

Innovation and Integration of digital technologies to healthcare - Advancing regulatory science through collaboration.

## Heidi Dohse

### Tour de Heart



In 1982, Heidi Dohse was diagnosed with a rare heart arrhythmia and underwent a successful AV ablation procedure leaving her heart 100% pacemaker dependent. Due to pacemaker lead extraction complications in 2006, she experienced reduced heart muscle function and was diagnosed with heart failure. After Heidi had open-heart surgery in 2010, and with the help of her pacemaker data, wearable devices, and mobile apps, she had the insights she needed to get from the hospital bed to the finish line of her first bike race. Since then, she has completed multiple road and mountain bike endurance races in many countries. Most recently, she crossed the finish line of IRONMAN Arizona in November 2019.

Heidi is passionate about improving patient outcomes and uses her athletic events to inspire people living with heart issues. She partners with physicians and researchers worldwide to provide insights regarding the patient experience and ideas for engagement. She travels globally, educating audiences on digital health, data, and healthcare. Heidi recently retired from her position as Sr. Program Manager for Google Cloud Healthcare & Life Sciences organization to focus on her non-profit organization Tour de Heart.

She is a member of the MDIC Science of Patient Input working group, selected as a member of the NESTcc Active Surveillance Methodology Working Group, and Heart Rhythm Society's Cardiovascular Digital Health Journal editorial board.

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**Eric Friedman, B.S., M.S.**

**Google**



Eric Friedman is the co-founder of Fitbit and currently is Fitbit's VP of research at Google. Previously, Eric served as an Engineer Manager at CNET Networks, as a Co-Founder of Wind-Up Labs, a founding engineer of Epesi Technologies, and a technical member of the Real-Time Collaboration Group at Microsoft Corporation. Eric holds a B.S. and M.S. in Computer Science from Yale University. He was selected to serve as a member of our board of directors due to the perspective and experience he brings as our Co-Founder and CTO.

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**Jon Hunt, Ph.D.**

**MDIC**



Jon has over 30 years' experience in the Medical/Medical Device Industry with extensive domestic and international experience in general management, clinical/regulatory, sales and marketing. He has diverse experience in Fortune 500 companies as well as start-up environments.

He formerly held executive positions at Bardy Diagnostics, Cameron Health, Cardiac Pathways, St. Jude Medical, and Cardiac Pacemakers

Jon was the President and CEO of Bardy Diagnostics, Inc. from October 2013 – November 2017. Prior to joining Bardy Diagnostics, Jon spent the previous 11 years as the Vice President of Clinical & Regulatory Affairs with Cameron Health, Inc. (acquired by Boston Scientific Corporation in June 2012). Jon spent the previous 10 years with Cardiac Pacemakers, Inc., St. Jude Medical and Cardiac Pathways Corporation. Jon began his career with Cardiac Pacemakers, Inc. (now Boston Scientific Corporation) as the Director of Clinical Programs; he subsequently held positions at St. Jude Medical in Clinical Affairs and as the Business Unit Director for the Cardiac Rhythm Management division for Europe, the Middle East and Africa. At Cardiac Pathways Corporation, Jon held various executive positions as Vice President of International Sales and Marketing and Vice President of Worldwide Sales and Marketing. Jon received his Ph.D. in Motor Control from The Pennsylvania State University, his Master's from California State University, Long Beach and his undergraduate degree from Keele University in the United Kingdom.



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**Bakul Patel, MS, MBA**

**FDA | CDRH**



BAKUL PATEL is the Director for Digital Health Center of Excellence, at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies.

Mr. Patel, in 2013, created the term “software as a medical device” (SaMD) and under his leadership the International Medical Device Regulators Forum (IMDRF) established the globally harmonized definition of SaMD. Mr. Patel subsequently led global regulators at IMDRF to create and author the globally harmonized regulatory framework for SaMD. The concepts, principles and vocabulary created in harmonized regulatory framework has been used as a foundation and adopted by medical device regulatory bodies in the European union, Japan, Canada, Brazil, Australia and in the USA by US-FDA.

Mr. Patel is currently leading the effort for the agency in developing an innovative software precertification program to reimagine a pragmatic regulatory approach for Digital health that aims for patients and providers to have timely access to safe and effective digital health products.

Prior to joining FDA, Mr. Patel held key leadership positions in several sectors including telecommunications industry, semiconductor capital equipment industry, wireless industry and information technology industry. His experience includes Lean Six Sigma, creating long and short-term strategy, influencing organizational change, modernizing government systems, and delivering high technology products and services in fast-paced, technology-intensive organizations. Mr. Patel earned an MS in Electronic Systems Engineering from the University of Regina, Canada, and an MBA in International Business from The Johns Hopkins University.



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## Joseph Sapiente

### MDIC



Joseph joins MDIC with over 37 years of medical device experience in quality and regulatory compliance, product registration, continuous improvement and new product development and innovation. Joseph has led Quality Operations and Compliance at Medtronic. He has held executive leadership roles in quality, regulatory, clinical affairs and professional medical education and training at Covidien, Tyco HealthCare and US Surgical. He led the Quality Begins with Me culture initiative for Covidien and the enterprise – wide QBWM role out at Medtronic.

Before joining MDIC, Joseph was the Vice President of Quality Assurance and Regulatory Affairs, Surgical, Breast, Skeletal Health, for Hologic, Inc., manufacturers of life saving and life enhancing technologies in women’s health including, Breast Health, Skeletal, Gyn Surgical and Diagnostic Solutions. In addition to his role at Hologic, Joseph served as Industry Chair and Steering Committee Chair of MDIC’s Case for Quality collaborative community and AdvaMed Case for Quality Working Group. Joseph has been an active member of the Case for Quality program at MDIC since 2012.



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**Cassie Scherer, J.D.**

**Medtronic**



Cassie Scherer is the Director of Regulatory Policy, U.S., on the Global Regulatory Policy team at Medtronic. In her position, she leads US regulatory policy work with a focus on policy work relating to digital health technology and AI and machine learning tools and systems. Before Medtronic, Cassie was Special Counsel at Covington and Burling. At Covington, Cassie provided strategic regulatory counsel to medical device and digital health companies. Cassie's practice focused on premarket review, compliance with FDA's pre- and post-market requirements relating to medical devices and FDA jurisdictional issues. Cassie also served at FDA where she was Associate Chief Counsel in FDA's Office of Chief Counsel and Director of Strategy and Regulatory Operations in CDRH's Office of Center Director. While at FDA, Cassie advised and consulted on a broad range of matters relating to emerging medical device issues, responding to Congressional inquiries, implementing legislation relating to medical devices, reviewing premarket appeals of regulatory decisions made by CDRH, and developing regulations and key FDA guidance documents, including FDA's general wellness guidance.

Cassie holds a J.D. from the University of Virginia Law School. She lives in the Boston area with her husband and two daughters. She enjoys traveling and being active outdoors, including hiking, biking, and running. Cassie is also a certified yoga teacher and loves doing yoga in her free time.

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**Jithesh Veetil, Ph.D.**

**MDIC**



Dr. Jithesh Veetil, PhD joined MDIC as a Program Director to lead Data Science and Technology initiatives. His prime focus at MDIC is to aid in the development of regulatory grade tools based on computational modeling & simulation science relevant to clinical applications, This program builds upon the success MDIC has had with the Virtual Patient model that resulted in mock submission for clinical trials augmented with virtual patient data. These exciting programs in the pre-competitive MedTech sector will be carried out in collaboration with MDIC members and their engineers, statisticians, regulatory professionals, and medical doctors. The goal is to utilize the External Evidence Methods (historical, prospective and concurrent data- including but not limited to – Digital Evidence, Clinical Trial Data, Real World Evidence-RWE, Electronic Health Records-EHR, and Patient reported Outcomes-PRO) to better understand safety, efficacy and performance of medical devices. Dr. Veetil also leads the cybersecurity projects at MDIC

Dr. Veetil has extensive experience in designing and development of programs towards modernizing scientific workforce and practices by building academic-industrial-nonprofit collaboration through his work at National Institutes of Health (NIH) campus as the Lead Scientist and Program Manager for the Foundation for Advanced Education in the Sciences (FAES). Previously, Jithesh worked with Global Biological Standards Institute (GBSI), a Washington DC based non-profit as its Scientific Program Manager, leading the development and implementation of multiple programs on science policy, communications, and advocacy, including those related to cell line authentication, antibody validation, and reproducibility in biomedical research and development. Dr. Veetil also served as the Operations Manager for Preludesys Inc., working with international clientele from medical, IT, insurance and paralegal organizations on medical/healthcare data management.

Dr. Veetil completed his PhD in Biomedical Engineering at University of Arkansas, Fayetteville, AR, followed by postdoctoral fellowship at NIH. He has published numerous peer-reviewed manuscripts, reviews and book chapters. He also holds Masters in Biotechnology and Bachelors in Food Technology.

