
# 2026 Program Themes

## Preclinical, Clinical, and Translational Sciences

### Theme 1: Integrating In Vitro Data with In Silico and Quantitative Modeling Approaches to Drive Translational Decisions

**Keywords**: In Vitro ADME; Drug Enzymes and Transporters; Target Engagement; Drug Discovery; Lead Optimization; Candidate Selection; IVIVE; Mechanistic and Static Modeling; PBPK Modeling; QSP; Translational Modeling; Human Dose Projection; Drug-Drug Interactions (DDI); Preclinical Development; AI/ML; Physiologically Relevant In Vitro Systems; Quantitative Decision Frameworks; Digital Twins (early application), PK/PD Modeling, New Modalities

This theme focuses on the integration of in vitro data, in silico modeling, and quantitative pharmacology approaches, including IVIVE for DDI assessment, PBPK, QSP, mechanistic modeling, and emerging AI/ML methods to support drug discovery, preclinical development, and translational decision-making. Together, these approaches inform compound selection, enhance prediction of DDI risk, and optimize exposure-response relationships, and guide translation from preclinical-to-human. Programming should emphasize cross-disciplinary integration and translational continuity.

## Theme 2: Innovative Preclinical and Translational Strategies to Enhance Predictability and Support Successful Drug Development

**Keywords**: Preclinical Development; Translational Science; Predictive Models; Disease-Relevant Models; New Approach Methodologies (NAMs); Animal Models; Organ-on-a-Chip; Microphysiological Systems; Translational Biomarkers; Quantitative PK/PD; Digital Twins (biologically informed); Mechanistic Disease Modeling; Virtual Organs; Systems Pharmacology; Model-Based Translation; Human Relevance; Regulatory Science

This theme highlights innovative preclinical, animal model-based, and translational strategies, along with emerging regulatory approaches. Areas of focus include novel experimental models, fit-for-purpose animal models, New Approach Methodologies (NAMs), organ-on-a-chip and microphysiological systems, translational and mechanistic biomarkers, and quantitative PK/PD and translational modeling frameworks. Integration of experimental systems with biologically informed digital twins provides a quantitative framework for translating mechanistic insights from preclinical and NAM-based models to human-relevant outcomes. These approaches aim to reduce or replace animal use where scientifically appropriate, decrease uncertainty in human translation, and strengthen early scientific decision-making across academia, industry, and regulatory settings.

## Theme 3: Integrating Clinical Trials, Real-World Data, MIDD, and AI/ML to Transform Clinical Development and Evaluation

**Keywords:** Clinical Trials; Real-World Data (RWD); Model-Informed Drug Development (MIDD); Artificial Intelligence/Machine Learning (AI/ML); Clinical Development; Trial Design; Dose Optimization; Patient Centric; Drug-Drug interaction (DDI); Special Population; Exposure- Response Analysis; Real-World Evidence (RWE); Regulatory Science; Post-Marketing Evaluation

This theme explores how clinical trials, real-world data (RWD), model-informed drug development (MIDD), and artificial intelligence/machine learning (AI/ML) can be integrated to transform clinical development and evaluation. Emphasis is placed on innovative approaches to trial design and execution, dose optimization, patient selection, and evidence generation. This theme also highlights the role of quantitative modeling and advanced analytics in supporting regulatory interactions, while addressing challenges in data quality and transparency. Methodological rigor, lifecycle learning, and integration of evidence from development through post-marketing to support robust regulatory and clinical decision-making are other topics that fall under this theme.

# Bioanalytics

## Theme 1: Bioanalysis at the Edge: Building Evidence When the Rulebook Is Still Being Written

**Keywords**: Qualification with Limited Guidance, Bioanalytical Strategies for NAMs; Measurements from NAMs; HRMS; qPCR and ddPCR; Biomarkers; Immunogenicity (ADA/NAb); AI/ML in Regulatory-Facing Documentation; Omics; Robotic and Automated systems; Cross-Validation; Digital Twins; Cell-Based Assays; Functional Assays; Standardization Challenges; Scientific Community-Driven Standards

As bioanalytical science expands into areas where established guidance is limited, evolving, or absent, the ability to build trust by demonstrating comparability and regulatory readiness becomes a critical discipline. This theme focuses on assay development, qualification, and validation under uncertainty, including emerging methodologies, scientific community-driven standards, and cross-validation frameworks designed to support regulatory-facing decisions. This theme also emphasizes evolving standardization approaches based on user and platform experiences, with the goal of keeping validation and reference material paradigms in dialogue with the standard-setting, compendial, and regulatory community.

Topics of interest include assay qualification/validation when guidance is evolving; HRMS and -omics integration; cell-based and functional assays; qPCR and ddPCR within modern frameworks; automation and robotics to improve reproducibility; AI/ML-enabled workflows suitable for regulated environments; and bioanalysis strategies in the absence of (or alongside) animal models, including NAM platforms. Submissions are also encouraged on bioanalytical approaches to immunogenicity assessment (e.g., ADA/NAb methods, assay standardization, comparability strategies, and fit-for-purpose frameworks), as well as integrated platforms for execution, data capture, and documentation. Digital twin applications for evaluating method performance or supporting method transfer in regulated contexts, particularly, when integrated with PK/PD needs, is also welcome.

## Theme 2: Measuring the Unmeasurable: Bioanalytical Innovation for Emerging Therapeutic Modalities

**Keywords**: High Sensitivity and Specificity; Cell and Gene Therapies; Multiplexing; Flow Cytometry and Cell-Based Assays; Difficult-to-Quantify Analytes; NGS; Collaborations Across Computational, CMC, Discovery, and Translational Sciences

As innovative medicines outpace traditional measurement strategies, this theme highlights bioanalytical advances that enable the development of emerging therapeutic modalities by expanding the toolkit, increasing sensitivity and specificity, and aligning measurement approaches with the biological reality of each modality and with intended clinical decisions and endpoints.

Topics of interest include ultra-sensitive, high-specificity workflows; selecting modality-appropriate measurements for complex analytes; multiplexed bioanalysis and orthogonal confirmation; NGS-, ddPCR-, and ultra-sensitive nucleic acid–based assays for gene editing and RNA medicines; and analytics designed for limited datasets. Work emphasizing cross-disciplinary collaboration across discovery, computational biology, engineering, CMC, and translational sciences is also encouraged.

### Theme 3: From Sample to Decision: Patient-Centric Workflows, Automation, and the Evolving Role of Bioanalysis

**Keywords**: Complex Matrices; Low-Volume Sampling; Whole Blood; PBMC; Stability; Viability; Functional Integrity; Decentralized Sampling; At-Home Sampling; Physician-Office Sampling; Site Alignment; Automation; Chain of Custody, Chain of Identity, and Cold Chain Logistics; AI-Assisted QC; Standardized Data Pipelines; Reproducible Processing; Essential PK; Translational and Clinical Biomarkers; Trend Monitoring; Fit-for-Purpose Statistics; Bioanalysis-to-Decision; Reporting Acceleration; Auditability

Modern drug development increasingly requires bioanalytical teams to deliver more than reliable measurements. Bioanalytical scientists are expanding their role from generating results to transforming them into insights, enabling faster, clearer development decisions. This theme spans the full bioanalytical value chain, from sample collection and matrix strategy through data processing and quality intelligence, while emphasizing the emerging responsibility of bioanalytical scientists in data interpretation and decision support, including integrated bioanalysis with “essential PK analysis” deliverables and the interpretation of translational and clinical biomarker data to strengthen decision-making.

Submissions are encouraged on patient-centric and decentralized sampling workflows, complex matrices, whole blood and PBMC analyses, low-volume and hybrid approaches, and strategies to preserve analyte stability and functional integrity across sites. Contributions may also highlight bioanalytical scientists’ integrated role in bioanalysis/PK data analysis, automation-enabled workflow, and AI-assisted QC and trend monitoring, standardized and traceable processing from instrument output to decision-ready outputs, and fit-for-purpose analytical approaches (e.g., variability, comparability, exposure-relevant summaries, and biomarker-based data interpretation frameworks) that reduce cycle time, improve cross-functional alignment, and maintain reproducibility and auditability in regulated environments.

## Manufacturing and Analytical Characterization

### Theme 1: Advancing Manufacturing Techniques for Pharmaceuticals/ Biopharmaceuticals

**Keywords**: Combination Products; Antibody Drug Conjugates (ADCs); Vaccines; Peptides; Oligonucleotides; Cell and Gene therapies; Long Acting Injectables (LAIs); Biosimilars; Monoclonal Antibodies (mAbs); Small Molecules and Biological Drug Products; Single Use Systems (SUS); Process Analytical Technologies (PAT) Tools; Quality Systems; Characterization; Complex Excipients such as Polymers’ Lipid Nanoparticles (LNPs); Facility Design that Implements End-to-End Process; Regulatory Challenges; Impurity and Control Strategies; Lifecycle Management; Sterile Manufacturing; Global Manufacturing Practices

This theme showcases cutting-edge approaches that enable faster, cleaner, and more reliable pharmaceutical and biopharmaceutical manufacturing that spans traditional and novel modalities. data-rich case studies addressing SUS, PAT-enabled quality systems, complex excipients (polymers, LNPs), continuous manufacturing, scale-up, technology transfer, and end-to-end facility design that integrates sterile operations, packaging, and sustainability without compromising compliance are encouraged. Submissions should highlight impurity and control strategies, lifecycle management, and global manufacturing practices, including lessons learned and success stories. Perspectives that articulate regulatory challenges and considerations—with clear implementation outcomes—are encouraged from industry, academia, CDMOs, and health authorities.

## Theme 2: Seeing What Matters — Next-Generation Characterization & In-Vitro Tools for Pharmaceuticals & Biopharmaceuticals

**Keywords**: Liposomes & LNPs; Nanomedicines; Dissolution; Polymers; ADCs; AI-Enabled Image Based Techniques for LAI; Peptides; Cell and Gene Therapies, Oligonucleotides; RNA; Particle Characterization; Small Molecules; Drug-Device Combination Products; Biopredictive Dissolution Methods; In vitro-in vivo Correlations (IVIVCs); Inhalation and Nasal Products; Microneedle and Transdermal Products and Advancement in the Development of In-Vitro Tools; Regulatory Considerations for Generic Development, and Impurity Detection and Characterization Strategies

This theme elevates characterization science across small molecules, biologics, and complex delivery systems for traditional and novel therapies—including liposomes, nanomedicines, LAIs, inhalation and nasal products, organs-on-a-chip, mechanistic in vitro tools, and microneedles/transdermals. Proposals covering innovative analytical methods and AI-enabled image-based techniques that reveal structure/process/performance relationships; higher order structure and biophysical approaches, biopredictive dissolution and IVIVC/IVIVR advancing clinical relevance; and particle/surface characterization that is robust and transferable are encouraged. In addition, proposals that demonstrate impurity detection and characterization strategies, lifecycle management, and regulatory considerations for generic and biosimilar development are especially welcome. Orthogonal approaches, uncertainty management, and case studies that show how improved analytics reduce risk, accelerate release, and enhance decision-making for academia, industry, CDMOs, and regulators alike should be emphasized.

## Theme 3: Technological Advancements in Advanced Manufacturing and Characterization for Novel Modalities & Cross-Modality Complex Products and Delivery Systems

**Keywords**: AI/Machine Learning/Data-Driven Analytics; Predictive Modeling and Multivariate Approaches; Digital Manufacturing Automation, Digital Twins; Regulatory Alignment; Scale-Up Implementations; Robust Analytics; Integrated Quality Systems; New Approaches for QbD and Design Space; Stability; Spectroscopy and Mass Spectrometry; Particle Characterization Technologies; AI-Enabled Predictive Tools for In-Silico Studies and Mutagenic Impurities; Generics; Biosimilars; Systems Modeling; Technology Transfer

This theme focuses on predictive and digital technologies that connect development to GMP execution across drug modalities. Case-driven examples of AI/ML, predictive modeling, and digital twins that enable digital manufacturing, continuous manufacturing, robotic closed systems for aseptic operations,

automation, lab automation, data integrity, and robust analytics within integrated quality systems are invited. Submissions should emphasize new approaches to QbD and design space, regulatory alignment, (including model verification/validation/maintenance), and scale-up implementations that streamline technology transfer across sites and networks—including applications to generics and biosimilars. Examples of spectroscopy/mass spectrometry and particle characterization technologies applied as in-line/at-line inputs, PAT signals, or model verification data supporting digital operations (rather than standalone characterization) are welcome. Submissions on predictive stability and AI-enabled in-silico tools for mutagenic impurities, with quantified impact and a clear line-of-sight from model outputs to manufacturing decisions are also highly encouraged.

## Formulation and Delivery

### Theme 1: Transforming Formulation and Delivery Technologies Through Predictive Modeling and AI/ML Tools

**Keywords**: AI/Machine Learning-Guided Formulation Design; Predictive Modeling; Formulation Informatics; Excipient Selection and Screening; High-Throughput Formulation Screening; Formulation Performance and Stability Prediction; Formulation-Level Impurity and Nitrosamine Risk Assessment; Formulation Sustainability

Data-driven modeling and AI/ML-enabled tools are redefining how drug formulations and delivery systems are designed, optimized, and evaluated. This theme focuses on the predictive and computational approaches for formulation-decision making, covering areas like excipient selection, optimization, performance and stability prediction, and risk assessment. Submissions based on approaches driving AI/ML, such as leveraging prior or platform knowledge, are invited. Key topics of interest include advances in formulation informatics, high-throughput screening, early impurity/nitrosamine risk, sustainability metrics used to inform material and design choices, IVIVC/IVIV relationship (IVIVR)-informed formulation design. Case studies and real-world development success stories on how AI- and data-driven approaches are being operationalized to formulation efficiency and performance are invited. Related to this, submissions on regulatory considerations associated with the use of AI/ML in drug product development are also highly encouraged.

### Theme 2: Breakthrough Materials and Technologies for Emerging and Evolving Drug Products

**Keywords:** Advanced Materials; Formulation-Enabling Technologies; Novel and Sustainable Excipients; Delivery Platforms; Structure-Function Relationships; Formulation Performance; Controlled and Targeted Delivery; In Vitro Release and Dissolution Testing; Complex Drug Products, Packaging and Sustainability.

Advances in material science and formulation technologies are reshaping what is possible in drug product design and delivery. These advancements cover a vast landscape of modalities, including small molecules, peptides, biologics, and advanced therapeutic medicinal products (ATMP). This theme highlights material-- and technology-driven innovation that enables robust, high-performing drug products without restriction to specific modalities or routes of administration. Submissions that address the role of novel and sustainable excipients, functional materials, and delivery platforms in enabling formulation and product stability, improving bioavailability, and shaping delivery performance are encouraged. Other topics of interest include relevance of material properties, novel packaging considerations, excipient/packaging material-active moiety interactions, extractables/leachable, innovations in container-closure systems, and formulation design considerations shaping drug product behavior across diverse use cases.

### Theme 3: Next-Generation Patient-Centric Drug Product Design and Delivery: Innovation and Real-World Impact

**Keywords**: Patient-Centered Drug Product Design; Usability and Adherence; Drug-Device Combinations; Non-Invasive and Minimally Invasive Delivery; Quality Target Product Profiles (QTTPs); Lifecycle Management; Translational Implementation.

Patient-centric considerations are increasingly driving formulation and delivery decisions across the pharmaceutical lifecycle. This theme emphasizes how formulation and delivery design choices translate into usability, adherence, and consistent product performance under real-world conditions, positioning patient needs as central design inputs rather than downstream considerations. Programming should examine formulation and delivery strategies that enhance ease of use and reduce treatment burden, such as drug-device combinations and patient-focused delivery solutions across diverse real-world scenarios and patient populations,. QTPPs provide a unifying framework for aligning formulation attributes with patient, clinical, and use-scenario requirements. By connecting formulation innovation with implementation and real-world adoption, this theme shows how formulation and delivery science translate into meaningful patient impact through cross-sector collaboration and regulatory engagement.

## Professional Advancement Track

Today’s pharmaceutical scientists must manage their own professional advancement in an increasingly complex and dynamic environment. This includes proactively determining which skills to develop, which scientific areas to pursue, and what strategies to employ as they navigate the job market.

The PharmSci 360 Professional Advancement Track presents a dozen sessions for scientists at all career stages. These sessions are designed to help them determine their career strategy and the skills necessary to achieve their goals.

Attention: AAPS is especially interested in speakers who work in the pharmaceutical industry as recruiters, career coaches, talent managers, economists, financiers, and similar roles that give the speaker experience with the scientific labor market and the forces affecting today's scientists as they develop their careers.

AAPS is also especially interested in session proposals featuring speakers who have not participated in the PharmSci 360 Professional Advancement track in the recent past, or who have done so with extraordinary success.

### Theme 1: Building a Skillset for the Future

**Keywords**: AI; Resumes; Cover Letters; Recommendations; Certifications; LinkedIn, Recruiters; Interviewing; Presenting

This theme highlights practical job-seeking skills for early-to-mid career scientists as well as insights into how technology is changing the way hiring works. Ideal topics include choosing an employer; AI in hiring processes; developing a competitive resume; interview strategies; understanding professional and scientific positioning as a candidate; getting published; and presenting your science.

### Theme 2: Navigating the Business of Science

**Keywords**: Private Equity; Venture Capital; Investors; Networking; Interdisciplinary Science; Employment Contracts; Intellectual Property; Business Plans; Scaling; Executive Management

These sessions emphasize business skills and strategies for scientists at all career stages, including identifying the scientific fields that are most promising based on scientific position, forecasting the future of therapeutic areas for a career; employment contracts; pitching a start-up; managing and owning intellectual property; developing private and public funding; networking with key opinion leaders; and moving into the C-Suite.

### Theme 3: Career Strategy in an Evolving Pharmaceutical Landscape

**Keywords:** Change Management; Talent Management; International Relations; Business Ethics; Markets

These sessions provide enterprise-level insights into the U.S. pharmaceutical labor market and skills for pursuing mid-career goals. Topics include economic and market forecasts for pharmaceutical science; how to recruit and retain key talent; managing a modern workforce; managing consultants; communicating with partners; and creating ethical workplaces.