FDA/PQRI WORKSHOP ON THE REGULATORY FRAMEWORK FOR THE UTILIZATION OF ARTIFICIAL INTELLIGENCE IN PHARMACEUTICAL MANUFACTURING

Biographies

Day 2 – September 27, 2023

SESSION 3: Use of Artificial Intelligence within the Pharmaceutical Quality System

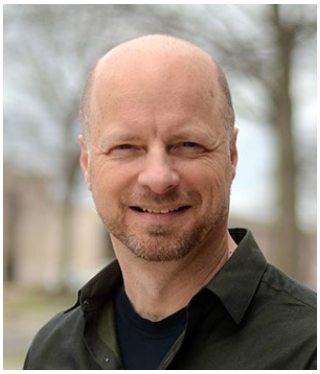
Moderator:

Diane Paskiet, MS
Director of Scientific Affairs
West Pharmaceutical Services
Diane.Paskiet@westpharma.com

Diane Paskiet has over twenty-five years of experience in the pharmaceutical industry. She is currently Director of Scientific Affairs at West Pharmaceutical Services where she is involved in science and regulatory programs associated with safety and compatibility of pharmaceutical packaging and delivery systems. Previous to this role she was in charge of site operations for West-Monarch Analytical Laboratories. She is the Chair of the Product Quality Research Institute (PQRI) Steering Committee and Chair of the Extractables and Leachables Parenteral Drug Product Working Group. Diane is also on the faculty of the Parenteral Drug Association Training Institute. She has author/co-author a number of papers and book chapters related to pharmaceutical packaging, delivery systems and combination products.

Speakers:

Trent Stone, MS
President
Varya Virtual
trent.stone@varyavirtual.com



Trent has over 25 years of experience in information technology and executive leadership. His company is a pioneer in the space of Data and Transformation and Orchestration. In addition to working with several pharmaceutical companies, Varya Virtual has been a partner of the Emerging Technologies Consortia. Their flagship platform, Iota, was recently featured in American Pharmaceutical Review.

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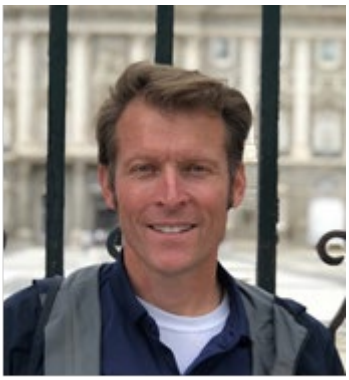
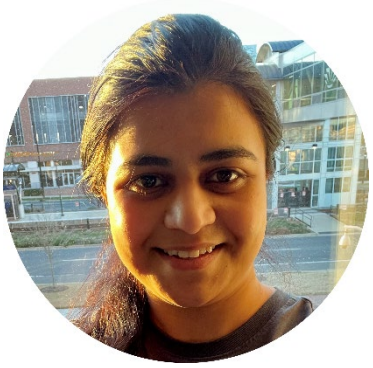
Biographies – September 26-27, 2023

Marc Horner Ph.D.
Distinguished Engineer
Ansys
marc.horner@ansys.com

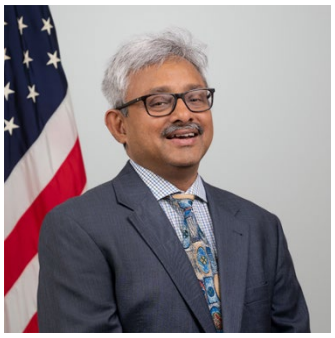


Dr. Marc Horner is a Distinguished Engineer leading technical initiatives for the healthcare industry at Ansys. Marc joined Ansys after earning his Ph.D. in Chemical Engineering from Northwestern University in 2001. Marc currently holds a number of industry leadership positions, with a focus on model credibility frameworks, regulatory science, and clinical applications. These include Vice Chair of the ASME VVUQ-40 Sub-Committee and Avicenna Alliance Global Harmonization Task Force Leader. Marc is also an Executive Committee Member of the IMAG/MSM Credible Practice of Modeling & Simulation in Healthcare project, which aims to establish a task-oriented collaborative platform that outlines credible practices of simulation-based medicine.

Nandini Rakala Ph.D., M.S., B.S.
Visiting Associate, Data Scientist
Center for Drug Evaluation and Research (CDER), FDA
nandini.rakala@fda.hhs.gov



Dr. Nandini Rakala is a Mathematician and Data Scientist, currently working as a Visiting Associate within the Center for Drug Evaluation and Research at the U.S. FDA. Dr. Rakala earned her Ph.D. in Operations Research in May 2020, from the Department of Mathematical Sciences at Florida Tech, with her primary research work in Optimization and Machine Learning. She also holds a master's degree in Applied Mathematics and Computing and a bachelor's degree in Mathematics Honors from India. During her past four and a half years with the agency, Dr. Rakala has worked on multidisciplinary regulatory research projects, employing her expertise in operations research, machine learning, natural language processing, programming skills, and knowledge of efficient quality management practices regarding pharmaceutical manufacturing. She is currently serving as an Analytics Team Lead, Developer, and Subject Matter Expert on critical OPQ programs such as the Quality Management Maturity, Quality Metrics, Predictive Modeling of Pharmaceutical Quality System Effectiveness, Prioritization of Field Alert Reports, Quality Signal Detection, Topic Modeling of Post-Market Surveillance Data, and Research BAAs; thereby helping innovate FDA's regulatory processes to drive greater efficiencies. Dr. Rakala has presented as an invited speaker, served as a session chair, and lead workshops at various global industry conferences and academic seminars, and is a recipient of several awards.

<table>
<tr>
<td>Panelists:
Saumyendu “Saum” Ghosh, Ph.D.
Director, Office of Information Systems Management (OISM), Office of Regulatory Affairs (ORA), FDA
saumyendu.ghosh@fda.hhs.gov
  </td>
<td>Dr. Saumyendu “Saum” Ghosh is the Director of the FDA/ORA Office of Information Systems Management (OISM) as well as the ORA Associate Deputy Chief Information Officer (ADCIO). As OSIM’s Director he leads ORA-wide IT activities to optimize systems and data for operational work and decision making in support of public health.

Over Dr. Ghosh’s 30-year career, he has guided many Fortune 100 clients through transformational change, helping reengineer how they serve customers, partners, and employees. His executive leadership experience in enterprise software and services has focused on relationship building and process improvement. He has more than a dozen published or accepted peer-reviewed articles and has won numerous honors throughout his professional and academic career, such as Outstanding Reviewer Award from the Journal of Enterprise Information Management, Emerald Publishing.

Most recently, Saum served as global senior engagement manager at Amazon Web Services (AWS), where he guided customers in adopting innovative AWS Cloud solutions around migration, data science, machine learning, and artificial intelligence. Previously, he led Infor’s Program Management Office (PMO), initially leading a $100M+ portfolio and ultimately starting an innovative delivery assurance program, where he managed a group of PMO directors for Infor’s $800M business. Saum also successfully managed the delivery assurance of Infor's most challenging implementations globally.

Saum earned his Ph.D. and Master of Engineering in project management from the University of Maryland, College Park, and Master of Statistics from the Indian Statistical Institute in Kolkata, India. In addition, he received Project Management Professional (PMP), Certified in Risk and Information Systems Control (CRISC), and Certified Data Privacy Solutions Engineer (CDPSE) certifications. He resides in Maryland with his wife and teenage son.</td>
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<td>Christina Meissner, Ph.D.
AGES Austrian Agency for Health & Food Safety, Institute Surveillance and EMA
christina.meissner@ages.at</td>
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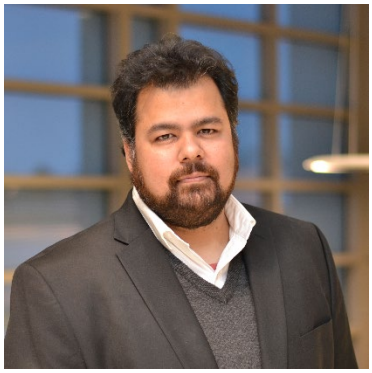
SESSION 4: Lifecycle Approaches to Management of Artificial Intelligence

Moderator:
Cat Vicente
Associate Director, Enterprise Regulatory Outreach,
Johnson & Johnson
CVicent3@its.jnj.com

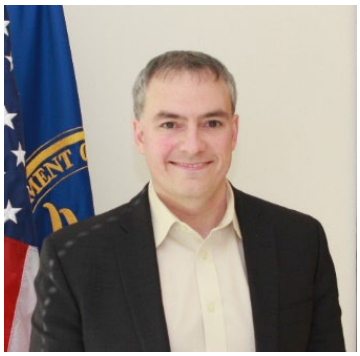
Catherine Vicente (Cat) has over 18 years' experience in various roles and functions throughout the pharmaceutical industry, ranging from both roles in the laboratory as well as roles within quality & compliance in the Consumer Segment. Cat currently works as Associate Director for the Johnson & Johnson Regulatory Compliance group called Enterprise Regulatory Outreach (ERO), where Cat specializes in regulatory intelligence detection, analysis and communication, analytical laboratory compliance, compendial compliance topics, as well as digital business strategy.

Speakers:

Gaurav Chopra, Ph.D.
Associate Professor
Purdue University
gchopra@purdue.edu



Prof. Gaurav Chopra is a tenured faculty in the Departments of Chemistry and Computer Science at Purdue University, an AnalytiXIN (Analytics Indiana) fellow of life sciences and manufacturing, a core member of Regenstrief Center for Healthcare Engineering and the Director of Merck-Purdue Center - a Merck funded Center supporting projects across Purdue University. Gaurav did his PhD in computational mathematics with Michael Levitt (2013 Nobel Laureate in Chemistry) at Stanford University School of Engineering and was a JDRF Fellow in experimental immunology with Jeffrey Bluestone at University of California (UCSF) School of Medicine. Chopra laboratory is a world leading center to develop and integrate artificial intelligence (AI), machine learning (ML) and closed-loop automation and manufacturing infrastructure for healthcare, drug discovery, and experimental immunology to combat diseases such as cancer and neurodegeneration. His work is funded by several federal agencies and companies, such as National Institutes of Health (NIH), Department of Defense (DoD), Defense Threat Research Agency (DTRA), National Science Foundation (NSF), Merck & Co, to name a few. Among numerous awards and recognitions, a recent notable one is that Chopra group's AI/ML drug discovery and closed-loop automation platform won the Grand Prize by the National Institutes of Health (NIH) as part of a worldwide competition. Outside of academia, Gaurav has co-founded two companies – Meditati Inc. that develops 'smart' drugs for mental health indications and BrainGnosis Inc. that develops AI-guided brain prognosis, diagnosis and digital therapeutics for diseases. Gaurav is committed to diversity in academia and have been the co-PI of NSF-REU award that selects underrepresented minority undergraduate students in STEM and funds them to do summer research with faculty at Purdue University. To

	increase diversity and openness in science for all ages, Gaurav's lab has also developed a virtual reality-based drug discovery game called MINT and have conducted several outreach events for K-12 and university students to enhance their love for science.
Gert Thurau, Ph.D. Head of Manufacturing Technology and Innovation Advocacy in CMC Reg Policy F. Hoffman-La Roche, Basel gert.thurau@roche.com 	**Dr. Gert Thurau** is the Head of Manufacturing Technology and Innovation Advocacy in the CMC Reg PTR Policy team at Hoffmann- La Roche in Basel, Switzerland. His responsibility includes the regulatory advocacy for the adoption of advanced technologies in GMP manufacturing – covering the spectrum from continuous processing, use of process models, robotics and artificial intelligence, to name a few. Most recently, he participated on behalf of EFPIA in the first EMA Quality Innovation Group "Listen and Learn" session in March 2023, and served on the regulatory panel discussion at the FDA workshop on "Advancing Innovative Manufacturing Approaches" on June 8th, 2023. Over the last 20 years, he has been involved in many key initiatives and regulatory interactions in the field of technology and regulatory innovation, Quality by Design, including Real-Time Release Applications, advanced control systems but also the implementation of ICH Q12. Previous responsibilities at Roche include the lead of the synthetic molecule Reg CMC team with 2 successful submissions to the FDA and Health Canada Pilot Program on Established Conditions.
Panelists: **Thomas O'Connor, Ph.D.** Deputy Director, Office of Testing and Research (OTR)/OPQ/CDER/FDA Thomas.oconnor@fda.hhs.gov 	**Thomas O'Connor**, PhD is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related regulatory challenges through scientific approaches. The impact of OTR research and testing is utilized to support regulatory assessment and policy development in areas such advanced manufacturing, drug quality standards, characterization of complex drug substances and drug products, and post market product quality and public health issues. Tom is a co-author of several papers on emerging pharmaceutical technology such as continuous manufacturing, 3D printing, and the utilization of modeling and simulation for quality assurance. Through the ETT he has contributed to the review of several regulatory applications utilizing novel technologies. He is the co-chair of the OPQ Manufacturing Science and Innovation Center of Excellence and is a member of the advanced manufacturing working groups within the FDA. Tom has been at the FDA since 2013 serving in various roles including as a chemistry reviewer in the Office Generic Drugs and a team leader in the immediate office of the Office of Pharmaceutical Quality. Prior to joining the FDA, Tom worked at ExxonMobil Research and Engineering where he held job functions in both process analytical technology and process control. Tom earned a B.S. in chemical engineering from the Cooper Union and a Ph.D. in chemical engineering from Princeton University.

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Marcel Hoefnagel, Ph.D. Senior Assessor Biopharmaceuticals Medicines Evaluation Board (CBG-MEB), The Netherlands and EMA mh.hoefnagel@cbg-meb.nl 	• Biologist, with a PhD in (Plant) Biochemistry, Leiden University 1993). • Senior Assessor of Biopharmaceuticals (since 2002), specialised in vaccines, allergens, biosimilars, immunogenicity, and cell and gene therapy products. • Since January 2023 Chairman of the Quality Innovation Group (QIG; EMA). The QIG supports the translation of innovative approaches to the design, manufacture and quality control of medicines. • Since 2020 Chairman of the Substance Validation Group (SVG). The SVG is involved in development and maintenance of EU-SRS (EU- Substance Registration System). • Involved in various research projects to support the assessment of (bio)pharmaceuticals and other regulatory activities.
Shawn Forrest Digital Health Specialist Digital Health Center of Excellence (DHCoE)/FDA shawn.forrest@fda.hhs.gov 	Shawn Forrest is a Digital Health Specialist in the Digital Health Center of Excellence (DHCoE) at the FDA. He served as a biomedical engineer lead reviewer and supervisor over review of cardiovascular devices, including a variety of artificial intelligence/machine learning (AI/ML)-enabled medical devices, for the agency for 14 years. For the past 2 years he has co-led the DHCoE AI/ML program developing related policy and resources for the agency.