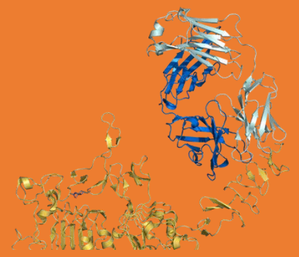
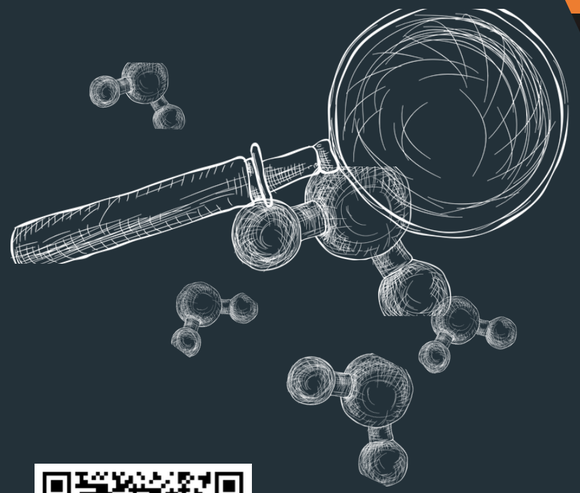
2024 SAPA Scientific Symposium

Sino-American Pharmaceutical Professionals Association



Innovation with Versatility:

New Approaches from Benchtop to Bedside



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Saturday, April 20, 2024

Rutgers Robert Wood Johnson Medical School

675 Hoes Lane West, Piscataway, NJ 08854

The 2024 Scientific Symposium, a flagship event of the Sino-American Pharmaceutical Professionals Association (SAPA), will be held in-person on April 20th at Rutgers Robert Wood Johnson Medical School. The theme of this year's symposium is "Innovation with Versatility: New Approaches from Benchtop to Bedside". It includes a morning plenary session and 3 afternoon parallel sessions in the following areas: New and Advanced Modalities: Discovery and CMC, Emerging Platforms and Novel Technology in Clinical and Medical Development, and Workshop on Generative AI.

This year we have invited world-renowned scientists, entrepreneurs, as well as senior executives of leading pharmaceutical companies to share their perspectives. Plenary speakers include: Xiaorong He, PhD, MBA, SVP, Site Head Development US, Head of Global Development Science, Boehringer Ingelheim Pharmaceuticals, Inc., Manisha Desai, PhD, MBA, Vice President of Drug Product Development, Bristol Myers Squibb, and Yang Qiu, PhD, Chief Scientific Officer, Duality Biologics, and Malaz Abutarif, PhD, MBA, Vice President, Global Head of Quantitative Clinical Pharmacology, Daiichi Sankyo Inc.

This SAPA forum, slated to be a confluence of cutting-edge technologies, versatile innovation platforms, emerging modalities & targets, and new clinical/medical approaches, aims to bring positive energy and potential collaboration to the event participants as well as promising changes to the communities we serve.

- Please Check the registration website page for more details for prices (SAPA members and students can enjoy additional discounts).

Also a friendly reminder to register your parking reservation ahead of the arrival (registration details provided during the registration process).

Agenda At a Glance

Time	Sessions, Speakers and Panelists			
9:00 am – 12:10 pm	**Plenary Session (Main Auditorium)**			
9:00 – 9:05 am	Opening Remarks, Zheng Chen			
9:05 – 9:10 am	SAPA President Remarks, Jack Wu			
9:10 – 9:40 am	Exploring New Frontiers - Transforming Non-clinical Safety Assessment with Innovative Approaches, Xiaorong He			
9:40 – 10:10 am	Challenges and Opportunities in Antibody Drug Conjugates Development, Qiu Yang			
10:10 – 10:30 am	Coffee break and group picture			
10:30 – 11:00 am	Antibody-Drug Conjugates (ADCs): Gaining Momentum in Cancer Therapy, Manisha Desai			
11:00 – 11:30 am	Dose Selection for ADC Drug Development: The Use of Population PK and Exposure-Response Analyses to Optimize Dose in Patients, Malaz Abutarif			
11:30 am – 12:00 pm	Panel discussion: Enhancing R&D Ecosystem and Accelerating Innovation through Collaboration, all plenary speakers			
12:00 – 12:10 pm	Plenary Session Closing Remarks, David Cragin			
12:10 – 1:30 pm	Lunch & Picture			
12:30 – 1:15 pm	Sponsor Presentations (Crystal Pharmatech and Medicilon)			
1:30 – 3:05 pm	Parallel Session I (West Lecture Hall) New and Advanced Modalities: Discovery and CMC	Parallel Session II (East Lecture Hall) Emerging Platforms and Novel Technology in Clinical and Medical Development	Parallel Session III (Dean's Conference Room 123) Workshop on Generative AI	1:1 meetings
3:05 – 3:25 pm	Coffee Break			
3:25 – 5:00 pm	Parallel Session I (West Lecture Hall) New and Advanced Modalities: Discovery and CMC	Parallel Session II (East Lecture Hall) Emerging Platforms and Novel Technology in Clinical and Medical Development	Parallel Session III (Dean's Conference Room 123) Workshop on Generative AI	1:1 meetings

Plenary Session

Main Auditorium

Xiaorong He, PhD, MBA

Senior Vice President, Site Head Development US,
Head of Global Development Sciences,
Boehringer Ingelheim Pharmaceutical Inc.

Xiaorong He is a Senior Vice President at Boehringer-Ingelheim Pharmaceutical Company, based in Ridgefield, CT. As the Site Head of Non-clinical Development US, she is responsible for shaping the site strategy, overseeing people development, ensuring site compliance, and collaborating with other members of the Country Management Committee to steer initiatives and strategies that impact the entire Boehringer Ingelheim USA. By providing leadership and guidance to a team of 450 scientists, she helps drive innovation to ensure that breakthrough therapies are developed efficiently and effectively.

As the Head of Global Development Sciences, she is responsible for guiding her team to drive adoption of transformative innovation, cultivating a culture of scientific excellence and engagement, and integrating patient centricity and sustainability into the development of novel medicines within Global Development with sites in Germany, US, Japan and China.

Xiaorong has more than 20 years of experience in both big Pharma and startup companies. She received her Pharmacy BS from Beijing University, MS from University of Minnesota, Ph.D. in Pharmaceutical Sciences from Purdue University and MBA degree from Western Michigan University. She is the board member of IQ Consortium.

Exploring New Frontiers - Transforming Non-clinical Safety Assessment with Innovative Approaches

Drug safety is paramount in the pharmaceutical domain, with many drugs faltering during preclinical and clinical phases due to safety concerns. This not only escalates attrition rates but also impedes the timely progression of potential therapeutic candidates, thus amplifying development costs. The conventional paradigms of Non-clinical Safety Assessment face significant limitations, necessitating a shift towards alternative approach methodologies (NAMs) that promise enhanced efficacy and reliability and promote 3Rs (refine, reduce, and replace animal studies). This presentation will spotlight the integration of cutting-edge approaches such as organ-on-a-chip technologies, stem cell research, and artificial intelligence, with a special focus on the pivotal role of generative AI. We elucidate how generative AI not only synergizes with but also amplifies the potential of these innovative techniques, thereby offering a comprehensive and cohesive framework for conducting toxicology assessment. Join us as we navigate through this transformative era, heralding a new dawn in the realm of safety assessment with the confluence of traditional and novel methodologies.

Plenary Session

Main Auditorium

Qiu Yang, PhD

Chief Scientific Officer,
Duality Biologics

Currently, CSO of Duality Biologics with

- Over 20 years of MNC drug discovery and development experience with demonstrated success of leading drug discovery, translational medicine and early clinical development programs. Contributed to the discovery and progression into clinic of over 15 drug candidates and drug approvals including the most recent FDA BTD Patritumab Deruxtecan (HER3-DXd).
- Previously as Co-chair of cross-ADC program, Senior Director of Translational Medicine at Daiichi Sankyo; Director, Head of Translational and Biomarker Research at Janssen; Director, Head of Molecular Discovery Research at GSK China.
- Postdoc in Human Genomics at Lawrence Berkeley National Lab, PhD in Molecular Biology from University of Texas at Austin, and Undergraduate from University of Science and Technology in China.

Challenges and Opportunities in Antibody Drug Conjugates Development

Antibody Drug Conjugates (ADCs) have significantly influenced clinical practice in recent years, marked by numerous FDA approvals and a growing array of ADCs entering clinical development pipelines. The distinct mechanism of action inherent to ADCs sets them apart from traditional small molecule drugs or biological agents, underlining their unique therapeutic potential. Delving into the historical trajectory of ADCs in both preclinical and clinical settings offers valuable insights crucial for shaping the next generation of molecules. As our comprehension of ADCs deepens, new avenues for innovative approaches emerge, fostering the evolution of therapeutic strategies.

In this discussion, we will explore the multifaceted landscape of ADC development, addressing key challenges and opportunities. From refining dose selection to optimizing patient and indication selection, navigating combination strategies, and devising strategies to surmount resistance mechanisms. By dissecting these intricacies, we aim to illuminate pathways towards enhanced efficacy and broader clinical impact in the realm of ADC therapeutics.

Plenary Session

Main Auditorium

Manisha Desai, PhD, MBA

Vice President, Drug Product Development,
Bristol Myers Squibb

Manisha Desai has over 25 years of experience in the biopharma industry. As VP of Drug Product Development at Bristol-Myers Squibb (BMS), Manisha is responsible for design and development of patient centric commercial drug products for BMS's pipeline of synthetic and biologic assets from discovery transition through launch. Manisha has broad experience in end-to-end CMC development including formulation, process design & development, scale up and technology transfer of oral and parenteral drug products including combination products to manufacturing sites. Manisha has deep expertise in leading strategic partnerships; building effective teams; leading large organizations and enterprise teams; shaping organizational culture and leading through change.

Manisha earned her Bachelor & Master of Pharmacy degree from The University of Mumbai, India; Masters in Pharmaceutical Sciences from The University of Missouri-Kansas City; Ph.D. in Pharmaceutical Sciences from The University of Michigan; and Executive MBA from NYU Stern School of Business.

Antibody-Drug Conjugates (ADCs): Gaining Momentum in Cancer Therapy

Antibody drug conjugates (ADCs) are being increasingly used either alone or in combination with other agents as first line cancer therapy because of the specificity with which they engage with antigen on cancer cell. The target engagement specificity rendered by the antibody in ADC, coupled with targeted delivery of the cytotoxic agent to cancer cell leads to cancer cell death and minimizes damage to the healthy cells. The maturity in the ADC technology both with regards to novel antibody/protein formats as well as diverse linkers and cytotoxic warheads has enabled targeting more and more oncogenes thereby expanding the tumor indications for ADCs, including difficult to treat tumor types. With about dozen approved products in the US and several hundred molecules in clinical development, it is not surprising that ADCs are driving multi-billion dollar dealmaking frenzy since last year. This presentation provides a broad overview on mechanism of action of ADCs; design, development, commercialization, and challenges; major business deals; as well as new frontiers in development of these conjugates that has the potential to transform cancer treatment and beyond.

Plenary Session

Main Auditorium

Malaz Abutarif, PhD, MBA

Vice President, Global Head of Quantitative Clinical Pharmacology, Daiichi Sankyo Inc.

Malaz A AbuTarif is the Vice President and Global Head of the Quantitative and Clinical Pharmacology Department at Daiichi-Sankyo Inc with over 70 scientists in the department globally. He has over 20 years of post-doctoral Clinical Pharmacology and Pharmacometric experience in the Pharmaceutical Industry. Malaz is a Pharmacist by training and then obtained his PhD in Pharmaceutics with specialty in PKPD and research focused on Clinical Pharmacology and Modeling and Simulation. He Started his post-doctoral industry career at J&J Pharmaceutical R&D and has had increasing responsibilities throughout his career in Schering-Plough Research Institute, Bristol Myers Squibb and Daichi-Sankyo Inc.

Dose Selection for ADC Drug Development: The Use of Population PK and Exposure-Response Analyses to Optimize Dose in Patients

It is critically important to select the right dose and dosing regimen for medicines to maximize efficacy and minimize undesired effects in patients. Population PK and analyses correlating drug exposures with efficacy and safety endpoints provide an efficient approach to help dose selection for therapeutic drugs in general. ADCs provide unique additional challenges since ADCs have several components circulating in the blood, and each of those components can contribute to efficacy and/or safety.

In this presentation, the analyses used to help choose an optimum dose for Enhertu (Trastuzumab deruxtecan, T-DXd) will be discussed. An evaluation of the relationship between trastuzumab deruxtecan (T-DXd) pharmacokinetic exposure and efficacy/safety endpoints in patients with human epidermal growth factor receptor 2-positive (HER2+) breast cancer (BC) will be detailed.

New and Advanced Modalities: Discovery and CMC

West Lecture Hall

Session Chair:
Jianming Kang and Yu Tian

Parallel Session I

Time	Sessions, Speakers and Panelists
1:30 – 1:35 pm	Opening Remarks: Jianming Kang, PhD, Senior Scientist, Regeneron Pharmaceuticals Inc.
1:35 – 2:05 pm	Inhalable Lung-derived Exosomes for Treating Respiratory and Cardiovascular Metabolism Diseases Yujia Jing,VP R&D, Xsome Biotech Inc
2:05 – 2:35 pm	Technology Progress and CMC Focus on Autologous CAR-T Manufacturing Kaiyuan Jiang, Associate Director, Johnson & Johnson Innovative Medicine
2:35 – 3:05 pm	AAV-Mediated Gene Therapy and Genome-Editing for Neurodegenerative Diseases Renping Zhou, Associate Dean of Research,Professor, Rutgers, Ernest Mario School of Pharmacy
3:05 – 3:25 pm	Coffee Break
3:25 – 3:55 pm	Potency Strategy and Assay Standardization for Antibody-Drug Conjugates Dengyun (Daisy) Sun, Principal Scientist, Merck & CO
3:55 – 4:25 pm	Revisiting the Crucial Role of Amino Acids as Excipients in Protein-Based Drug Product Development Haichen Nie, Associate Director, Teva Pharmaceuticals
4:25 – 4:55 pm	Panel Discussion
4:55 – 5:00 pm	Closing Remarks: Yu Tian, Senior Scientist, Merck & Co.

New and Advanced Modalities: Discovery and CMC

New and advanced modalities have continued to emerge in the recent era, which include gene and cell therapies, antibody-drug conjugates, radio-conjugates and beyond. 2023 witnessed the approval of the first CRISPR-Cas9 therapy and the increasing deal volume in antibody-drug conjugates space. The evolving therapeutics landscape brings grand challenge to candidate discovery, process development and product attribute control.

This session will explore and discuss the topics of antibody-drug conjugates, AAV gene and cell therapeutics, extracellular vesicle therapeutics and protein therapeutics. The invited speakers from academia and industry will highlight the effort and learnings in fundamental biology discovery, basic translational research as well as process and analytical and control strategy for product development and commercialization. Attendees will have the opportunities to gain insight from experts in the new frontier of biology discovery, take a technical deep dive into how to ensure robustness product process and quality control by applying optimized workflow and analytical methods for these types of new and advanced modalities.

Parallel Session I

Parallel Session I

West Lecture Hall

Inhalable Lung-derived Exosomes for Treating Respiratory and Cardiovascular Metabolism Diseases

Yujia Jing, PhD

VP R&D,
Xsome Biotech Inc.

Dr. Yujia Jing devoted 7 years in the R&D center of AstraZeneca at Gothenburg, Sweden. During the time, he has been leading and supporting several preclinical and clinical stage programs, within therapeutic areas of cardiovascular renal metabolism diseases and vaccines. The focus of his work was developing novel formulation for delivering new modality drugs such as peptides, antisense oligonucleotides, mRNA & samRNA. Since joining Xsome Biotech in Raleigh, North Carolina, United States, he has been leading the development work of Xsome's lung derived exosome pipelines of rare respiratory diseases (IPF/COPD), acute lung injury and other cardiovascular metabolism diseases. He is also establishing the company's next generation platform for nucleic acids delivery, using exosomes as a drug carrier system.

Technology Progress and CMC Focus on Autologous CAR-T Manufacturing

Kaiyuan Jiang, PhD

Associate Director,
Johnson & Johnson Innovative Medicine

Dr. Kaiyuan Jiang holds the position of Associate Director of Cell Therapy Process Development at Johnson & Johnson Innovative Medicine. He currently spearheads a team dedicated to pioneering next-generation cell manufacturing platforms tailored for both autologous and allogeneic cell therapies and leading CMC activities for asset programs.

In his experience, Dr. Jiang served as a Senior Engineer and Team Lead at Kite/Gilead Sciences, where he played a pivotal role in supporting various aspects of research, process development, technology transfer, and regulatory submission for clinical CAR-T programs. Dr. Jiang earned his Ph.D. in Biomedical Engineering from the University of Florida, with a research focus on devising immunomodulating strategies for cell transplantation in the treatment of Type 1 diabetes. His expertise also extends to the comprehensive development of drug products for both autologous and allogeneic CAR-T cell therapies. Dr. Jiang has contributed to several high-impact research articles published in prestigious journals and has filed patent applications in the field of biomedical engineering.

Parallel Session I

West Lecture Hall

AAV-Mediated Gene Therapy and Genome-Editing for Neurodegenerative Diseases

Renping Zhou, PhD

Associate Dean of Research,Professor,
Rutgers, Ernest Mario School of Pharmacy

Dr. Zhou obtained his Ph.D. in Molecular Biology in 1989 at UC Berkeley. He performed postdoctoral training at the National Cancer Institute, Fredrick, MD before joining Ernest Mario School of Pharmacy (EMSOP), Rutgers University in 1993. He is currently Professor and Associate Dean of Research of EMSOP. The goal of Dr. Zhou's research is to understand what and how biological signals regulate normal and pathological processes in the nervous system. His laboratory has been investigating the molecular mechanisms by which cell surface proteins regulate embryonic development. Dr. Zhou's studies have shown that ephrin family cell surface signals play key roles in many biological processes including lens development and axon guidance during neural development. Loss of ephrin-A5 activity leads to defects in regulations of animal male aggression and maternal care. Dr. Zhou's recent effort has been directed towards understanding molecular signals that may regulate survival of neurons, glia, and oligodendrocytes, and designing effective viral vectors for gene therapy of neurological disorders including Fragile-X, amyotrophic lateral sclerosis, and multiple sclerosis.

Potency Strategy and Assay Standardization for Antibody-Drug Conjugates

Dengyun (Daisy) Sun, PhD

Principal Scientist,
Merck & CO.

Dr. Dengyun (Daisy) Sun is a principal scientist in Analytical Research & Development, Merck & Co. She received her PhD degree from Pennsylvania State University in 2011. After graduation, Dr. Sun worked on vaccine development for several years, then moved to Biologics, CGT and ADC fields. Dr. Sun is leading an ADC analytical working group to set up analytical strategy, oversee method development and validation, and support regulatory filling. Dr. Sun is also leading a high-performance team to develop and standardize cell based assays for advanced modalities.

Parallel Session I

West Lecture Hall

Revisiting the Crucial Role of Amino Acids as Excipients in Protein-Based Drug Product Development

Haichen Nie, PhD

Associate Director,
Teva Pharmaceuticals

Haichen Nie works for Teva Pharmaceuticals as an Associate Director, leading a team that develops formulations for biologic drug products and evaluates the application of novel excipients in various dosage forms. Before joining Teva, Haichen worked at Merck & Co. and AbbVie Inc., focusing on formulation and process development. He received his Ph.D. from the Department of Industrial and Physical Pharmacy at Purdue University and possesses extensive experience in preclinical development, formulation and process optimization, and commercial manufacturing.

Specializing in physicochemical characterization, spectroscopic analysis, and the development of oral and sterile drug products, Haichen has authored over 35 peer-reviewed publications in pharmaceutical journals and has been granted several patents, starting in 2016. Haichen also works as an adjunct Associate Professor at Purdue University College of Pharmacy, teaching both PharmD and PhD students on dosage forms, physical pharmacy, and pharmaceutical solids.

As a volunteer, he is an EO member of SAPA-GP, leading outreach and engagement efforts. He serves as a member on the Editorial Advisory Boards of AAPS PharmSciTech, Drug Development and Industrial Pharmacy, and the Journal of Pharmaceutical Sciences. In addition, he is an expert committee member for the US Pharmacopeia and has served as the chair of the AAPS excipient community since 2021. In 2023, Haichen received the IPEC Henk De Jong Industrial Research Achievement Award in Excipient Technology in recognition of his contributions to excipient technology and the innovative use of excipients in pharmaceutical sciences.

Emerging Platforms and Novel Technology in Clinical and Medical Development

East Lecture Hall

Session Chairs:
Xiaowei Sun and Llorente Bonaga

Parallel Session II

Time	Sessions, Speakers and Panelists
1:30 – 1:35 pm	Opening Remarks: Xiaowei Sun, PhD, Senior Scientist, Bristol Myers Squibb
1:35 – 2:05 pm	Clinical Pharmacology Considerations on Rheumatoid Arthritis Drug Development Jin Zhou, Director, Clinical Pharmacology Sciences, Gilead Sciences
2:05 – 2:35 pm	Leveraging PK and PK/PD Modeling for Dosing Optimization in Anti-infectives Jiajun Liu, Senior Pharmacokineticist, U.S. FDA
2:35 – 3:05 pm	Use of Circulating Tumor DNA to Guide Precision Medicine in the Clinic can Improve Cancer Diagnosis, Treatment Selection and Monitoring Rachel Tam, Senior Principal Clinical Biomarker Scientist, Bristol Myers Squibb
3:05 – 3:25 pm	Coffee Break
3:25 – 3:55 pm	Advancement of Biomarker Analysis Regulations and Technologies in Drug Development and Clinical Diagnosis Jian Wang, Senior Director, Bioanalytical and Biomarker, Crinetics Pharmaceuticals
3:55 – 4:25 pm	Targeting Diverse B-Cell Lymphomas with Epcoritamab, a DuoBody®-CD3xCD20 Bispecific Antibody: Bridging Preclinical and Clinical Research in Translational Medicine Jimin Zhang, Principal Scientist and Translational Medicine Lead, Genmab
4:25 – 4:55 pm	Clinically Relevant Neutralizing Antibody Assay for New ADC: Killing or Not Killing Weifeng Xu, Sr. Principal Scientist, Merck & Co.
4:55 – 5:00 pm	Closing Remarks: Llorente Bonaga, PhD, Senior Director, Merck & Co.

Emerging Platforms and Novel Technology in Clinical and Medical Development

The clinical and medical development landscape is experiencing a significant shift which are driven by emerging platforms and novel technologies. These advancements result in revolutionizing the healthcare landscape, thereby offering novel solutions to long-standing challenges and unlocking new possibilities in patient care. The speakers from academia and industry will discuss various topics, such as a) clinical pharmacology considerations in drug development, b) optimization of dosing strategies in anti-infective therapies, c) circulating tumor DNA for precision oncology, d) advancements in biomarker analysis regulations and technologies, e) clinically relevant neutralizing antibody assay for new ADCs, and f) exploration of targeted therapies in translational medicine.

Collectively, these topics focus on the pivotal role of emerging platforms and novel technologies in shaping the future of clinical and medical development, fostering innovation, and driving improved patient outcomes.

Parallel Session II

Parallel Session II

East Lecture Hall

Clinical Pharmacology Considerations on Rheumatoid Arthritis Drug Development

Jin Zhou, PhD

Director, Clinical pharmacology Sciences,
Gilead Sciences

Dr. Zhou currently serves as Director of Clinical Pharmacology at Gilead Sciences, where she is responsible for Clinical Pharmacology aspects of various clinical development programs, with a special focus on inflammation therapeutic area. Her areas of expertise encompass both biologics and small molecule development. Prior to her current role at Gilead Sciences, Dr. Zhou spent a decade at Boehringer Ingelheim, where she made significant contributions to the progression of projects of various stages. She holds a PhD from the University of Minnesota.Additionally, Dr. Zhou contributed to the SAPA community through her volunteer work and served as the president of SAPA-Connecticut for the term 2017-2018.

Leveraging PK and PK/PD Modeling for Dosing Optimization in Anti-infectives

Jiajun Liu, PharmD, MSc

Senior Pharmacokineticist,
U.S. FDA

Jiajun Liu, PharmD., MSc. is currently a Senior Pharmacokineticist in the Division of Pharmacometrics, Office of Clinical Pharmacology (under OTS/CDER) at the FDA. As a pharmacometrics reviewer, Dr. Liu's current work primarily involves analysis and interpretation of PK and PK/PD analysis to support regulatory submissions across various therapeutic areas. Prior to joining the Agency in 2020, Dr. Liu received his PharmD degree from Midwestern University Chicago College of Pharmacy. Dr. Liu developed a strong interest in clinical research throughout his pharmacy curriculum, and in particular, in PK and PK/PD of anti-infective agents. After graduation in 2016, Dr. Liu completed a 1-year clinical pharmacy training at Edward Hines, Jr. Veterans Administration Hospital in the Chicago area, and following that, a 3-year clinical and translational pharmacotherapy fellowship in infectious diseases at Midwestern University and Northwestern Memorial Hospital at downtown Chicago. Concurrently, Dr. Liu also completed the Master of Science in Clinical Investigation from Northwestern University.

Parallel Session II

East Lecture Hall

Use of Circulating Tumor DNA to Guide Precision Medicine in the Clinic can Improve Cancer Diagnosis, Treatment Selection and Monitoring

Rachel Tam

Senior Principal Clinical Biomarker Scientist,
Bristol Myers Squibb

Rachel is a Senior Principal Clinical Biomarker Scientist with 14 years of experience in the pharmaceutical industry where she conducts cutting-edge cancer research.

Rachel's expertise lies in cancer biology, exploratory biomarker discovery, innovative biomarker assays and immunotherapies in both pediatric and colorectal cancers where she has advanced the field of precision medicine. Her work has been published in scientific journals and her dedication to finding innovative solutions for cancer treatment continues to advance scientific knowledge and improving patient outcomes.

Additionally, Rachel is actively involved in mentoring young scientists and volunteering in STEM programs serving underserved middle school students in the community.

Advancement of Biomarker Analysis Regulations and Technologies in Drug Development and Clinical Diagnosis

Jian Wang, PhD

Senior Director, Bioanalysis/Biomarker,
Crinetics Pharmaceuticals

Sr. Director of Bioanalysis/Biomarker at Crinetics Pharmaceuticals since 2020. Senior Principal Scientist in Bioanalytical Sciences at Bristol-Myers Squibb (1997-2020). Ph.D. in analytical chemistry from Michigan State University (1990-1994), Postdoctoral Fellow at National Institutes of Health (NIH) in Maryland USA (1994-1996), B.S. from Beijing University (1987). DMPK in GSK (1996-1997). 30+ years of experience in discovery and regulated bioanalysis in pharmaceutical industry managing internal and outsourced PK, biomarker, and clinical diagnostic analysis of both small and large molecules in LC/MS, ligand binding and ligand binding-LC/MS hybrid platforms as well as using IVDs. Co-coordinator of Regulated Bioanalysis Interest Group at ASMS. Bioanalysis Zone leader as an advisory expert panel. Served as a sub-team lead of AAPS ADC bioanalysis committee.

Parallel Session II

East Lecture Hall

Targeting Diverse B-Cell Lymphomas with Epcoritamab, a DuoBody®-CD3xCD20 Bispecific Antibody: Bridging Preclinical and Clinical Research in Translational Medicine

Jimin Zhang, PhD

Principal Scientist and Translational Medicine Lead, Genmab

Dr. Jimin Zhang is a Principal Scientist and Translational Medicine Lead at Genmab, playing a pivotal role in advancing EPKINLY (epcoritamab), a DuoBody®-CD3xCD20 bispecific antibody, in hematology. He contributed to the recent FDA approval of EPKINLY for relapsed or refractory (R/R) diffuse large B-cell lymphoma (DLBCL) and the submission of an sBLA for R/R follicular lymphoma (FL). He also spearheads translational medicine in expansion into other indications like mantle cell lymphoma (MCL) and chronic lymphocytic leukemia (CLL), alongside combination therapies. Before joining Genmab in 2021, Dr. Zhang served as an Associate Principal Scientist at Insmed, a global company focused on serious and rare diseases, where he led Preclinical Pharmacology and Clinical Biomarkers efforts with increasing R&D responsibilities. His 7-year tenure saw significant contributions to the NDA package and FDA approval of ARIKAYCE, and involvement in Phase 2 & Phase 3 clinical development of brensocatib. Dr. Zhang holds a B.S. in biochemistry from Sun Yat-sen University in Guangzhou, China, and a Ph.D. in immunology from Rutgers University Robert Wood Johnson Medical School in New Jersey. His Ph.D. research primarily focused on T-cell biology and tumor immunology, earning him the prestigious Stanley S. Bergen, Jr. M.D. Medal of Excellence upon graduation.

Clinically Relevant Neutralizing Antibody Assay for New ADC: Killing or Not Killing

Weifeng Xu, PhD

Sr. Principal Scientist, Merck & Co.

Weifeng has been in the field of immunogenicity for more than 10 years. Recognized as an expert in the field, he is co-leading AAPS neutralization antibody (NAb) work group with multiple publications and patents. At Merck, Weifeng established Cell Assay Group within PCD Regulated Bioanalytics to support NAb assays for biologic therapeutics and cell therapy, as well as infectivity, neutralizing, and bacteriology methods for vaccines. He was the Bioanalytical Lead for Merck's COVID-19 vaccine, first cell therapy and is now supporting the 21-valent V116 pneumococcal vaccine. He is also overseeing bioanalytical strategy for all the collaborative ADC pipelines with Daiichi Sankyo and Kelun-Biotech.

Workshop on Generative AI

Dean's Conference Room 123

Session Chairs:
Lixia Yao and Zhiwei Yin

Parallel Session III

Time	Sessions, Speakers and Panelists
1:30 – 1:35 pm	Opening Remarks
1:35 – 3:05 pm	Unlocking Generative AI: a practical guide for non-techies, session I Lixia Yao, PhD, President and CEO, Polygon Health Analytics LLC
3:05 – 3:25 pm	Coffee Break
3:25 – 4:55 pm	Unlocking Generative AI: a practical guide for non-techies, session II Zhiwei Yin, PhD, Senior Manager, Bristol Myers Squibb

Unlock the potential of Generative AI in our hands-on workshop, designed specifically for non-techies. Delve into the foundations of AI, learn the art of prompt engineering with ChatGPT and other leading Large Language Models, and navigate the MidJourney basics with ease for creating images. We'll also explore cutting-edge topics like video generation. This workshop is your gateway to understanding and harnessing the power of state-of-the-art Generative AI applications for work and life! No technical background is required for participation.

Parallel Session C

Dean's Conference Room 123

Unlocking Generative AI: a practical guide for non-techies, session I

Lixia Yao, PhD

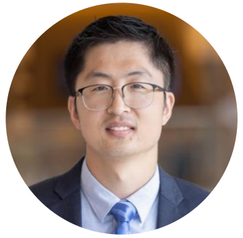
President and CEO,
Polygon Health Analytics LLC

Dr. Lixia Yao is the founder and CEO of Polygon Health Analytics LLC, which specializes in developing high-quality real-world data (RWD) and real-world evidence (RWE) in disease areas with pressing unmet medical needs.

With a PhD in Biomedical Informatics from Columbia University, Dr. Yao previously worked as the director of Real-world Data Analytics & Innovation at Merck and an Associate Professor in Biomedical Informatics at Mayo Clinic. She has cultivated a deep understanding of RWD and authored 60+ peer-reviewed articles on prestigious journals such as Nature Biotechnology, Genome Research, and Drug Discovery Today with a H-index of 20.

Dr. Yao received the Career Development Award in Biomedical Informatics from the National Library of Medicine (2016-2019). She is also a Fellow of the American Medical Informatics Association (FAMIA) and served as the Chair of the AMIA KDDM working group (2020-2022). Currently, she holds the additional roles of Member Engagement Co-Chair for the Oncology Special Interest Group at the Professional Society for Health Economics and Outcomes Research (ISPOR), SAPA Executive Council (EC), and Adjunct Associate Professor in the Department of Health Services Administration and Policy at Temple University.

Unlocking Generative AI: a practical guide for non-techies, session II



Zhiwei Yin, PhD

Senior Manager,
Bristol Myer Squibb

Dr. Zhiwei Yin currently serves as a Senior Manager at Bristol Myers Squibb within the Business Insights & Analytics - Commercial Data Science division, where he focuses on harnessing modeling and AI technology to enhance patient engagement with BMS medications. Before this, he had extensive tenure in small molecule drug R&D with research experiences in drug substance process development, crystallization, material science, and pre-formulation. With a strong passion in data, he has built digital capabilities to enable high throughput experimentation (HTE), portfolio management, and business decision-making.
Dr. Yin obtained his PhD in Chemistry from City University of New York and had computer science training from New York University.

Symposium Organizing Committee

Event Chairs

Zheng Chen, PhD

David Cragin, PhD

Event Committee

Llorente Bonaga, PhD
Xi Cheng, MS, MPH
Yong Guo, PhD
Chenchao Gao, PhD
Brian Jiang, MS
Jianming Kang, PhD
Yongmei Li, PhD
Jiaying Liu, PhD
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Xiaole Shen, PhD
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Yang Wang, PhD, MBA
Lankun Yang, MS
Lixia Yao, PhD
Zhiwei Yin, PhD
Zhou Yu, MS
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Juntao He, MS
Shuo Huang, PhD
Chengfei Huang, PhD
Siyu Jiang, MPH
Chen Kang, PhD
Yannuo Li, PhD
Wen Shi, PhD
Ada Xia Wu, JD/MBA
Willie Wu, PhD
Linxuan Yan, JD

About SAPA

The Sino-American Pharmaceutical Professionals Association (SAPA) was established in 1993 and is headquartered in the center of the pharmaceutical corridor in New Jersey, USA. Since its inception, SAPA rapidly became one of the most active Chinese American professional associations in the US with eight chapters and more than 6,000 members.

SAPA's members are primarily from large and mid-sized pharmaceutical and biotech companies in the US, with areas of expertise covering almost every aspect of pharmaceutical research and development as well as production.

The organization's large membership base and their superb scientific and technical abilities has allowed SAPA to be a key source for knowledge exchange on the latest developments in the pharmaceutical, biotechnology, and generic drug industries.

As a non-profit organization registered in the US, SAPA receives generous sponsorship and support from numerous multinational companies in the US and overseas. SAPA will continue to provide a broad platform for scientific and technical discussion, talent exchange, and training for the colleagues in the pharmaceutical industry from the US and China.

Professional Expertise of SAPA Members

- Drug discovery, research and development
- Preclinical and clinical research and development
- Application and registration of new drug and biologics to the US FDA
- Production and manufacture of pharmaceuticals and biological products
- Commercial and marketing of pharmaceutical and biological products
- Generic product development and technology

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WWC, P.C. CERTIFIED PUBLIC ACCOUNTANTS

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https://sapaweb.org

8 pm on the 8th day of every month.

SAPA Career Talk 8@8 is a virtual webinar series hosted on the 8th day of every month at 8 pm. We will discuss career hot topics and address concerns related to SAPA members and friends. These sessions are complimentary to all.

Scan the QR code on the right to register for the event, and join us from 8:00 – 9:30 pm, on the 8th day of each month. Please note that at the Zoom registration page you can register for all of the 2024 8@8 monthly program, so please make sure to select the right month from the pull-down menu. After registering, you will receive a confirmation email containing information about how to join the session.

Sino-American Pharmaceutical Professionals Association

2024 SAPA Corporate Sponsor Summit

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Friday, May 31, 2023
Novartis
East Hanover, NJ

2024 SAPA

HEALTHCARE INVESTMENT Forum & Roadshow

"WHERE SCIENCE MEETS CAPITAL"

美中藥協 SAPA

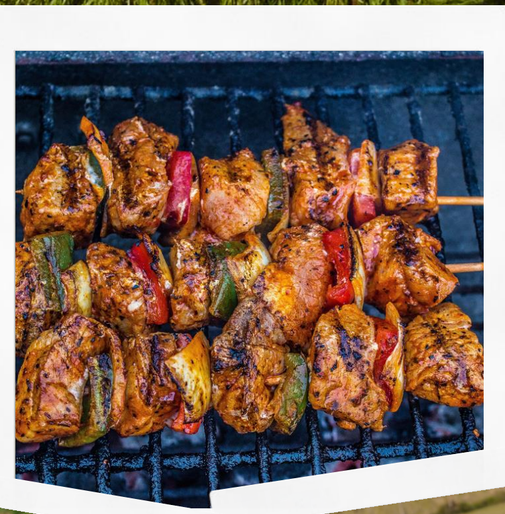
Sino-American Pharmaceutical Professionals Association

Saturday, June 22, 2024
New York, NY

Sino-American
Pharmaceutical
Professionals
Association

2024 SAPA Summer Picnic

Sunday, August 20, 2024
Oak Grove Pavilion, Duke Island Park
191 Old York Road
Bridgewater, NJ 08807



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Sino-American Pharmaceutical Professionals Association

2024 SAPA Annual Conference

Redefining Medicine: Navigating Resilience, Transforming Lives

Thursday, Friday and Saturday, September 26 - 28, 2024
Hyatt Regency New Brunswick
2 Albany St., New Brunswick, NJ 08901

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Celebrating 30 Years Anniversary
1993 - 2023

SAPA Mission

As a global organization, SAPA's mission is:

- To promote advancement of pharmaceutical science and biotechnology
- To contribute to public health education
- To promote entrepreneurship, healthcare investment and business cooperation
- To foster career development of pharmaceutical professionals

Sino-American Pharmaceutical Professionals Association

Connecting dots to grow together

www.sapaweb.org