

Poster Abstract Tracks/Topics (Review Groups)

AAPS **PharmSci 360** will combine all the energy of a large scientific conference with the intimacy of a small niche gathering. There are five robust tracks covering all aspects of the pharmaceutical sciences, including both chemical and biomolecules.

IMPORTANT Note: in the submission site, the structure below; Track, Subtrack, Primary Topic, Subtopic, and Secondary Topic, are referred to as Review Groups. You will be prompted to select the Review Group that best fits your abstract.

Review Group (Track/Topic) Selection Process

1. Select the Track that best fits your research. (*see below*)

* Preclinical Development

* Bioanalytics

* Clinical Pharmacology

* Manufacturing and Bioprocessing

* Formulation and Quality

2. Select the Subtrack (Biomolecules or Chemical Entity).

3. Select the Primary Topic that best fits your research.

4. From your Primary Topic, select the best Subtopic for your research. If no listed term fits your research, select 'Other'. (*Note: There may not be a subtopic available for your Primary Topic.*)

5. If your Subtopic shows Secondary Topic choices, make the best selection. If no listed term fits your research, select 'Other'. (*Note: There may not be a Secondary Topic available for your Subtopic.*)

TRACK	SUBTRACK	PRIMARY TOPIC	SUBTOPIC	SECONDARY TOPIC
Bioanalytics	Biomolecules	ADCs and Peptide Quantification	Electrospray Ionization	
			Hybrid LBA/LCMS	
			Ligand Binding Assay (LBA)	
			Other	
		Bioanalytical Innovations and Applications		
			Biomarker/Pharmacodynamic Measurement	

Biomarker Quantification	Target Engagement/Receptor Occupancy		
	Technologies other than LBA and Mass Spec (e.g., Flow, PCR) Other		
Drug Quantification	Endogenous Homologs Quantification		
	Other Methods/Techniques		
	Pharmacokinetic Measurements	Intact	
		Free	
		Surrogate	
Total			
Other			
	Post-Marketing Commitment		
	Therapeutic Drug Monitoring		
Immunogenicity	ADA Test Methods		
	Cell-Based Methodologies		
	Immunogenicity Risk Assessments		
	Neutralizing Antibody Methods		
	Other		
In Vivo and Ex Vivo Biotransformation	Evaluation of Biotransformation In Vivo		
	Impact of Biotransformation on Immunogenicity		
	Impact of Biotransformation on PK		
	Molecule Variants Quantification Ex Vivo		
Life Cycle Management of Bioanalytical Methods	Collaboration with Other Partners (Co-development)		
	General Life Cycle Management		
	Methods Transfer and CRO Management		
	Other		
Novel Modalities	ADCs		
	Alternative Scaffold		
	CAR-T		
	Cell-Based Therapy		
	Encapsulated Drugs (Lipid, Nanoparticle, and Viral Vectors)		
	Multi-specific Antibodies		
	Nanoparticle Based Modalities		
	Oligos, RNAs and Locked Nucleic Acids		
Other			
Other			

		Reagents and Reference Standards	Life Cycle Management	
			Quality Control and Characterization	
			Stability	
			Other	
		Regulations (BMV/GLP/GCP/CLIA)	Biomarkers	
			Drug (and Metabolites)	
			GCP/GLP Compliance for Bioanalytical Labs	
			General Topics	
			ICH	
			Immunogenicity	
			Samples and Reagent Stability	
			Bioanalytics Risk Assessment and Strategy (Tiered Strategies)	
		Other		
Samples and Laboratory Management	Laboratory Information Management System (LIMS)			
	Microsampling and Dried Blood Spots			
	Post-Collection Sample Condition and Record Management			
	Other			
Vaccines	Methods/Techniques			
	Protective Titer Assessment			
	Other			
Chemical Entities	ADCs and Peptide Quantification	Electrospray Ionization		
		Hybrid LBA/LCMS		
		Ligand Binding Assay (LBA)		
		Other		
	Analyte Stability	Ex Vivo		
		In Vitro		
		Other		
	Applications			
	Biomarker Quantification	Biomarker/Pharmacodynamic Measurement		
		Methods to Assess Disease Heterogeneity		
Target Engagement/Receptor Occupancy				
Technologies Other than Mass Spec (e.g., PCR)				
Other				

		Drug Quantification	Endogenous Homologs Quantification	
			Other Methods/Techniques	
			Pharmacokinetic Measurements	
			Therapeutic Drug Monitoring	
		Immunogenicity	ADA Test Methods	
			Other	
		In Vivo and Ex Vivo Biotransformation	CYP450 Assessment	
			Evaluation of Biotransformation In Vitro or In Vivo	
			Impact of Biotransformation on Immunogenicity	
			Impact of Biotransformation on PK	
Metabolite Quantification				
	Other			
Life Cycle Management of Bioanalytical Methods	Collaboration with Other Partners (Co-development)			
	General Life Cycle Management			
	Methods Transfer and CRO Management			
	Other			
Novel Modalities	Alternative Scaffold			
	Encapsulated Drugs (Lipid, Nanoparticle and Viral Vectors)			
	Multispecific Antibodies			
	Nanoparticle Based Modalities			
	Oligos and Locked Nucleic Acids			
	Other			
Other				
Reagents and Reference Standards	Life Cycle Management			
	Quality Control and Characterization			
	Stability			
	Other			
Regulations (BMV/GLP/GCP/CLIA)	Biomarkers			
	Drug (and Metabolites)			
	GCP/GLP Compliance for Bioanalytical Labs			
	General Topics			
	ICH			
	Immunogenicity			
	Samples and Reagent Stability			
	BioanalyticsI Risk Assessment and Strategy (Tiered Strategies)			
	Other			

		Samples and Laboratory Management	Informed Consent	
			Laboratory Information Management Systems (LIMS)	
			Microsampling and Dried Blood Spots	
			Post-collection Sample Condition and Record Management	
			Other	

TRACK	SUBTRACK	PRIMARY TOPIC	SUBTOPIC	SECONDARY TOPIC
Clinical Pharmacology	Biomolecules	Biostatistical Methodologies	Bayesian Methods	
			Regulatory Recommendations	
			Statistical Analysis Models	
			Statistical Reporting	
			Tools/Software	
		Other		
		Clinical Trials	Designs and Methodology	
			Dosing Strategies	
			Ethics in Clinical Trials	
			Modeling and Simulation	
			Monitoring	
			Patient Stratification	
			Regulatory Guidance	
		Other		
		Immunogenicity	ADA	
			Clinical Relevance	
			Neutralizing Antibody	
			Other	
		In Vitro Studies	ADME	
			Biomarkers/Pharmacodynamic Measures	
Blood to Plasma Partitioning				
Drug Transport and Drug Interactions				
Genetic Variation/PGx Testing				
Protein Binding				
Other				
Modalities	ADCs			
	Alternative Scaffold			
	CAR-T			
	Cell-Based Therapy			
	Encapsulated Drugs (Lipid, Nanoparticle and Viral Vectors)			
	Multispecific Antibodies			
	Nanoparticle-Based			
	Oligos, RNAs and Locked Nucleic Acids			
	Vaccines			
Other				

Modeling and Simulation	Absorption Model	
	Allometric Scaling	
	Comparator Modeling	
	Decision Making	
	Dose Project/Selection/Justification	
	Imaging Based Approach	
	In Vivo-In Vitro Correlation (IVIVC) Modeling	
	Maternal/Fetal PK Model	
	Pediatric Model	
	Pharmacometrics	
	Physiologically Based Pharmacokinetics (PBPK) Model	
	PK/PD Modeling	
	Population PK Modeling	
	Quantitative Systems Pharmacology (QSP)	
	Tools/Software	
Other		
Other		
Regulatory Guidance/Submissions	CDISC	
	Clinical Study Reports (CSRs)	
	Clinical Trial Protocols	
	CTD/eCTD Models 1 to 5	
	Data Management	
	FDA/EMA/PMDA Meetings	
	Labeling	
	NDA/BLA/ANDA Submissions	
	Safety	
Other		
Type of Human Studies	Bioequivalence/Biosimilars	
	Diseased Population	
	Drug-Drug Interaction (DDI)	
	First-Time-in-Human (FTIH)	
	Food Effect	
	Geriatric	
	Multiple Ascending Dose (MAD)	
	Pediatric	
	Radio-Labeled Mass Balance and ADME	
	Relative and Absolute BA	
	Single Ascending Dose (SAD)	
	Thorough QT/QTc (TQT)	
Other		

	Chemical Entities	Biostatistical Methodologies	Bayesian Methods	
			Regulatory Recommendations	
			Statistical Analysis Models	
			Statistical Reporting	
			Tools/Software	
			Other	
		Clinical Trials	Designs and Methodology	
			Dosing Strategies	
			Ethics in Clinical Trials	
			Modeling and Simulation	
			Monitoring	
			Patient Stratification	
			Regulatory Guidance	
		Other		
		In Vitro Studies	ADME	
			Biomarkers/Pharmacodynamic Measures	
Blood to Plasma Partitioning				
Drug Transport and Drug Interactions				
Genetic Variation/PGx Testing				
Protein Binding				
Other				
Modeling and Simulation	Absorption Model			
	Allometric Scaling			
	Comparator Modeling			
	Decision Making			
	Dose Project/Selection/Justification			
	Imaging Based Approach			
	In Vivo-In Vitro Correlation (IVIVC) Modeling			
	Maternal/Fetal PK Model			
	Pediatric Model			
	Pharmacometrics			
	Physiologically Based Pharmacokinetics (PBPK) Model			
	PK/PD Modeling			
	Population PK Modeling			
	Quantitative Systems Pharmacology (QSP)			
	Tools/Software			
Other				

		Regulatory Guidance/Submissions	CDISC Clinical Study Reports (CSRs) Clinical Trial Protocols CTD/eCTD Models 1 to 5 Data Management FDA/EMA/PMDA Meetings Labeling NDA/BLA/ANDA Submissions Safety Other	
		Type of Human Studies	Bioequivalence/Biosimilars Diseased Population Drug-Drug Interaction (DDI) First-Time-in-Human (FTIH) Food Effect Geriatric Multiple Ascending Dose (MAD) Pediatric Radio-Labeled Mass Balance and ADME Relative and Absolute BA Single Ascending Dose (SAD) Thorough QT/QTc (TQT) Other	

TRACK	SUBTRACK	PRIMARY TOPIC	SUBTOPIC	SECONDARY TOPIC	
Formulation and Quality	Biomolecules	Administration	In-Use Compatibility		
			Nasal/Pulmonary		
			Ocular		
			Otic		
			Strategies		
			Trans-dermal		
			Other		
		Analytical	(Sub)Visible Particles		
			Excipients		
			Impurities		
			Modality Specific Methods		Cell Therapy
					Free Oligonucleotide
					Gene Therapy
					Protein
					Vaccine/Tolerance Induction
			Other		
			New Technology		
		Potency/Bioassay			
		Other			
		Drug Delivery	Extended Release (Non-implant)		
			Implants		
			Other Routes of Administration		Ocular
					Otic
			Other		Trans-dermal and Topical
Other	Other				
Drug Delivery, Devices, and Drug Device	Design Control				
	Hardware				
	Human Factor Engineering				
	New Delivery Technologies				
	Patient-Centric Development				
	Software				
Formulation	Cell Therapy				
	Free Oligonucleotide				
	Gene Therapy				
	Protein	Developability Assessment			
		Excipients			
		General Liquid Formulation Topics			
		Syringes			
		High-Throughput Screening			
		Lyo			
		Other			

			Vaccine/Tolerance Induction	
			Other	
		Other		
		Primary Packaging	Compatibility	
			Container Closure Integrity	
			Extractables/Leachables	
			New Materials	
		Regulatory Considerations	(Sub)visible Particles	
			Accelerated Approval Pathways	
			Bioequivalence	
	Biosimilars			
	Innovative Technologies			
	Inspections and GMP's			
	Large Market Developments			
	New Regulations and Guidances			
Risk Assessment Implementation				
Smaller Market Developments				
Stability Requirements				
Chemical Entities	Analytical	Drug Release Measurement	Biorelevant Dissolution	
			Cascade Impaction	
			Dissolution	
			Drug Release from Other Dosage Forms	
			Other	
	Excipients			
	Impurities and Degradation	Forced Degradation		
		Impurity Quantitation		
		In Silico Prediction of Stability		
		Other		
	Method Development Strategies			
		New Analytical Technologies		
		Process Analytical Technology and Continuous Release Testing		
		Other		
	Biopharmaceutics	BCS, DCS		
Bioequivalence (also Regulatory)				
Comparability Assessments				
IVIVC				
Predictive Modeling				
Other				

		Drug Delivery	Extended Release (Non-implant) Implants	
			Other Routes of Administration	Ocular
				Otic
				Trans-dermal and Topical
		Other		
		Drug Delivery, Devices, and Drug Device	Design Control	
			Hardware	
			Human Factor Engineering	
			New Delivery Technologies	
			Patient-Centric Development	
			Software	
		Formulation	Amorphous and Co-crystal Systems	
			Bioavailability Enhancement	
			Drug Substance Properties	
			Excipients	
			Fixed Dose Combinations	
			Inhalation and Nasal	
			Oral	Immediate Release
				Modified Release
			Parenterals	
			Preformulation	
Special Populations				
Other				
Primary Packaging	Compatibility			
	Container Closure Integrity			
	Extractables/Leachables			
	New Materials			
Regulatory Considerations	(Sub)visible Particles			
	Accelerated Approval Pathways			
	Bioequivalence			
	Biosimilars			
	Innovative Technologies			
	Inspections and GMP's			
	Large Market Developments			
	New Regulations and Guidances			
	Risk Assessment Implementation			
	Smaller Market Developments			
Stability Requirements				

TRACK	SUBTRACK	PRIMARY TOPIC	SUBTOPIC	SECONDARY TOPIC			
Manufacturing and Bioprocessing	Biomolecules	Automation	Computer Validation				
			Other				
		Biosimilar Manufacturing	Biosimilarity Assessment				
			Patent Protection				
			Other				
		Drug Product Manufacturing and Development	Aseptic Technologies and Sterilization	Filling			
				Filtration			
				Mixing			
				Other			
			Cell Therapies	Freezing and Thawing			
						Lyophilization and Drying Technologies	
			Manufacturing and Assembly of Drug/Device Combinations	Manufacturing of Drug Delivery Systems			
						Primary Packaging	Container Closure Integrity
			Process Optimization	Protein Aggregation during Processing and Immunogenicity		Syringes	
						Secondary Packaging	Vials
						Storage Considerations	Other
						Vaccines	
						Viral and Non-viral Vectors and Gene Therapy	
						Visible and Subvisible Particles	
						Visual Inspection	
						Other	
						API Packaging and Storage	Cell Line Development
		Cell Therapies					
Clonality Assessments							
Expression Systems							
Genetic and Cell Line Engineering							
Mammalian Cell Fermentation							
Media Development							
Microbial/Yeast Fermentation							
Process Optimization							

		Protein Aggregation during Processing and Immunogenicity	
		Purification and Virus Removal	
		Vaccines	
		Viral and Non-viral Vectors and Gene Therapy	
		Other	
	General Aspects and Strategies	Change Control	
		CMO Management	
		Drug Master Files	
		Drug Substance and Drug Product Shipment	
		Electronic Records	
		Handling Control Substances (DEA)	
		Inspections and GMP	
		Lean Manufacturing	
		Life Cycle Management	
		Manufacturing Economics	
		Materials Management and Warehousing	
		Regulatory Strategy	
		Supply Chain	
		Other	
	Health, Safety, and Environment	Containment and Isolators	
		High-Potent Drug Manufacturing	
		OEL and PDE	
		Other	
	Innovative/Novel Processing Technologies and Concepts	For Use in Drug Product Manufacture	
		For Use in Drug Substance Manufacture	
		Other	
	Integrated and Continuous Processing and Manufacturing	For Use in Drug Product Manufacture	
		For Use in Drug Substance Manufacture	
		Other	
	Manufacture of Clinical Supplies	Blinding of Comparator Drugs	
		Phase Appropriate GMP	
		Other	
	Other		

		Plant Engineering and Maintenance	Clean Media		
			Facility Design		
			Media		
			Media Fills		
			Modeling and Scheduling Multiproduct Batch Plants		
			Modular Manufacturing		
			Plant Incident Investigations		
			Other		
		Process Design and Controls	Cleaning Validation		
			Control of Impurity Formation		
			In-Process Controls		
			Process Analytical Technology and Parametric/Real-Time Release		
Process Modeling and Simulations					
Process Validation					
QbD and Assessment of Process Parameters					
Scale-Up/Process Transfers					
Statistical Process Controls and Six Sigma					
Use of Prior Knowledge and Risk-Based Approaches					
Other					
Single-Use and Disposable Systems	For Use in Drug Product Manufacture				
	For Use in Drug Substance Manufacture				
	Leachables and Extractables				
	Other				
Chemical Entities	Automation	Computer Validation			
		Other			
		Aseptic Technologies and Sterilization		Filling	
				Filtration	
				Mixing	
				Other	
		Freezing and Thawing			
		Liquids Manufacture		Oral and Topical Liquids	
				Other	
		Lyophilization and Drying Technologies			
Manufacturing and Assembly of Drug/Device Combinations					
Manufacturing of Aerosols and DPI					
Manufacturing of Drug Delivery Systems					

		Drug Product Manufacturing and Development	Primary Packaging	Blisters
				Bottles
				Container Closure Integrity
			Process Optimization	
			Secondary Packaging	
			Semi-solids Manufacture	Cremes
				Nanoemulsions, Nanocapsules, Liposomes, Solid Lipid Nanoparticles
				Other
			Solids Manufacture	Capsules
				Powders
				Tablets and Granules
				Other
			Storage Considerations	
			Visual Inspection	
		Other		
		Drug Substance Manufacturing and Development	API Kilo Lab	
			API Packaging and Storage	
			Control of Impurity Formation	
			Crystal Structure/Polymorph Screening	
			Crystallization Development	
			Filtration	
			Genotoxic Impurities	
			Milling and Micronization Technologies	
			Particle Size Control	
			Process Chromatography	
			Process Optimization	
			Purification	
Other				
General Aspects and Strategies	Change Control			
	CMO Management			
	Drug Master Files			
	Drug Substance and Drug Product Shipment			
	Electronic Records			
	Handling Control Substances (DEA)			
	Inspections and GMP			
	Lean Manufacturing			
	Life Cycle Management			
	Manufacturing Economics			
Materials Management and Warehousing				

			Regulatory Strategy	
			Supply Chain	
			Other	
		Generic Manufacturing	Patent Protection	
			Pharmaceutical Equivalence Assessment	
			Other	
		Health, Safety, and Environment	Containment and Isolators	
			Explosion Protection	
			Green Chemistry	
			High-Potent Drug Manufacturing	
			OEL and PDE	
			Solvent Recovery	
			Other	
		Innovative/Novel Processing Technologies and Concepts	For Use in Drug Product Manufacture	
			For Use in Drug Substance Manufacture	
			Other	
		Integrated and Continuous Processing and Manufacturing	For Use in Drug Product Manufacture	
			For Use in Drug Substance Manufacture	
			Other	
Manufacture of Clinical Supplies	Blinding of Comparator Drugs			
	Phase Appropriate GMP			
	Other			
Other				
Plant Engineering and Maintenance	Clean Media			
	Facility Design			
	Media			
	Media Fills			
	Modeling and Scheduling Multiproduct Batch Plants			
	Modular Manufacturing			
	Plant Incident Investigations			
	Other			
	Cleaning Validation			
	Control of Impurity Formation			
	In-Process Controls			
	Process Analytical Technology and Parametric/Real-Time Release			

		Process Design and Controls	Process Modeling and Simulations Process Validation QbD and Assessment of Process Parameters Scale-Up/Process Transfers Statistical Process Controls and Six Sigma Use of Prior Knowledge and Risk-Based Approaches Other	
		Single-Use and Disposable Systems	For Use in Drug Product Manufacture For Use in Drug Substance Manufacture Leachables and Extractables Other	

TRACK	SUBTRACK	PRIMARY TOPIC	SUBTOPIC	SECONDARY TOPIC
Preclinical Development	Biomolecules	ADME	In Vitro	Metabolizing Enzymes
				Protein Binding
				Transporter
			Other	
			In Vivo	
				Pharmacokinetics
		Other		
		Discovery	Biology	In Silico
				In Vitro
				In Vivo
				Receptor/Target Interactions
				Target Identification
			Other	
			Biology/Efficacy	In Silico
				In Vitro
				In Vivo
			Chemistry	Structure Activity Relationships
				Other
			Conjugation	
				Novel Drug Modality
				Payload-Linker
Identification/Optimization				
Protein/Gene Engineering and Expression				
Receptor/Target Interactions				
Structure Activity Relationships				
Target Identification and Selection				
Vaccines	Antigen Evaluation			
	Disease and Pathogen Evaluation			
	Immunogenicity			
	Innate/Adaptive Immunity			
	Novel Delivery Strategies			
	Parasite Biology			
	Preclinical Formulation and Adjuvants			
Other				
Other				
	Genomics			
	Metabolomics			
OMICS	Proteomics			
Other				

		Safety	Cellular and Molecular Toxicity		
			De-risking Strategies		
			Immuno-toxicity		
			IND Enabling Studies		
			Mechanistic Toxicity		
			Screening Toxicity Studies		
			Other		
		Translation	Drug-Drug Interactions		
	Human Dose Projections		Allometric (PBPK) Other		
	Model Based Drug Development				
	PK/PD				
	Other				
	Chemical Entities	ADME	In Vitro	Metabolizing Enzymes	
				Protein Binding	
Transporter					
Other					
In Vivo			Pharmacokinetics		
			Other		
		Discovery	Biology	In Silico	
In Vitro					
In Vivo					
Other					
Receptor/Target Interactions					
Target Identification					
Chemistry		Structure Activity Relationships			
	Other				
	In Silico				
	In Vitro				
	In Vivo				
	Novel Drug Modality				
	Target Interactions				
Other					
OMICS	Genomics				
	Metabolomics				
	Proteomics				
Other					

		Safety	Cellular and Molecular Toxicology	
			De-risking Strategies	
			Immuno-toxicity	
			IND Enabling Studies	
			Mechanistic Toxicity	
			Screening Toxicity Studies	
			Other	
		Translation	Drug-Drug Interactions	
			Human Dose Projections	Allometric
				Physiologically Based Pharmacokinetics (PBPK)
				Other
			Model Based Drug Development	
PK/PD				
Other				