# PharmSci 360 Tracks

**Discovery and Basic Research Track**

Basic research advances fundamental knowledge and predictions that form the scientific foundation for progress in applied science. Discovery research leads to new scientific ideas, theories, applications, and ways of thinking that form the basis of growth and development in different fields. Generating this critical knowledge is the first step toward inventing new tools, sparking therapeutic innovation, and enabling a more rapid and successful delivery of novel drugs to the market.

**Preclinical & Translational Sciences**

This area of science connects discovery and basic research with human medicine. This track covers the development of knowledge of targets, biological mechanisms, disease characteristics, and intended patient populations using preclinical and clinical data to anticipate, understand, and optimize the use of a new drug in humans. For submission to a regulatory agency for human trials, preclinical and translational deliverables include: (1) pharmacology studies in efficacy models; (2) nonclinical safety studies and risk mitigation strategies; (3) determination of pharmacokinetic and pharmacodynamic properties of the drug molecule, its metabolites, formulations, and delivery devices' (4) developing biomarkers to support patient selection, pharmacodynamics, and surrogate endpoints; (5) early clinical development to determine or confirm clinical pharmacology, mechanism of action, efficacy and safety, and relate this knowledge to findings in cells or animal models; and (6) useful application of modeling and simulation to integrate and learn from cross-study results throughout drug development.

**Bioanalytics**

Bioanalytics covers the science of quantitative measurement of selected analytes in biological fluids and tissues after a therapy is administered to animals or humans. It is broadly used across all therapeutic modalities (including small molecule, biologic, and gene and cell therapies). Bioanalytics also covers the measurement of immunogenicity (immune response) to those therapies and the measurement of endogenous molecules (biomarkers) whose concentrations are representative of the disease or the biological effect of the therapy. Bioanalytics are also applied to address new challenges with legacy products and in support of overall lifecycle management.

**Manufacturing and Analytical Characterization**

This track combines the manufacturing and analytical characterization of source materials (API) and drug products for small molecules, biologics, and gene and cell therapies. It covers the critical aspects of API and drug product manufacturing for both new therapies and modalities and well-characterized products (life-cycle management). Synthetic and biologics manufacturing processes are both considered. In addition, it explores different analytical characterization procedures to assure quality, safety, and efficacy throughout the product development and lifecycle. New analytical approaches, including those that measure multiple product attributes (MAM), as well as questions around the establishment and measurement of critical quality attributes (CQAs) are considered here as are regulatory and compendial compliance developments, including questions of international harmonization among ICH, WHO, and others. This track also covers life cycle management and issues that arise with new requirements for legacy products.

**Formulation and Delivery**

This track focuses on the key challenges surrounding pharmaceutical formulation, in which different excipients and the pharmaceutically active drug substance are combined to produce a suitable drug product. The delivery aspect explores novel devices and non-traditional formulations that overcome challenges that cannot be addressed using more traditional formulation approaches.