Good Bioanalytical Sciences in Drug Development

Timely bioanalytical support is essential to improve the success rate of drug candidates moving along the pipelines and allows decision to be made early to modify/improve the drug candidates or terminate the program. Bioanalytical support in development also presents some unique challenges. Preclinical and clinical bioanalytical support is under strict regulations where the data generated is under high regulatory scrutiny. Contemporary topics ranging from cutting-edge technology such as **dried blood spot (DBS)** to unique method validation challenges for **biomarker measurement** are gaining wide acceptance in the scientific community yet these may not have been well defined in the regulatory bioanalysis guidance. Another unique bioanalytical challenge is to support a good metabolic selectivity coverage. Usually at the early stages of preclinical, information on metabolites is not well characterized and definitive human ADME study is usually not run till later stages. It is often time uncertain how many metabolites should be included in the assay. Insufficient coverage of the metabolites measurement would leave no coverage of safety margin in clinical trials should a minor metabolite in animal species become a significant one in human. On the other hand methods measuring too many metabolites could result in high failure rates, a highly undesirable feature not only costly but also leads to regulatory question regarding to the entire method validity. **Tiered approach for metabolite measurement** based on the needs is gaining acceptance by both regulatory agencies and industry scientists. Bioanalytical scientists should also be aware of the gap that exists between method development/validation and sample analysis. Even though the batch acceptance is based on the pass or fail of calibration standards and quality control samples, one must be fully aware that incurred samples can't be totally mimicked by fortified standards and QCs. **Incurred sample reanalysis (ISR)** and **unexpected events investigation** are just two examples that are currently used to address this issue. The fourth unique characteristic of the bioanalytical support is the globalization of the method usage. Bioanalytical method developed and validated at one location can be transferred and validated at another site of the same company or to an outside laboratory. How to efficiently **transfer and validate method** to meet the regulatory requirements in a cost-effective manner must be considered. Use of good bioanalytical sciences to address these unique bioanalytical challenges will be discussed at this session, lead by opinion leaders in these areas.

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