010
  - EBF, 2009, 2010
  - CVG, April 2010
  - NBC, May 2010
  - AAPS, November 2010
Consultation period

[World map showing consultations in North America, Latin America, Europe, Africa, Asia, and Oceania.]
From draft to final: some of the main changes

• LBA section separated, totally re-written
• Clarification of scope
• GCP, GLP: input from GLP inspectors working group
From draft to final: some of the main changes

• Pre-study validation
  – Full, partial, cross-validation
  – Matrix effects: haemolysed and lipemic samples separated, other option for excipients
  – Matrix effects: added level close to ULOQ
  – Between-run P&A: number of samples no longer specified
  – Stability testing (long-term, blood…)

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From draft to final: some of the main changes

• In-study validation
  – Overall P&A of QC samples: calculate and report, investigate if > 15 %. Problem mainly for bioequivalence trials.
  – No PK repeats: for bioequivalence trials
From draft to final: some of the main changes

• Others
  – ISR: specified number of samples, better definition of situations where needed
  – Separated validation report and analytical report
  – No need to provide SOPs if enough details in the reports
EMA guideline on BMV

- Official questions on the guideline

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EMA guideline on BMV

Thank you for your attention