UBEC

INDUSTRY PANELISTS

Victor Garcia
Global Vice President Regulatory Affairs @ Varex Imaging Corporation

As an industry expert and key opinion leader in the area of product classification, Victor Garcia has worked with governmental agencies and industry experts to advance regulatory science and its importance to influence new standards of care to adopt novel or convergent technologies to meet safety & efficacy paradigms of the 21st century. Victor is a previous chair of the Utah Regulatory Affairs Professional Society, University of California SD graduate program advisor, University of Utah graduate advisor & guest lecturer, life sciences industry expert for the Office of SLC Mayor and supporting mentorship of STEM programs. Recently, Victor has focused on the increased use of artificial intelligence and machine learning within the diagnostics imaging ecosystem is a core competency to address real world workflows and data types of segmentation within the patient imaging event, i.e. software as a medical device.

Brenda Mann
Founder and President @ Marinda Therapeutics

Brenda K. Mann, PhD, is Founder and President of Marinda Therapeutics, LLC. Marinda is developing biomaterials for vaginal applications, including vaginitis and wound healing. She is adjunct faculty in Biomedical Engineering at the University of Utah and a registered patent agent. Dr. Mann was previously Senior VP for R&D at EyeGate Pharmaceuticals, and a Co-Founder and VP for R&D at SentrX Animal Care. She was also founding faculty of Keck Graduate Institute and serves on its Corporate Relations Board. Dr. Mann was elected to the *American Institute for Medical and Biological Engineering (AIMBE)* College of Fellows in 2022. She is a strong proponent of youth science education and has served as the Director of the University of Utah Science and Engineering Fair since 2006.

Jessica Smith
Corporate Vice President and Chief Regulatory Officer @ Integra LifeSciences

Jessica Smith, PhD, is the Corporate Vice President and Chief Regulatory Officer at Integra LifeSciences (Princeton, NJ), a $1.5B revenue multinational company and global provider of neurosurgical solutions, regenerative technologies, and surgical instrumentation. She oversees all global regulatory activities and serves as a member of the Executive Leadership Team. Prior to joining Integra, Jessica led corporate and business unit regulatory organizations for Hillrom, Becton Dickinson and CR Bard. In these roles, Jessica has served on both the Senior Leadership and Executive Leadership Teams and has had global regulatory responsibilities for a broad range of product families and classifications. Jessica has also served as an elected leader for the Bard Women's Leadership Forum and BD's Women's Initiative Network (WIN), serves on the board of the University of Utah Board of Governors and Engineering Alumni Association, and has been a guest speaker at various MedTech forums and education platforms. Jessica holds a BSc in Civil Engineering, and a Masters of Engineering (bioengineering), and PhD in Bioengineering, all from the University of Utah. She has also authored several peer-reviewed publications, was previously a licensed professional engineer, and holds a U.S. Regulatory Affairs Certification.

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Kim Dobaj
Sr. R&D Engineering Manager, PMO @ Stryker Neurovascular

Kim Dobaj is a leader with 25+ Years in the Medical Device industry with various leadership roles in R&D, Operations, Manufacturing Engineering, Project Management and Supply Chain. She has enjoyed learning and contributing to a variety of medical device industries and companies. Most recently, she has worked at Stryker Neurovascular where devices to treat stroke are designed, manufactured, and distributed. Kim is a practitioner of Lean and Six Sigma methodologies and has been instrumental in transforming several manufacturing sites, resulting in significant efficiency gains. She is passionate about learning, developing people and delivering results and has also been an active leader in the Stryker Women's Network. Kim served as an adjunct professor at the University of Colorado, Denver where she developed and taught a practical course on New Product Development. She earned a M.S. in Material Science and Engineering from the University of Utah and a B.S. in Pre-medicine from the University of Nevada, Reno. She and her family love to be outdoors and have found an ideal home in the Salt Lake City Valley.

Lynne Shwed
Sr Director, Engineering @Edwards Lifesciences

Lynne Shwed is a Senior Director of Engineering in New Product Development for Edwards Lifesciences currently focused on transcatheter heart valve replacement. Lynne has 20 years of medical device industry experience in new product, process, and technology development for disposable and implantable medical devices. Lynne is motivated by projects and products that have the potential to make a significant, positive impact in others' lives and is passionate about teaching and mentoring young engineers and driving teams to do things better tomorrow than we do today. Lynne holds a B.S. in Chemical Engineering from Penn State University and a M.S. in Material Science and Engineering from the University of Delaware.

Amarinder (Sunny) Gill
Director of Quality, Post-Market @ ICU Medical

Amarinder "Sunny" Gill is a proven quality leader of product realization, sustaining engineering, and risk management for high-growth organizations. Sunny has over 20 years of medical device and biotech experience in progressive leadership positions at companies including Kimberly-Clark Healthcare (Ballard Medical), Moog Medical Devices Group, Polarity TE, Attwill Medical Solutions, and Scientia Vascular. Currently, Sunny is the Director of Global Complaints Management and Device Safety Regulatory Reporting at ICU Medical. Sunny holds degrees in both Chemical Engineering and Material Science from the University of Utah (GO UTES) and a Masters of Science in Regulatory Affairs from San Diego State University. Sunny is a Certified Quality Engineer and Six Sigma Green Belt from American Society for Quality (ASQ), part of the Regulatory Affairs Professional Society leadership team for the Utah chapter, and guest lectures in the University of Utah Biomedical Engineering program.

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Meet our UBEC keynote speaker:

MARK PAUL

Mark Paul is the new Executive Director of the University of Utah Health Center for Medical Innovation (CMI). With a passion for device innovation ignited by witnessing the emergency caesarean delivery of his first child, Mark brings 32+ years of experience in the medical device industry to the CMI. In addition to roles at Proctor & Gamble and Boston Scientific, Mark previously served as the President of global medical device manufacturer Stryker's neurovascular division. In his time, the division grew from $230M to $1.3B+ in annual sales in 70 countries worldwide. Mark's career brought landmark devices with clinical data for the treatment of Hemorrhagic and Ischemic Stroke. Born and raised in SLC, Utah, he is a fourth-generation graduate of the U. His great-grandfather was in the university's first class in 1850. Both his grandfather and father followed that tradition. His mother was a U of U cheerleader. Mark was ASUU Student Body President, His wife, Jana (Nursing '87), is also a University of Utah alumna. The tradition continues for a fifth generation, as three of their four children have graduated from the U, while the fourth enters his sophomore year on campus.