Workshop

Towards harmonised implementation of the ICH M10 Guideline

Chapter 7, Chrom&LBA

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15 November 2022, Barcelona

Themes/questions discussed today

- **Joint discussion Chromatography and LBA**
  - **Endogenous molecules and surrogate matrix**

- Separate discussions in Chromatography and LBA
  - Parallelism
  - Recovery and microsampling/dried matrix
  - New or Alternative Technologies
  - Diagnostic kits

Chapter 7 is new but endogenous drugs are not

- **Biomarkers are out of scope**
- Only relevant for therapeutics drugs that are **identical to endogenous**
- Replacement therapy has been used since last century
  - Insulin for Type 1 diabetes – First treatment in 1922 and Nobel price in 1923, first fully human recombinant in 1978
  - Coagulation factor replacement therapy in hemophilia - 1964
  - Growth hormone for growth deficiency since - 1958
  - Hormone replacement therapy (HRT) started in the 1960s – estrogen for menopause, osteoporosis, cardiovascular events
- Modern drugs are often slightly modified versions of endogenous compounds and thus specific bioanalysis is possible: chapter 3 or chapter 4

Endogenous molecules and surrogate matrix text from M10 chapter 7.1

Matrix:

“In those cases where matrices without interference are not available, the following approaches can be used to calculate the concentration of the analyte in the study samples”

1. “the surrogate matrix approach”
2. “the surrogate analyte approach”
3. “the background subtraction approach”
4. “the standard addition approach”

QCs:

“The QCs should resemble study samples and should be prepared in the same matrix”

“All QC concentrations used for validation should be aliquots of the authentic biological matrix”

EBF proposal for implementation:

- Approach adopted for each program should be scientifically and technology driven.

Acknowledgements

- Delegates attending previous EBF workshops on M10
- The EBF community for EMA public consolidation period in 2019 on M10
- The EBF community and workshop delegates for the responses on the pre-survey in 2022

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