FDA

GMP

45th International Good Manufacturing Practices Conference

March 8 - 11, 2021

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March 8, 2021

Dear Colleagues,

I am pleased to welcome you to the 45th International Good Manufacturing Practices Conference. Due to the ongoing pandemic, this year's meeting looks a little different. I invite you to join, engage, and learn!

This conference was established in conjunction with the U.S. Food and Drug Administration in 1976 to create an annual ongoing dialogue between regulatory agencies and the pharmaceutical industry on important issues in drug compliance and quality. The conference is widely recognized as the top international GMP meeting in the world and offers attendees the unique opportunity to meet with U.S. FDA, Health Canada, MHRA, and other global regulators and industry experts.

The conference agenda is filled with high-level FDA and global regulatory agency and industry leaders. This year, the conference will focus on meeting challenges in pharmaceutical manufacturing. The conference will include sessions on GMP Inspection Recognition and Reliance, Remote Auditing, Sterility Assurance, Post-Approval Change Management, GMP Challenges for OTC Manufacturers, Nitrosamine Impurities, GMP Challenges in Animal Health Products, along with many updates on inspection trends and new guidance documents.

I thank you for your continued support of this conference!

Michael G. Bartlett, Chair
Georgia Athletic Association Professor in Pharmacy
Associate Dean for Science Education, Research, and Technology
University of Georgia College of Pharmacy

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AGENDA

MONDAY, MARCH 8

Times are Eastern Standard Time (EST)

Welcome Michael Bartlett, Chair, GMP Kelly Smith, Dean, UGA College of Pharmacy	2:00 p.m.
COVID Vaccines: Expediting Development While Ensuring Product Quality Robin Levis, FDA	2:30 p.m.
Q&A Session	3:15 p.m.

AGENDA

TUESDAY, MARCH 9

Times are Eastern Standard Time (EST)

Update from the Office of Regulatory Affairs Alonza Cruse, FDA	8:30 a.m.
Q&A Session	9:15 a.m.
GMP Inspection Recognition and Reliance Initiatives Mark Birse, Parexel	10:00 a.m.
Development of a Remote Auditing Program Tor Gråberg, AstraZeneca	10:45 a.m.
Q&A Session	11:30 a.m.
Lunch Break	
Update from CDER Quallyna Porte, FDA	1:00 p.m.
Health Canada Inspection Trends and Case Studies Kent Downing, Health Canada	1:45 p.m.
Q&A Session	2:30 p.m.
Impact of COVID-19 on the Pharmaceutical Supply Chain Robin Kumoluyi, Johnson & Johnson	3:15 p.m.
Sterility Assurance for ATMPs: From Isolators Back to Grade A Vanessa Figueroa, Quality Executive Partners	4:00 p.m.
Q&A Session	4:45 p.m.

AGENDA

WEDNESDAY, MARCH 10

Times are Eastern Standard Time (EST)

Case Studies from GMP Inspections CAPT Ileana Barreto-Pettit, FDA	8:15 a.m.
BREXIT and GMP Inspections Tracy Moore, MHRA	9:00 a.m.
Q&A Session	9:45 a.m.
OTC Monograph Reform in the 2020 CARES Act Barbara Kochanowski, CHPA	10:30 a.m.
GMP Quality Management for OTC Manufacturers Jennifer Ahearn, ESi, Inc.	11:15 a.m.
Q&A Session	12:00 p.m.
Lunch Break	
Post-Approval Change Management Anil Sawant, Merck	1:00 p.m.
Combating Counterfeit Pharmaceuticals with Technology Ravi Kalyanaraman, BMS	1:45 p.m.
Q&A Session	2:30 p.m.
Analytical Challenges for Nitrosamine Method Development and Testing in Pharmaceuticals Beverly Nickerson, Pfizer	3:15 p.m.
Addressing Nitrosamine Concern in Pharmaceuticals - USP New General Chapter <1469> Edmond Biba, USP	4:00p.m.
Q&A Session	4:45 p.m.

AGENDA

THURSDAY, MARCH 11

Times are Eastern Standard Time (EST)

CMC of New Animal Drugs Laura Huffman, FDA CVM	8:15 a.m.
Principles and Practices of Good Manufacturing as required by the Virus-Toxin-Serum Act Kendall Graber, USDA CVB	9:00 a.m.
Q&A Session	9:45 a.m.
Advanced Learning Modalities Utilizing Technology Tyler DeWitt, Quality Executive Partners	10:30 a.m.
Pharmaceutical Innovation: Challenges and Opportunities from an Industry Perspective Socrates Kyritsis, Novartis	11:15 a.m.
Q&A Session	12:00 p.m.
Lunch Break	
Supplier Qualifications - USP General Information Chapter in Development Desmond Hunt, USP	1:00 p.m.
(Some) Legal and Regulatory Issues to Consider Relating to Quality Agreements Alan Minsk, AGG	1:45 p.m.
Q&A Session	2:30 p.m.
Laboratory and OOS Investigations James Stumpff, Parexel	3:15 p.m.
Data Analytics: Holistic Approach to implement the digital plant Wilfred Mascarhenas, Eli Lilly	4:00p.m.
Q&A Session and Conference Wrap Up	4:45 p.m.

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GOOD MANUFACTURING PRACTICES (GMP) CONFERENCE PROGRAMMING COMMITTEE

	Michael Bartlett, Chair	Associate Dean for Science Education, Research, and Technology University of Georgia College of Pharmacy
	Jennifer Ahearn	Principal, Practice Group Director Regulatory & Compliance, Pharmaceutical, and Medical Devices Engineering Systems, Inc.
	Sarah Barkow	Lead GxP External Engagement Bristol Myers Squibb
	Robert Coleman	Senior Compliance Expert, Pharmaceuticals IHL Consulting Group, Inc.
	Cledwyn Davies	GMP Compliance Specialist Porton Biopharma (UK)
	Seppe de Gelas	Regulatory and Quality Affairs Director Indigo
	Robert Geiger	Senior Vice President, Business Development AmbioPharm, Inc.
	Grace Gowda	Director International Biomedical Regulatory Sciences Program University of Georgia College of Pharmacy
	Tor Gråberg	Head of Operations, Quality Compliance, and External Affairs AztraZeneca (Sweden)
	Steve Greer	Executive Coach, Speaker, and Consultant Genesis Assist, LLC
	Johnna Hodges '02	Assistant Director International Biomedical Regulatory Sciences Program University of Georgia College of Pharmacy
	Alexander Jacks III	Senior Vice President Quality Assurance Vero Biotech, LLC

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GOOD MANUFACTURING PRACTICES (GMP) CONFERENCE PROGRAMMING COMMITTEE

	Kristen Mandello '99, '11	Signal Detection and Signal Management Zoetis, Inc.
	Marie Mathews '89, '13	Associate Director, GxP External Engagement Bristol Myers Squibb
	Crystal Mersh	President and CEO Quality Executive Partners (QxP), Inc.
	Alan Minsk	Partner and Practice Leader of Food and Drug Team Arnall, Golden & Gregory, LLP
	Bill Paulson	Editor-in-Chief International Pharmaceutical Quality (IPQ)
	JoAnn Pittman	Public Affairs Specialist United States Food and Drug Administration
	Prabhakar Reddy	Principal Scientific Liaison - Team Leader Science - General Chapters United States Pharmacopeia (USP)
	Gurvinder Singh Rekhi	Academic Professional University of Georgia College of Pharmacy
	Sam Silva	Vice President of Business Development FK Biotecnologia SA (Brazil)
	Ronald Tetzlaff '83, '87	President Tetzlaff Consulting Services, LLC
	Nelson Webb	Director Quality Assurance - External Engagement Proctor & Gamble

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2021 Speakers

Questions for the speakers?
Submit them here:

Jennifer Ahearn

Principal and Practice Group Director
Regulatory & Compliance, Pharmaceutical, & Medical Devices
Engineering Systems, Inc.

Jennifer specializes in pharmaceutical and medical device regulatory compliance. She has served numerous roles within the FDA including bench chemist, domestic and international investigator, technical liaison for the FDA's Office of Criminal Investigations, and member of the FDA's National Training Cadre making her an expert in the interpretation and application of cGMP regulations in 21 CFR 210/211 relating to pharmaceutical manufacturing, and 21 CFR 820 relating to medical devices.

Ahearn has assisted pharmaceutical and medical device companies preparing for FDA inspections, as well as responding to FDA 483 observations after an inspection. She has worked to resolve technical and FDA compliance issues for virtually all pharmaceutical dosage forms and medical device classes. Jennifer has worked with manufacturers with such aspects as sterility, material supply chain, vendor auditing, validation programs, laboratory and manufacturing investigations, laboratory and manufacturing audits, and CAPA implementation.

Ileana Barreto-Pettit R.N., M.P.H.

Captain, U.S. Public Health Service

Drug National Expert

U.S. Food and Drug Administration

CAPT Barreto-Pettit is currently an FDA Drug National Expert. She is responsible for providing technical and programmatic expertise to the FDA field offices and Centers and provides inspectional assistance to domestic and foreign offices on complex pharmaceutical inspections and regulatory matters. She joined FDA in 1999 as an Investigator in the FDA San Juan District in Puerto Rico and transferred to the Florida District in 2003. Since then, she has conducted hundreds of GMP and pre-approval drug inspections worldwide.

CAPT Barreto-Pettit has been an Instructor in the FDA Basic Drug School for the last 13 years and she is a frequent Speaker at pharmaceutical industry conferences. She is a Commissioned Officer in the U.S. Public Health Service and has over 34 years of experience in the federal government.

She received a B.S. in Biology from Iowa State University, a B.S. in Nursing from Jacksonville State University, and a Master's in Public Health from Nova Southeastern University.

Edmond Biba, Ph.D.

Senior Scientific Liaison,
Science - General Chapters

U.S. Pharmacopeial Convention

Dr. Edmond Biba works as Senior Scientific Liaison for General Chapters Department-Science Division at United States Pharmacopeial Convention. Edmond has held several positions at USP since joining USP in 2001, as scientist in the Research and Development Laboratory (6 years), as reference standards scientist in Reference Standards Evaluation Department (8 years) and currently as USP scientific liaison to the USP General Chapters-Chemical Analysis Expert Committee and USP General Chapters-Physical Analysis Expert Committee.

Prior to joining USP, Dr. Biba was a National Research Council-Walter Reed Army Institute of Research Postdoctoral Fellow in the Medicinal Chemistry Department of Experimental Therapeutic Division conducting research on bioassay directed drug discovery and mechanism of action based design and the synthesis of new antimalarial drug candidates.

Dr. Biba received his Ph.D. in Chemistry-Synthetic Chemistry from the American University, Washington DC, and a B.Sc. in Chemical Engineering/Chemistry from University of Tirana, Tirana, Albania. Dr. Biba is member of Sigma Xi, The Scientific Research Honor Society, American Chemical Society, American Association of Pharmaceutical Scientists, and a member of Pharmaceutical Quality Technical Committee of the Pharmaceutical Quality Research Institute (PQRI).

Mark Birse

Vice President
Technical, Regulatory Consulting Services

Parexel International

Mark is a strategically orientated regulatory compliance professional, with a career spanning the regulation of pharmaceuticals and medical devices. Mark has a passion for ensuring patient safety through delivering pragmatic, risk proportionate and innovative approaches to regulation, with a demonstrated success in building and leading high-performing teams responsible for multimillion-pound income.

Prior to joining Parexel, Mark previously worked at the MHRA where held a number of leadership roles, including Deputy Director Inspection, Enforcement & Standards Division and Head of MHRA Inspectorate and Process Licensing Group, a team with over 75 GXP inspectors. In these roles, Mark worked extensively with international regulators including FDA, EMA and TGA developing compliance and risk-based inspection methodologies with a focus on inspection collaboration and reliance. He was an Executive Bureau member of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) and also assessed the capability and performance of regulators and provided international training for both regulators and industry. Mark also held leadership roles in the MHRA Medical Device Division with responsibilities for Devices Safety and Surveillance & Software and Apps. Mark's background is in GMP having initially joined the MHRA in 2002 as a GMP Inspector where he performed inspections globally. Prior to joining MHRA he spent 10 years in Industry with responsibilities for technology transfer and supplier auditing.

Mark is a chemist, a Fellow of the Royal Society of Chemistry and he holds Chartered Chemist and Chartered Scientist status. Mark has been an eligible Qualified Person since 2003 and is an IRCA Principal Auditor under the PQMS-GMP scheme.

Alonza Cruse

Director, Office of Pharmaceutical Quality Operations (OPQO)

Office of Regulatory Affairs (ORA)

U.S. Food and Drug Administration

Alonza Cruse is Director, Office of Pharmaceutical Quality Operations (OPQO) within the FDA Office of Regulatory Affairs (ORA). His office is responsible for all pharmaceutical quality inspections and investigations, working in conjunction with FDA's Center for Drug Evaluation & Research (CDER) and Center for Veterinary Medicine (CVM). Additionally, Mr. Cruse continues to lead ORA's pharmaceutical collaboration efforts under the program alignment initiative.

From 2013 - 2015 Mr. Cruse served as the Director (Acting) of the Office of Medical Products & Tobacco Operations (OMPTO) within ORA, overseeing activities such as Generic Drug User Fee Amendments (GDUFA) implementation, pharmacy compounding, and the development of a New Inspection Protocols Program (NIPP). From 2000 - 2015, Mr. Cruse was the Director, FDA's Los Angeles District Office, where his responsibilities included providing executive leadership to implementing, managing and evaluating FDA's regulatory operations. Mr. Cruse first joined ORA in 1983 as a microbiologist. He received his Bachelor of Science degree in Medical Technology from York College (City University of New York).

Tyler DeWitt, Ph.D.

Executive Director, Innovation

Quality Executive Partners, Inc.

Tyler DeWitt works at the intersection of science, technology, and education. He is the Executive Director of Innovation at Quality Executive Partners (QxP) and Virtuosi VR. Tyler contributes technical expertise on Microbiology and on Advanced Therapies manufacture, and he also works to design learning experiences that are appropriate and engaging for adult learners. In addition to his work at QxP, Tyler is the creator of one of the most popular instructional channels on YouTube, and he is the video author for the newly released textbook "Interactive General Chemistry," published by Macmillan Learning. Tyler holds an Sc.B in Biochemistry from Brown University, and a Ph.D. in Microbiology from MIT, where he was a National Science Foundation Fellow.

Kent Downing

Regulatory Compliance and Enforcement Specialist

Regulatory Operations and Enforcement Branch

ROEB GMP Inspection West

Health Canada

Government of Canada

Kent Downing is a Health Canada GMP Inspector based in Vancouver on the West Coast of Canada. He has been with Health Canada for 13 years in his role as a Compliance and Enforcement Specialist performing GMP inspections for both active pharmaceutical ingredients and finished dosage forms.

He has been active on Health Canada's GMP Committee since 2008, was former Chair of the National Inspection Rating Review Group (IRRG) and been involved in the drafting of Canadian GMP guidance. From 1999 to 2008, he worked for multiple drug developers, with increasing management responsibility in drug development, drug GMP manufacturing and quality.

Vanessa Figueroa

Executive Director, Microbiology

Quality Executive Partners, Inc.

Vanessa Figueroa, Executive Director of Microbiology, has more than 15 years combined experience in Pharmaceutical, Biotechnology and Medical Device industries. Mrs. Figueroa has expertise in sterility assurance, contamination control, environmental and utilities monitoring programs and quality control laboratory management. Her consulting experiences have spanned both domestic and international top pharmaceutical companies, applying both US and global regulatory standards of quality.

She is also the Product Manager for Series 1 of Virtuosi, an innovative and revolutionary education and training product for the pharmaceutical industry. Mrs. Figueroa has a Bachelor's degree in Molecular Biology from State University of New York at New Paltz, and a Master's degree in Molecular Biology and Microbiology from San Jose State University. She is an active and publishing member of several professional organizations, such as the Parenteral Drug Association, American Society of Microbiology and Association for Women in Science.

Kendall Graber

Senior Biologics Specialist

Center for Veterinary Biologics

U.S. Department of Agriculture

Kendall Graber became interested in the veterinary vaccine industry while working summers at a small veterinary vaccine company near his home in South Dakota. Following graduation from South Dakota State University in 1986, he accepted a job in Research and Development with Grand Laboratories. In 1990 he accepted a job at Fort Dodge Animal Health, a global manufacturer of agricultural and companion animal vaccines. While there he held positions in R&D, Quality Control, Production, and Quality Assurance, reviewing and approving serial release of domestic and international veterinary biologics. During this time he also served on the USP 1237 Virology Test Methods Ad hoc Advisory Panel as well as the Fetal Bovine Serum Advisory Panel of the United States Pharmacopeia.

Mr. Graber's experience grew following the Pfizer Animal Health acquisition of Fort Dodge Animal Health and subsequent sale to Boehringer Ingelheim Vetmedica, Inc. in 2009. One of the highlights of this period was learning the different products, processes, and raw materials used in different products at different sites. In 2010, Kendall was offered a job at the United States Department of Agriculture's Center for Veterinary Biologics in Inspection and Compliance working with the Quality Section. Mr. Graber currently serves as Facilities Manager and his responsibilities involve performing firm inspections as well as internal audits of the CVB Laboratory, and implementing the provisions of the Virus-Serum-Toxin Act (VSTA) to assure that pure, safe, potent and effective veterinary biologics, are available for the diagnosis, prevention, and treatment of animal diseases. His experiences have afforded him the opportunity to participate in and review a wide range of inspections, internal audits, investigations and root cause analysis evaluations.

Tor Gråberg

Head of Operations, Quality Compliance, and External Affairs

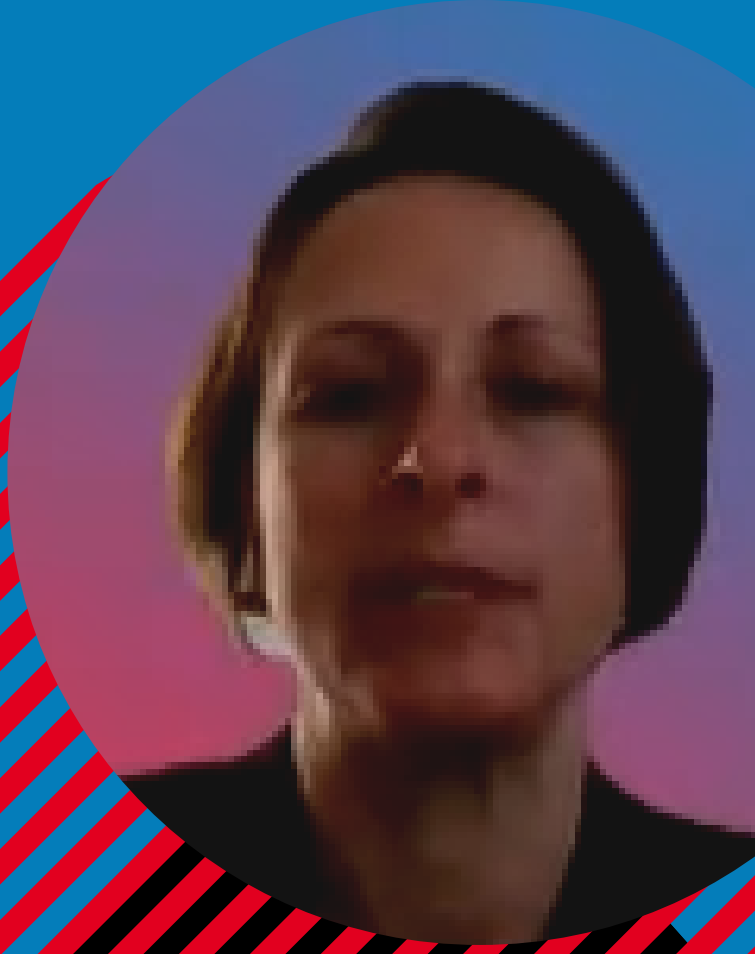
AztraZeneca (Sweden)

Tor Gråberg works at AstraZeneca since 2015 as Head of Operations Quality Compliance and External Affairs. As such he is e.g. accountable for managing Global Quality Audits within AstraZeneca sites, marketing companies, external suppliers and contract manufacturers.

He holds a diploma of M.Sc. Pharmacy from Uppsala University and started his career in the pharmaceutical industry as production manager during 13 years. He was Chief Pharmaceutical Inspector and Head of Drug Inspectorate with the Medical Products Agency (MPA) in Sweden, where he worked for 19 years. He was Chairman of the Pharmaceutical Inspection Co-operation Scheme (PIC/S) 2010–2011 and during twelve years also a member of PIC/S Committee.

He is currently a member of PDA RAQAB (Regulatory Affairs and Quality Advisory Board), member of EQPA (European QP Association) Advisory Board and he represent AstraZeneca at EFPIA TDEG (European Federation of Pharmaceutical Industries Associations, Technical Development Expert Group).

Laura Huffman



Policy Advisor, Microbiologist

Office of New Animal Drug Evaluation

Center for Veterinary Medicine

U.S. Food and Drug Administration

Laura Huffman joined the FDA in 2004 and is currently a serving as a policy advisor for CVM's Pre-Approval Inspection Program in the Division of Manufacturing Technologies, Office of New Animal Drug Evaluation at CVM. Her roles include pre-approval inspection and mutual recognition policy for CVM as well as sterile manufacturing review and policy. She also serves as CVM's representative to USP's Expert Committee for Microbiology.

Prior to joining the FDA, Laura worked in regulation and manufacturing of food and biologics.

Laura received a Bachelor of Science in Biology and a Master of Science in Food Science and Technology, both with microbiology focus, from Virginia Tech.

Desmond Hunt, Ph.D.

Principal Scientific Liaison

Science - General Chapters

U.S. Pharmacopeia

Dr. Desmond G. Hunt has been with USP since 2005 and holds the position of Principle Scientific Liaison in the Compendial Science Group-General Chapters. He is the scientific liaison to the Packaging and Distribution and Dosage Forms Expert Committees, where he works to develop and revise USP Standards.

He has authored many publications and peer-reviewed articles and is a frequent speaker and instructor on topics related to pharmaceutical packaging, particulate matter in parenteral and ophthalmic dosage forms and good storage and transportation practices. He participates on several industry Working Groups and Technical Committees related to his areas of expertise.

Dr. Hunt obtained his M.S. and Ph.D. from the University of Texas at Austin and prior to joining USP, was a Research Fellow at the National Institutes of Health, Bethesda, MD, USA

Ravi Kalyanaraman, Ph.D.

Director
Global Analytical Technology

Bristol-Myers Squibb

Ravi Kalyanaraman is a director at Bristol-Myers Squibb Company in Global Analytical Technology group with Global Product Development and Supply. He received his Ph.D. from the University of Idaho in 1996 and did his post-doctoral work at the University of Puerto Rico. He has been with Bristol-Myers Squibb since 2002.

His work with Bristol-Myers Squibb has been focused on developing new and novel techniques to detect pharmaceutical counterfeits. His interests are mainly in using vibrational spectroscopic techniques, such as Raman, mid and Near-Infrared (NIR) for pharmaceutical counterfeit detection and for product authentication. He leads a team in global quality organization that is involved in the analysis of products received from complaints and from corporate security groups. He also leads a group that supports manufacturing investigations..

Barbara Kochanowski, Ph.D.

Senior Vice President
Regulatory and Scientific Affairs

Consumer Healthcare Products Association

CHPA CONSUMER HEALTHCARE PRODUCTS ASSOCIATION
Taking healthcare personally.

Barbara Kochanowski is responsible for regulatory affairs activities, including cooperative programs with the U.S. Food and Drug Administration, ingredient safety, and dietary supplement programs at CHPA.

Prior to joining CHPA in 2009, Kochanowski worked for more than 23 years in R&D at The Procter & Gamble Company (P&G), retiring in December 2008 as director, global personal health care, oral care, and feminine care product safety and regulatory affairs and corporate microbiology. She is experienced in pharmaceutical, medical device, and dietary supplement regulatory affairs, Rx-to-OTC switch, product safety, clinical research, and pharmacovigilance. While at P&G, Kochanowski was very active in CHPA activities, serving as chair of the Scientific Affairs Committee from 2007-2009, which brought with it an ex officio position on the CHPA Board of Directors for the same period.

Kochanowski is a member of the American Society of Nutrition. She also serves on the board of directors of the American Foundation for Pharmaceutical Education. She received her B.S. from Pennsylvania State University and M.S. and Ph.D. in Nutritional Sciences from the University of Illinois.

Robin Kumoluyi

Vice President & Chief Quality Officer, Pharmaceuticals

Johnson & Johnson

Robin Kumoluyi is the Vice President and Chief Quality Officer, Pharmaceuticals atJohnson & Johnson Corporation. Robin has responsibility for Quality & Compliance for the Global Pharmaceuticals Segment in Pre-Market R&D, Supply Chain and Post Market Commercial. Prior to her current role, Robin was VP, Global Quality Services at Johnson & Johnson, where she drove the organization's Enterprise Quality transformation by defining, leading, and executing the strategic direction and oversight of the Quality Policies, Standards, Digital Healthcare, Innovation and Analytics, Value Chain Quality, and the overall Q&C Strategy and associated processes. Her proven track record spans thirty years of robust experience leading change while holding senior leadership roles within Quality, R&D, and Manufacturing Compliance in the pharmaceutical and food industries. Her broad expertise encompasses a wide portfolio of product types including OTC, Biological, Pharmaceutical, Devices, Veterinarian, Nutraceuticals, and Food and Beverage products.

As a leader, Robin knows it is her responsibility to enable people to achieve their fullest potential. She is committed to the well-being of her colleagues, peers, and community, actively collaborating with people and teams in the name of career growth and progress. She is a champion for diversity and inclusion, which she knows fosters innovation and drives business success. Steadfast in the belief that what is good for the person is good for the organization, she fully embraces her role as a guide and coach and considers it the most rewarding part of her work. She actively engages with industry and leadership organizations such as ISPE (Women in Pharma), PDA, and Rx360, where she was co-leader of the audit operations group. She is an active member of Advancing Women Executives (AWE), an organization creating equity and economic development in the workplace, and Achieving Women's Excellence in Supply chain Operations, Management and Education (AWESOME) and United Way.

Robin holds a bachelor’s degree in Biological Sciences (specializing in microbiology) from Rutgers University and a master’s degree in Quality Assurance and Regulatory Affairs from Temple University School of Pharmacy. A native of New Jersey Robin currently lives in North Carolina with her husband and son.

Socrates Kyritsis

Area Head
Regulatory Affairs CMC

Novartis

Socrates is an Area Head in Regulatory Affairs CMC at Novartis, and is based in Basel Switzerland. In this role, Socrates leads a team of regulatory affairs professionals supporting a portfolio of small-molecule oncology products that span the product lifecycle from first-in-human clinical trials to post-approval change management and maintenance. Socrates also works cross-functionally with R&D and manufacturing to support the evaluation and introduction of innovative pharmaceutical manufacturing technologies, including continuous manufacturing for small and large molecules.

Socrates has over 27 years of experience in the pharmaceutical industry, with a combination of experience in pharmaceutical development, technology transfer, commercial manufacturing technical support, and regulatory affairs. Before joining Novartis in 2013, Socrates worked at Schering-Plough, Pfizer, and Merck. Socrates holds a Bachelor of Science degree in bioengineering from the University of Pennsylvania, Philadelphia PA and a Master of Science degree in chemical engineering from Columbia University, New York NY.

Robin Levis, Ph.D.

Deputy Director
Division of Viral Products

Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

U.S. Food and Drug Administration

Dr. Robin Levis has worked at the US Food and Drug Administration since 1995. She is currently the Deputy Director of the Division of Viral Products in the Office of Vaccines Research and Review at CBER/FDA; a position she has held since 2006. Prior to this position, she served as the Regulatory Coordinator for the Division of Viral Products (2002-2006) and served as a Senior Staff Fellow in the Laboratory of Vector Borne Viral Diseases (1995-2002). Her initial research work at the FDA related to flavivirus replication and the role of the NS1 protein. She then transitioned to be the lead CMC reviewer for licensed rabies virus vaccine products and rabies vaccine and related products under development. Throughout her time at FDA, Dr. Levis has served as a CMC specialist on many pre-licensing and compliance inspections for CBER.

In addition to her work in the Office of Vaccines at CBER, she serves as an observer to EDQM Group 15 for vaccines that develop vaccine specific quality monographs for the European Pharmacopeia, is on the Scientific and Ethics Advisory Committee for the Innovative Medicines Initiative (IMI) funded VAC2VAC consortium, and serves on several vaccine working groups for the Coalition for Pandemic Preparedness Innovations. Her role on these International working groups is to provide regulatory support to CMC development and product quality.

Prior to coming to the FDA, Dr. Levis received her PhD from Washington University in St. Louis, Missouri. She conducted two post-doctoral fellowships, one at the NIH working on polyoma- and papillomavirus replication and the second at The Uniformed Services University of Health Sciences on species specificity of viral replication of human coronaviruses.

Wilfred Mascarenhas

Advisor for Data and Analytics
Manufacturing and Quality IT

Eli Lilly and Company

Wilfred Mascarenhas is an Advisor for Data and Analytics in Manufacturing and Quality IT at Eli Lilly and Company. Wilfred has over 18 years of experience in Manufacturing IT and over 23 years in Data and Analytics. Following his graduation in 1990 from IIT Bombay - Engineering, Wilfred obtained a Masters in Mechanical Engineering from Virginia Tech and later a Masters in Computer Science from Purdue University. In his current role, Wilfred provides leadership for the technical direction and innovation in the Data and Analytics space for Manufacturing and Quality. Wilfred is an active member of several cross Pharma and Life Sciences forums such as Bio Phorum for IT (BPIT) and Parenteral Drug Association (PDA).

Alan Minsk

Partner

Leader of Food & Drug Practice

Arnall, Golden & Gregory, LLC

Arnall Golden Gregory LLP

Alan is a partner and leader of the Food & Drug practice. He advises pharmaceutical, biologic, medical device, cosmetic and food companies (including dietary supplements and medical foods) on all legal and regulatory matters relating to the U.S. Food and Drug Administration. He counsels clients on a wide variety of FDA-related issues including regulatory strategies and life cycle management, combination products, FDA enforcement, FDA inspections, corporate compliance, market exclusivity, product promotion and advertising, product liability, clinical trials and imports and exports. In addition, Alan works with life science companies and venture capital firms on regulatory diligence matters involving acquisitions, divestitures, regulatory opinion letters, co-promotions and licensing agreements. He also drafts and reviews agreements relating to clinical trials, quality, and contract manufacturing. Alan conducts in-house training on FDA and fraud and abuse topics.

Alan serves as general counsel of Sharing Alliance Inc., a pharmaceutical trade organization focused on compliance with the Prescription Drug Marketing Act, fraud and abuse compliance, and sample accountability. He has written book chapters, articles and bulletins on a wide variety of issues, including 505(b)(2) NDAs, orphan drugs, product promotion, quality agreements, compliance, and medical device regulation. He currently serves on a number of editorial boards for professional publications, including the RAPS Focus magazine, and the Food and Law Drug Institute's Food and Drug Journal. Alan is nationally recognized by Chambers USA for “Life Sciences: Regulatory/Compliance” has been selected for inclusion in the international publication of Who’s Who Legal for “Life Sciences: Regulatory” and is recognized by Best Lawyers for “FDA Law”.

Tracy Moore

Expert GMDP Inspector

Medicines and Healthcare products Regulatory Agency (MHRA)

Tracy has been a GMP Inspector since 2011 and prior to joining the MHRA worked in the pharmaceutical industry for 22 years working across most dosage forms within Quality and technical roles. Her experience ranges from starting as a QC analyst to holding senior managerial and technical positions and she is an eligible Qualified Person in the UK. Tracy is currently lead of the MHRA Inspectorate Technology team responsible for providing guidance and strategy for new and emerging technologies and data integrity.

To assist in MHRA pandemic efforts, Tracy is currently also participating in the MHRA Task Force for supply chain aspects in particular with vaccines supplies and inspections. Tracy is the deputy of the PIC/S Strategy and Development Sub Committee and leads specific PIC/S working groups.

Beverly Nickerson, Ph.D.

Associate Research Fellow
Analytical Research and Development

Pfizer, Inc.

Dr. Beverly Nickerson is an Associate Research Fellow in the Analytical Research and Development Department at Pfizer Worldwide Research, Development and Medical in Groton, CT. Her primary responsibilities include working on cross-functional project teams to develop and execute strategies for development of drug candidates, developing/validating/transferring analytical methods, addressing analytical and project development issues. and writing sections for regulatory submissions and queries. Prior to joining Pfizer, Dr. Nickerson was with Hoffmann-La Roche in Nutley, NJ.She obtained her Ph.D. in Analytical Chemistry from the University of North Carolina at Chapel Hill.

In addition, Dr. Nickerson has been involved in several organizations during her career and was previously Chair of the Analysis and Pharmaceutical Quality section of AAPS and was a Member of the USP 2010-2015 General Chapters Dosage Forms Expert Committee. She is currently a member of the IQ Consortium Dissolution Working Group.

Quallyna Porte

Branch Director (Acting)

Office of Compliance, Office of Manufacturing Quality, DDQ1, GCB1

Center for Drug Evaluation and Research (CBER)

U.S. Food and Drug Administration

Quallyna Porte is a Branch Chief (Acting), in the Office of Manufacturing Quality in CDER's Office of Compliance leading a team responsible for regulatory oversight of the human drug manufacturing industry.

Prior to joining the FDA, Quallyna worked in the pharmaceutical and biotech industries for 18 years. She worked at Baxter Healthcare Corporation (Bioscience Division – Vaccines) in various roles of increasing responsibilities starting with Quality Control up to Facility Quality Management Representative. In the latter role, Quallyna oversaw the commercial manufacturing and release of vaccine products to various geographies, and finally the transfer of technology overseas. She also led the Quality Assurance organization at Emergent BioSolutions in the establishment of Quality Systems at a new facility, qualification of said facility, and subsequent cGMP manufacturing of Phase I to III clinical products.

Quallyna is a Six Sigma Green belt who received her BS in Biology from Saint Paul's College and an MBA from the University of Maryland, University College.

Anil Sawant, Ph.D.

Senior Vice President
Global Quality Assurance

Merck

Anil Sawant is Senior Vice President of Global Quality Assurance at Merck. His responsibilities include managing the MMD Quality Management System, Divisional Quality Assurance functions, and identification and mitigation of GMP and GDP compliance risk at Merck manufacturing sites, external manufacturers, and suppliers. Anil oversees the Global GMP Audit program, Compliance Remediation & Support, Medical Device & Combination Product Quality, Sterile Products & Microbiology QA, Product Compliant Management, Data Integrity, Quality Assurance of GMP IT Systems, Quality Systems Improvement Program, and GMP related external advocacy. Anil has over 25 years of experience in the pharmaceutical industry.

Prior to joining Merck in July 2015, he served in executive positions at Johnson & Johnson and Pfizer. Anil holds a BSc Honors and an MSc Honors Degree in Microbiology & Biochemistry from Panjab University, India, and a PhD in Microbial and Biochemical Sciences from Georgia State University. He is recipient of the GSU Distinguished Alumni Achievement Award, has co-authored numerous scientific papers in peer reviewed journals, and is a frequent speaker at regulatory conferences. Anil serves on the Board of Directors of the Parenteral Drug Association, and was a member of the Board of Directors of Georgia State University Alumni Association.

James Stumpff, R.Ph.

Principal Consultant
Regulatory & Access

Parexel

James Stumpff has over 30 years of combined FDA and Industry biopharmaceutical and medical device compliance experience. In his role, he provides proven compliance strategies and solutions for medical device and biopharmaceutical clients and projects including oral solids, injectables, implantable devices, biosimilars and combination products.

As a thought leader in compliance strategies for the medical device and biopharmaceutical industries, he has assisted multiple clients in the lifting of medical device and biopharmaceutical warning letters. Recent clients include orthopedic and ophthalmic implant, cardiopulmonary support, biologic, biosimilar, vaccine, oral solid, topical and combination product manufacturers. Stumpff has conducted consent decree audits and remediation in both medical device and biopharmaceutical facilities and also successfully guided medical device and biopharmaceutical clients' preparation for and management of multiple pre-approval and cGMP inspections, including oral solids, injectables, implantable devices, biosimilars and combination product.

James received his B.S. in Pharmacy from the University of Missouri – Kansas City.

Be a Bulldog!

REGULATORY SCIENCES
master's program

A CAREER IN REGULATORY SCIENCES

The rapidly expanding biomedical industries necessitate a greater number of Regulatory Affairs professionals to manage the FDA approval process of new products and maintain regulatory compliance. Specialized and convenient education is crucial for professionals to apply complex principles in an ever-changing regulatory environment. This program is for individuals with a clear objective to cultivate a career in regulatory sciences and those with an industry background desiring advanced education in regulatory management.

UGA's **Master of Science for Regulatory Sciences Program** covers regulatory requirements for Pharmaceutical, Biologics, Medical Devices, Veterinary Products, and Combination Products.

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UNIVERSITY OF GEORGIA
International Biomedical Regulatory Sciences
College of Pharmacy

MASTER'S PROGRAM

The Regulatory Sciences Master's Program is designed so that students can take classes part-time in an online environment.

38 total semester hours

Course topics include the 14 semester hours in the RS certificate

Program:
- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Food & Drug Law (3 hrs)
- Current Good Manufacturing Practices (4 hrs)
- Ethics in Research (3 hrs)

Additional core courses:
- Quality Control & Quality Assurance (3 hrs)
- Process Control & Validation (3 hrs)
- Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 hrs)
- FDA Applications & Submissions (4 hrs)
- Master's Thesis or Project (3 hrs)

Advanced electives are:
• Applied Project or Internship • Clinical Trials Design and Monitoring • Clinical Trials Project Management • Understanding the Role and Function of the United States Food and Drug Administration • Good Clinical Practice Regulations for Drugs, Biologic Products, and Medical Devices • European Pharmaceutical and Biologics Regulatory Sciences • Latin American Pharmaceutical and Biologics Regulatory Sciences • Drug Safety • Chemistry, Manufacturing, and Controls

Sample part-time schedule:

Fall Semester
- Quality Assurance & Quality Control (3 hrs)
- Clinical Trials Design and Monitoring (4 hrs)

Spring Semester
- Applied Project (3 hrs)
- FDA Applications & Submissions (4 hrs)

Summer Semester
- Biostatistical Applications for the Pharmaceutical and Biotechnology Industries (3 hrs)
- Clinical Trials Project Management

Application, enrollment and other information is available at **rx.uga.edu/academic-programs/ibrs** or by emailing regsciences@uga.edu.

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A Unit of the College of Pharmacy

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REGULATORY SCIENCES
certificate program

A CAREER IN REGULATORY SCIENCES

The rapidly expanding biomedical industries necessitate a greater number of Regulatory Affairs Professionals to manage the FDA approval process of new products and maintain regulatory compliance. Specialized and convenient education is crucial for professionals to gain an understanding of the scientific and technical background of new products.

This program plan is ideal For Working Professionals and consists of 14 semester credit hours, delivered by internet-based instruction with occasional live sessions. The Regulatory Sciences Graduate Certificate coursework can be applied toward the UGA Master of Science degree program with an emphasis in Regulatory Sciences.

UGA's educational program and degree option for Regulatory Sciences professionals covers:

- *Pharmaceutical* • *Biologics* • *Medical Devices*
- *Veterinary Products* • *Combination Products*

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CERTIFICATE PROGRAM

The Regulatory Sciences Certificate Program is designed so that students can take classes part-time can complete the Graduate Certificate Program in one academic year (including summer semester).

14 total semester hours

Course topics include:

- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Food & Drug Law (3 hrs)
- Current Good Manufacturing Practices (4 hrs)
- Ethical Issues in Research (3 hrs)

Sample part-time schedule:

Fall Semester

- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Ethical Issues in Research (3 hrs)

Spring Semester

- Current Good Manufacturing Practices (4 hrs)

Summer Semester

- Food and Drug Law (3 hrs)

Application, enrollment and other information is available at **rx.uga.edu/academic-programs/ibrs** or by emailing regsciences@uga.edu.

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CLINICAL TRIALS DESIGN AND MANAGEMENT
certificate program

A CAREER IN CLINICAL TRIALS MANAGEMENT

Geared toward a wide range of professionals, the **Clinical Trials Design & Management Certificate Program** provides a foundation for preparing candidates to lead and manage the development and implementation of scientifically valid clinical study designs, including monitoring of clinical trials and directing daily clinical trial operations. The interdisciplinary program encompasses core competency areas integral to the drug product development and medical device design validation required for federal regulatory clearance.

The **Clinical Trials Certificate Program** offers graduate credit courses leading to a UGA graduate certificate and, if a student completes additional graduate courses, the certificate course work may be applied toward a Master of Science Degree in Pharmacy with an emphasis in Regulatory Sciences.

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College of Pharmacy
Clinical Trials Design & Management

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UNIVERSITY OF GEORGIA
Gwinnett Campus

CT CERTIFICATE PROGRAM

The Clinical Trials Design & Management Certificate Program is designed so students can take classes part-time and complete the Graduate Certificate Program in one academic year (including summer semester).

17 total semester hours

Course topics include:

- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs)
- Ethical Issues in Research (3 hrs)
- Clinical Trials Design & Monitoring (4 hrs)
- Project Management in Clinical Trials (3 hrs)

Sample part-time schedule:

Fall Semester

- Intro to the Pharmaceutical, Biotechnology & Device Industries (4 hrs)
- Ethical Issues in Research (3 hrs)

Spring Semester

- Clinical Trials Design & Monitoring (4 hrs)

Summer Semester

- Biostatistical Applications for Pharmaceutical & Biotechnology Industries (3 hrs)
- Project Management in Clinical Trials (3 hrs)

Application, enrollment and other information is available at **rx.uga.edu/academic-programs/ibrs** or by emailing regsciences@uga.edu.

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FDA

GMP

THANK YOU FOR ATTENDING

We appreciate your continued support of this conference. You are invited to respond to this survey to share your experience.

See you next year!