SPEAKER BIOGRAPHIES

JUDITH (JUDY) ARCIDIACONO, M.S.

INTERNATIONAL REGULATORY EXPERT, U.S. FOOD AND DRUG ADMINISTRATION

Judy has been at the FDA for 32 years. For the first 18 years she worked in the Division of Cell and Gene Therapy as a research/reviewer. In this role, she conducted research on the human immunological response to xenotransplantation products and reviewed clinical trial applications for NK cell and T cell therapies, and xenotransplantation products. She is currently the lead for policy development for xenotransplantation products.

As an International Regulatory Expert, Judy represents FDA/CBER/OTAT points of view in the development of international regulatory policies and the development of international standards for regenerative medicine therapies. She serves as the secretariat for the International Pharmaceutical Regulators Programme (IPRP) Cell Therapy Working Group and Gene Therapy Working Group. She leads regulatory training activities for Advanced Therapies and Biotherapeutics in the APEC Centers of Regulatory Training Excellence.

Judy also leads the Standards Development Program for Regenerative Medicine Therapies (RMT) in OTAT. She represents FDA in ISO TC 276 Biotechnology and serves as a liaison to ASTM F04 Committee on Tissue Engineered Medical Products (TEMPs). She works closely with the National Institute for Standards and Technology (NIST) and the Standards Coordinating Body (SCB) to foster the development of standards that support innovation and product development in the RMT field.

JARED R. AUCLAIR

ASSOCIATE DEAN OF PROFESSIONAL PROGRAMS AND GRADUATE AFFAIRS, COLLEGE OF SCIENCE, NORTHEASTERN UNIVERSITY

Jared R. Auclair is currently the Associate Dean of Professional Program and Graduate Affairs in the College of Science at Northeastern University and Associate Teaching Professor in the department of chemistry and chemical biology. In addition, Dr. Auclair is the Director of the Biopharmaceutical Analysis Laboratory (BATL), the Asia-Pacific Economic Cooperation Center of Regulatory Excellence in Biotherapeutics and Advanced Therapies and oversees the International Council for Harmonisation training. Lasting, Prof. Auclair serves as the Technical Supervisor for the Life Science Testing Center at Northeastern University, which is a state and CLIA-certified lab. Dr. Auclair collaborate with both academic researchers, industry, and government in the area of biopharmaceutical development and analysis. He has expertise in mol. biology, protein biochemistry, analytical chemistry, protein crystallography, and biological mass spectrometry; and is interested in use inspired research for the biotechnology industry.

SPEAKER BIOGRAPHIES

NIMI (MANTEJ) CHHINA, JD, PHD, RAC

SENIOR DIRECTOR, GLOBAL R&D AND REGULATORY POLICY
GLOBAL REGULATORY AFFAIRS
BIOMARIN PHARMACEUTICAL INC

Nimi (Mantej) Chhina serves as Senior Director and Head of Global R&D and Regulatory Policy at BioMarin Pharmaceutical Inc. Nimi joined BioMarin in 2017 as Director, leading US Regulatory Policy. Prior to joining BioMarin, Nimi spent 7 years at the US Food and Drug Administration (FDA), where she served in multiple roles including as team lead in the Division of Medical Policy Development in the Center for Drug Evaluation and Research (CDER).

Nimi received her MS (honors school) in human genetics from Guru Nanak Dev University in India; PhD in biotechnology and functional genomics from George Mason University, VA (USA); and JD from University of the District of Columbia David A. Clarke School of Law (USA). Also, she received the Regulatory Affairs Certification (RAC) as well as a certificate in legislative affairs from the Government Affairs Institute at Georgetown University, DC (USA).

Nimi is based in the Washington, DC area, and is actively engaged on the R&D and regulatory policy development landscape. In her personal life, she loves traveling and spending quality time with her family.

TRACY DIANIS

DIRECTOR, GLOBAL REGULATORY AFFAIRS, BIOSIMILARS, AMGEN

Tracy Dianis joined Amgen in 2019 as Director of Global Regulatory Affairs with responsibility for the Global Regulatory Lead (GRL) team supporting the biosimilar portfolio, inclusive of development and lifecycle management (LCM) programs.
Tracy has over 20 years industry experience in Regulatory Affairs. She started her career at Takeda supporting a variety of drugs from pre-IND through initiation of global Phase 3 studies. She then spent 9 years at Baxter BioScience with regulatory responsibility for the following products in her tenure: ARALASTÒ, ISOLEXÒ cell selection system and Autologous CD34+ cell therapy, as well as biosurgery combination products and vaccines. In 2013, she joined Hospira (acquired by Pfizer in 2015), where she was the GRL for Hospira's first biosimilar, RETACRITÒ, leading the team through successful execution of BPD meetings, the 351(k) BLA submission and FDA Oncologic Drugs Advisory Committee (ODAC), which led to US approval in May 2018. At Amgen, she has strategic oversight of regulatory activities for 11 biosimilars in the current portfolio including potential treatments for chronic inflammatory diseases and cancer. There are currently five biosimilars approved in the U.S. (AMJEVITA™, MVASIÒ, KANJINTIÒ, AVSOLAÒ, RIABNI™) and three approved in the European Union (EU) in Amgen's portfolio. Several biosimilars now have approvals worldwide including countries in Latin America, Asia Pacific, and the Middle East.
Tracy holds a BS in Microbiology from University of Iowa and a MS in Biotechnology from Northwestern University.

SPEAKER BIOGRAPHIES

MARKUS GOESE, PHD

HEAD EU CMC, REGULATORY POLICY
F. HOFFMAN-LA ROCHE LTD

Markus Goese holds a Ph.D. in Biochemistry/ Organic Chemistry from the Technische Universität München (Munich), Germany. He has more than 20 years of industry experience in various companies (Roche, DSM, Novartis) in Pharmaceuticals and Fine Chemicals Research, Development and Commercialization. For the last 15 years, he has been working in CMC Regulatory Affairs, initially on Biopharmaceutical Products in early- and late-stage development. In 2011, he took on the responsibility as EU Lead CMC Regulatory Policy for Roche Pharma Global Technical Operations. Markus is based in Basel, Switzerland. He is currently Chair of EFPIA's Manufacturing and Quality Expert Group (MQEG) and EFPIA Deputy Topic Lead for ICH Q12 (Technical and regulatory considerations for pharmaceutical product lifecycle management).

JEEWON JOUNG, PHD

DIRECTOR, RECOMBINANT PROTEIN PRODUCTS DIVISION, MINISTRY OF FOOD AND DRUG SAFETY, KOREA

Dr. Jeewon Joung is director of Recombinant Protein Products Division in NIFDS/MFDS Republic of Korea. She is responsible for managing assessment for quality, safety and efficacy of recombinant protein products including biosimilar products during IND and NDA process. She got her PhD in biotechnology from the Ewha Women's University in 2002. She began her carrier as a quality reviewer from 1993 in Biotechnology division KFDA (Former MFDS) and has more than 28 years of experience of review and approval of biotech products including biosimilar products. She also has many experiences in establishment of biological and biosimilar guidelines in Korea. In 2007 and 2008, she was seconded to WHO Immunization, Vaccine Biologicals department as a Scientist. At there, she was responsible officer for development of WHO Guideline of Similar Biotherapeutic Products and still she is a drafting group member of that guideline. From 2013~2019, MFDS acted as the chair of International Pharmaceutical Regulators Program(IPRP) Biosimilar Working Group(BWG) and she was a key player in advancement of that group by supporting development of many deliverables. Currently, she still actively involves herself in that group's activity.

SPEAKER BIOGRAPHIES

KOWID HO

TECHNICAL REGULATORY (CMC) POLICY BIOLOGICS F. HOFFMANN-LA ROCHE LTD.

Kowid Ho is working at F. Hoffmann-La Roche Ltd.'s Global Pharma Technical (CMC) Regulatory Policy in Basel, Switzerland, where he performs senior strategic review on projects and advises on Roche global positions for Biologics.

Kowid has over 20 years of experience in the regulatory affairs of biotech products (Quality aspects), including 13 years at ANSM (Agence nationale de sécurité du médicament et des produits santé). He has been a member of European Medicines Agency (EMA) Biologics Working Party (BWP), Biosimilar Working Party (BMWP), and PAT team. He participated in the drafting of several European guidelines (e.g., EMA process validation, biosimilar, Monoclonal antibody, EDQM HCP and rDNA) as well as international guidances (e.g., ICH Q11, ICH Q12, WHO guideline for biotherapeutic protein). He is currently a member of ICH Q12 IWG, IFPMA ATWG and is co-chairing EFPIA MQEG-ERAO ATMP team.

SRINIVASAN KELLATHUR, PHD

DIRECTOR, ADVANCED THERAPY PRODUCTS BRANCH, SINGAPORE HEALTH SCIENCES AUTHORITY

Dr. Srinivasan KELLATHUR is currently Director, Advanced Therapy Products Branch at Singapore Health Sciences Authority overseeing policy reviews, drafting of regulations and guidelines, and registration of cell, tissue and gene therapy products. He is also the Adjunct Assistant Professor at the Duke-NUS Centre of Regulatory Excellence. He is a co-lead, together with US FDA, for the regulatory convergence initiatives for advanced therapy products under the auspices of APEC regulatory harmonization steering committee. Srini sits on national and international committees, and advisory board on cell, tissue and gene therapies. He holds a PhD from Faculty of Medicine, National University of Singapore (NUS) and post-doctoral research at NUS, Institute for Infocomm Research Agency for Science, Technology and Research, Singapore, and the Johns Hopkins University School of Medicine.

SPEAKER BIOGRAPHIES

ANNA KWILAS, PHD

CMC REVIEWER & TEAM LEAD, GENE THERAPY BRANCH, U.S. FOOD AND DRUG ADMINISTRATION

Dr. Kwilas received her Ph.D. in Biomedical Science from The Ohio State University in 2010 with an emphasis in Molecular Virology & Gene Therapy and Translational Science. She performed her graduate research at The Research Institute at Nationwide Children's Hospital examining the potential application of respiratory syncytial virus as a gene therapy vector for the treatment of cystic fibrosis.

Dr. Kwilas performed her post-doctoral research at the National Cancer Institute investigating the efficacy of modified vaccinia virus Ankara and adenovirus-based cancer vaccines alone and in combination with other approved and investigational cancer therapeutics.

Dr. Kwilas received the Interagency Oncology Task Force Fellowship in 2015. She began conducting research at FDA involving the generation of safer vector producing cells with the use of CRISPR/Cas9 genome editing technology and participating in gene therapy product CMC review. Since May 2016, Dr. Kwilas has been a full-time gene therapy CMC reviewer at the FDA. In 2019, Dr. Kwilas became a Team Lead in the Gene Therapy Branch focusing on the regulation of gene therapy products incorporating genome editing.

MICHELLE LIMOLI, PHARM.D

U.S. FOOD AND DRUG ADMINISTRATION, INTERNATIONAL PROGRAMS

Biography to be provided

SPEAKER BIOGRAPHIES

MICHAEL MUNA

SENIOR DIRECTOR, GLOBAL R&D AND REGULATORY POLICY INTERNATIONAL AT BIOMARIN

Michael Muña serves as Senior Director, Global R&D and Regulatory Policy – International Policy at BioMarin Pharmaceutical Inc., actively engaged in the R&D and regulatory policy development and landscape in the LATAM, APAC, EE, MEA regions, and Canada. He also held several positions at BioMarin including Senior Director and Head of Regulatory Affairs (RA) International (LATAM, APAC, EE, MEA and Canada), Senior Manager, RA Clinical and Manager, Quality Control. Prior to joining BioMarin, Michael spent 6 years at Onyx Pharmaceuticals, a company dedicated to developing new cancer therapies, and was involved in the development of ONYX-015 (replication-selective modified adenovirus) treatment of nasopharyngeal cancer. Other research experience included research at the University of Washington's Alzheimer Research Center.

NOLAN POLSON

VICE PRESIDENT OF STRATEGIC PRODUCT QUALITY, GLAXO SMITH KLINE

Dr. Nolan Polson is the Vice President of Strategic Product Quality at Glaxo Smith Kline (GSK) where he and his team oversee global end-to-end Product Quality of cell therapy, biologics, and small molecule programs during clinical development and commercialization. He is an experienced professional in providing program CMC leadership, product quality, and technical oversight during CMC development in support of commercialization efforts for large molecule and cell therapy programs to global markets. Nolan was instrumental in the successful commercialization of two cell therapy programs, Breyanzi (liso-cel) and Abecma (ide-cel), that were approved by the FDA in 2021. He has worked previously in the industry with increasing levels of responsibility within Research and Development, Quality Control, Formulations, Global Product Quality, and CMC Leadership at Amgen, Janssen, Juno Therapeutics, Celgene, and Bristol Myers Squibb. He has a keen understanding of process development and considers Quality as a strategic partner with the technical teams to drive holistic control strategies that ensure product quality and patient safety.

SPEAKER BIOGRAPHIES

CAMILLA SANTOS, PHD

DIRECTOR, PRODUCT QUALITY
AMGEN

Dr. Camilla Santos is a Director, Product Quality, at Amgen. Camilla provides program oversight for Amgen's global Stability Business Process, and she and her team support the stability strategy, data review, and data reporting of late stage and commercial products in addition to providing technical support to Amgen's Product Quality department with a focus on data management. Camilla is an experienced biotech professional with over 18 years at Amgen and roles of increasing scope in the Process Development and Quality functions, supporting analytical method development, technology transfers, comparability, and stability of biologics. With a strong interest in education and mentoring, Camilla was a member of the USP Biologics Stability Expert Panel, where she worked on a guideline for stability and testing of biologics (companion chapter to USP <1049>), and she supports training programs coordinated through Northeastern University. Her experience prior to Amgen encompasses working with controlled drug delivery systems and adventures as a US Navy officer. Camilla holds a PhD in Medical Sciences from Brown University and a Bachelor of Science in Biomedical Engineering from Rensselaer Polytechnic Institute.

KIM SCHULTZ

GENE THERAPY
REVIEWER, US FOOD & DRUG ADMINISTRATION

Invited, to be confirmed

SPEAKER BIOGRAPHIES

KEITH WONNACOTT, PHD

VICE PRESIDENT
REGULATORY AFFAIRS,
LEXEO THERAPEUTICS

Dr. Wonnacott has spent his entire career as a regulatory professional in the field of advanced therapies with extensive experience in both government and industry.He is currently the Vice President of Regulatory Affairs at Lexeo Therapeutics. Lexeo is a small biotech company developing AAV-based gene therapies for neurologic and cardiac indications and currently has several clinical stage programs and a variety of preclinical programs. He also serves as the Chair of the Regulatory Affairs Committee for the American Society of Gene and Cell Therapy (ASGCT) and is on the regulatory affairs committee of the Alliance for Regenerative Medicine. Previously, Dr. Wonnacott worked at Pfizer where he led regulatory efforts to aid the clinical development of their AAV-based gene therapies. His work included both developing regulatory strategy and influencing regulatory policy related to cell and gene therapy. Dr. Wonnacott also spent three years with Novartis Pharmaceuticals as a director of regulatory affairs in the Cell and Gene Therapy group. In that role he advised on regulatory strategy and led the team responsible for developing the CMC module for the Kymriah (tisagenlecleucel) BLA, which became the first ever FDA approved gene therapy product in 2017. Prior to working at Novartis, Dr. Wonnacott was the Chief of the Cellular Therapies Branch at the Center for Biologics Evaluation and Research (CBER) at the U.S. Food and Drug Administration (FDA). His branch was responsible for the CMC review for all cellular therapies including stem cells, immunotherapies, cancer vaccines, allogeneic pancreatic islets, xenotransplantation products, and tissue engineered products.Dr. Wonnacott has published several articles and book chapters on the regulation of advanced therapies.
Dr. Wonnacott received his Ph.D. in Microbiology and Immunology from The Pennsylvania State University College of Medicine, Hershey, Pennsylvania and his Bachelor's degree in microbiology at Brigham Young University, Provo, Utah.