

# Scientific Validation / Fit-For-Purpose Validation and GLP



**PRAHEALTHSCIENCES**

**DATE**

22 November 2018

**PRESENTED BY**

Martine Broekema, Ph.D.

Associated Director of  
Bioanalytical Sciences

Large Molecules



# Scientific / Fit-For-Purpose Validation and GLP

1. Is it allowed to perform a SV or FFP validation for an assay that is used to support GLP pre-clinical PK studies?
2. Should we claim GLP for SV or FFP validations in support of pre-clinical GLP bioanalytical studies?

**Case study** showing differences in opinion



# SV or FFP validations and GLP

Situation:

- Pharmacodynamic assay
- Supportive PK assay (in CSF)
- Supporting Pre-clinical Multi-site GLP bioanalytical study

Request from sponsor:

Perform a SV / FFP validation with GLP claim



# SV or FFP validations and GLP

## Differences in opinion between Sponsor and CRO

Sponsor: SV or FFP validation is sufficient but GLP claim is required

PRA (QA/Project management): proposed to change to full validation with GLP claim; based on internal SOP

**Advice Dutch GLP inspector asked and input provided during recent inspection**



# Perform a SV or FFP validation for support of GLP pre-clinical PK studies?

## Recent GLP inspection at PRA (September 2018)

Focus on non-standard GLP studies (e.g. pre-clinical SV/FFP validation studies)

### Conclusions:

- GLP does not dictate the content of the validation
- It is allowed to perform SV / FFP validation for the support of pre-clinical multisite GLP bioanalytical studies



# GLP claim for SV or FFP validations?

OECD Good Laboratory Practice: Frequently asked questions (FAQ)

<http://www.oecd.org/env/ehs/testing/glp-frequently-asked-questions.htm#MethodValidation>

## Method Validation

### 1. Should method validation be completed prior to the initiation of a GLP study?

There is no requirement to finalise the validation of all methods that will be used to conduct a GLP study before the initiation of the study. However, there is an expectation that methods are fully validated before the results of the study are considered to be valid (posted on 21 January 2016).

### 2. What standard should be applied to the validation of methods which are used in GLP studies and how should it be applied?

Unless stipulated in national regulations, **there is no requirement to perform method validation in compliance with GLP.** Since parameters of the validated method are used in the GLP study (for example threshold, linearity, accuracy, precision, stabilities, equipment settings, etc.), data should be accurately recorded and stored in a manner that protects its integrity. Validation data may be required for study reconstruction and, consequently, it should be retained for an appropriate period of time.