SECTION & FOCUS GROUP DESCRIPTIONS

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SECTION	DESCRIPTION
Analysis and Pharmaceutical Quality (APQ)	analytical techniques, regulatory and compendial issues, and assurance of quality
Biotechnology (BIOTEC)	research, development, and commercialization of new biotechnology-based pharmaceuticals
Clinical Pharmacology and Translational Research (CPTR)	therapeutics and clinical assessment of drugs and biological: experimental design, conduct and analysis of clinical trials; regulatory aspects of clinical trials and drug registration; risk assessment, therapeutic extrapolation from animals to humans; pharmacoepidemiology; drug interactions; and in appropriate populations, therapeutic efficacy/safety and response to alternative dosage forms
Drug Discovery and Development Interface (DDDI)	focuses on issues at the critical interface between drug discovery and drug development; discovering, optimizing, and effectively transitioning preclinical candidates into the clinical development phase
Formulation Design and Development (FDD)	share experimental results, consider new formulation and dosage form technologies, and discuss issues and concerns regarding the design and development of formulations/drug products for all dosage forms
Manufacturing Science and Engineering (MSE)	application and advancement of science and technology to the process development and manufacture of pharmaceutical and pharmaceutically-related products including medical devices and active pharmaceutical ingredients
Pharmacokinetics, Pharmacodynamics and Drug Metabolism (PPDM)	biopharmaceutics, pharmacokinetics, pharmacodynamics, drug metabolism and transport of pharmaceutical products and therapies
Physical Pharmacy and Biopharmaceutics (PPB)	physicochemical and biological factors that impact the design and delivery of small molecules and biologics and focuses on preformulation, biopharmaceutics, drug absorption, nanotechnology, and drug delivery systems design and performance including targeted drug delivery
Regulatory Sciences (RS)	regulatory compliance, GMP, clinical and pre-clinical practices; the legal aspects of pharmaceutical development; and protection of intellectual property

FOCUS GROUP	DESCRIPTION
Animal Pharmaceutics and Technology	scientists in the animal health industry or involved in the veterinary pharmaceuticals field, and those who use animal models in the development of human drug products
Chemical and Biological API Manufacturing Technology	small molecule and large biologic issues related to the manufacture of active pharmaceutical ingredients (API)
Bioanalytical	chromatographic assays applied to quantitative and qualitative investigations of small and large molecules in biological matrices that support drug discovery and development
Bioequivalence	scientific issues relating to the demonstration of bioequivalence and biosimilarity that allow for sound regulatory policy decisions; PK, statistical designs, and metrics for equivalence of different dosage forms
Biomarkers in Translational Medicine	how to translate in vitro and laboratory findings into clinical applications and to facilitate drug development (qualifying and fitness of use)
Biosimilars	biosimilars as a broad topic (bioanalysis, manufacturing, regulatory, trials design, etc.), allowing decisions to be made not just within a sub-specialty group, but to provide feedback/perspectives from all areas involved in the biosimilar pipeline
Chemistry, Manufacturing, and Controls (CMC)	technical and regulatory CMC topics associated with the development of pharmaceuticals
CMC Statistics	utilization of appropriate statistical methodology
Contract Research Organization (CRO)	issues of interest to CROs, partners, and customers including the industry-sponsored, pre-clinical CMC (Chemistry, Manufacturing and Controls), as well as clinical research programs globally
Dermatopharmaceutics	study of skin and associated structures, skin permeation technologies, topical and transdermal product development as well as members involved in cosmeceuticals, regulatory and marketing of these pharmaceutical products
Discovery Modeling and Simulation	cross-disciplinary view on how modeling is applied in the drug discovery and preclinical space including medicinal chemistry, pharmaceutics, drug metabolism and PK, and toxicology
Drug Candidate Selection	integrated and cross-disciplinary view on assessing developability for compound selection and development, much in line with how it is actually assessed in the pharmaceutical industry
Drug Metabolism	all aspects of the biotransformation of chemicals and therapeutic agents as well as the conditions that influence metabolism and those that are affected by biotransformation processes
Drug Transport	state-of-the-art techniques to study drug transport and to enhance knowledge about the mechanisms of action of drug transporters
Excipients	understanding of excipients and their use in pharmaceutical formulations including understanding of excipient quality, functionality, drug-excipient interactions and regulatory considerations
Generic Pharmaceuticals	development and manufacture of generic pharmaceutics
Inhalation and Nasal Technology	art and science of pharmaceutical inhalation aerosol and nasal drug delivery systems
In Vitro Release and Dissolution Testing	development of useful and standardized methods to meet the challenges of new dosage forms and to improve or encourage innovation of new methodologies, provide a more in depth understanding of the IVIVC
Ligand Binding Assay Bioanalytical	technologies and issues pertaining to the bioanalysis of analytes by nonchromatographic assays, including binding assays, immunoassays, activity- and cell-based assays

Lipid-Based Drug Delivery Systems	use of lipid-based systems in drug discovery and product development to effectively overcome physical and biological barriers related to poor aqueous solubility and stability, membrane permeability, drug efflux and bioavailability
Microdialysis	sampling technique that permits collection of molecules in the interstitial fluid of various organs with minimal tissue damage; current applications and future potentials in quantitative drug research and development
Modified Release	mechanistic understanding, formulation design & development, process development & scale-up, as well as the related regulatory aspects of modified release dosage forms
Nanotechnology	control of matter on a scale smaller than 1 micrometer, normally between 1-100 nanometers, as well as the fabrication of drug and gene delivery devices and diagnostics on this same length scale
Non-Clinical Dose Formulation and Analysis	technical and regulatory topics associated with nonclinical dose formulation analysis; dosing of poorly soluble, poorly permeable drug substances, and analytical challenges
Nutraceutical and Natural Products	drug discovery and development of nutraceuticals, dietary supplements, and natural products
Ocular Drug Delivery and Disposition	novel drug delivery system design for ocular applications; emerging trends in ocular pharmacokinetics such as the use of microdialysis technique for aqueous and vitreous humor kinetics; and cellular and molecular basis of ocular drug delivery (e.g., cell culture models, epithelial electrophysiology, drug efflux pumps, and cytochrome P450 isoenzymes)
Oral Absorption	human oral absorption (e.g., species differences in permeability, gastrointestinal tract regional differences in permeability, intestinal metabolism, in vitro/in vivo correlations, compound library for oral absorption research)
Patient-Centric Drug Development, Product Design, and Manufacturing	based on existing or new formulation and drug delivery technologies, along with efficient, highly flexible, and innovative manufacturing technologies and platforms that allow the provision of personalized therapeutics like individual dose strength, fixed dose combinations, and appropriate packaging solutions, etc., but also efficient adherence monitoring systems
Pharmaceutical Impurities	technical and regulatory topics associated with impurities for both small molecule and biologic medicines.
Pharmaceuticals in Global Health	application of pharmaceutical sciences to the solution of global health issues
Pharmaco-imaging	amalgamation of imaging and pharmacology that provides additional information that could not otherwise be obtained using traditional techniques and allows for a more precise, faster and direct translation of data from a preclinical to clinical context
Pharmacogenomics (PGx)	genetic causes of individual variations in drug response; pharmacogenomics more broadly involves genome-wide analysis of the genetic determinants of drug efficacy and toxicity
Pharmacometrics	quantitative concepts of pharmacometrics in the discovery, development, regulatory approval, and market utilization of therapeutic agents
Preformulation	characterization of physical and chemical properties of both small and large-molecule drug substances or drug products, and is performed at both the early-stage and mid-stage development in pharmaceutical development and manufacturing
Process Analytical Technology	system for designing, analyzing, and controlling manufacturing processes through timely measurements (i.e., during processing) of critical quality and performance attributes of raw and in-process materials, to ensure final product quality
Process Development	design, development, analysis, and optimization of technical processes

Process Modeling and Simulation	application of physics based (such as Discrete Element Models, Computational Fluid Dynamics, Finite Element Analyses), engineering and mathematical modeling (statistical models such as LVM) techniques to better understand, control, develop and improve pharmaceutical manufacturing processes (both API and DP)
Protein Aggregation and Biological Consequences	qualitative and quantitative aspects of aggregation of therapeutic protein products, to discuss and develop techniques to study aggregation and factors that cause aggregation and to discuss potential impact of aggregation including immunogenicity and for example kinetics, (bio) activity
QbD and Product Performance	Quality by Design (QbD) paradigm and biopharmaceutics, and its potential impact on enhancing drug product quality
Stability	issues with stability testing and interpretation of new regulatory guidances relating to stability testing of API and finished products
Sterile Products	science and technology of parenteral products including sterile products that cover a range of therapeutic entities from small molecules to large biologics
Systems Pharmacology	drug action at the molecular, cellular, tissue, organ, organism, and population levels
Targeted Drug Delivery and Prodrug	site-specifically deliver or activate the therapeutic compounds in the site of action
Therapeutic Product Immunogenicity	interpretation, presentation and clinical application of immunogenicity, and pursue validation of the risk factors and underlying cause-effect relationships affecting the immunogenicity of therapeutic products