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

Biographies

Day 1 – September 26, 2023

Welcome to Conference and PQRI Overview and Introductory Remarks

Glenn E. Wright
President and CEO
Parenteral Drug Association (PDA)
wright@pda.org

Glenn Wright currently serves of the Chairman of the Board at PQRI and as the President and CEO at PDA. Glenn has more than 30 years of experience in the pharmaceutical industry. Serving in various technical and senior leadership positions at Eli Lilly, Amgen, and Pfizer. He has extensive technical, regulatory, and quality expertise in both small molecule and biologic drug substance manufacturing as well as sterile injectable drug product manufacturing. Glenn has served on the PDA Board of Directors, Science Advisory Board, and Program Advisory Board. In addition, he has chaired numerous industry meetings, Task Forces, and Steering Committees. Glenn is a frequent speaker at industry events. He received his BS and MS degrees in Microbiology from Southern Illinois University.

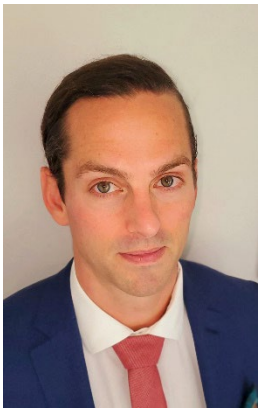
SESSION 1: FDA Introduction to State of Artificial Intelligence Regulatory Framework

Speakers:

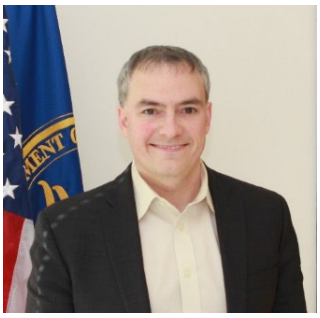
Patrizia Cavazzoni, MD. Director, Center for Drug Evaluation and Research (CDER), US Food and Drug Administration (FDA)

Patrizia Cavazzoni, M.D., is the director of the Center for Drug Evaluation and Research (CDER) at the U.S. Food and Drug Administration. The Center's mission is to ensure that safe, effective and high-quality drugs are available to the public. To achieve this, CDER regulates the medical products under its jurisdiction throughout their lifecycle, oversees the development of new and generic drugs, evaluates applications to determine whether drugs should be approved, monitors the safety of drugs after they are marketed, conducts research to advance regulatory science and takes enforcement actions to protect the public from harmful products. Dr. Cavazzoni joined the FDA in January 2018 as CDER's Deputy Director for Operations where she has led several key initiatives on behalf of the organization. She also served as Acting Principal Deputy Commissioner of Food and Drugs from January 2019 to February 2019.

Dr. Cavazzoni received her medical degree at McGill University and completed a residency in psychiatry and a fellowship in mood disorders at the University of Ottawa. During her training, she was an investigator in clinical trials of novel antipsychotic and antidepressant medications and became a research collaborator within the International Group for The Study of Lithium Treated Patients. She subsequently received a full-time appointment to the Faculty of Medicine at the University of Ottawa and joined the Mood Disorders Program at the Royal Ottawa Hospital, where she treated patients suffering from severe mood disorders, taught students and conducted research on genetic predictors of bipolar disorder

	as part of a multidisciplinary international collaborative effort, authoring numerous peer-reviewed scientific publications. After her tenure in academic medicine, Dr. Cavazzoni worked in the pharmaceutical industry for several years and held senior executive positions in clinical development, regulatory affairs, and safety risk management in large companies across multiple therapeutic areas, until she joined the FDA. Dr. Cavazzoni obtained certification by the American Board of Neurology and Psychiatry in 1997 and 2008 and was a fellow of the Canadian Royal College of Physicians and Surgeons from 1997 until 2023. She is a fellow of the Canadian College of Neuropsychopharmacology and a recipient of the American College of Psychiatrists' Laughlin Fellowship.
Adam Fisher, Ph.D. Director, Science Staff OPQ/CDER/FDA adam.fisher@fda.hhs.gov 	**Adam Fisher**, Ph.D. is the Director, Science Staff in the Office of Pharmaceutical Quality (OPQ) in the Center for Drug Evaluation and Research at the U.S. Food and Drug Administration. In this position, Dr. Fisher focuses on engaging FDA stakeholders and supporting advanced manufacturing technologies. At the FDA, he has served in positions of increasing responsibility: a primary and secondary reviewer of Abbreviated New Drug Applications and Drug Master Files, a Team Lead, a subject matter expert on complex drug substances and advanced biomanufacturing, and a liaison to the United States Pharmacopeia BIO1 Expert Committee. He joined the FDA in 2014 as a chemical engineer with expertise in the synthesis of biomolecules. Dr. Fisher's work prior to joining the FDA focused on the microbial production of proteins and glycoproteins for a host of applications. His Ph.D. dissertation concentrated on the use of the secretion pathways of bacteria to perform protein engineering. Prior to the FDA, Dr. Fisher was the co-founder and Chief Science Officer of a startup company focused on microbial technologies for the production of glycoproteins. He earned his B.S. degree at the University of Maryland College Park (Chemical Engineering) and his Ph.D. at Cornell University (Chemical & Biomolecular Engineering).

Thomas O'Connor, Ph.D.
Deputy Director, Office of Testing and Research (OTR)/OPQ/CDER/FDA
Thomas.oconnor@fda.hhs.gov

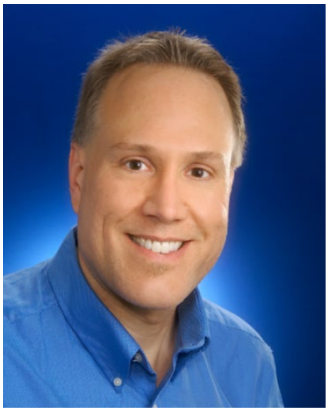


Thomas O'Connor, PhD is the deputy director of the Office of Testing and Research in the Office of Pharmaceutical Quality and is the vice-chair of CDER's Emerging Technology Team (ETT). His responsibilities include managing research and testing projects that answer and anticipate pharmaceutical quality-related 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.

SESSION 2: Use of Artificial Intelligence in Process Development, Process Monitoring, and Commercial Batch Trend Monitoring

Moderator:

Doug Kiehl
Senior Director
Eli Lilly and Company
kiehl_douglas_e@lilly.com



Doug Kiehl is currently a Senior Director at Eli Lilly and Company and leads the newly formed Disruptive/Transformative Technologies Team (DT3), with focus on digital transformation, automation, extractables/leachables and next-gen bioprocess. He also formed and leads Lilly's Digital Twin Center of Excellence. He has over 40 years' experience with application of advanced mass spectrometry in characterization of diverse chemical entities, 28 years of which are in the Pharmaceutical Industry. He serves as a member of the United States Pharmacopeia (USP) Packaging and Distribution Expert Committee, Vice Chair for the Product Quality Research Institute (PQRI) Steering Committee, PhRMA Topic Lead for the International Council for Harmonisation (ICH) Q3E Guideline for Extractables and Leachables (E&L) Expert Working Group, Executive Governing Council for the SEMI Consortium (SEMI), Board of Directors for the Extractables/Leachables Safety Information Exchange (ELSIE) Consortium, Chair for the International Society for Optics and Photonics (SPIE) Defense and Commercial Sensing Conference and founding member of the Biomolecule Reactivity Consortium. He has published his work in several peer-reviewed and trade journals, and has organized, chaired and presented at a number of conferences.

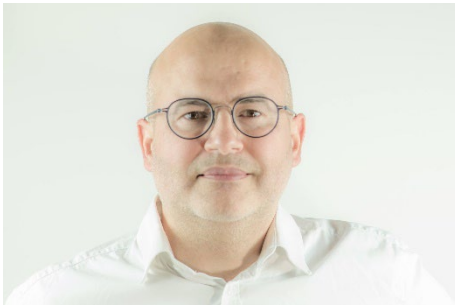
Speakers:

Richard D. Braatz
Edwin R. Gilliland Professor of Chemical Engineering
Massachusetts Institute of Technology
braatz@mit.edu

Dr. Richard D. Braatz is the Edwin R. Gilliland Professor of Chemical Engineering at MIT, where he conducts research into advanced biomanufacturing systems. He leads process analytics, mechanistic modeling, and control systems for several projects on campus, including in monoclonal antibody, vaccine, and gene therapy manufacturing. Dr. Braatz received an M.S. and Ph.D. from the California Institute of Technology and was the Millennium Chair and Professor at the University of Illinois at Urbana-Champaign and a Visiting Scholar at Harvard University before moving to MIT.

Dr. Braatz has collaborated with more than 20 companies including Novartis, Pfizer, Merck, Bristol-Myers Squibb, Biogen, Amgen, Takeda, and Abbott Labs. He has published over 300 papers and three books, including Fault Detection and Diagnosis in Industrial Systems. Dr. Braatz is a Fellow of IEEE, IFAC, AIChE, and AAAS and a member of the U.S. National Academy of Engineering.

Romain Veillon, PharmD
Director, Vision Technology MSAT, GSK
romain.veillon@gsk.com



Romain holds a PharmD in industrial Pharmacist (Lyon France). After a short period in Sanofi France learning Freeze-drying, he moved to Eli Lilly France to support aseptic manufacturing, filling line and freeze-drying line projects. Then, Romain moved to Belgium to GSK. After many years in R&D development, engineering and MSAT, he is now Director of Vision Technology and Vision center of Competency. He is team leader for defect kit manufacturing and global validation policies. Last 15 years, he focused on design & installation of many new automated Inspection machines on six sites. Romain has developed expertise in Deep Learning applied to VI, he is now fellow at GSK in this field. Currently he is leading digitalization AVI program on multiple sites. Also, Romain is regular speaker to PDA and A3P, and is Co-Chairing PDA Visual Inspection Forum in US and Europe since 2018.

Kim Wilson
Business Consultant Executive
Dassault Systèmes
kim.wilson@3ds.com

Kim Wilson is a Life Sciences Business Value Consultant for Dassault Systèmes, working with Pharmaceutical, BioTech and MedTech companies to accelerate digital transformation of processes from Ideation through Manufacturing.

Virtual Twin technology helps business reimagine what is possible throughout every stage of the product lifecycle by transforming how products are developed, produced, and commercialized. Companies can switch to digital vs paper driven systems, to data vs document based processes, and to virtual vs physical testing and experimenting. Products can be developed and brought to market faster and more cost effectively, testing can be more efficient and save time, facility layout, resources and safety activities can be optimized, and sustainability goals can be accelerated. With capabilities in CAD Design, Scientific Informatics, Molecular Modeling & Simulation, Data Science, Laboratory Informatics, Formulation Design, Quality & Compliance, Manufacturing Analytics, Virtual Commissioning, and Planning & Scheduling, businesses can transform how products are developed, produced, and commercialized.

Kim is a Chemical Engineer and has worked in Manufacturing, Product and Marketing Management, Business Strategy and Consulting. She designs value-based business solutions by working cross-functionally and vertically within organizations, incorporating experiences from a variety of industries. Kim previously worked for Dow Chemical, PPG and a MedTech start-up and is active with BioPhorum (Cell & Gene Therapy, MES of the Future, and Lab of the Future), Boston Women in Manufacturing and MassMEDIC.

Recent Publication Collaborations
-CGT personas and user stories: What people need the systems to do to support the supply of cell and gene therapies
-Standardizing traceability of personalized cell and gene therapies
-Virtual Twins for Biomanufacturing Podcast
-CGT actors and process maps: Who does what in the supply of different cell and gene therapies

<table>
<tr>
<td>Panelist:

Sharmista Chatterjee, Ph.D.
Division Director, Division of Pharmaceutical Manufacturing II
OPQ/CDER/FDA
sharmista.chatterjee@fda.hhs.gov
  </td>
<td>Sharmista Chatterjee is currently the Division Director in Division of Pharmaceutical Manufacturing II, within FDA's Office of Pharmaceutical Manufacturing Assessment (OPMA). Sharmista has been with the FDA since 2006. During her tenure she has been actively involved in many agency initiatives that include Quality by Design (QbD), FDA-EMA QbD pilot program, Emerging Technology Program (ETP), KASA, NIR guidance, Continuous Manufacturing, and in the Framework for Regulatory Advanced Manufacturing Evaluation (FRAME) . Prior to joining the agency in 2006, she spent around 10 years in industry. Her industry experience was primarily in process development and modeling in diverse areas that ranged from consumer goods to pharmaceuticals with companies such as United Technologies Corporation (now Raytheon), Procter and Gamble (P&G), and Forest Laboratories (now Allergan). She received a bachelor's degree in Chemical Engineering from Indian Institute of Technology and a PhD in Chemical Engineering with a co-major in Biomedical engineering from Iowa State University.</td>
</tr>
<tr>
<td>Ben Stevens, Ph.D., MPH
Director CMC Policy and Advocacy GSK
ben.x.stevens@gsk.com

  </td>
<td>Ben Stevens is a Director of CMC Policy and Advocacy at GSK and has nearly 15 years of drug discovery and regulatory experience. Prior to GSK, Ben was a Director of Regulatory Affairs CMC at Alnylam where he led the regulatory CMC program for vutrisiran prefilled syringe in over 30 countries, and the initial US NDA and EU MAA submissions, including one of the earliest Notified Body assessments under the newly implemented EU MDR. Before Ben joined Alnylam, he was a Principal Consultant at PAREXEL and an acting Branch Chief in the Office of New Drug Products (ONDP) at the FDA. At FDA, Ben worked closely with several key policy groups (OPPQ, ORP), partnered with CDRH on matters related to combination product review, and was a government liaison to USP. Before FDA, Ben spent seven years in medicinal chemistry R&D at Pfizer and Merck. Ben has broad regulatory CMC experience in small molecules, peptides, oligonucleotides, botanicals, and combination products. At GSK, Ben leads CMC policy and advocacy for several priority areas, including biologics, CGT, oligonucleotides, and advanced manufacturing. Ben represents GSK in numerous external trade and association working groups (e.g., PhRMA, BIO, IQ, EFPIA, NIIMBL, ISPE, PDA, Biophorum), where he has led and supported policy positions and interactions with numerous global regulators. He received a Ph. D. in Chemistry from the University of Pittsburgh, a M.P.H. from the Johns Hopkins Bloomberg School of Public Health, and is a co-author of over 30 publications and patents.</td>
</tr>
</table>

Leticia Martinez-Peyrat, Ph.D., Pharm.D.
Senior Quality Assessor
ANSM (French National Agency for Medicines and Health Products Safety)
Leticia.martinez-peyrat@ansm.sante.fr

Leticia Martinez-Peyrat is Doctor of Pharmacy and holds a PhD in Pharmaceutical Technology from the University of Paris-11 (now Paris-Saclay), France.

She joined ANSM, the French medicines agency, in 2008 after few years spent in industry in research and development as formulation manager. She is an EMA (European Medicines Agency) Quality expert for human medicines (chemical products).

Since 2009, Dr Martinez-Peyrat has been involved in the review of several Quality-by-Design applications including the first Continuous Manufacturing EU centralised applications.

Through her membership within former EMA PAT Team (2014-2019), she participated in the construction of the EU regulatory pathway for the pharmaceutical enhanced approaches in a harmonised way with international partners, in particular in the frame of the EMA-FDA pilot program for parallel assessment of Quality-by-Design applications (2011-2016).

She has been accompanying the setting up of ICH guidelines from Q8 to Q13 in the EU regulatory landscape and facilitating their implementation in regulators' common practice.

In March 2022 she contributed to the drafting of the Concept Paper for the European Commission on New manufacturing methods, which addresses the innovations of tomorrow, in the frame of the revision of the EU general pharmaceuticals legislation.

In September 2022, Dr Martinez-Peyrat was appointed member of the EMA Quality Innovation Group (QIG).