2022 Program Themes

**Discovery and Basic Research**

**Theme 1: Rapid Discovery of Therapeutics: Past Experience and Computational Approaches**

**Keywords:** antibody and antibody drug conjugates therapy, antiviral drug, -omics, AI, *in silico*, virtual screening, computational chemistry

There is overwhelming need for the rapid discovery and development of therapeutics. AI technologies, such as machine and deep learning, are introduced to accelerate drug discovery and reduce the costs of drug development. Although the evolution of '-omics' methodologies is still in its infancy, both the pharmaceutical industry and patients could benefit from their integration into the drug development process. While the rapid discoveries of therapeutic antibodies and antiviral drug against emerging infectious diseases and proliferative diseases seem to happen overnight, the reality is researchers spend decades understanding the underlying mechanisms for these novel therapies. Submissions are encouraged to cover research and development that enable rapid discovery of therapeutics, including recent breakthroughs in antibody therapy and antiviral drug (i.e., molnupiravir, ritonavir), drug repurposing, computer-assisted drug design, novel high-throughput, multivalent drugs and large-scale methodologies, statistical and computational analyses.

**Theme 2: Oncotargets: Challenges & Opportunities**

**Keywords:** Oncogenes, tumor suppressor genes (TSG), signaling pathways, DNA repair, solid tumors, hematologic malignancies

In this symposium, we will focus on the recent discoveries of novel targets for cancer therapy. Also, submissions are encouraged for novel anticancer drugs derived from medicinal plants or small molecules and the hurdles associated with their development, toxicity and drug approval.
Theme 3: Microbiome: Impact in Pharmaceutical Development and Disease

**Keywords:** microbiome, pharmacokinetics, pharmacodynamics, toxicity, neurologic diseases, diet, probiotic, immunity, metabolites

The microbiome has drawn great attention in recent years due to connections to different processes in the human body, from digestion to neurologic diseases. Aberrations in the microbiome are being shown to have impact on disease presence and progression. Variations in the microbiome can impact the absorption, degradation, and toxicology of administered active ingredients. Administration of appropriate microbial combinations is being shown to mitigate disease and/or improve outcomes. Submissions should focus on the fundamental understanding of the microbiome, how the microbiome impacts the pharmacokinetics of drugs, and the impacts of how the microbiome can be altered.

Theme 4: Epigenetic Drug Targets and Epigenetic Modifiers

**Keywords:** Epigenetics, DNA methylation, histone acetylation, histone methylation, histone deacetylase inhibitors, DNA methylation inhibitors

Epigenetic alternations comprise reversible and heritable changes in DNA methylation and multiple histone modifications that regulate gene expression. Epigenetic dysregulation is observed in a variety of diseases affecting multiple body organs. With the development of various drugs targeting epigenetic regulators, epigenetic-targeted therapy has been applied in the treatment of hematological malignancies and currently in clinical trials to treat different solid tumors. In this symposium, submissions should focus on novel epigenetic targets and the development of small molecules targeting these aberrant epigenetic marks to treat different diseases.

Theme 5: Cells as Carriers of Therapy: From Factories to Hitchhiking

**Keywords:** cell delivery, cell factory, ex vivo gene therapy, exosomes, extracellular vesicles, cell membrane

Cellular therapeutics have become one of the fastest growing areas of therapeutic development. Beyond chimeric immune cells, therapeutics produced from administered cells are being developed to treat diseases as cell factories. Cells have been demonstrated to collect and distribute administered drug delivery systems, typically particles, to sites of disease. More recently, cells have been loaded, both internally and externally, with therapeutic molecules to utilize the cells’ inherent properties to overcome limitations that have been identified with micro- and nano-particles. Submissions should focus on the fundamental understanding of the modification and utilization of cells as therapeutics, interactions of cells and therapeutics to impact their biodistribution, interactions of cells to control pharmacokinetics, and other basic science areas where cells may be utilized in pharmaceutical applications.
**Theme 6: Targeted Drug Discovery and Molecular Pharmacology**

**Keywords:** PROTACs, molecular glue, proteasome, targeted protein degradation, protein-protein interaction, molecular pharmacology

Submissions are encouraged to cover fundamental understanding and novel technologies related to targeted drug discovery and molecular pharmacology. For instance, protein degraders are completely re-defining common rules of drug design. PROTACs, molecular glues, and other small molecule-based modalities are being used for previously “undruggable” protein targets for drug discovery and therapeutic applications. The theme is not limited to PROTACs and is open to other drug design approaches.

**Preclinical Development**

**Theme 1: Bridging the Cross-Functional Silos To Expedite Compound Progression Into The Clinic**

**Keywords:** Cross-functional interaction, DMPK, toxicology, pharmacology, formulation, drug delivery, new modalities, establishing proof-of-concept, poor ADME properties, in vitro-in vivo correlation, biomarkers

With novel therapeutic targets and evolving modalities to drug these targets, drug research continues to remain complex and constantly reinvents itself as it adapts to the changing landscape. To accelerate bringing innovative medicines that are safe and effective to patients, it is imperative that various drug properties are not interpreted in a silo but contextualized cross-functionally across scientific disciplines.

The theme of this symposium is to explore how intersection of various scientific disciplines enabled acceleration of compounds from preclinical development to the clinic, and to focus on the challenges and pitfalls between cross-functional collaborations in drug research and development. The interaction may be between multiple scientific disciplines including (but not limited to) DMPK, toxicology, clinical pharmacology, biology, drug delivery, bioanalytical. Some examples of the cross-functional interaction would be modeling PK-toxicology relationships, identifying and monitoring biomarker for target engagement/toxicity, utility of novel animal models to understand biology/toxicity/PK, establishing a preclinical proof-of-concept for a novel target despite poor ADME properties.

**Theme 2: Breaking Through Barriers in Preclinical Development to Improve Clinical Translation**

**Keywords:** clinical translation, new technology, modeling, AI/machine learning, novel excipients, biodistribution, poor solubility, high plasma protein binding, extrahepatic metabolism, highly metabolically stable, permeability, species differences, human dose projections
Remarkable scientific advancements have greatly improved our understanding, and consequently, shifted our perspective and approach to drug research. However, as challenges continue to remain, especially with novel therapeutic targets and with evolving modalities, collaborative scientific efforts are necessary to assure the efficacy and safety of drug candidates into the clinic.

The theme of this symposium is to identify these obstacles and to explore how to best bridge these gaps. Some examples of these challenges are (but not limited to) permeability across biological barriers (not only the brain, but other tissues and organs such as the nerve and the liver), utility of novel excipients (such as permeation enhancers and patient-centric formulations like LAI, drug-device combinations, implants), PK/PD for drugs exhibiting asymmetrical biodistribution, species-differences between preclinical species and human (as in ADME, pharmacology and toxicology), predicting human dose for compounds that are highly bound, highly stable, low solubility, as well as scaling extrahepatic metabolism and incorporating AI/machine learning in designing molecules.

Unique and novel case studies depicting specific examples of success stories as well as highlighting opportunities for research to improve translation are encouraged.

**Theme 3: Overcoming Pitfalls in Moving Compounds from Preclinical Development to the Clinic: Examples from Bench to Bedside**

**Keywords**: new target/modality, drug discovery, drug development, case studies

One key objective of preclinical development is to identify molecules which enable clinical experiments to test the biological hypothesis to ultimately deliver safe and efficacious drugs to patients. The process of drug development is filled with stories of success and failures. These stories are a testament to the scientific acuity and prowess of the scientists who labored to bring molecules into the clinic, and it would be of tremendous benefit to learn from their experience.

The theme of this symposium is to learn about how the teams overcame hurdles in preclinical development to bring molecules into the clinic, and consequently, how the molecules fared in the clinic. Case studies and specific examples connecting preclinical data to the clinic are encouraged.

**Bioanalytics**

**Theme 1: “Beyond Legacy Therapeutics - Navigating the Path Less Traveled”**

**Keywords**: novel modalities, cell therapy, gene therapy, novel delivery systems, Lipid Nanoparticles (LNP), Adeno-Associated Virus (AAV), Oligonucleotides, small interfering RNA (siRNA), vaccines, regulatory guidance

Drug development has evolved with the emergence of novel therapeutic modalities beyond legacy therapeutics like small molecules and monoclonal antibodies. These novel modalities, to include cell and
gene therapies, oligo therapeutics and vaccines with unique delivery systems and platforms, require bioanalytical characterization with uncommon analytical methods. This theme will provide an opportunity to share bioanalytical strategies for understanding the assessment of pharmacokinetics and immunogenicity of these therapeutics with limited regulatory guidance.

Theme 2: “Sample Challenges, Yet Opportunities”

**Keywords:** Exotic matrices, ocular matrices, patient centric sampling, microsampling, surrogate matrix, sample handling, non-liquid matrices

There are many encountered challenges associated with the nature of samples that are used in bioanalytical sample analysis. These sessions will encompass challenges, perhaps as a result of the pandemic, that are driving the acceleration of opportunities to move towards less invasive, more convenient and more patient-centric collection of samples (e.g., remote collection, microsampling systems), and exposed bioanalytical opportunities because of supply chain constraints. These sessions will also include overcoming challenges of handling unconventional matrix types (e.g., tissues, cells, surrogate matrices and exotic matrices).

Theme 3: “A Look into the Future of Bioanalytics”

**Keywords:** Harmonization, best practices, cutting-edge technology, digital biomarkers, artificial intelligence (AI), machine learning, Immunohistochemistry (IHC), imaging, next generation sequencing (NGS), high resolution mass spectrometry (HRMS), green analytical chemistry

The evolving world of drug development has brought innovations in technologies and platforms used in bioanalytics as well as the need for adaptability and flexibility when thinking about best practices in the field. This theme will bring in sessions that include bridging in cutting-edge technologies (e.g. HRMS, NGS, AI and digital biomarkers), resurrecting older technologies in bioanalysis, potential bridging between current and new technologies and thinking outside the box to find the best way to harmonize bioanalytical processes.

Clinical Pharmacology

**Theme 1: COVID Pandemic and Beyond: Role of Clinical Pharmacology in Development of Non-COVID and COVID Drugs**

**Keywords:** Modify clinical trial, endpoint, sample size, modeling and simulation, regulatory interactions, novel techniques and approaches, real world evidence (RWE), pandemic, COVID

COVID has changed the way we live our lives. It has also brought numerous challenges in drug development. For COVID related drugs and vaccines, development timelines were shortened to months between initiation of non-clinical studies to FIH dosing, which normally would take years in pre-
pandemic development situations. For non-COVID drugs, enrollment in the clinical trials were put on hold or trials were modified worldwide as companies worked to determine the best next steps in providing a means for significant therapeutics to reach patients.

For COVID treatment, numerous novel techniques and approaches were established for the development of vaccines and therapies to overcome the disease. For non-COVID drug development, clinical pharmacologist had to find novel ways to continue drug development, which included, but were not limited to changes in sample size, handling missing or changing PK and PD sampling time points, application of modeling and simulation for regulatory filing, changes to study drug administration/discontinuation, adding COVID specific language and numerous regulatory interactions to submit appropriate and timely submission package.

This theme will cover the application of clinical pharmacology to accelerate/modify global drug development for COVID and non-COVID therapies during the pandemic and beyond and discuss the modified/novel methods for future drug development.

**Theme 2: Model Informed Drug Development (MIDD): Role in Dose Selection, Vulnerable Populations, and Biowaivers**

**Keywords**: MIDD application, dose selection, bioequivalence biowaiver, special populations, pregnancy, lactation, neonates, premature babies, regulatory interactions

The value of MIDD in decision-making during drug development and regulatory approval has been well established. MIDD utilizes the totality of information about a drug in a quantitative manner and allows extrapolation of that information to new situations.

Appropriate dose selection is critical for success of any new therapy. Additionally, there is growing pressure from health authorities to test a wider range of doses early in clinical development. With more dose groups being tested, the role of modeling and simulation that involves exposure-response analysis is critical to selection/prediction of appropriate dose to be tested in registration clinical trials.

Drug development in vulnerable populations involves making drug administration and dosing decision that can be complicated with long-term risks to the health of the patients. In case of the maternal and prenatal health, these decisions involve more than 1 person. Health of the mother and child during pregnancy and the first years of life are crucial to healthy growth and development from conception, through pregnancy, birth, post-partum period, infancy, and the first few years of early childhood. Optimization of the nutrition, treatment of pregnancy complications nutritional supplementation of premature babies and neonates if required due to low birth weight are extremely important measures to ensure future health of the society. Modeling could represent a predictive tool to support the medicine benefit–risk decision and inform dose adjustment in this vulnerable population.

Application of modeling has also expanded towards biowaivers for drugs. Model-informed drug development (MIDD), specifically physiologically-based pharmacokinetics (PBPK) leveraging in vitro data, is a proven, cost-effective option to consider as compared to running an in vivo comparative clinical BE endpoint study.

This theme provides an opportunity to discuss applications of MIDD to support:
1) Dose/regimen selection, including adaptive designs with minimal sampling, exposure-response analysis to support doses that may not have been studied in clinical trials;

2) Collection of information about vulnerable populations (including maternal and neonatal subjects) through observational studies and scavenged blood samples, data collection and sharing and application of different modeling techniques to optimize dosing and sampling strategies in silico; and

3) Biowaivers for bioequivalence studies.

Regulatory challenges associated with these applications will also be presented.

**Theme 3: Translational Biomarkers: From Bench to Bedside**

**Keywords**: Biomarkers; Companion diagnostics; Drug development; Precision medicine; Translational medicine, Regulatory acceptance, Bridging

Rapid growth in biomarker and translational research has been driven by the need to improve patient outcomes and reduce costs and time associated with drug development. The evolution of personalized medicine is dependent upon the development and application of clinically valid biomarkers, as well as companion diagnostics capable of accurately identifying and measuring a particular biomarker of interest. Considerations for successful development include biological rationale for use, measurement method feasibility/assay considerations, and characterization of the relationship between the measurement to the disease/population/drug development area.

This theme provides an opportunity to discuss the role of biomarkers in clinical decision making and drug-diagnostic co-development. Successful examples of bridging non-clinical biomarkers to clinical biomarkers covering efficacy and safety, patient selection & stratification strategies, use of biomarkers as surrogate endpoints, applications of multiplexed biomarker analysis, pathways for biomarker development and regulatory acceptance, and development of companion diagnostics for personalized medicine will be presented.

**Manufacturing and Analytical Characterization**

**Theme 1: Analytical and Predictive Approaches in Drug Development and Manufacturing**

**Keywords**: PAT biopharmaceuticals, characterization of novel small molecules, analytical characterization of long-acting injectables, machine learning and analytics, AI principles in analytical development, multivariate modeling, dissolution and release of novel dosage forms
Themes should center around analytical characterization of extended release formulation (e.g. long acting injectables, implants), peptides, characterization of novel excipients for vaccine delivery, novel adjuvants, process analyzer technology (PAT) for biopharmaceuticals (PAT for process attributes, real time monitoring of cell cultures), regulatory and quality approaches to novel materials, and in small molecules - risk assessment approaches for nitrosamines including real-life experiences based on interactions with agencies. This will also include mathematical, modeling (mechanistic, empirical) and data-science based approaches to streamline the development, manufacturing and delivery of medicines. Themes may also focus on the use of machine learning and AI principles to development, modeling and simulation of formulation processes, driving towards material sparing approaches to drug development, multivariate modeling, simulating manufacturing failure modes, applications of modeling to risk assessment.

**Theme 2: Novel Manufacturing Approaches in Pharmaceuticals and Biopharmaceuticals**

**Keywords:** On-demand manufacturing, automation, mRNA manufacturing platforms, manufacturing of lipid nanoparticles, podular manufacturing, process optimization, adaptive supply chains, flexible manufacturing, process analytics for manufacturing, systems modeling

Topics for this theme will focus on continuous manufacturing, on-demand manufacturing to meet global needs, novel particle engineering approaches, automation in manufacturing, manufacture of other novel modalities such mRNA, vaccines, ICH Q12/Q13 for novel manufacturing platforms – e.g., podular manufacturing. Operational excellence topics such as process optimization, facilities, adaptive supply chains/increased manufacturing flexibility, and advanced process analytics for manufacturing (e.g., MSPC, system modeling) will also be included.

**Theme 3: Cross-Modality and Modality Agnostic Approaches to Development and Manufacturing**

**Keywords:** Analytical quality by design (QbD) approaches in novel modalities, antibody-drug conjugates (ADCs), adjuvants, vaccines, life cycle management approaches, analytical characterization of ADCs, analytical development of novel excipients and adjuvants, impurity characterization of small molecules in biologics, manufacturing and analytical issues in cell and gene therapy, control strategy for ADCs, vaccines with small molecule adjuvants

This will be a hybrid set of sessions that are modality agnostic as well as explore topics that are cross-modality. Modality agnostic topics include analytical QbD, analytical life-cycle management and risk assessment approaches. Cross-modality topics include regulatory and quality challenges around small molecules used in large molecule products – ADCs, adjuvanted vaccines. This session will also explore analytical challenges at the interface of modalities such as characterization of bioconjugates of small and large molecules, impurity characterization of small molecules components of biologics and vaccines, and control strategies for cross-modality products.
Theme 1: Recent Development in Prophylactic Therapies and Vaccines

Keywords: Prophylactic therapies, Vaccines, Delivery technologies, Efficacy, Stability

Prophylactic therapies and vaccines have shown the real benefit to humanity of preventative options against various diseases. Significant limitations to current prophylactic approaches include the need for chronic administration, patient non-adherence to therapy, and delivery efficacy. This theme focuses on what are the key considerations for the design and development of prophylactic therapies and vaccines. The session can be broken into prophylactic therapies (chemical track) and vaccine delivery (biomedical track). Topics on the chemical track include new drug delivery systems and strategies to achieve efficacious drug concentrations in reservoir sites using targeting approaches and reducing cellular efflux and metabolism to prolong effective drugs. Topics on the biomedical track include novel approaches in vaccine design of improving vaccine efficacy, administration convenience and stability.

Theme 2: Advances in Engineering Technologies for Drug Substance and Enabling Drug Product

Keywords: Engineering technologies, nanoparticles, excipients, spray drying, wet polishing, supercritical fluid processing, 3D printing

Today's engineering technologies enable the development of optimal pharmaceutical products that improve various therapeutic and commercial benefits by enhancing drug delivery temporally and spatially. Ranging from fast-dissolving API to nanoparticle engineering, the theme focuses on a wide range of technologies formulating therapeutic modalities beyond small molecules to nucleic acids, peptides, proteins, vaccines, and antibodies. Potential topics include the formation of “right-size crystals” of API, API and excipients co-crystallized or co-precipitated to form particles to desired material by spray drying, wet polishing, supercritical fluid processing, 3D printing, and nanoparticle preparation. The application of nanoparticles has come to fruition with development of lipid nanoparticles for delivery of mRNA for the covid vaccines. Design of lipid nanoparticles for delivery of biomolecules, specifically RNA would be covered.

Theme 3: Evolution in Patient-Centric Drug Formulation and Delivery

Keywords: Patient centered products, long-acting injectables, IV pumps, transdermal patches, microneedles, caregiver

Patient-centricity and user-friendliness are fast-becoming key drivers of innovation in drug development. Drug product design first must take into consideration patient needs, benefits, and specific disease-driven limitations on how the drug product is going to be used by the patient. This theme focuses on patient perspectives on the convenience of administration, non-invasive route of administration, reducing dosing burden, and achieving targeted delivery of new modalities by using
sustained-release products, long-acting injectable, IV pump, transdermal patch, microneedle, and nanomedicines to address the needs of specific patient populations such as pediatrics, geriatrics, dysphagia patients, or the cognitively impaired. Unique cases of patient-centered product development reviewed by the patient and caregiver are encouraged. Regulatory considerations such as stability/compatibility, human factors evaluation leading to optimizations in considering patient-centric development could also be included.

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**Career Development**

**Track: Find Your Why -- Discover a Purpose for You**

Career Development session proposals should target early and mid-career scientists.

Experts who work with scientists, especially career coaches, hiring managers, and others from outside of AAPS' scientist-oriented membership are encouraged to submit proposals.

**Theme 1: Discover Your Why**

Reflect on yourself and your career so far to answer the questions that will help you shape a purpose-driven life that satisfies you! Topics that may fall under this theme include: Developing self-awareness and empathy; building an understanding of your personal values; identifying and using your personal strengths and weaknesses; work-life balance; and finding your interests and motivations in order to find your focus.

**Theme 2: How to Think Strategically About Your Career Development**

Make a plan to build the successful career that you want to have. Topics that may fall under this theme include: Developing your career despite the limitations of the pandemic; diversifying your career strategy; pushing back on stereotypes that are affecting your career growth; taking feedback and having hard conversations; what hiring managers really want in today’s candidates; the tools and expectations powering today’s job market; developing, using, and giving back to your network; determining how you are perceived and the effect you have on your interactions with your team and supervisor; knowing when and why to job-hop; talking to the public and the media about your science; what to expect from a mentor, a coach, or a sponsor; and how to adapt to the new “normal” of work-life balance, communication, working environment, and job market during the pandemic.

**Theme 3: Creating Diverse and Inclusive Workplaces**

Share best practices and discuss challenges in creating diverse and inclusive workplaces in science. Topics that may fall under this theme include discovering your why as a BIPOC; engaging alt-neural
employees in the workplace; strategizing your career to foster diversity and inclusion; recognizing and managing discrimination among employees; recognizing and celebrating differences in the workplace; creating and sustaining a more inclusive workplace environment; how to create and drive DEI initiatives from every role; how to be an ally to diverse colleagues; how to create safe spaces for colleagues.

**Keywords:** Career, Coaching, Hiring, Self-Awareness, Empathy, Values, Strength, Work-Life Balance, Feedback, Job, Networking, Management, Supervision, Emotional IQ, Public Speaking, Communication, Mentor, Diversity, Equity, Inclusion