2023 Program Themes

Bioanalytical Track

Theme 1: Old Platform, New Tricks

Keywords: LC-MS, LBA, Gyros, Biomarkers, ADCs, novel modalities, cell therapy, gene therapy, ADA Isotyping

Drug therapies continue evolve and so do the bioanalytical strategies used to characterize them. Unconventional use of legacy technology platforms that have been around for decades can answer some questions. This theme will share strategies for using legacy technology platforms to resolve today's unique bioanalytical challenges.

Theme 2: Emerging Platforms and New Challenges

Keywords: Critical reagents for novel modalities, microsampling advancements, ddPCR, HRMS, innate immunity, expamers, bioanalytical strategies

The advent of novel next generation modalities like cell and gene-based therapies is driving development of non-conventional assay platforms to assess PK of such therapeutics. Gene-expression-based molecular assays and cellular kinetics using flow-based assessments can replace detection of proteins through conventional LBA-based approaches. Similarly, immunogenicity assessments now require cellular immune response assessments performed using low volumes of samples and high throughput proteomics-based measurements. Challenges to obtaining high-integrity whole blood sample from terminally ill and pediatric populations is also driving an evolution in sampling techniques.

Theme 3: Risk Assessment of Next Generation Biologics

Keywords: Risk assessment, regulatory guidance, learnings from previous biologics

The risk assessment process identifies risks throughout development, spanning discovery, early process development, non-clinical safety/toxicology, and clinical development. For recombinant proteins and monoclonal antibodies, these risks have been characterized and delineated, and tools and assay platforms identified to mitigate such risks have been qualified for application. For next generation biologics with more complexity, which include multi-domain constructs, fusion proteins, and cell and gene therapy-based products, the risk factors identified are unique and diverse, and relate to the sequence and structure of the

intended therapeutic and can also be contributed by the vehicles, formulations, and delivery approaches. Hence, novel tools and assays are required to perform such risk assessments. Understanding potential risks enables a robust and streamlined bioanalytical strategy in clinic. The bioanalytical assessments may require novel platforms and may require customization to address risks that could not be mitigated in preclinical development.

Pharmaceutical Analysis Track

Theme 1: Lab of the Future

Keywords: Artificial intelligence, advances in modeling, sustainability, miniaturization

As laboratory science evolves, advances in robotics and computers are making it possible for scientists to delegate some of their work to machines and algorithms. Advances in analytical technologies have enabled the characterization of smaller samples, in-situ, in nondestructive and greener ways. Advances in manufacturing require some labs to be located in production areas. This theme discusses key elements of the modern analytical lab, designed to meet the needs of future (and already current) ways of working in pharmaceutical research and manufacture.

Theme 2: Analytical Challenges in Developing Novel Modalities

Keywords: Biologics, conjugates, cell therapies, novel synthetic modalities

The traditional approach to analytical characterization of pharmaceuticals is undergoing a paradigm shift. Analytical chemists must deliver on the therapeutic opportunity offered by the evolving nature of drug modalities. This theme focuses on recent advances in analytical method development and testing of novel biologic modalities like protein/mAB conjugates, cell-therapies, and novel synthetic modalities like macrocyclic peptides, mRNA, lipids.

Theme 3: Clinically Relevant Specifications

Keywords: Dissolution testing, PBPK models, harmonized global control strategies

Clinically relevant specifications have been defined as test procedures and acceptance criteria that identify and reject/accept drug product batches that are likely to perform inadequately/adequately in the indicated patient population. This theme focuses on opportunities to align and harmonize product attributes, analytical procedure requirements, and specifications with the delivery of patient medicines that are safe and efficacious.

Theme 4: Analytical Tools to Enable Continuous Manufacturing

Keywords: Control strategies, drug substance continuous manufacturing, biologics continuous manufacturing, PAT, regulatory assessment.

Developing and implementing advanced manufacturing processes is critical to maintaining the supply of safe medicines while managing the associated cost. This theme focuses on analytical strategies to support the development of advanced processes such as continuously manufactured active pharmaceutical ingredients and drug products.

Theme 5: Life Cycle Management of Analytical Procedures – Regulatory Implications

Keywords: Analytical procedure development, post-approval change management, ICH Q12, ICH Q14, performance monitoring, global regulatory guidelines.

Better methods produce better data to support better decision-making. This theme discusses the challenges and opportunities for managing analytical methods throughout the product life cycle, including enhanced development as well as post-approval activities such as performance monitoring, continuous improvement, and change management. Relevant guidelines that provide a science and risk- based regulatory framework for change management of analytical procedures such as ICH Q12 and ICH Q14 will be discussed, and the USP <1220> chapter concepts will also be explored.