

BUILD Consortium Member Biographies

Dennis Black, Director of e-Business, Becton, Dickinson, has over 25 years of experience within the medical



device industry and has worked in a variety of different roles. He joined BD, a leading medical technology company in 1998 and currently works within the BD Solutions and Services group. Dennis is focused on developing and implementing a variety of supply chain solutions and related services. Other responsibilities include implementing FDA's Unique Device Identification (UDI) regulation within BD and collaborating with select customers on initiatives to reduce healthcare costs. Dennis currently serves on the GS1 Healthcare Global Leadership Team; the GS1 US Executive Leadership Committee; and the Strategic Market Place Initiatives (SMI) Board of Directors. He actively participates in various industry work groups within

SMI, Global Healthcare Exchange (GHX), AdvaMed, and the Association for Healthcare Resource & Materials Management (AHRMM) to help solve a variety of healthcare challenges.

Kevin Capatch, Director of Supply Chain Technology and Process Engineering at Geisinger Health System, utilizes



Lean Thinking to focus on magnifying the value and eliminating the waste in the core value streams. Kevin's evangelistic leadership style and manufacturing-based operational expertise, combined with his information systems background, has allowed him to stimulate new thinking and promotion of process redesign in Geisinger's supply chain information and supply delivery systems. Kevin remains a trainer in the Geisinger Quality Institute. He continues to serve in external leadership roles: Healthcare Transformation Group (HTG), Community Advisory Board (CAB) for GS1 Healthcare, member of multiple GS1 workgroups, and a member of ASC x12 workgroup. He has

completed AHRMM's Healthcare Supply Chain Leadership Institute and completed his Master's Degree in Project Management. In his spare time, he and his wife Diane, support their two son's passion for auto and motorcycle restoration.

Jeff Dressler, MBA is the Director of Clinical Research for Abbott Laboratories. Jeff is responsible for Data



Management, Quality, Innovation, and Alliance at Abbott. Jeff has previously been responsible for working with the Global Commercial organization within Abbott to use Innovation to drive bringing products to diverse markets. Prior to joining Abbott Jeff was a consultant helping organizations solve Information Technology and Business Process challenges. He received his MBA from the University of California Berkeley and his BS from the University of Illinois Champaign Urbana.

Curtis Dudley is the Vice President of Performance Solutions at Mercy. Curtis and his team are responsible for



designing and deploying solutions that drive clinical, operational, and financial performance improvement. He oversees the identification and use of tools, technology, metrics and dashboards across the entire care continuum, driving more predictive and dynamic decisions that help optimize the Mercy experience for caregivers and patients. Curtis has more than 20 years' experience in supply chain and information technology. He has held various positions with Mercy that include management positions in the operating room, warehousing and distribution, regional supply chain leadership, and I.T. He has led a number of key implementations including the OmniCell point of use system, Lawson supply chain

management software, a medication administration safety program, the TECSYS warehouse management system for pharmacy distribution. He also worked with industry leaders to implement the first Perfect Order program within health care and has pioneered the adoption of GS1 standards and the use of Unique Device Identifiers in the EHR. Curtis is a member of the Association for Healthcare Resource & Materials Management (AHRMM). He also has served as an advisory board member to a number of different health care technology companies.

Jo Carol Hiatt, MD, MBA is the Chair of the National Product Council for Kaiser Permanente and also chairs KP's



Inter-Regional New Technologies Committee. She is a partner in Southern California Permanente Medical Group (SCPMG) and is currently Assistant Medical Director, SCPMG Business Management. Dr. Hiatt chairs Southern California's Technology Deployment Strategy Team as well as the Oversight Committee for Integrated Medical Imaging. Dr. Hiatt joined Kaiser Permanente as a general surgeon at Panorama City, later serving as Chief of Surgery at that location and member of the SCPMG Board of Directors. Dr. Hiatt received her undergraduate degree from Stanford University and her medical degree from Duke University. She trained in general surgery at UCLA. In addition to her

clinical degree, Dr. Hiatt received an MBA from UCLA's Anderson School of Management. She was designated an American College of Surgeons Health Policy Scholar in 2013.



Theodore Heise, PhD, RAC, has over 25 years of experience in regulatory affairs, and currently is Vice President Regulatory and Clinical Services at MED Institute. In this capacity, Dr. Heise leads the company in developing scientifically robust regulatory and clinical study strategies for its clients: entrepreneurs, consultants and developers bringing new medical products through the complex steps of the development process. Graduating *Magna Cum Laude* with a BS in chemistry from the University of Nebraska at Omaha, Dr. Heise went on to earn a Ph.D. in analytical chemistry from Iowa State University. He has

been a member of the Regulatory Affairs Professionals Society since 1993, and the American Chemical Society since 1988. Dr. Heise is active in policy development for medical device postmarket surveillance programs, representing Cook Medical on the corporate stakeholder board for the SVS/Vascular Quality Initiative and participating in various projects within MDEpiNet (e.g., RAPID) and BUILD. Dr. Heise is also a U.S. delegate to TC 194, the technical advisory committee for international consensus standards that govern biocompatibility

testing (ISO 10993) and clinical investigations of medical devices (ISO 14155). He is the convener of TC 194/WG 14, the working group with oversight of 10993-18 that covers material characterization.



Kay Hysell, Director of Supply Chain Informatics at Mayo Clinic, leads a diverse team that specializes in supply chain analytics solutions, metrics and dashboards, data standards and integrity, ERP system support and project management. She has over 25 years of supply chain operational experience, transforming procure to pay into an enterprise procure to pay organization, and leading multiple integral system implementations. Kay is an active member of the Healthcare Transformation Group (HTG), is a member of the GS1 Healthcare Executive Leadership Group, and serves on multiple GS1 workgroups. She

holds a Masters of Business Administration (MBA) degree from Capella University, specializing in Project Management.

Tom Maughan is the Senior Product Development Engineer at DePuySynthes.

Bart Phillips, MS is a Senior Manager of Data Solutions for the Data Science function in the Scientific Strategic



Organization within Medtronic. In this role he leads the development of technical and analytic solutions aimed at modernizing post market surveillance. Additionally, he is a champion for the adoption of healthcare data standards across the enterprise and participates in many cross-company initiatives designed to create alignment and momentum for the company in leveraging real-world healthcare data. He was previously the Director of Operations, Clinical Integration for Valence Health. In this role he developed and oversaw the implementation and management of a data

aggregation and reporting solution for physician networks that focused on delivering patient management tools to physician offices to improve the quality and cost of care. Within this role he led the development of the company's first generation enterprise master patient index and clinical practice guideline database engine products. Mr. Phillips has held technical and analytic leadership roles in numerous healthcare associations. Most notably, he worked closely with physician leaders on the rollout of the American College of Surgeons National Surgical Quality Improvement Program (ACS NSQIP). Mr. Phillips received his undergraduate degree in biomedical engineering from Washington University in St. Louis and his Mastr of Science in Applied Statistics from DePaul University in Chicago.

Terrie Reed, MS Industrial Engineering, recently returned to FDA as Senior Advisor for UDI Adoption after having



a one year opportunity to work with experts in device informatics research at Duke Clinical Research Institute. Ms. Reed has spent her career advocating for the operational integration of data standards and informatics principles into healthcare and government systems in order to improve the efficiency of regulatory submissions and public health reporting. Her latest role as Senior Advisor for UDI Adoption is the culmination of years of systems analysis, information science, and regulatory science experience aimed at significantly improving device evaluation and decision-making through the adoption of unique device identification (UDI) across the device

ecosystem.

Cynthia Shumway is the Director of Supply Chain & Support Services Business Applications for Intermountain Healthcare.



Angela Silvestri, RAC is a Director, Regulatory Affairs at Stryker. As part of the corporate RA team, she is the Global Process Owner for UDI, and manages the US UDI program activities for RAQA and GUDID submissions and is responsible for the implementation of international UDI requirements. She participates in several industry associations' UDI working groups. Prior to joining to Stryker, she worked for DePuy Synthes in regulatory compliance auditing and monitoring and spent 20 years in premarket and post market regulatory affairs. As a new member to the UDI community, she is interested in Global UDI harmonization and UDI adoption activities. She has a bachelor's degree from Villanova University, and is Regulatory Affairs Certified.



Brad Steger is Global Project Manager for Unique Device Identification (UDI) Systems for Zimmer Biomet. His duties include providing subject matter expertise for GS1 Specifications and publishing to the GDSN. He previously held the position of Labeling Manager, where he implemented the labeling system for Biomet at 94 sites around the globe. Mr. Steger has extensive experience in Software and Process Validations, has practiced Manufacturing Engineering in two Fortune 500 companies and served as the MRI Compatibility Subject Matter Expert for Biomet. His unique skills set allows him to provide new insights and perspectives to the industry groups and Standards Committees on which he participates. Mr. Steger received degrees in Computer Integrated Manufacturing and Manufacturing Engineering Technology from Ball State University and is a Certified Biomedical Auditor and Project Management Professional PMP®.



Paul D. Varosy, MD, FACC, FAHA, FHRS is the director of cardiac electrophysiology in the Department of Veterans Affairs (VA) Eastern Colorado Health Care System and Associate Professor of Medicine at the University of Colorado Denver. As an undergraduate, he attended the University of California, Los Angeles, and then earned his medical degree at the University of California, San Diego. He trained in internal medicine, cardiovascular medicine, and clinical cardiac electrophysiology at the University of California, San Francisco. Dr. Varosy's interests focus on measurement and improvement of quality of care among patients with heart rhythm disorders and arrhythmia devices. He was a recipient of a Research Career Development Award from the VA Office of Health Services Research and Development (VA HSR&D) evaluating real-world outcomes among veterans with implantable cardioverter defibrillators (ICDs). He serves in several leadership roles at the National Cardiovascular Data Registry (NCDR), the development team for the Safety of Atrial Fibrillation Ablation Registry Initiative (SAFARI), and he holds leadership roles at the Heart Rhythm Society, the American College of Cardiology, and the American Heart Association focused on performance measures development, health policy, and quality improvement. Most recently, he led the development of NCDR's AFib Ablation and Left Atrial Appendage Occlusion Registries. Within the Veterans Health Administration, he co-chairs the integrated project team implementing real-time locator system technologies for logistics/inventory management in VA cardiac catheterization and cardiac electrophysiology laboratories nationwide. Dr. Varosy resides in Centennial, CO, a suburb of Denver, with his wife and three children. He is an avid guitarist, cyclist, aviator, and skier.

Kirk Wiedmeier is the Corporate Director of Operations for Duke University Health System's Supply Chain Management Operations. In this new role for Duke, Kirk developed and created a new unified organizational structure for operations, technology systems and clinical resource management. Kirk is the Principal Lead on Duke University's UDI (Unique Device Identifier) Implementation Project. He continues to serve as a Member Partner of the HTG (Healthcare Transformation Group) as the executive representative of Duke University. Active member of Association for Healthcare Resource & Materials Management (AHRMM). Kirk brings more than 20 years' experience in IT, Account Management and all channels of Supply Chain operations. He received his Bachelor's degree from the Northwest Nazarene University and is currently working towards completing his Master's Degree in Business Administration from Boise State University.



Previous Members:

Leslie Kelly Hall

Mike Schiller