



International Alliance for
Biological Standardization

www.iabs.org

E-BOOK



12th Statistics Workshop:

From Data to Patients – CMC Statisticians
Contributions to Quality, Safety, and Efficacy of
Pharmaceutical Products

October 20-22, 2026



Further
information

Rockville, MD, U.S.A.

HYBRID MEETING

TABLE OF CONTENTS



Sponsors	3
About the Conference	4
Scientific and Organizing Committees	5
Scientific Program	6
Upcoming IABS Conferences and Workshops	11
Biosketches & Abstracts	12

SPONSORS



ABOUT THE CONFERENCE



Every analysis, model, and decision in Chemistry, Manufacturing, and Controls (CMC) ultimately serves one goal—improving patient outcomes. CMC statisticians are at the forefront of this mission, ensuring that pharmaceutical products meet the highest standards of quality, safety, and efficacy.

Like chefs transforming ingredients into a finished dish, statisticians transform data using their knowledge, methodologies, and software, into insights that support sound decision making. In a regulated environment, our work is rigorously evaluated by health authorities, much like critics assessing whether a Michelin star is deserved. As Dr. Ji Hyun Lee, former ASA President, remarked: "I truly value every data point in my hand, because each one represents a patient's story, struggle and journey." This mindset reflects the broader reality across CMC: behind every data point is a patient, and our analytical rigor directly contributes to ensuring their safety and well-being.

This conference will highlight the critical role of statisticians across the CMC lifecycle through four core sessions:

1. Data – The early role statisticians can play in shaping data systems, improving data quality, as well as managing and leveraging increasingly complex datasets.
2. Software – The importance of reliable software—both point and click and code-based—, and their appropriate use, in producing sound statistical analyses in a regulated environment.
3. Methodologies – Three mini-keynotes highlighting the evolving landscape of statistical methodologies within CMC:
 - The fundamental role of frequentist statistics in CMC decision-making
 - The growing influence of Bayesian methods in uncertainty quantification, inference, and modeling
 - The potential of AI and machine learning for predictive modeling and process optimization
4. Regulatory Review – Perspectives from global health authorities on key statistical considerations in regulatory submissions.

Additionally, a workshop will provide practical overviews of the role SAS, JMP and R have in helping us transform data into insights.

This program reflects the Big Tent vision of statisticians' contributions to healthcare and reinforces the vital connection between statistical rigor and patient well-being.

SCIENTIFIC & ORGANIZING COMMITTEES



Scientific and Organizing Committee

Ruojia Li, BMS (Co-Chair)
Jia Liu, Pfizer (Co-Chair)
José Ramírez, Kite Pharma, a Gilead Company (Co-Chair)
George Atkins, Genentech
Timo Bailer, Boehringer Ingelheim
Fang Chen, SAS
Catherine Cheng, Novartis
Irina Gershgorin, Legend Biotech
Ashley Giambrone, Regeneron
Jennifer Kirk, FDA
Brooke Marshall, Eli Lilly & Co.
Oluyemi Oyeniran, Johnson & Johnson
Laura Pack, Moderna
Jayda Siggers, Health Canada
Christopher Thompson, AstraZeneca
Travis Wolter, Amgen
Jie Zhao, Merck
Madinina Cox, Events Manager, IABS/MC'Com
Camille Roux, Events Manager, IABS/MC'Com

Editorial Committee

Norman BAYLOR, Editor-in-Chief, Biologicals
Ruojia Li, BMS (Co-Chair)
Jia Liu, Pfizer (Co-Chair)
José Ramírez, Kite Pharma, a Gilead Company (Co-Chair)

SCIENTIFIC PROGRAM

Tuesday, October 20, 2026



8:30 am

Registration & Welcome Coffee

9:00 am

Introduction to IABS

Welcome to Workshop

Ruojia Li – Co-Chair, BMS

Jia Liu – Co-Chair, Pfizer

José Ramírez – Co-Chair, Kite Pharma, a Gilead Company

Keynote Session

9:15 am

More Than Numbers: How Everyday Statisticians Shape Science

Prof. Ji-Hyun Lee – University of Florida

Session I: Data

Session Chairs: Brooke Marshall & Ashley Giambrone

10:15 am

Session introduction

Brooke Marshall & Ashley Giambrone

10:20 am

From Data Foundations to Data Products: The Statistician's Role in Shaping CMC Data Strategy and Driving Scalable Analytics

Dan Liu – Ruojia Li, BMS

10:50 am

Beyond the Spreadsheet: Strengthening CMC Data Governance as the Foundation for Advanced Analytics and Regulatory Compliance

Sara Cook – Iliacook Statistical Consulting, LLC.

11:20 am

Break

11:35 am

From Data to Insight: Enabling Scalable, GxP-Compliant Analytics Through an Integrated Data Lake - Brenda Ramirez – Kite Pharma, a Gilead Company

12:05 pm

Panel Discussion

1:05 pm

Lunch Break

SCIENTIFIC PROGRAM

Tuesday, October 20, 2026



Session II: Software

Session Chairs: Travis Wolter & Fang Chen

2:05 pm

Session introduction

Travis Wolter & Fang Chen

2:10 pm

Transforming Clinical Research with Generative AI in SAS Viya

Pankaj Attri – SAS

2:40 pm

Beyond Control Charts: Adaptive, Model-Based Condition Monitoring with Generative AI for Biomanufacturing Process Monitoring - Mark Wolff – SAS

3:10 pm

BPC-Stat: An Integrated Software Ecosystem for Automated Process Characterization and Statistical Modeling

Melissa Matzke & Seth Clark – Merck & Co.

3:40 pm

Break

3:55 pm

Panel Discussion

4:55 pm

End of Day 1

SCIENTIFIC PROGRAM

Wednesday, October 21, 2026



8:30 am

Registration & Welcome Coffee

Session III: Methodologies

Session Chairs: Laura Pack, Timo Bailer

9:00 am

Session introduction

Laura Pack & Timo Bailer

9:05 am

Mini Keynote – The fundamental role of frequentist statistics in CMC decision making - Rick Burdick, Burdick Statistical Consulting, LLC

9:35 am

Mini Keynote – The growing influence of Bayesian methods in uncertainty quantification, inference, and modeling in CMC studies

Stan Altan, Johnson & Johnson

10:05 am

Let Models Speak: Machine Learning Process Models with Interpretable AI Agents - Gang Wang, Moderna

10:35 am

Break

11:00 am

Panel Discussion

12:00 pm

Lunch Break

Session IV: Regulatory Review

Session Chairs: Catherine Njue, Health Canada & Jennifer Kirk, FDA

1:00 pm

Session introduction

Catherine Njue & Jennifer Kirk

1:05 pm

Application of Bayesian Methodologies in CMC Statistics – Areas of Focus
Mark Quinn, Health Products Regulatory Authority (HPRA)

SCIENTIFIC PROGRAM

Wednesday, October 21, 2026



1:35 pm

Parallelism Testing Methods for Potency Bioassay Curves

Dr. Meiyu Shen, CDER/FDA

2:05 pm

Considerations for Bayesian-Informed CMC Regulatory Submissions

Jun Gao, BRDD, Health Canada

2:35 pm

Break

2:50 pm

Panel Discussion

3:50 pm

Discussion on Predictive Modelling

Moderators: Travis Wolter, Ruojia Li & Jia Liu

4:50 pm

End of Day 2

SCIENTIFIC PROGRAM

Thursday, October 22, 2026



8:30 am

Registration & Welcome Coffee

9:00 am

Workshop 1 by JMP

Jeff Upton – JMP

10:00 am

Workshop 1 by JMP: Automating CMC Analytic Workflows with JMP

Max Kuhn – Posit PBC

11:00 am

Break

11:25 am

Workshop 3 by SAS

Fang Chen – SAS

12:25 pm

Workshop Summary

12:40 pm

End of Workshop and Invitation to 2027 Workshop

UPCOMING IABS CONFERENCES & WORKSHOPS



**3rd IABS Workshop on Real
World Evidence:
Pragmatic Randomized
Controlled Vaccine Trials:
towards global alignment and
methodological standards**

*November 18-19, 2026
Leiden, The Netherlands*



**ASFaVIP FINAL STAKEHOLDER
MEETING - ASF: An Analysis of
Current Situation of Vaccine
Development; Licensing
Procedures and Possible
Eradication Approaches**

*December 3, 2026
Frankfurt, Germany*



**5th Controlled Human
Infection Model
Workshop**

*Spring 2027
Bangkok, Thailand*



**Analytics in Cell Therapy:
Ensuring Quality in Flow
Cytometry established
guidelines for Flow
Cytometry And QC needs in
Cell Therapy**

*Autumn 2027
Barcelona, Spain*

ABSTRACT



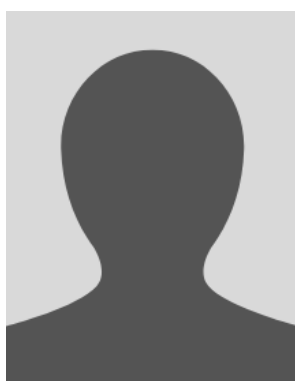
The growing influence of Bayesian methods in uncertainty quantification, inference, and modeling in CMC studies

Stan Altan, Fellow, JJIM Statistics and Decision Sciences

Bayesian methods provide a coherent, probability-based framework for estimation, inference, and prediction. They are particularly valuable to CMC statisticians, who are engaged in the design of experiments, complex hierarchical (linear and nonlinear) models, and cross-sectional data collection. Bayesian methods help address the central goal of CMC studies: elucidating relationships between quality attributes and process/formulation parameters, thus ensuring safety and efficacy. Bayesian methods can be regarded as facilitating patient centric quality consideration.

This presentation reviews the published literature on Bayesian applications in the CMC space and traces the trajectory of their increasing adoption. I will highlight the range of CMC topics where Bayesian approaches have been applied and discuss practical considerations, including prior specification, predictive distributions, interpretability, and regulatory implications. Underpinning this trend is the fundamental appeal of probability based decision making offered by Bayesian methods.

BIOSKETCH



Pankaj Attri
SAS

Pankaj Attri is an AI/ML Solutions Architect focused on leveraging advanced data science and artificial intelligence to support customers in the Life Sciences and Healthcare industries at SAS. He partners with these organizations to design and implement state-of-the-art custom solutions that accelerate innovation across research, development, and clinical operations. This includes supporting critical workflows such as clinical trial data submission processes, as well as broader applications of AI and data management across drug discovery, diagnostics, and healthcare delivery.

Beyond solution development, Pankaj plays a key role in educating customers on SAS's Data and AI Solutions capabilities, delivering impactful demonstrations, and translating complex technologies into clear business value.

Pankaj brings together a background in Chemical Engineering (B.Tech) from IIT Bombay, India and a Master's in Computer Science from NC State University, USA.

ABSTRACT



Transforming Clinical Research with Generative AI in SAS Viya **Pankaj Attri, SAS**

This session explores how Generative AI (GenAI) capabilities of SAS Viya, including code generation, synthetic data creation, and RAG enabled agentic AI with MCP server connectivity, can empower biostatisticians and programmers to accelerate drug development.

The session will also showcase industry-specific copilot solutions that can automate clinical data workflows, improve productivity, and reduce manual effort across the clinical development lifecycle. We will also examine cost-effective approaches for harmonizing real-world data (RWD) into the OMOP common data model, enabling epidemiologists to conduct both exploratory and confirmatory analyses more efficiently.

By leveraging GenAI, organizations can generate data-driven insights, create robust privacy-compliant datasets for experimentation, automate routine processes to enhance cross-functional collaboration, and drive innovation.

BIOSKETCH



Timo Bailer
Boehringer Ingelheim

Timo studied econo-mathematics at Ulm University and the University of West Florida. He finished his M.Sc thesis within the pharmaceutical area on Bayesian Modelling of Adverse Events in 2014. Afterwards he joined Boehringer Ingelheim and held different positions within the field of CMC Statistics.

Currently he is heading the global CMC Statistics BioPharma department of Boehringer Ingelheim responsible for the life-cycle products at all global production sites in Germany, Austria, USA and China. Timo is part of the IABS Statistics Workshop since 2018 and supports the Scientific Organization Committee since 2021. From 2023 - 2024, Timo was also co-chairing the Scientific Organization Committee of the IABS Statistics Workshop.

BIOSKETCH



Prof. Rick Burdick
Burdick Statistical Consulting, LLC

Rick is an Emeritus Professor of Statistics, on the faculty of Arizona State University for 29 years, and former Quality Engineering Director at Amgen, Inc. for 10 years. He presently works part-time as an advisor for Adsurgo consulting. He has been working on statistical issues concerning CMC applications for the past 19 years, and has written over 80 journal articles and four books. He is a Fellow of the American Statistical Association and served on the USP Statistics Expert Committee from 2010-2020. He received his Bachelor's Degree in Statistics from the University of Wyoming and his Masters and Doctorate degrees in Statistics from Texas A&M University.

ABSTRACT



The fundamental role of frequentist statistics in CMC decision making **Rick Burdick, Burdick Statistical Consulting, LLC**

The Food and Drug Administration (FDA) draft guidance “Manufacturing Changes and Comparability for Human Cellular and Gene Therapy Products,” issued in July 2023, listed the term “statistics” or “statistical” over 30 times and recommended to “consult with a statistician before discussing the study design and statistical approach with FDA.” The European Medicines Agency (EMA) document “Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development” issued in 2021 cited these same words over 80 times. It is clear that statistical analysis is critical for the successful development and manufacturing of pharmaceutical products. Peterson et al. (2009) provides an excellent description of the statistical techniques to support these activities. This talk will provide a statistical toolbox including interval estimators, regression modeling, hypothesis testing, process control, and mixed models. To some this may seem like a modest toolbox, but it will be demonstrated that these tools can be used in a variety of critical CMC applications.

BIOSKETCH



Mr. Fang Chen
SAS

Fang Chen is a Director of Advanced Statistical Methods at SAS Institute Inc. and a Fellow of the American Statistical Association. He manages the development of statistical software for SAS/STAT®, SAS/QC®, and analytical components that drive SAS® Visual Statistics software. Also among his responsibilities are the development of Bayesian analysis software and the MCMC procedure. Before joining SAS, he received his Ph.D. in statistics from Carnegie Mellon University.

BIOSKETCH



Mrs. Catherine Cheng
Novartis

Catherine Cheng is a CMC statistical lead at Novartis Gene Therapies. Her team provides technical expertise and statistical support from analytical development to commercialization. Prior to joining Novartis Gene Therapies, Catherine worked at Merck, BMS and Eli Lilly from 2001 to 2020. Catherine holds a BS in Chemical Engineering and MS in Statistics and Engineering.

BIOSKETCH



Dr. Seth Clark
Merck & Co.

Seth Clark holds a Ph.D. in Statistics from Virginia Tech and has 24 years of experience providing statistical leadership across pharmaceutical research and development. His expertise includes experimental design and data analysis for biologics development, assay development and validation, RNAi therapeutics, animal studies, formulation and manufacturing processes, stability studies, and a broad range of Chemistry, Manufacturing, and Controls (CMC) applications.

ABSTRACT



BPC-Stat: An Integrated Software Ecosystem for Automated Process Characterization and Statistical Modeling

Seth Clark, Song Liu, Melissa Matzke, Merck & Co.

Process Characterization (PC) is a critical activity in the biopharmaceutical product development lifecycle, essential for establishing a robust commercial manufacturing process control strategy under a Quality by Design (QbD) framework. PC involves the rigorous evaluation of how process parameters affect critical quality attributes. However, the statistical modeling required to support this evaluation—historically executed via manual point-and-click JMP implementation—is often characterized by long, tedious, and error-prone workflows. To address these systemic bottlenecks, we have developed BPC-Stat, a fully integrated JMP add-in designed to function as a comprehensive software ecosystem. In this presentation, we will demonstrate how BPC-Stat intersects with the core pillars of the CMC lifecycle. We will showcase its capability to manage complex Data architectures via cloud integration; its use of unified, multi-language Software (bridging point-and-click JMP with code-based Python and R) for reliable execution in regulated environments; its application of robust statistical Methodologies for process characterization; and its automated generation of compliance-ready reports designed to support seamless Regulatory Reviews.



Dr. Sara Cook
Iliacook Statistical Consulting, LLC.

Dr. Sara Cook is a visionary executive leader with deep expertise in data governance, CMC Statistics, advanced analytics. She currently serves as the Senior Vice President of Data Governance and Data Management at Citi, and is the Founder and President of Iliacook Statistical Consulting, LLC. Throughout her career, Dr. Cook has built a proven track record of delivering innovative data strategies and collaborative solutions across highly regulated fields, including the biotechnology, pharmaceutical, vaccine, and cell/gene therapy industries.

Highly relevant to her focus on CMC data governance, Dr. Cook previously served as the Head and Director of the Center of Excellence for Data Science, Advanced Analytics, and CMC Statistics at Novavax. In this capacity, she established and chaired the enterprise data governance program, translating data challenges into pragmatic action plans encompassing people, processes, and technology. She provided broad, critical support across CMC Statistics and preclinical areas, strategically developing global process characterization strategies and Continued Process Verification (CPV) programs. Dr. Cook brings extensive hands-on experience in addressing complex regulatory CMC inquiries, utilizing Quality by Design (QbD) methodologies, and authoring technical responses for the FDA.

In her current executive role, Dr. Cook successfully operationalizes enterprise data governance frameworks by aligning domain-level processes with strict regulatory commitments. She actively enhances end-to-end data management by uplifting data catalogs and lineage, and by designing comprehensive controls to ensure data quality and compliance. Through her consulting practice, she continues

BIOSKETCH



2/2

to support clients in optimizing robust biomanufacturing processes, technology transfers, and analytical methods through advanced statistical data analysis.

Dr. Cook holds a Doctorate of Philosophy in Chemical Engineering from Lehigh University, alongside a Master of Science and an Honors Bachelor of Science in Chemical Engineering from Drexel University. She is a recognized thought leader who serves on the Industrial Advisory Board for Drexel University's Department of Chemical Engineering. She is also a frequent invited speaker on the intersection of AI, advanced analytics, and biotechnology at prominent industry conferences, including the PDA and PDA/PQRI.

ABSTRACT



Beyond the Spreadsheet: Strengthening CMC Data Governance as the Foundation for Advanced Analytics and Regulatory Compliance **Sara Cook, Iliacook Statistical Consulting, LLC.**

As Chemistry, Manufacturing, and Controls (CMC) datasets grow in complexity, the traditional silos between data collection and statistical analysis are becoming untenable. This presentation explores the strategic role of data governance not merely as an administrative task, but as the essential architecture required to support the modern CMC lifecycle.

Effective data governance directly impacts the reliability of Statistical Software; without robust data integrity and standardized formats, even the most advanced validated platforms risk “garbage in, garbage out” scenarios. Furthermore, this foundation is a prerequisite for the adoption of sophisticated Methodologies. While Bayesian methods, AI, and machine learning offer transformative potential for process optimization, their predictive power is strictly limited by the quality and traceability of the underlying data.

From a Regulatory Review perspective, health authorities increasingly expect a holistic “data-first” approach. By implementing strategic data systems early in the development cycle, sponsors can ensure seamless data packages that withstand rigorous global audits. This session will outline best practices for statisticians to lead data quality initiatives, ensuring that CMC data is not just stored, but is strategically managed to enable high-velocity innovation and regulatory submissions.

BIOSKETCH



Mr. Jun Gao
BRDD / Health Canada

Jun Gao is a Senior Biostatistician with the Office of Biostatistics, Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Health Canada. He has more than 15 years of experience in the regulatory review of statistical methodologies and applications for Chemistry, Manufacturing, and Controls (CMC) quality and clinical submissions. In addition, he is a statistical consultant to staff within the quality laboratories in BRDD as well as to the virology research and cell therapy research teams at BRDD. He also has previous experience in population epidemiology applied to oncology.

His current interests focus on the thoughtful use of innovative statistical methods, including Bayesian approaches, in the quality assessment of biologics. He is particularly interested in integrating statistical evidence with product and process knowledge, and promoting multidisciplinary collaboration to support effective CMC decision-making.

ABSTRACT



Considerations for Bayesian-Informed CMC Regulatory **Jun Gao, BRDD / Health Canada**

Bayesian methodology can be applied, where appropriate, to integrate historical or prior knowledge with new data to update estimates of a product or quality attribute in Chemistry, Manufacturing, and Controls (CMC) assessments. As interest in these Bayesian methods continues to grow, collaboration among industry and regulators can help advance their effective use in CMC development and regulatory submissions.

This presentation will share emerging perspectives from quality and statistical reviewers within Health Canada's Biologic and Radiopharmaceutical Drugs Directorate (BRDD) regarding the quality review of Bayesian-informed CMC submissions.

The discussion will explore how Bayesian approaches can support CMC decision-making, with particular attention to the thoughtful use of prior information, the connection between statistical modelling and process knowledge, and the interpretation of results within the broader scientific context.

Effective reporting can facilitate multidisciplinary understanding and constructive dialogue between sponsors and regulators. Some thoughts on reporting Bayesian analyses will also be shared, including clear descriptions and/or justification of the CMC objective, current and historical data and information, prior distributions, modelling assumptions, posterior results, diagnostic assessments, and sensitivity analyses.

Finally, two successful submissions will illustrate how Bayesian approaches have been used in quality submissions. These examples will highlight the importance of early collaboration, transparent communication, and integration of statistical evidence with product and process knowledge. Overall, the presentation aims to encourage continued dialogue and support the appropriate use of Bayesian methods in CMC development and regulatory decision-making.

BIOSKETCH



Irina Gershgorin
Legend Biotech

Irina Gershgorin is currently leading Analytics and Statistics within Global MSAT at Legend Biotech, where she supports commercial manufacturing. She holds an Hon. B.Sc. from the University of Toronto and a PhD in computational biology from the Courant Institute at NYU. Prior to joining Legend, Irina spent nearly eight years at Novartis Cell and Gene Therapies, supporting KYMRIAH, the first ever cell therapy to be approved, as well as other pipeline programs. In addition to regular CMC support, Irina's work has focused on correlational analyses. She has applied statistical and machine learning methods to investigate relationships between product attributes, manufacturability and clinical outcomes, with findings presented at ASH, ASCGT, AACR, and IABS.

BIOSKETCH



Dr. Ashley Giambrone
Regeneron

Ashley studied Biostatistics at State University of New York at Albany. She finished her PhD in the statistical area of non-likelihood-based model evaluation in 2013. Afterwards she completed a post-doctoral program at Weill Cornell Medical College in the School of Epidemiology and Biostatistics. Currently, she is leading a team of statisticians at Regeneron Pharmaceuticals, Inc. supporting all aspects of drug manufacturing. Ashley joined the IABS Scientific Organizing Committee in 2022.

BIOSKETCH



Dr. Jennifer Kirk
FDA/CBER

Jennifer L. Kirk received her doctorate in biostatistics from the University of Washington. After her Ph.D., she joined U.S. Food and Drug Administration's Center for Biologics Evaluation and Research as a statistical reviewer. She spent 5 years as a reviewer of clinical and CMC statistics for vaccines, allergenics, and live biotherapeutics. For the past four years, she has served as the Lead Mathematical Statistician in the Device and Non-Clinical Evaluation branch as the lead for the CMC statistics team. Her team provides statistical support to CBER's product, manufacturing, and facilities reviewers for a wide range of biologics including, vaccines, allergenics, live biotherapeutics, cell and gene therapies, tissues, and therapeutic proteins.

BIOSKETCH



Max Kuhn
Posit

Max Kuhn works at Posit PBC (nee RStudio) and develops software for data analysis and modeling. He previously worked in pharmaceutical and molecular diagnostic research for more than 18 years. Max's interests are in predictive modeling and machine learning, and he is the author of six R packages, including the caret package and tidymodels framework. He and Kjell Johnson published the bestselling book *Applied Predictive Modeling* in 2013, which won the Ziegel award from the ASA that year. Max holds a B.S. in Mathematics and a Ph.D. in Biostatistics.

ABSTRACT



Workshop: AI Tooling for Data Analysis **Max Kuhn, Posit**

As large language models continue to permeate our work, we'd like these tools to be as good at data analysis as they are for software development. These are two different problems, and while LLMs are very intelligent, they are not that wise when it comes to data analysis.

This workshop will describe and demonstrate Posit AI. This tool, integrated into Posit's applications (RStudio and Positron), helps users perform data analysis and modeling in a safe, efficient, and effective environment.

We'll describe some design goals and illustrate with an example data set.

BIOSKETCH



Prof. Ji-Hyun Lee
University of Florida

Prof. Ji-Hyun Lee is Professor of Biostatistics at the University of Florida and Associate Director for Cancer Quantitative Sciences at the UF Health Cancer Center. She provides strategic leadership and promotes collaborative, rigorous research across the center. Dr. Lee holds a master's and doctoral degrees in Biostatistics from UNC Chapel Hill. Her work focuses on clinical trial design, group randomized trials, and best statistical practices. She is a Fellow of the American Statistical Association (ASA), a certified PStat®, and served as ASA's 120th President in 2025. She now serves as ASA Past-President, championing initiatives that strengthen the statistical community and promote data-science practice.

ABSTRACT



More Than Numbers: How Everyday Statisticians Shape Science **Prof. Ji-Hyun Lee, University of Florida**

Modern scientific research is increasingly multidisciplinary, collaborative, and data-driven. Yet the role of statisticians is often misunderstood as limited to numbers, software, sample-size justification, or final-stage data analysis. In this talk, I reflect on the everyday work of collaborative statisticians in clinical and translational research environments. Drawing from real experiences in cancer research, clinical trials, and team science, I discuss how statisticians help shape scientific questions, study design, interpretation, and decision-making throughout the research process. I also explore statistical leadership, communication, and the often quiet but essential influence statisticians have in advancing rigorous and meaningful science.

BIOSKETCH



Dr. Ruojia Li
BMS

Ruojia Li leads the Quantitative Sciences & Digital Transformation group within the Biologics Development organization at Bristol-Myers Squibb. Her team is responsible for CMC statistics, data science, clinical method performance monitoring, and manages digital transformation efforts across the organization. Ruojia holds a bachelor's in Mathematics from Peking University, and a Ph.D. in Statistics from University of Wisconsin Madison.

BIOSKETCH



Dan Liu
BMS

Cassie Liu is a senior principal statistician in Biologics Development Department at Bristol Myers Squibb. Over the 10 years with BMS, she has provided statistical supports in various CMC projects, including stability analysis and specification assessment for IND/BLA filings, statistical and ML modeling, risk assessment, bioassay analysis, design of experiment, analytical method performance monitoring, dataflow integration, and automation, etc. She received a master's degree in statistics from University of Connecticut and bachelor's degree in statistics from Nankai University in China. Prior to joining BMS, she was a statistician in a health-related research lab at Yale University.

ABSTRACT



From Data Foundations to Data Products: The Statistician's Role in Shaping CMC Data Strategy and Driving Scalable Analytics

Dan (Cassie) Liu, Ruoja Li – BMS

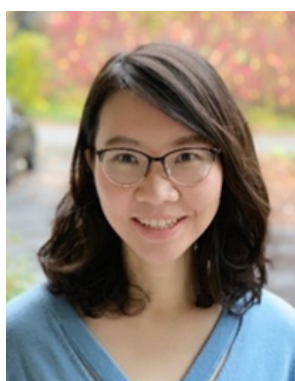
As CMC organizations accelerate their digital transformation journeys, the ability to enable robust, scalable analytics, digital innovation, and advanced modeling depends on more than sophisticated methods—it requires high-quality, well-structured, and interoperable data. This presentation explores the evolution from fragmented data landscapes to integrated data ecosystems and highlights the critical role statisticians can play in shaping data strategy, not only as consumers of data but also as architects of how data is defined, structured, governed, transformed into reusable data products, and leveraged for decision-making.

Drawing on practical experiences from CMC data transformation initiatives, we will share key lessons learned in building data foundations that enable scalable analytics. Topics include fostering effective collaboration among statisticians, domain scientists, and IT partners, designing data assets with analytical objectives in mind, and establishing scalable approaches to data governance and stewardship. We will also discuss the organizational and cultural transformations required to operationalize data strategy, including defining clear data ownership, promoting data literacy, and embedding data stewardship practices across functions.

The presentation highlights the unique strengths statisticians bring to data strategy. Their deep understanding of data context, variability, uncertainty, and analytical intent positions them to bridge domain science, data engineering, and advanced analytics. By expanding their impact beyond statistical analysis, statisticians can help create purposeful data products that accelerate analytics, enhance decision-making, and drive digital innovation. Embedding statisticians in data strategy ultimately enables more scalable analytics and contributes to improved product quality, patient safety, and development outcomes across the CMC lifecycle.

Importantly, we will discuss practical pathways for statisticians to evolve from analytical contributors to strategic leaders, expanding their influence across the data-to-decision value chain and helping shape the future of data-driven CMC organizations. Attendees will leave with an actionable framework for advancing from analysis-focused roles to data strategy leadership, enabling broader organizational impact and accelerating digital transformation across CMC.

BIOSKETCH



Mrs. Jia Liu
Pfizer

Jia got her PhD degree in statistics from Iowa State University. She has worked as a CMC statistician in Pfizer since 2013. Jia has substantial knowledge and experience in analytical method development, bioassay evaluation, reference material bridging, assay validation and transfer. She has successfully supported multiple CMC regulatory submissions. Jia is also interested in Bayesian methodology, machine learning, design of experiments, and linear-mixed models.

BIOSKETCH



Ms. Melissa Matzke
Merck & Co.

Melissa Matzke (M.S. Statistics, Oregon State University) is a Senior Principal Scientist at Merck & Co., Inc., with over 25 years of experience in statistical sciences across consumer goods, government research and pharmaceutical research and development. Her expertise includes design of experiments, data structure and management, development and implementation of pipeline methods, and statistical applications supporting Chemistry, Manufacturing, and Controls (CMC).

ABSTRACT



BPC-Stat: An Integrated Software Ecosystem for Automated Process Characterization and Statistical Modeling **Seth Clark, Song Liu, Melissa Matzke, Merck & Co.**

Process Characterization (PC) is a critical activity in the biopharmaceutical product development lifecycle, essential for establishing a robust commercial manufacturing process control strategy under a Quality by Design (QbD) framework. PC involves the rigorous evaluation of how process parameters affect critical quality attributes. However, the statistical modeling required to support this evaluation—historically executed via manual point-and-click JMP implementation—is often characterized by long, tedious, and error-prone workflows. To address these systemic bottlenecks, we have developed BPC-Stat, a fully integrated JMP add-in designed to function as a comprehensive software ecosystem. In this presentation, we will demonstrate how BPC-Stat intersects with the core pillars of the CMC lifecycle. We will showcase its capability to manage complex Data architectures via cloud integration; its use of unified, multi-language Software (bridging point-and-click JMP with code-based Python and R) for reliable execution in regulated environments; its application of robust statistical Methodologies for process characterization; and its automated generation of compliance-ready reports designed to support seamless Regulatory Reviews.

BIOSKETCH



Dr. Catherine Njue
BRDD / DMBR

Dr. Catherine Njue is the manager for the Office of Biostatistics in the Biologic and Radiopharmaceutical Drugs Directorate (BRDD), Health Canada. In this position, she leads the biostatistics team that is primarily involved in evaluating the statistical methodology of clinical trials and other sources of evidence for biologics (e.g., vaccines, blood products) and related biotechnology products and radiopharmaceuticals. She also provides statistical expertise in the drafting, review and implementation of standards and guidelines developed by Health Canada, ICH, and WHO working groups.

Dr. Njue received her Ph.D. in Statistics from the University of Manitoba in Winnipeg, Manitoba, Canada. After two years as a Biostatistician at CancerCare Manitoba, she joined Health Canada where she remains. Dr. Njue has extensive experience as a statistical consultant, which began at the Statistical Advisory Service, University of Manitoba, where she worked throughout her doctoral program. At CancerCare Manitoba, she collaborated with researchers in the Department of Preventive Oncology and Epidemiology on the design and analysis of epidemiological studies. She also provided statistical consultation to researchers from various other departments within CancerCare Manitoba.

BIOSKETCH



Dr. Oluyemi Oyeniran
Johnson & Johnson Innovative Medicine

Olu is a Senior Principal Scientist in the Statistics and Decision Sciences Department at Johnson and Johnson Innovative Medicine. He specializes in providing advanced statistical support across the biologics development and manufacturing lifecycle, including CMC regulatory filings (specification setting, shelf-life determination), analytical methods (development, method validation and transfers), manufacturing and formulation (cell banking, risk assessment, process validation), and continuous manufacturing. His areas of focus include experimental design, the use of linear and non-linear mixed effects models, Bayesian methods, machine learning, and statistical applications in continuous manufacturing. He holds a PhD in Statistics from the Bowling Green State University.

BIOSKETCH



Laura Pack
Moderna Inc.

Laura has leveraged her scientific and statistical expertise to drive innovation in biotechnology operations functions for the past 20+ years. Throughout her career, Laura has focused on supporting clinical, latestage, and commercial biologics and small molecule programs, CMC statistics and overall product quality strategy. She is passionate about teaching statistics to the many dedicated scientists that she encounters in the CMC community.

Laura currently leads the CMC Quantitative Sciences function at Moderna, Inc. Her team includes CMC statisticians, data scientists, & mechanistic/predictive modelers who partner with scientists across CMC functions to support objective decision making so that the company can bring important medicines to patients.

Laura holds bachelor's degrees in chemistry and biochemistry from the University of Colorado and a master's in applied statistics from Colorado State University. She has served on the IABS Statistics Workshop Scientific Organizing Committee since 2018 and on the AAPS CMC Statistics Community Leadership Team since 2016.

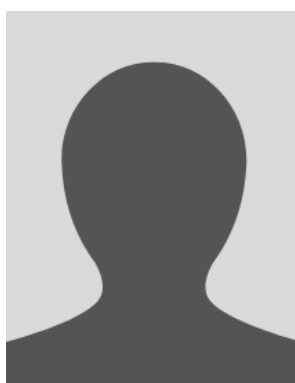
BIOSKETCH



Mark Quinn
Health Products Regulatory Authority

Mark works as a statistician at the Health Products Regulatory Authority in Ireland.

BIOSKETCH



Brenda Ramirez
Kite Pharma

Brenda Ramírez is a statistical leader with more than 35 years of experience applying statistics, analytics, and data science across biotechnology, biopharmaceutical manufacturing, and advanced manufacturing industries. She has led global initiatives supporting process development, process validation, continued process verification (CPV), commercial manufacturing, and regulatory submissions.

Brenda is co-author of Douglas Montgomery's Introduction to Statistical Quality Control: A JMP Companion and Analyzing and Interpreting Continuous Data Using JMP. She has published extensively on statistical quality control and process monitoring and introduced the Stability Ratio metric that was implemented in JMP® Version 13. Her current work focuses on applying artificial intelligence and advanced statistical methodologies to enhance process monitoring, accelerate insight generation, and support digital transformation in biopharmaceutical manufacturing.

Brenda is a recognized thought leader in applied statistics and process analytics, with a longstanding record of innovation in statistical quality control, process monitoring, and data-driven decision making through industry publications, conference presentations, and professional leadership. She holds graduate degrees in Applied Statistics (Worcester Polytechnic Institute) and Industrial Engineering (Rensselaer Polytechnic Institute).

ABSTRACT



From Data to Insight: Enabling Scalable, GxP-Compliant Analytics Through an Integrated Data Lake

Brenda Ramirez – Kite Pharma, a Gilead Company

As data volume and complexity grow in pharmaceutical manufacturing, statisticians are increasingly challenged to translate fragmented data into reliable, actionable insights. Traditional approaches—often dependent on manual processes and disconnected systems—limit visibility, slow decision-making, and introduce inefficiencies.

Beyond analysis, statisticians play a critical role in defining how data are structured, standardized, and governed to ensure they are fit for purpose in a regulated environment. Their perspective shapes key elements such as analytical data models, parameter harmonization, and data quality frameworks—ensuring the data lake supports meaningful, interpretable, and defensible analyses.

The talk will highlight how statisticians, in collaboration with IT and quality, drive the development of scalable, compliant data systems that support decision-making. This perspective underscores the evolving role of the statistician—from data consumer to architect of data ecosystems that ultimately enhance product quality and patient outcomes.

BIOSKETCH



Dr. Jose G. Ramirez
Statistical Advisor

José is currently the Chief Statistician within the Global MSAT group at Kite, a GILEAD company. In this role, he provides statistical leadership in the use, promotion, and adoption of best statistical approaches, including Bayesian methods. In his many years of experience in the semiconductor, electronics, and biotech industries, he has worked closely with engineers and scientists to help them make sense of data, and through collaborative education, help promote statistical thinking.

José received a licentiate degree in mathematics from Universidad Simón Bolívar in Caracas, Venezuela, and both an MS in applied statistics and a PhD in statistics from the University Wisconsin-Madison, where he was one of the founding members of the Center for Quality and Productivity Improvement. He has won both the SAS Users Group International (SUGI) best-contributed statistics paper, and the SAS User Feedback Award, and has written two books for SAS Press. In 2026 he was recognized by the University Wisconsin-Madison, School of Computer, Data & Information Sciences, with the Distinguished Achievement Award “for a career spent crossing boundaries — between engineering and science, industry and academia, data and medicine.”

ABSTRACT



Parallelism Testing Methods for Potency Bioassay Curves

Meiyu Shen, PhD, Office of Biostatistics, Center for Drug Evaluation and Research, FDA

FDA announced plans to phase out animal testing requirement for monoclonal antibodies and other drugs in April 2025. Since then, significant development in statistical methods has made for supporting the FDA initiative to promote use of non-animal bioassay. For instance, a cell-based bioassay not requiring animals might offer an attractive alternative to a mouse LD50 bioassay testing for biological products potency (a critical quality attribute). To reduce measurement variability, the relative potency methodology is adopted for testing the reference material and test material concurrently. Criteria for accuracy, linearity, parallelism should be met for determining a cell-based bioassay as a fit-for-use analytical method. Assuming a test material behaves like dilution or concentration of a reference, we propose assessing the parallelism of dose-response curves of a test material against a reference with parameter difference-based equivalence tests with margins determined from historical data analyzed with the four-parameter logistic model. Simulation studies are conducted to evaluate the proposed method's ability to identify parallelism and non-parallelism across various scenarios.

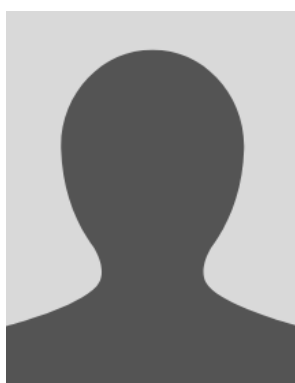
BIOSKETCH



Mr. Christopher Thompson
AstraZeneca

Chris leads the CMC statistics group for biologics development at AstraZeneca. He has spent the last 20 years working in CMC both in the lab and as a statistician. His recent focus has been how statistics can leverage platform knowledge to improve decision making. In addition to IABS, Chris is also involved with the IQ consortium and co-chairs the workgroup for Bayesian statistics in CMC for the ASA.

BIOSKETCH



Jeff Upton
JMP

Jeff Upton is a Principal Systems Engineer for JMP Statistical Discovery, which creates interactive and highly visual statistical discovery software designed for scientists and engineers. He supports sales and customer development in Northern California's life sciences space.

Before joining JMP, Upton held engineering R&D positions with Roche Molecular Solutions, Synthetic Genomics, and Genentech. Working in these roles, he gained experience in assay development and validation, workflow automation, and data analysis and visualization using JMP. He received a bachelor's degree in biochemical engineering at the University of California, Davis, and a master's in engineering management and leadership at Santa Clara University.

ABSTRACT



Automating CMC Analytic Workflows with JMP **Jeff Upton, JMP**

As pharmaceutical organizations continue to generate larger and more complex datasets, statisticians are increasingly challenged to deliver timely, consistent, and defensible analyses across the CMC lifecycle. This workshop explores how JMP supports the automation and standardization of analytic workflows, enabling teams to move beyond ad hoc analyses toward scalable, repeatable decision-making processes. Attendees will see examples of how interactive workflow building, reusable scripts, and automated reporting can reduce manual effort while improving analytical consistency. The session also highlights JMP's quality-focused capabilities, including process monitoring, statistical process control, capability analysis, root-cause investigation, and multivariate visualization. Practical examples will illustrate how these tools can be combined into end-to-end workflows that support development, technology transfer, validation, and commercial manufacturing. Particular emphasis will be placed on enabling collaboration between statisticians, process scientists, engineers, and quality organizations through transparent and reproducible analyses. Attendees will leave with ideas for applying workflow automation and quality analytics to accelerate CMC decision-making while maintaining the rigor expected in regulated pharmaceutical environments.

Also, two quick questions for you to help us better coordinate support for the event. I've cc'd Laura as she is helping out here. Thanks in advance for any answers you can provide.

- What will the exhibit table space look like? i.e. will we have enough room for a computer and monitor?

Is approval needed for any promotional materials or giveaways prior to the event?

BIOSKETCH



Dr. Gang Wang
Moderna

Dr. Gang Wang is Associate Director, Quantitative Sciences in the CMC Development department of Moderna, Inc., supporting statistics, mechanistic modeling, AI/ML, and data science for process development and mRNA pharmaceutical development platform. He graduated from MIT with a Ph.D. degree in chemical engineering, and has applied mechanistic modeling and machine learning technologies in the chemical and biopharmaceutical industries.

ABSTRACT



Let Models Speak: Machine Learning Process Models with Interpretable AI Agents **Gang Wang, Moderna**

Historical process data has been collected from different programs at Moderna, making it feasible for the development of machine learning (ML) models that can be used to deepen process understanding, predict process performance of new sequences, and accelerate process development.

A structured database has been designed with historical data from process development experiments linked with metadata such as sequence and process attributes. Interpretable machine learning models were used to identify relationship among manufacturability, sequence attributes, and process parameters. Digital platforms and applications were created as an interface for scientists and engineers to utilize prior knowledge as reference and compare with new experiments, and as an advisory tool to recommend optimal processes with explanations.

One of the potential challenges of ML-based process models is the generalizability of such models when applied to new mRNA sequences. In this presentation, we will focus on the approaches taken to enhance interpretability and further the trust of AI/ML-based solutions, and extend the discussion into developing AI agents on top of interpretable workflows.

BIOSKETCH



Dr. Mark Wolff
SAS

Dr. Wolff is an Advisory Industry Consultant for Health and Life Sciences at SAS Institute and a Visiting Fellow at the Frost Institute for Data Science and Computing at the University of Miami. He is an accomplished practitioner and lecturer in advanced and predictive analytics. His current focus is the application of machine learning and artificial intelligence to the design of intelligent decision support systems.

ABSTRACT



Beyond Control Charts: Adaptive, Model-Based Condition Monitoring with Generative AI for Biomanufacturing Process Monitoring **Mark Wolff, SAS**

Biomanufacturing processes generate high-frequency, high-dimensional process data along with intermittent analytical assessments. Statistical process control is predicated on fixed control limits and an assumption of stable and predictable conditions that may not be present in complex biological systems used for production of large-molecule therapeutics. Living organisms, raw material attributes, and operating conditions all vary inherently.

This presentation describes an intelligent condition monitoring framework that extends classical statistical process control through the integration of two analytically distinct but complementary components. Model-based monitoring develops empirical or mechanistic representations of expected process behavior and evaluates observed departures in real time, supporting predictive detection of process drift and informed adjustment of operating conditions within established design space boundaries. Statistical anomaly detection operates concurrently, applying multivariate methods to identify signals that fall outside the explanatory scope of existing process models, evaluating the deviations for which no model exists.

Upon confirmation of a deviation or anomaly, an automated prompt generation layer queries a structured, vectorized knowledge base containing process development records, batch histories, regulatory guidance, and curated scientific literature. This process automates root cause analysis of the anomaly. A large language model operating under retrieval-augmented generation returns a structured response comprising a contextual explanation of the deviation, ranked probable contributing factors, and recommended corrective actions. Validated outcomes are collected and used to refine both the monitoring models and the knowledge base, supporting consistent and informed responses to recurring deviation patterns across batches and campaigns and creating an intelligent, learning system. The framework is designed to meet regulatory expectations for process control, traceability and explainability. Statistical process monitoring and governed generative AI are integrated to support early deviation and anomaly detection, reduce investigational burden, minimize waste and improve yield and quality.

BIOSKETCH



Mr. Travis Wolter
Amgen

Travis R. Wolter received a masters in predictive analytics from Northwestern University and bachelors of science in statistics from the University of Wisconsin Madison. He has held multiple positions in biotech product and process development with a focus on statistical applications to address novel unmet need. Currently he is a member of the global CMC statistics team at Amgen, part of the wider Quality and Operations team

BIOSKETCH



Jie Zhao, Associate Director
Merck

Associate Director Statistician in CMC with 7 years of experience supporting development through commercialization. Leads experimental design and advanced statistical analyses for process capability, analytical method validation, comparability, and stability, including rapid response to regulatory requests. Develops robust statistical/ML tools, supports root-cause investigations impacting product quality, and communicates clear, actionable recommendations to technical and non-technical stakeholders.