

# 2023 SMDP MedTech Mentors



## Deb Appleyard, MD, Senior Safety Officer, Johnson & Johnson

Deborah Appleyard, MD earned her Bachelor of Science degree in Biology from Williams College - Williamstown, MA and completed her medical degree at The Perelman School of Medicine at the University of Pennsylvania in Philadelphia, PA. She then went on to complete an internship, residency, and fellowship in Orthopedic Surgery and Orthopedic Trauma Surgery at Rhode Island Hospital – Brown University in Providence, RI. Following her orthopedic trauma fellowship, Deb completed a second fellowship at OrthoCarolina in Charlotte, NC in Orthopedic Spine Surgery. She is board certified by the American Board of Orthopedic Surgery. Deb is also a graduate of Boston University School of Public Health in Boston, MA

where she earned a Master's degree in Public Health, with a focus on international health and health policy.

Deb has 3 years of experience in the medical device industry at Johnson & Johnson, with experience in Spine Medical Affairs as the Medical Director for the MDR transition as well as within Medical Safety for the DePuy-Synthes company as both a medical safety officer responsible for the TECA (trauma, extremities, craniomaxillofacial and animal) orthopedic portfolio and as senior safety officer, broadly responsible for safety across the DePuy-Synthes organizations. During this time, she has utilized her clinical knowledge and experience to effectively advocate for patients in orthopedic medical device development and orthopedic medical device safety.

Prior to joining Johnson & Johnson in 2019, Deb was in clinical practice and spent some transitional time working in the insurance industry. In her first role after fellowship training, she founded an orthopedic and spine practice on St. Croix, USVI (U.S. Virgin Islands) successfully bringing to life the first operative spine practice fully based in the USVI. Deb continues to have a passion for health outcomes across the globe and actively pursues opportunities for collaboration in this area. When she is not working, Deb enjoys spending time with her four children and two dogs watching soccer, sailing, hiking, biking or just enjoying a sunset!



## Sandra Binns, Senior Director Global Regulatory Affairs, J&J MedTech, Ethicon

Sandra Binns is the Head of Ethicon Regulatory Affairs, Regulatory Clinical, Torax, NeuWave, Software & Capital Equipment at Johnson and Johnson MedTech. Sandra joined J&J in April 2022 and is responsible for supporting the advancement of the Ethicon innovation portfolio by creating effective regulatory strategies, maintaining global market access, shaping the external regulatory environment, and supporting the growth of R&D talent.

Sandra serves on the Ethicon Regulatory Affairs Leadership Team. She is also very active in J&J's African Ancestry Leadership Council, Diversity Recruitment Council, MedTech Global Regulatory Talent Champions, Women's Leadership & Inclusion (WLI) and the National Society of Black Engineers.

Sandra has more than 20 years of regulatory experience and is a proven global leader with extensive regulatory and technical expertise in Medical Devices, Software; Programming, Drugs (OTC and NDA), and combination products. Prior to J&J Sandra spent 10 years at GlaxoSmithKline (GSK), where she led various global Regulatory and Compliance teams and has also held various regulatory leadership roles at Colgate-Palmolive, Merck, and Siemens Medical. Sandra has served as an educator, an aircraft Biomedical Engineer for the NGO Orbis International, an in-hospital Clinical Engineer, and a Telemedicine programmer.

Sandra holds a Bachelors and Masters degree in Biomedical Engineering, has obtained her RAC from the Regulatory Affairs Society (RAPS) and has served as an instructor for RAPS.



## Scott Blair, Senior Director, Diversity, Equity & Inclusion (DEI), B.Braun

Scott is an accomplished educator, mentor/coach and diversity, equity and inclusion thought leader and practitioner. Scott joined B. Braun in April 2022 as its inaugural DEI leader in the role of Senior Director for DE&I. Blair is responsible for building upon and implementing strategies that will encourage and build an inclusive and diverse workforce throughout the Company. He also has the privilege of leading B. Braun's dynamic Employee Resource Group community and supporting the Company's health equity, sustainability, and supplier diversity work.

Scott brings close to 20 years of experience in Higher Education, having served in a variety of inaugural DEI leadership positions committed to advancing DEI including professional development facilitation faculty/staff recruitment and strategic planning efforts focused on Inclusive Excellence. Blair has also led and aided academic and experiential learning supports for underrepresented

students and recruitment and retention efforts at both the undergraduate and graduate student level. He currently is a member of the National Association of Diversity Officer's in Higher Education (NADOHE) and numerous regional efforts in the Lehigh Valley (PA) community to advance DEI and serves as a member of the Inclusion & Diversity Roundtable community with AdvaMed.

Scott holds an Master's degree in Higher Education Administration and a Bachelor of Science in Education/Secondary Education-English from Kutztown University of Pennsylvania. He also holds an Executive Leadership Certificate from the University of Southern California's Rossier School of Education - Race and Equity Center.



### **Rosa Casiano Maldonado, Senior Manager of Engineering, Amgen Manufacturing Limited**

Rosa Casiano Maldonado is a Senior Manager Engineering at Amgen Manufacturing Limited based in Puerto Rico. She holds a Chemical Engineering bachelor's degree from the University of Puerto Rico, Mayagüez Campus. She started her professional career at Amgen in 2012, as an Associate Engineer in the Process Development department. Over the past eleven years, she has transitioned through multiple roles of increasing responsibilities in Process Development, Manufacturing, and Engineering organizations. Currently, she manages a group of eleven (11) engineers providing 24/7 support to drug substance manufacturing operations. In addition, she leads continuous improvement initiatives, new product introductions, and provides technical assistance to commercial operations. She is a mother of two beautiful kids, enjoys playing volleyball, and relaxing at the beach. Also, it is important to note that she is terrified about anything related to cockroaches.



### **Celia Cruz, PhD, Vice President - Synthetic Molecule Development & Commercialization, Eli Lilly**

Celia Cruz, PhD is Vice President of small molecule development and commercialization at Eli Lilly and Co. Celia's group is comprised of organic and analytical chemists, pharmaceutical scientists, and engineers responsible for process design and development of both drug substance and drug products. She is responsible for enabling small molecule drug development and the technical capabilities that prepare Eli Lilly for the future. Prior to joining Lilly, Celia was the director of the Division of Product Quality Research in the Office of Testing and Research at the FDA. In this role, Celia led regulatory scientists focusing on applied research and development with specific expertise in solid oral dosage forms and the implementation of emerging technologies for advanced manufacturing. At the FDA, she was a member of the Emerging Technologies Program, a Quality by Design Liaison, CDER Nano Working Group leader and a subject matter expert for continuous manufacturing. Prior to joining the FDA in 2010, Celia was a Principal Development Engineer at Merck in West Point, PA. At Merck, Celia led the development and commercialization of multiple solid oral dosage pharmaceutical products and was responsible for the introduction of new processes and capabilities, such as hot melt extrusion and Quality by Design.

Celia earned her Bachelor of Science and Doctor of Philosophy degrees in chemical engineering from Brown University (Providence, RI) and Carnegie Mellon University (Pittsburgh, PA), respectively.

Celia loves to cook, the outdoors (especially if swimming is involved!), listening to music and spending time with her husband and two teenage daughters.



### **Gemma Dickenson, PhD, Vice President - Pharmacokinetics/Pharmacodynamics (PK/PD), Eli Lilly**

Gemma Dickinson, PhD joined Eli Lilly and Company in 2008 as a Research Scientist in the Global PK/PD organization. After 5 years as a PK/PD project leader for various projects in oncology and neuroscience, she moved to Indianapolis and eventually joined the ADME organization as director of Mechanistic Pharmacokinetics and Computational ADME, eventually leading the group as Associate Vice President. She recently rejoined the PKPD as Vice President of the global organization.

Gemma is a recognized expert in the area of mechanistic pharmacokinetics physiologically based pharmacokinetic modeling. She seeks to advocate for, and demonstrate the value of, model informed approaches for drug discovery and development. Gemma holds a bachelor's degree in Pharmacology (2003) and a PhD in Pharmacokinetics (2007) from The University of Sheffield. She is passionate about the importance of diversity and inclusion in science and works to elevate the role of women and girls in STEM. In her spare time, Gemma enjoys travel, literature and scuba diving.



## Jessica Gwinnup, Associate Vice President – Delivery Systems and Technology, Eli Lilly

Jessica Gwinnup is currently the Associate Vice President of Delivery Systems & Technology for the Delivery, Device & Connected Solutions (DDCS) organization at Eli Lilly. In this role, she provides technology and engineering leadership to support product discovery and development for delivery systems across Lilly's therapeutic portfolio. She also serves as a mentor through the Women's Engineering Network and acts as the D&I Champion for the DDCS organization. Since joining Lilly in 2008, Jessica has held various technical and leadership positions in device development, primarily focused on the application of design control requirements for combination products and medical devices. She received a Bachelor of Science degree, magna cum laude, in Mechanical Engineering with a Minor in Biomedical Engineering from Michigan State University. In her free time, Jessica enjoys spending time with her husband, Zach and their two children.



## Liwei Hui, PhD, R&D Scientist III, Millipore Sigma

Liwei Hui, PhD is a R&D Scientist III at MilliporeSigma, focusing on developing drug delivery products. She received her PhD in Materials Science from University of Science and Technology of China, followed by postdoctoral training at University of Pittsburgh and Lawrence Berkeley National Lab. She has a decade of experiences in nanomedicine and medical device development with 20+ peer-reviewed publications and patents. Outside work, she likes to explore all kinds of trails with her family and friends.



## Loren Lane, Head of Innovation HR Engagement and Inclusion Relationship Management, Global DE&I, EMD Serono

As a member of the global DE&I team at EMD Serono (Merck KGaA), Loren is responsible for defining the long-term vision, strategy, and roadmap for DE&I's external strategic partnerships to drive the DE&I strategy and building the organization's DE&I reputation in the external market. Additionally, she, along with her team develop frameworks to ensure the company's internal networks (Employee Resource Groups) are aligned to the overall DE&I strategy. Before assuming this role, she served as a Thought Leader Liaison-Neurology and Key

Account Manager-Neurology for EMD Serono, where she discovered her passion for advocating for and understanding the issues around neuro disparities and health equity.

Loren holds a Master of Business Administration from the University of Houston's C.T. Bauer College of Business and a Bachelor of Arts in Journalism from Rutgers University.

As a devoted mother, wife, and professional, Loren is committed to servant leadership, both at Southern Illinois University (where her husband serves as Chancellor) and in the Houston community. Previously, she was an adjunct professor at Lone Star College and mentored students through graduation. She is passionate about advancing DE&I to ensure equitable opportunities for all. Her motto, inspired by Mahatma Gandhi, is "The best way to find yourself is to lose yourself in the service of others."

Loren is a member of Jack and Jill of America Inc., Alpha Kappa Alpha Sorority Incorporated, and The Links Incorporated. She and her husband, Dr. Austin A. Lane, have three children.



## Jennie McNab, PhD, Global Hip Product Development Manager, Smith & Nephew

Jennie McNab, PhD is the Global Hip Product Development Manager at Smith & Nephew. Prior to joining the Smith & Nephew she spent 10 years as an engineer at Medtronic. Jennie holds a master's degree in mechanical engineering and a PhD from Case Western Reserve University.



## Yusuf Oni, PhD, Associate Director, Bristol Myers Squibb

Yusuf Oni, PhD is an Associate Director at Bristol Myers Squibb where he is involved in all aspects of primary packaging & device development in the parenteral product development space. Prior to joining BMS, Yusuf was a Senior Engineer with the Materials Science and Technology group at BD Medical. There, he led the design and development of material solutions for various medical products and packaging applications. Yusuf is also involved in academic instruction. He currently serves as an Adjunct Faculty in the Biomedical Engineering department at New Jersey Institute of Technology. Yusuf holds a BSc degree in Chemical Engineering from New Mexico Institute of Mining and Technology and a PhD in Mechanical and Aerospace Engineering (with a concentration in Materials Science) from Princeton University. In his spare time, Yusuf likes to spend time with his family. Beyond that, he enjoys watching sports, reading Psychology and Philosophy books, and catching up on technological advances.





## Andy Ratz, PhD, Senior Vice President, Drug Delivery, Devices & Connected Solutions, Eli Lilly

Andy currently is Sr. Vice President of the Delivery, Device and Connected Solutions organization at Eli Lilly and Company. He provides leadership and direction to the integrated design and development of medical devices (mechanical, electromechanical and software), drug device combination products, and packaging systems for the biotech, genetic medicine, and synthetic molecule portfolios. His organization is responsible for the innovative design of new drug delivery platforms, comprehensive portfolio management, development of in-depth control strategies, and global product registration. He has worked for Eli Lilly and Company for over 25 years, with significant experience across all phases of drug discovery and development, medical device design through commercialization, and global marketing applications. Andy graduated from Indiana University with a B.S. in chemistry and earned his Ph.D. in chemistry from Harvard University.



## Gordon Ruane, Executive Director of Process Development, Amgen

Gordon leads the Process Development team and is responsible for the Drug Product New Product Introductions, equipment evaluation, validation (process, cleaning, and equipment), process characterization, and commercial support. He also provides scientific troubleshooting, technical process knowledge in investigations for Amgen Inspection and Packaging, Amgen Oral Solid Dose, and Amgen Drug Product Formulation and Filling.

Gordon started his career at Amgen in 2006 in Ireland as Sr. Manager Manufacturing, and since then has held a variety of roles of increasing responsibility within Manufacturing, Engineering and Process Development in Amgen Puerto Rico and Amgen Netherlands.

Prior to Amgen, Gordon worked for such companies as Genzyme, Guidant and Bausch & Lomb. Overall, he brings with him a wealth of 28 years of versatile experience in the industry. Gordon has a bachelor in Science and a Masters of Science in Food Engineering from University College Cork Ireland.

Gordon's interest include gardening, rugby and motorcycles.



## Kim Sepulveda, Director of Engineering, Amgen

Kimberly Sepulveda is the Director of Customer Insights at Amgen. Kim loves this role because she is passionate about incorporating the patient voice into all aspects of the product lifecycle. At Amgen, Kim also led teams of engineers developing and launching combination products and teams of scientists bringing molecules from the discovery phase to first-in-human clinical trials. Prior to joining Amgen, Kim led a multidisciplinary team of engineers at Stryker Orthopaedics to design, develop, and launch the Triathlon Tritanium Knee System. Kim also held engineering roles at Northrop Grumman, designing production parts and performing structural analyses for

the F/A-18 Super Hornet. She also worked at L-3 Space & Navigation to develop and manufacture precision guidance devices for space vehicles.

Kim is excited to mentor and share lessons learned through her 20 years of experience in product development, project and team leadership, lifecycle management, supplier management, and customer engagement within the aerospace, medical device, and biotech industries.

Kim holds a bachelor of science degree in Mechanical Engineering from Cornell University and a Systems Engineering Certificate from California Institute of Technology. She is a Six Sigma Green Belt and is a certified Project Management Professional (PMP).

Kim loves running, outdoor adventures, salsa dancing, and spending time with family and friends.



## Temitope Sodunke, PhD, Director BIA Strategy, Competitive Intelligence, Bristol Myers Squibb

Temitope Sodunke, PhD is the Strategy Lead for the Business Insights and Analytics organization at BMS, working with the Chief Analytics Officer and the Executive Leadership Team to develop, execute, measure, and refine key strategic initiatives and to optimize business impact through high value data, analytics, and intelligence service delivery. Temitope has over 15 years of experience across multiple industries (Pharma, Defense, Finance, and

MedTech) and her areas of expertise include innovation, strategy, and new product development. Temitope received her BSE in Biomedical Engineering from the University of Rochester and completed her graduate studies (MSE in Chemical Engineering and PhD in Mechanical Engineering) at the University of Pennsylvania and Drexel University. She also completed a post-doctoral fellowship in Radiation Oncology at Harvard/MGH. When she is not working, she enjoys eating various Southeast Asian and West African dishes, traveling, and spending time with her family.





## Susan Spitz, PhD, Senior Director of Clinical Research Translational Sciences, Incyte

Susan Spitz, PhD is a Senior Director in the Translational Sciences department at Incyte Corporation. Sue has over 25 years of experience in the pharmaceutical and biotechnology industries. At Incyte, she leads the translational strategy for clinical studies of novel oncology drugs to understand the mechanism of action of therapeutics and identify biomarkers that predict which patients may benefit from drug treatment.

Sue received her Ph.D. in Chemistry from Lehigh University, Masters in Clinical Immunology from Drexel University, and B.S. in Biology from Muhlenberg College. She has held positions of increasing responsibility at DuPont Pharmaceuticals, Janssen Pharmaceuticals, and MedImmune/Astra Zeneca; leading groups in Translational Sciences and Clinical Pharmacology. In addition, she has contributed to the successful registration of drugs in multiple therapeutic areas including cardiovascular, autoimmunity and oncology. In addition to being an SMDP mentor, Sue is the President of the Philadelphia Chapter of HBA (Healthcare Businesswomen's Association), a member of SITC (Society for Immunotherapy of Cancer), and a member of AAPS (American Association of Pharmaceutical Scientists). Her hobbies include skiing, tennis and attending theater and music performances.



## Anand Subramony, PhD, Vice President, Drug Delivery, Devices and Connected Solutions, Eli Lilly

Anand Subramony, PhD is Vice President within the DDCS (Delivery, Device, and Connected Solutions) at Eli Lilly's Medicines Innovation Hub and he provides leadership to early development and novel delivery technologies for our next generation therapeutics and new modalities.

Prior to joining DDCS in April of 2023, Anand was Vice President of the Biologics Engineering and Targeted Delivery group, R&D, at AstraZeneca (AZ). In this role, he led various cross-functional teams and initiatives in the areas of nanomedicine (for targeted delivery, enabling new modalities and creating technology platforms), antibody-drug conjugates, and drug delivery of new modalities including cell therapy. He also provided leadership to external innovation and particularly to CoSolve, an AZ open innovation platform that integrated compelling technologies to the portfolio (CoSolve | AstraZeneca Open Innovation). Prior to that role Anand headed the Drug Delivery & Device Development at MedImmune and built an internal team that focused on combination product development, connected devices, digital biomarkers and sensors as well as advanced novel delivery technologies including oral peptide delivery and other novel controlled release drug delivery technologies.

Prior to that position, Anand was Principal Fellow and Head of Novel Delivery Technologies at the Novartis Institutes for BioMedical Research (NIBR, Cambridge, MA), head of the Materials Science group (E-TRANS) at Alza /J&J (Mountain View, CA), and Director of Materials Science & Drug delivery at Dr. Reddy's Laboratories (Bridgewater, NJ). With his broad experience in pharma biotech, Anand brings innovation and scientific rigor coupled with execution excellence and sense of urgency toward drug development to create patient centric products. He has established and managed high-performing teams in all his roles. Anand holds an MS degree in Materials Science Engineering (IIT, Bombay) and a PhD degree from Purdue University. He was a research scientist at the University of Washington, Seattle, before taking up industrial positions. With several refereed publications and patents, he is a sought-after Key Opinion Leader in the area of drug delivery and product development.



## Peter Thomas, Senior Manager Manufacturing, Amgen

Peter Thomas is currently the Senior Manager for Manufacturing at Amgen in Thousand Oaks, California. Prior to his currently role, he served Amgen in various other positions. Peter was also a QC Analyst at Watson Pharmaceuticals and a Scientist at Wyeth.



## Vincent Thomas, MD, Senior Medical Safety Officer, Johnson & Johnson

Vincent C. Thomas, MD is a pediatric cardiologist and electrophysiologist who has transitioned his career to the medical device and pharmaceutical industry. He completed his undergraduate degree in Biology at The George Washington University in Washington, DC and returned to his home state of Nevada for medical school at the University of Nevada School of Medicine. He completed his pediatric residency at Children's Hospital of Orange County and went on to fellowship in pediatric cardiology and electrophysiology at Emory University in Atlanta, GA. Following his training, Vincent practiced in both Nevada and Nebraska treating children and adults with congenital heart disease and arrhythmias. During his clinical practice, he pursued a Masters in Healthcare Administration at the University of Nevada- Las Vegas. In 2018, he became Medical Safety Officer for Biosense Webster, an electrophysiology company at Johnson & Johnson Medical Technology.

Vincent now works as Senior Safety Officer in the advanced R&D unit of Interventional Oncology at Johnson & Johnson. While his career is focused on the safety of patients, his life purpose is dedicated to the health and well-being of children. To that end, Vincent has started Guidance Medical, a non-profit organization supporting families and children with special healthcare needs.



## **Kirsten Tullia, Vice President, Payment & Health Care Delivery Policy, AdvaMed**

Kirsten Tullia, J.D., MPH, joined the Advanced Medical Technology Association (AdvaMed) in 2021 and serves as Senior Vice President in the Payment & Health Care Delivery Policy Department. In this position she covers a wide range of policy issues, with a particular focus on the Medicare fee-for-service payment systems, alternative payment models, and Medicare Advantage and commercial payor policy. Prior to joining AdvaMed, Kirsten was the Department Head for Health Policy at the MITRE Corporation, where she led teams supporting the Centers for Medicare and Medicaid Services in addressing healthcare quality and payment issues through strategic planning, research and evaluation, and regulatory development. She holds a B.A. from Southern Virginia University, a J.D. from the American University Washington College of Law, and an M.P.H. from the Johns Hopkins University Bloomberg School of Public Health.



## **Karthik Vaideeswara, PhD, Associate Vice President, Drug Delivery & Device Development, Eli Lilly**

Karthik Vaideeswaran is an Associate Vice President of R&D in the Delivery, Device and Connected Solutions (DDCS) organization of Eli Lilly and Company. He leads an integrated science, technology and commercialization team comprising of surface, analytical and polymer scientists, biomedical, materials, mechanical and chemical engineers as well as experienced project management professionals who collaborate internally/externally to (a) develop and deliver the container closure systems and drug delivery device solutions for all the molecules in the Eli Lilly product portfolio, (b) pursue next-generation delivery device platforms for Lilly's emerging delivery and device needs and (c) probe and understand the science and physiology of drug delivery and the underlying surface and interface phenomenon at a mechanistic level.

Karthik has a Masters in Polymer Chemistry (University of Madras), a PhD in Materials Engineering (University of Connecticut), post-doctoral research experience in Surface Science (University of Cincinnati) and a MBA (University of Kentucky). He has 25+ years of industrial experience encompassing multiple industries with a focus on (a) leveraging advanced materials in a variety of challenging applications and (b) incorporating increasing levels of project and people leadership roles along his career.

In terms of personal interests and hobbies, Karthik loves music (listening and singing), watching sports (NFL, NBA, IPL/Cricket and many more) and spending time with family and friends.



## **Angelina Volkova, PhD, Principal Investigator, Translational Sciences Bioinformatics, Incyte**

Angelina Volkova, PhD is an experienced computational biologist who applies and develops machine learning and data integration methods to study skin diseases. Her background includes expertise in data science, pipeline development, artificial intelligence, data visualization, drug development, and autoimmune diseases. Angelina pursued her undergraduate studies at Hunter College, majoring in biochemistry with a concentration in bioinformatics and minoring in computer science and mathematics. She earned her PhD in computational biology from New York University School of Medicine. Currently, she serves as a Principal Investigator at Incyte Corporation in the Translational Sciences Bioinformatics group, where she leads data analysis for clinical and preclinical projects within Incyte's Inflammation and Autoimmunity division. Apart from her work, she has a passion for traveling and exploring different parts of the world.