Director-at-Large — Bakul Patel is a distinguished digital health executive at Google recognized globally for his visionary leadership and expertise in digital health strategy. With over 30 years of experience spanning telecommunications, semiconductors, data storage, robotic automation, health information technology, and regulation, he has been instrumental in shaping U.S. regulatory policy. As the founding director of the FDA's Digital Health Center of Excellence, Patel led initiatives to integrate advanced technologies, including AI and machine learning, into healthcare. He is the architect of the FDA's "Digital Health Software Precertification Program" and coined the term "Software as a Medical Device (SaMD)," to help in establishing a globally harmonized regulatory framework. Patel's contributions include authoring foundational FDA guidance on mobile medical applications and fostering collaboration across global regulatory bodies, solidifying his influence as a top digital health policy champion.

Director-at-Large — Aaron Dunbar is an accomplished quality systems and regulatory compliance leader at Boston Scientific with over 20 years of experience in the medical device and healthcare industries. He is recognized for his expertise in quality systems development, corrective and preventive actions, and post-market surveillance. Dunbar has held executive leadership roles at Boston Scientific and Olympus, where he led global compliance initiatives, audit programs, and regulatory strategy implementation. His career includes significant contributions at the U.S. FDA, where he conducted regulatory inspections and investigations, earning multiple awards for outstanding performance. A trusted partner and servant leader, Dunbar excels at fostering collaboration with regulatory bodies, driving continuous improvement, and mentoring future leaders. He has played a key role in transitioning organizations to meet evolving regulatory requirements, including EU MDR and MDSAP certifications. Actively engaged in industry working groups, Dunbar continues to shape global quality and compliance standards while promoting a strong quality culture.

Director-at-Large — Monica Wilkins is a seasoned leader in quality systems and regulatory compliance with over 35 years of experience spanning the medical device, healthcare, pharmaceutical, and regulatory industries. She currently serves as Divisional Vice President of Quality Systems and Strategic Support at Abbott, where she has held multiple leadership roles since joining in 2007. Prior to Abbott, Wilkins spent 12 years at the U.S. Food and Drug Administration (FDA), where she served as a Medical Device National Expert, Compliance Officer, and Medical Device Specialist. Her extensive career also includes roles in research, microbiology, quality control, and regulatory compliance across various industries. With a strong background in microbiology, quality assurance, and strategic deployment, Wilkins has been instrumental in shaping regulatory policies and driving continuous improvement initiatives for quality excellence in the healthcare industry.

Director-at-Large — Barrett Franklin is a highly accomplished healthcare executive with a proven track record in strategic planning, operational leadership, and quality management. As Chief Operations Officer for the VA New England Healthcare System, he oversees administrative functions across multiple medical centers, including finance, human resources, supply chain, and clinical service optimization. Throughout his career, he has successfully led multi-million-dollar cost-saving initiatives, expanded telehealth services, and improved workforce retention. Previously, he served as Interim CEO at multiple VA healthcare systems, where he spearheaded strategic partnerships, enhanced patient care models, and strengthened employee engagement. Known for his ability to align business strategy with patient

care excellence, Franklin is dedicated to fostering high-performing teams and driving efficiency in complex healthcare environments. His leadership has been instrumental in improving operational performance, financial sustainability, and overall patient experience within large, matrixed healthcare organizations.

Vice Chair, Sterilization — Jennifer Benolken is a seasoned medical device packaging expert at Dupont with over 30 years of experience in packaging, labeling, and sterilization across operations, R&D, engineering, and sales. She holds a degree in Manufacturing Systems Engineering from Kettering University and a master's in International Management from the University of St. Thomas. Benolken is actively involved in industry leadership, serving as co-chair for AAMI's ST/WG 7, U.S. Expert and Secretary for ISO TC198/WG7, and sub-committee chairperson for ASTM F02.50. A lifetime Certified Packaging Professional (CPPL) and former IoPP National Board member, she currently chairs its Medical Device Packaging Technical Committee. Additionally, she co-chairs the Kilmer Collaboration Teams and leads its Kilmer Innovations In Packaging (KiiP) group. As editor of the upcoming Medical Device Packaging Handbook (3rd edition), Benolken leverages her extensive expertise to educate and support medical device and pharmaceutical organizations, providing critical insights on Tyvek® packaging and sterilization.

Re-elections:

Vice Chair, HDO – Mike Busdicker

Mike Busdicker is the System Director of Clinical Engineering Shared Services at Intermountain Healthcare. He began his healthcare career in the U.S. Air Force, graduating from the DoD Biomedical Equipment Repair School in 1983. With seven years of active duty and 20 years in the Wisconsin Air National Guard, he rose to Chief Master Sergeant, serving as a Biomedical Technician, First Sergeant, and Human Resource Advisor, including a deployment to Iraq. Mike holds a bachelor's and master's degree in business from Baker College in Flint, Michigan. Before joining Intermountain, he held leadership roles at ServiceMaster, Aramark, TRIMEDX , and Alexian Brothers Healthcare. An active member of AAMI, ACHE, UHE, HIMSS, NH-ISAC, and MDSISC, he also serves on the AAMI Technology Management Executive Council. With expertise in clinical engineering and healthcare technology, Mike continues to drive innovation and operational excellence in the field.

Vice Chair, Industry – Diane Wurzburger

Diane Wurzburger, J.D., RAC, is an Executive of Regulatory Affairs and Quality for GE Healthcare, overseeing the U.S., Canada, and EMEA, as well as Global Regulatory Policy. With extensive experience in medical device regulation, compliance, clinical affairs, and reimbursement, she plays a key role in industry leadership. Diane co-chairs AdvaMed's Global Harmonization Work Group and chairs the Medical Imaging and Technology Alliance (MITA) Technical and Regulatory Committee. She has served as MITA's industry representative for MDUFA negotiations and currently chairs the NESTcc Governing Committee's Executive Committee. Diane holds a bachelor of Science in Biomedical Engineering from Boston University and a Juris Doctor from Seton Hall Law School. Her leadership in global regulatory strategy and advocacy has made her a key figure in advancing medical device innovation and compliance worldwide.

Director-at-Large – Larry Hertzler

Larry Hertzler brings over 40 years of experience in clinical engineering operations, working with hospitals, healthcare systems, and leading Healthcare Technology Management ISOs. He holds a bachelor of Science in Electrical Engineering from Purdue University and an MBA from Washington University's Olin School of Business, with additional training in Critical Thinking and Decision Making at the Wharton School. Larry is a Certified Clinical Engineer (CCE) and was previously a Registered Professional Engineer in Missouri. A Fellow of the Association for the Advancement of Medical Instrumentation (AAMI), he is also a founding member of the American College of Clinical Engineering (ACCE). He has held leadership roles on AAMI committees, including chairing the AAMI Credentials Institute (ACI). His career has been dedicated to advancing healthcare technology, regulatory compliance, and operational efficiency, making a lasting impact on the field of clinical engineering.

Director-at-Large – Herman McKenzie

Herman McKenzie is a Director in the Standards Interpretation Group at The Joint Commission, overseeing the Physical Environment Department. He provides standards interpretation, education, and survey guidance while managing compliance activities. With over 30 years in healthcare, he has held leadership roles in Clinical Engineering, Plant Operations, and Facilities Services across Chicagoland. Previously, he was instrumental in opening Illinois' first new hospital in 25 years. Herman is a Certified Healthcare Safety Professional (CHSP) and an active member of ASHE and HESNI, serving as HESNI's president from 2013-2014. He also serves on the Board of Directors for AAMI. He holds an MBA from Governors State University and a bachelor's degree in Electronics Management from Southern Illinois University. As a Certified Yellow Belt, he supports The Joint Commission's Robust Process Improvement® (RPI®) culture, leveraging data-driven strategies to enhance healthcare safety and efficiency.

Director-at-Large - Elizabeth F. Claverie, MS

Retired CAPT Elizabeth Claverie served in the U.S. Public Health Service as a specialist in microbiology, infectious diseases, and prevention. She began her career at the FDA's Center for Food Safety and Applied Nutrition, contributing to the President's 1997 Food Safety Initiative and research on Bacillus anthracis detection. She later received a NATO fellowship in Advanced Molecular Microbiology at the University of Birmingham. Transitioning to the FDA's Center for Devices and Radiological Health, she led infection control and prevention teams, overseeing regulatory responses to COVID-19, Ebola, and H1N1. Throughout her career, she held leadership roles in public health, mentoring and training teams in regulatory science. She was appointed by the FDA Commissioner as Ex-Officio to the CDC's Healthcare Infection Control Practices Advisory Committee (HICPAC). CAPT Claverie's expertise in microbiology and infection prevention has left a lasting impact on public health and medical device safety.