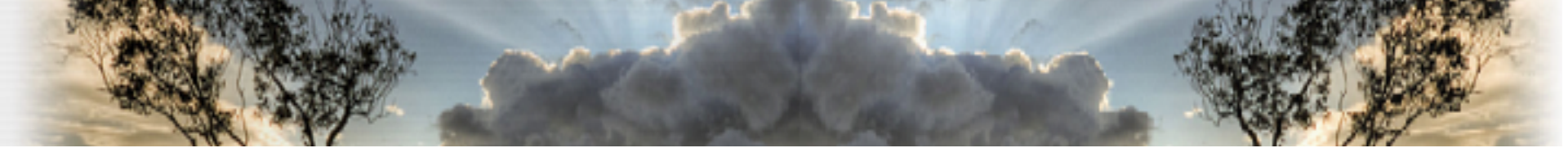

Commercial and Diagnostic Kits Paragraph 7.5, ICH M10 draft

Breakout Workshop Moderator – Arno Kromminga, on behalf of the EBF

Purpose and limitations of ICH M10, 7.5

- Commercial or diagnostic kits are sometimes co-developed with new drugs or therapeutic biological products for point-of-care patient diagnosis.
- Repurposes kits to measure chemical or biological drug concentrations during the development of a novel drug.
- The recommendations in this section of the guideline do not apply to the development of kits that are intended for point-of-care patient diagnosis (e.g., companion or complimentary diagnostic kits).

Aim of the workshop

- Identify challenges and agree on proposed recommendations for change on the paragraph
- We will split into 7 key areas
  1. Validation criteria
  2. Standards
  3. Quality controls
  4. Matrix
  5. Lot-to-lot variability
  6. Inter plate variability
  7. Have we missed something?

Break out session

- Tuesday, 21 May 2019, 8:30 – 10:00
- Room: URANO