Cambridge Biomedical

Validating multiple matrices to expedite development

At Cambridge Biomedical we are frequently asked by clients how they can expedite their development program, especially when moving from pre-clinical to first-in-human phases.

When developing a bioanalytical assay for our clients we follow the FDA guidelines and regulations.

For a true animal study we utilize the GLP regulations (link to FDA website http://1.usa.gov/1JT8NbI) and for human studies we conduct our validation according to GLP principles. In addition, if GCLP is required, we utilize the WHO regulations.

These guidelines require a specific set of processes to be followed to ensure that the validated assay meets the studies requirements. These typically include the following:

- Accuracy
- Precision
- Selectivity
- Sensitivity
- Stability
- Linearity
- Interference

As part of the validation process we must develop and validate the assay for each sample matrix that will be utilized in the study. For example, the pre-clinical work may require that mouse serum be utilized and for the next phase human serum.

During the validation process it is frequently possible to conduct the experiments with multiple matrices and produce only one validation report. While the cost and timeline for performing the joint validation will be greater than a single matrix validation it will be less than conducting two separate validations. In our experience clients can often reduce the overall timeline by approximately 25 to 30% and a consequent reduction in cost.

Each validation is unique and what we suggest is to engage in a detailed dialogue with our team before committing to the project and determining if it is possible to conduct a joint validation.

If you would like to explore this option in more detail please don't hesitate to contact us at info3@cambridgebiomedical.com

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