The EMA Guideline on bioanalytical method validation

EMEA/CHMP/EWP/192217/2009

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EBF Open Symposium
Barcelona, November 2011

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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

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History

- Concept paper Dec. 2008
- Draft guideline published Dec. 2009
- Consultation period till 31 May 2010
- Final guideline adopted July 2011
- Into effect 01 February 2012

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Consultation period

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

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Consultation period

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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

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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