Note

- These are excerpts from the discussion at JBF ICH-M10 workshop 2023. Please note that these do not represent the official position of JBF.

NA for General

- **Did not discuss** these topic on JBF M10WS 2023
  - PG-01: Scope - did ICH M10 or we raise the bar?
  - PG-02: Is it allowed to re-analyse positive predose in BE study?

General

G1: Scope interpretation - primary matrix definition

- **The guideline requires Method validation to be under GLP?**
  ➡ **Yes**

- **Apply the ICH M10 guideline for Biomarkers?** ➡ **No**

- **Apply the ICH M10 guideline for other types of studies beyond the intended PK/TK scope of M10?** ➡ **No**

Other topics of this theme were not covered in JBF M10 workshop.

General

G2: ISR in practice

- **Changed your process for ISR since ICH M10? ➡ No**

- **Are you performing ISR for more studies than required as per ICH M10? ➡ Yes** (**all clinical studies as much as possible**)

  - Not only to verify analytical method, but also **to perform quality checks** such as detecting operation errors.

G3: Updating historical validations – when, how and why (not)?

- **As part of implementing ICH M10, have you updated/re-validated previously validated assays (assays that were validated towards EMA-2012 and/or FDA-2018) requirements. ➡ Yes and No**

  Comments from Yes

  - Some companies only implement **new evaluation items** such as batch size evaluation and reinjection reproducibility. (Both clinical and non-clinical)

  Comments from No

  - If **only the evaluation method** (e.g., matrix effect) is changed, it will **NOT** be re-evaluated.

  - **Follow the guidelines** when conducting validation studies.

  - Depends on **the status of future study sample analysis**.

General

G4: Regulatory feedback from recent submissions/inspections

- **Do you have a recent FB on your implementation of ICH M10?**
  - ➡ **No**
    - **No company has used it** for approval applications yet.

G5: Cross validation - working in the new paradigm

- **Change your process of cross validation after ICH M10 became active?**
  ➡ **Yes**

- **Apply acceptance criteria on cross validation?** ➡ **Yes**
  - Evaluated using both **bias (plot)** and **ISR criteria**

- **Apply a correction factor for concentrations after cross validation?** ➡ **No**
  - The bias was not large to need correction.
  - There was an opinion that it is necessary to consult a statistical analysis expert when performing Bias analysis.

Other topics of this theme were not covered in JBF M10 workshop.