BRUCE ADAMS, Vice President Sales, Cadex Electronics, Inc.

Helping customers is Cadex's first priority. Bruce leads the customer-focused Cadex sales team, relying on over 20 years’ experience providing service and technology products to medical customers around the world. Bruce joined Cadex in 1996 after stops in clinical medical sciences and healthcare sales. He has a B.Sc in Biochemistry from the University of British Columbia and past Clinical Chemistry certification through the Canadian Society for Medical Laboratory Science.

SALIL BALAR, MS, MBA, Directory of Technology Management, ARAMARK Healthcare Technologies

Salil Balar, MS, MBA, is director of Technology Management with ARAMARK Healthcare Technologies at Charlotte, North Carolina. He is responsible for monitoring and improving quality and regulatory program in the environment of healthcare technology management. He worked for Arnot Ogden Medical Center, Elmira, New York, and Beaumont Hospital, Royal Oak, Michigan, before joining ARAMARK Healthcare Technologies. He holds a bachelor’s degree in mechanical engineering from Gujarat University, MS in biomedical engineering from Iowa State University, and MBA from Wayne State University.

DAVID BRADLEY, Director of Biomedical Engineering, Nationwide Children’s

David Bradley is the Director of Biomedical Engineering at Nationwide Children’s. In 2012 Nationwide Children’s completed the largest pediatric expansion in the US. Currently the hospital is the 4th largest and 4th busiest children’s hospital in the country seeing over 1 Million patients each year. Nationwide Children’s has partnered with Aramark Healthcare Technologies to provide its Biomedical Engineering services and the department is responsible for all clinical as well as research equipment. David previously served as an instructor in the USAF and has received his B.S. in Healthcare Administration and B.S. in Business Administration as A.S. Biomedical Engineering.
RICH BYCZEK, Global Technical Lead, Electric Vehicle & Energy Storage, Intertek

Rich Byczek is the global technical lead for electric vehicle and energy storage at Intertek. He has 18 years of experience in product development and validation testing, nine of which have been spent at Intertek. Rich is also an expert in the areas of energy storage, audio equipment and EMC. Rich sits on several SAE, IEC, UL and ANSI standards panels. He holds a Bachelor of Science in Electrical Engineering from Lawrence Technological University in Southfield, Michigan, and is based at the Intertek facility located in Plymouth, Michigan.

RON CHARNOCK, Chief Operating Officer, Kwikpoint

Ron Charnock is Chief Operating Officer of Kwikpoint and heads up Kwikpoint’s Health and Safety market practice. This practice is investing in a new initiative for Kwikpoint – Kwikguides for medical devices, especially for home medical devices that are increasingly moving from clinical settings to home health care. Kwikpoint has been a world leader in visual language communications for over 20 years and has published hundreds of quickguides with over 9 million in circulation. Kwikpoint kwikguides are used extensively in the military supporting our warfighters and by global healthcare wellness providers combatting major diseases.

CHAOCHAO CHEN, Center for Advance Life Cycle Engineering, University of Maryland

Dr. Chaochao Chen is a member of the research staff at the Center for Advanced Life Cycle Engineering (CALCE), University of Maryland, College Park. His research areas include battery prognostics and health management (PHM). Prior to joining CALCE, Dr. Chen spent over three years at the University of Michigan and Georgia Institute of Technology as a research fellow, working in PHM areas in collaboration with multiple organizations in industry and the military. Sponsored by the National Science Foundation, he has been within the CALCE battery team to develop innovative PHM algorithms to ensure the safety and reliability of battery. Dr. Chen has published over 20 scientific papers in his areas. He has served as a session chair for multiple international conferences and been invited to give talks in several international conferences and institutes.

RICHARD CONSTANTINEAU, Manager of Biomedical Engineering, Anne Arundel Medical Center

Richard Constantineau entered the Biomedical Engineering Field in 1991. His initial training in the Biomedical Engineering Field was done through the Army. After leaving the Army after eight years, Richard earned his degree in Electrical Engineering where he put his skills to use in the civilian world. Richard became the Manager of the Biomedical Engineering Department at Anne Arundel Medical Center in May of 2003. Under his leadership, the department has seen a tremendous growth within the organization. His main focus is to enhance patient safety and enhance patient outcomes through the various uses of technology. His work at Anne Arundel Medical Center has helped the medical center become one of the top hospitals in the state of Maryland.
CRISTIN DORGELO, Assistant Director for Grand Challenges, Office of Science and Technology Policy, Executive Office of the President

Cristin Dorgelo is Assistant Director for Grand Challenges with the Office of Science and Technology Policy in the Executive Office of the President, focusing the use of grand challenges and incentive prizes for open innovation. Prior to joining the Office of Science and Technology Policy in early 2012, Cristin was Vice President, Prize Operations for the XPRIZE Foundation, an educational nonprofit prize institute. As part of the XPRIZE team from 2006 through early 2012, Cristin managed all of the XPRIZE Foundation’s active competitions, including the $30MM Google Lunar X PRIZE, the $10MM Progressive Insurance Automotive X PRIZE, the $10MM Archon Genomics X PRIZE, the $2.5MM Northrop Grumman Lunar Lander X CHALLENGE, and the $2.4MM Wendy Schmidt Oil Cleanup X CHALLENGE. Before joining the XPRIZE Foundation, Cristin was part of the founding team of X1 Technologies as Director of Operations, helping the desktop search company develop its innovative software and grow from 0 to 40 employees from 2002 to 2006. Prior her work at X1 Technologies, Cristin worked on several groundbreaking startup companies at Idealab, including Energy Innovations, Omnilux, and XBeams. She also managed Idealab's knowledge management efforts. Cristin was part of the Leadership and Organizational Development group at Times Mirror before it was bought by Tribune Company in 2000. She started her career in Advertising Operations at the Los Angeles Times. Cristin holds a BA in History with a minor in Anthropology from UCLA.

John Dumas, Ph.D., Senior Member of Technical Staff, Global Device R&D, Hospira

Dr. John Dumas is a Senior Member of the Technical Staff at Hospira. He has served as a technical lead on wide variety of medical device hardware and software development projects. He received his B.S. in Chemistry and Engineering from Washington and Lee University and M.S. and Ph.D. in Biomedical Engineering from the University of North Carolina at Chapel Hill.

ALEX FAY, Sr. Business Development Manager, Quallion LLC

Alex Fay manages business development for the medical device market, and he oversees battery development programs at Quallion, a manufacturer of lithium ion batteries for medical, aerospace, and military applications.

Alex’s portfolio includes engagements with implantable medical device customers, including many in the neurostimulation field. He is spearheading the company’s expansion of its manufacturing capabilities through a grant from the California Energy Commission, and he also works closely with Quallion’s engineering teams to develop batteries with novel lithium ion chemistries, custom cell designs, and integrated safety features.

Prior to joining Quallion in 2011, Alex worked as a technology advisor to Mayor of Los Angeles. Alex is a graduate of UCLA.
PHILLIP FERRO, Director, Special Projects ASPR HHS

Phil is a fellow in the Department of Health and Human Services entrepreneurs program and the director of special projects for the Assistant Secretary of Preparedness and Response (ASPR). As a fellow he is working to develop “smart” durable medical equipment and health resiliency technologies for use in disasters. As the director of special projects Phil is responsible for interagency policy, planning and response efforts related to the medical impact of CBRN / WMD threats across the US Government as well as with our close military allies and public health partners. Of particular focus are the development, acquisition and use of vaccines, therapeutics, and diagnostics against WMD threats for military and civilian populations as well as the impact of emerging technologies on preparedness in this space.

Previously, Phil worked in the strategy and operations practice of Deloitte consulting, where he focused on biotech and pharma-mergers and acquisitions as well as Life Sciences corporate and R&D strategy. Earlier in his career Phil was a Microbiologist / Principle Investigator at the United States Army Medical Research Institute of Infectious Disease (USAMRIID), where his work focused on viruses of military interest. Phil holds a PhD in Virology and Masters of Science in Oncology.

DOMINICK FRUSTACI, Vice President of R&D, Greatbatch Medical

Mr. Frustaci earned his BS and MS degrees in Chemical Engineering from the State University of New York at Buffalo. Prior to joining Greatbatch, Dominick worked for 13 years at Scott Aviation, developing various life support technologies and products. These included gas adsorption and aerosol filtration systems for respiratory protection for both military and commercial applications and solid state oxygen systems for the aviation industry. He started his career at Greatbatch working in the area of medical batteries. Currently, he has responsibility for the R&D function for battery, high voltage capacitors, feedthrough & filtered feedthroughs, shield assembly, coated components and MRI technology areas used in implantable medical devices. He has been involved in numerous programs and technology development initiatives over the past 18 years while having the opportunity to work with many medical device companies. Mr. Frustaci is a member of the AAMI CRMD Committee. He holds over 25 US Patents.

HAMED GHODS, Sr. Electrical Engineer, Office of Science and Engineering Laboratories, CDRH, FDA

Hamed serves as Electrical engineer for Food and Drug Administration. His focuses and interest is safety and performance of medical devices.

Prior to joining FDA Mr. Ghods gained extensive experience designing Robotic, Automation and None Destructive Testing (NDT) equipment. Mr. Ghods interest is in area of control system algorithms, digital signal processing, VLSI and automation.

Mr. Ghods holds a BS in Electrical Engineering from Dalarna University Sweden and a MS in Electrical Engineering from New Jersey Institute of Technology. He has over 14 years of experience designing Robotic and Automation systems.
ANDREW GREBE, U.S. Office of Personnel Management, Innovation Lab

Andrew J. Grebe is a Business Operations Analyst at the U.S. Office of Personnel Management (OPM). Andrew has two operational programs in his portfolio, the Innovation Lab and the Presidential Management Fellows (PMF) Program. In this role, he drives the business implementation of solutions in a cost-effective way by determining the requirements of the program or projects, communicating them to all stakeholders and determining a path forward.

He brings technical, analytical, innovative, and cost effective approaches to these offices in the areas of budget, operations, contracting/acquisitions, business development and project management. In his efforts to become a catalyst for innovation and change, he has certifications in Human Centered Design and a Lean Six Sigma Black Belt.

Andrew joined the PMF Program in 2010 and the Innovation Lab in 2012. Prior to his work in the PMF Program Office, Andrew served as a student intern in OPM’s Employee Services, Resource Management Office.

Andrew graduated from Florida State University’s College of Business in the spring of 2010 with a Bachelor of Science degree in Finance.

ANTOINETTE HAZLETT, MSN, RN, Manager, Special Studies, Surveys and Research, Medical Product Safety Network (MedSun), CDRH, FDA

Antoinette (Tosia) Hazlett is the Manager of Special Studies, Surveys and Research for the Medical Product Safety Network (MedSun) in the Office of Surveillance and Biometrics. Tosia has been with FDA for 5 years. Prior to that time she was the Project Director for Clinical Report Review for the MedSun Program at Social & Scientific Systems in Silver Spring, Maryland. She has been with the MedSun Program since its beginning in 2002. In her current position, she is responsible for coordinating and conducting surveys and special studies with health care providers within the MedSun network of hospitals related to medical device use and safety. She also has specialized experience in research in health care focused on program development and evaluation of patient safety, health promotion activities, and disease management and prevention. Throughout her career she has held various leadership and management positions in diverse healthcare settings such as acute care, assisted living and long term care. She received a Bachelor of Science Degree in Nursing from Villanova University and a Master of Science Degree in Nursing from Georgetown University.

CHARLES HO, PhD, Scientific Reviewer, Office of Device Evaluation, CDRH, FDA

As a scientific reviewer in FDA/CDRH for almost 20 years, Charles Ho has led review teams responsible for approving/clearing many new medical devices to market, including the first magnetocardiograph and the first microvolt T-wave alternans recorder in the US. He is the FDA’s point person on non-invasive blood pressure monitors, and the Leader of the CDRH Battery Working Group. He has a Ph.D. degree in Physics.
RON KAYE, Team Leader, Human Factors Premarket Evaluation Team, Office of Device Evaluation, CDRH, FDA

Ron Kaye leads the Human Factors Pre-Market Evaluation Team which is located in the CDRH Office of Device Evaluation (ODE) and within the Division of Anesthesia General Hospital and Infection Control Devices (DAGID). The purpose of the FDA’s Human Factors Pre-Market Evaluation Team is to ensure that new medical devices are safe and effective for users. The main activity of the team is reviewing Human Factors content in new device submissions to the Agency. The HFPMET team also promotes human factors evaluation practices for medical devices, develops Human Factors Guidance, and participates with National and International Human Factors Standards development. Mr. Kaye has a BS degree in Psychology and Biology, and a MA in Applied Psychology. He has worked in the field of Human Factors for 30 years and the last 17 at FDA’s Center for Devices and Radiological Health (CDRH). Prior to joining the FDA, Ron worked with Human Factors and human performance testing, training analysis, and research on safety-critical systems such as nuclear power plant control rooms, military weapons and communications systems, aircraft cockpit systems, air traffic control systems as well as medical devices.

CDR MIKE KRUMLAUF, RN, BSN, NIH Clinical Center, USPHS

CDR Mike Krumlauf is a Nurse Consultant with the Research and Practice Development section of the Nursing Department at the National Institutes of Health (NIH) Clinical Center. He received his BS in Nursing from the University of New Hampshire in 1998. His clinical background is in Adult Hematology/Oncology and Blood and Marrow Transplantation. He has held an oncology certification through the Oncology Nursing Society since 2002. Since coming to the NIH in 1999, CDR Krumlauf has held a variety of nursing positions with both the Nursing Department and the National Cancer Institute. Currently, he serves as a research team leader and an associate investigator on clinical research studies specializing in health behaviors and chronic disease management. CDR Krumlauf has co-authored multiple abstracts and publications as well as presented at professional conferences at both the local and national levels. He has received an NIH Clinical Center Director’s Award for his ongoing efforts in creative leadership in unit-based nursing research.

JAKE KYPRIANOU, PhD, Senior Science Health Advisor, Center Science Council, CDRH, FDA

Dr. Iacovos (Jake) Kyprianou is a Senior Science Health Advisor with the CDRH Center Science Council Staff in the office of the Center Director. Dr. Kyprianou has been working with the battery working group over the past 2 years to promote cross-center collaboration, to open a dialogue and promote collaboration with external stakeholders and to ensure that the group has the resources it needs to achieve its goals and mission. Dr Kyprianou received his PhD from the Toshiba Stroke Research Center at the University at Buffalo, NY in the field of Imaging and Medical Physics, 2004. After a 3 year fellowship with the National Institute of Biomedical Imaging and Bioengineering, NIH he became a Principal Investigator in the Office of Science and Engineering Labs in CDRH doing research and premarket/postmarket consults related to x-ray imaging. Dr Kyprianou is also an Adjunct Assistant Professor at the University of Maryland College Park, Department of Bioengineering.
CHRIS LAVANCHY, Engineering Director, ECRI Institute

Chris Lavanchy joined ECRI Institute in 1983 as a Project Engineer in the Health Devices System. Early in his career, Mr. Lavanchy was responsible for investigating medical device problem reports and conducting comparative medical technology evaluations that were published in the *Health Devices Journal*. His work has spanned diverse technologies, ranging from critical care devices to batteries used to power wheelchairs.

Mr. Lavanchy has also provided consulting services for hospitals and has conducted numerous accident and forensic investigations involving medical device failures. Among the technologies these investigations included are intra-aortic balloon pumps, ventricular assist devices, hemodialysis machines, heart-lung bypass systems, and sterilization technologies. Based on his work in these areas, Mr. Lavanchy is recognized as an in-house expert and has provided expert witness testimony related to his investigations of these and other technologies.

Since 1995 Mr. Lavanchy has served as the Engineering Director for the Health Devices program. His chief responsibilities include overseeing special project work for internal and external clients, developing new business opportunities, serving as liaisons with other departments whose work is supported by the Health Devices group and working jointly with the group's Technical Director in developing quality control measures.

CAPT KIMBERLY LEWANDOWSKI-WALKER, National Expert in Medical Devices, Office of Regulatory Affairs, FDA

CAPT Lewandowski-Walker has a Doctor of Optometry Degree from Indiana University, a Master of Science in Human Services from Capella University, and a Bachelor of Science in Biology from Indiana University. She is a course developer and instructor for various FDA medical device training courses, including Basic Medical Device, Process Validation for Medical Devices, and Medical Devices: Electronics, Computers, and Materials. CAPT Lewandowski-Walker is a frequent speaker at medical device industry conferences, such as the FDA Medical Device Industry Coalition. Additionally, she is an ASQ Certified Biomedical Auditor and has completed the ISO 13485:2003 Lead Auditor course.

ALAN LIPSHULTZ, PE CCE CSP, AAMI & President of Healthcare Technology Consulting

Alan is a full time independent consultant on all aspects of healthcare technology. His clientele includes hospital systems, manufacturers, malpractice attorneys (plaintiff and defense) and patent attorneys. He has participated in two medical lawsuits brought because of medical device battery failure.

Prior to starting HealthCare Technology Consulting in 2011, Alan spent 37 years as Director of Clinical Engineering in two different major medical centers. Alan has an active member of AAMI since 1975. His current AAMI portfolio includes Co-Chair of Standards Board; Technology Management Council; Editorial Board for Biomedical Instrumentation & Technology (BIT); and member of 3 Standards Committees. Alan is Chair of NFPA 99 Technical Committee on Medical Equipment and on the American College of Clinical Engineering (ACCE) Board of Directors.
Alan is a licensed Professional Engineer in Delaware, Certified in Clinical Engineering, and a Certified Safety Professional.

**RADM NICOLE LURIE, USPHS, Assistant Secretary for Preparedness and Response, HHS**

Dr. Lurie is the Assistant Secretary for Preparedness and Response (ASPR) at the US Department of Health and Human Services (HHS). The mission of her office is to lead the nation in preventing, responding to and recovering from the adverse health effects of public health emergencies and disasters, ranging from hurricanes to bioterrorism.

Dr. Lurie was previously Senior Natural Scientist and the Paul O’ Neill Alcoa Professor of Health Policy at the RAND Corporation. There she directed RAND’s public health and preparedness work as well as RAND’s Center for Population Health and Health Disparities. She also served as Principal Deputy Assistant Secretary of Health in the US Department of Health and Human Services; in state government, as Medical Advisor to the Commissioner at the Minnesota Department of Health; and in academia, as Professor in the University of Minnesota Schools of Medicine and Public Health. Dr. Lurie has a long history in the health services research field, primarily in the areas of access to and quality of care, mental health, prevention, public health infrastructure and preparedness and health disparities.

Dr. Lurie attended college and medical school at the University of Pennsylvania, and completed her residency and MSPH at UCLA, where she was also a Robert Wood Johnson Foundation Clinical Scholar. She is the recipient of numerous awards, and is a member of the Institute of Medicine.

**WILLIAM MAISEL, MD, MPH, Deputy Center Director for Science and Chief Scientist, CDRH, FDA**

William H. Maisel, MD, MPH is Chief Scientist and Deputy Center Director for Science at FDA’s Center for Devices and Radiological Health (CDRH). He is responsible for providing leadership in the development, implementation, execution, management and direction of the Center’s broad national and international biomedical science programs.

Prior to joining FDA, Dr. Maisel was Associate Professor of Medicine at Harvard Medical School and Beth Israel Deaconess Medical Center in Boston. He is a Board-certified cardiologist with more than 15 years of clinical experience.

He is former Chair of the FDA Circulatory System Advisory Committees, and is a former member of the Center for Medicare and Medicaid Services Coverage Advisory Committee. Dr. Maisel received his undergraduate degree in biology from MIT, his medical degree from Cornell Medical College, and his Masters in Public Health from the Harvard School of Public Health. He has published more than 120 research manuscripts, book chapters, and scientific abstracts on regulatory science, device innovation, and medical device safety and effectiveness.
DAVID E. MARLOW, CBET, University of Michigan Health System

I have been working with and testing medical batteries for over 35 years in hospitals and have given presentations for AAMI secessions on the subject. During this time I have seen most of the problems and learned how to predict most of the failures.

Currently, I am involved with our Ventricle Assist Device (VAD) program, with special attention to battery support for these patients of which we have over 100 using battery support. I am also the go to guy for any other battery problems here. Besides batteries I also take care of our lasers, and am a member of the American National Standard Z136.3 Committee for safe use of Lasers in Health Care.

In my home life, reflective of my interest in batteries, I own and drive a Chevy Volt, participate in our local EV owners group and have built and use, my own battery powered lawn mower, powered by used LVAD batteries.

MICHAEL McALPINE, Assistant Professor of Mechanical and Aerospace Engineering, Princeton University

Michael McAlpine began his appointment as Assistant Professor of Mechanical and Aerospace Engineering at Princeton University in 2008 and is affiliated with the Department of Chemistry and the Princeton Institute for the Science and Technology of Materials (PRISM). He received a B.S. in Chemistry with honors from Brown University in 2000 and a Ph.D. in Chemistry from Harvard University in 2006. His research has focused on nanotechnology-enabled approaches to biointerfacing materials, for fundamental and applied investigations in the biological and energy sciences. His work has been featured in major media outlets, including Time Magazine and the New York Times. He has received a number of awards, most prominently a TR35 Young Innovator Award, an Air Force Young Investigator Award, an Intelligence Community Young Investigator Award, a DuPont Young Investigator Award, a DARPA Young Faculty Award, an American Asthma Foundation Early Excellence Award, and a Graduate Student Mentoring Award.

COLIN McCARTHY, Product Marketing Specialist, WiTricity Corporation

Colin joined WiTricity in 2012 as a Product Marketing Specialist. He has worked within WiTricity to identify new markets and potential applications for its groundbreaking technology. Prior to joining WiTricity, Mr. McCarthy worked as an Electrical and Embedded Systems Engineer for a number of small companies and startups. Mr. McCarthy holds a Masters of Business Administration from Worcester Polytechnic Institute as well as a BS, with a major in Electrical and Computer Engineering and a minor in Manufacturing Engineering, also from Worcester Polytechnic Institute.
MOHAN MISRA, President & CEO, ITN Energy Systems Inc.

Dr. Mohan Misra founded ITN Energy Systems in 1995, after serving 19 years with Martin Marietta (now Lockheed Martin) in Materials Research, Development and Manufacturing. Under Dr. Misra’s leadership, ITN has pioneered numerous new technologies and processes, resulting in successful product commercialization through four separate spinoff companies. ITN spinoffs Global Solar Energy and Ascent Solar Technologies have attracted over $500 M investment in bringing their thin-film CIGS photovoltaic products to the marketplace.

Throughout his career, Dr. Misra has developed and implemented several key technologies, including thin-film photovoltaics, smart materials and structures, advanced composites, and lightweight structures. Dr. Misra received Martin Marietta’s Jefferson Cup (the corporation’s highest award for outstanding technical achievement) in 1984 and 1987, Martin Marietta’s Inventor of the Year Award in 1982, and the American Foundrymen’s Society award for Outstanding Technical Achievement in 1980.

Dr. Misra is currently on the Colorado School of Mines Board of Trustees, the University of Washington’s Materials Science & Engineering Department Advisory Board, and is a Fellow of the American Society for Metals. Dr. Misra holds a BS-Metallurgical Engineering from Benaras Hindu University – India, a MS-Metallurgical Engineering from the University of Washington – Seattle, and a Ph.D.-Metallurgical Engineering from the Colorado School of Mines.

JOE PADILLA, National Sales Manager, Interstate All Battery

Joe Padilla is the National Sales Manager for Interstate All Battery. Relying on over 200 nationwide franchise locations, Joe works with hospitals and medical centers to develop battery maintenance programs for their portable medical equipment. Being one of the few, if not only, national battery suppliers who can perform local service, Joe helps custom design battery management programs for individual needs. Interstate currently works with over 1,750 hospitals in the areas of battery recycling, supply chain, and/or maintenance. Joe has a BA in Business Administration from Western Washington University.

MICHAEL ROOT, Fellow, Science, Boston Scientific Corp.

Michael Root, PhD is a battery electrochemist with over 20 years of experience in battery research and development as a team leader and hands-on individual contributor. He has worked with a number of primary and rechargeable energy storage systems for medical, consumer, military and OEM applications. His background and interests include:

- Research, design and product development of battery materials and systems.
- Characterization of electrochemical systems using a wide range of electrochemical, surface and bulk chemical analysis methods.
- Battery performance characterization and longevity modeling.
- Failure analysis and resolution of battery performance issues.

He is listed as an inventor on thirteen US patents and authored technical papers, book chapters and a book on batteries and electrochemistry.
CRAIG SCHMIDT, Sr. Director, Energy Systems Research, Medtronic Inc.

Craig Schmidt is Senior Director of Energy Systems Research at the Medtronic Energy and Component Center (MECC). The Energy Systems group is responsible for the development of new technologies for batteries, high voltage capacitors, and electrical feedthroughs.

Craig holds a Ph.D. in analytical chemistry from the University of Minnesota. He began his career as a chemistry professor at Bethel College and later at his alma mater, Tabor College. Prior to joining Medtronic in 1988, he worked for E.I. DuPont, Inc. in St. Paul, MN conducting research related to metal plating technology for printed circuit boards. Craig is a Medtronic Technical Fellow, a member of the Bakken Society (Medtronic’s highest technical award), a Fellow of the American Institute for Medical and Biological Engineering, and holds over 50 U.S. patents.

ASHISH SHAH, R&D Director of Primary Batteries, Greatbatch Medical

Ashish Shah’s academic background is in electrical engineering, plasma science, and plasma enhanced coatings, with a Ph.D in the area of superconducting materials. After receiving his degree from the University at Buffalo, he joined Greatbatch Medical and played a significant role in the research and development of tantalum electrolytic capacitors for use in implantable cardiac defibrillators. This resulted in the issuance of a number of patents, and in 1999, he was presented with the Niagara Frontier “Inventor of the Year” award for collaboration on breakthrough capacitor patents. He led the capacitor research group before transitioning to the leadership of capacitor manufacturing and welding engineering groups for a couple of years. He spent the next few years in battery research, developing and innovating in the QMR medium rate battery technology area. Presently Ashish is the R&D Director of Primary Batteries working on next generation Q and CFx battery technologies for use in cardiac and neuro devices. He is also the Director of the Materials Research group that supports and provides materials expertise to various divisions in Greatbatch while conducting research into new materials and material related issues for use in medical components and devices. In addition to his primary goal of leading the battery and materials research programs, he leads the AAMI Battery TIR committee and is also a contributing member on a number of other AAMI committees. Ashish maintains a relationship with Upstate New York Medtech as the Greatbatch representative on the science and technology committee. He also serves on the Industry Advisory Board of the Biomedical Engineering Department for a couple of universities. He holds over 20 US patents in the areas of battery and capacitor technologies.

KEN SKODACEK, Co-Leader, CDRH's Battery Working Group, FDA

Ken Skodacek is the co-founder and co-leader of the Center’s Battery Working Group which was formed to improve the performance and reliability of all battery-powered medical devices. He has over 20 years of experience working with medical devices. He started his career with Cardiac Pacemakers Incorporated as an electrical design engineer, designing and testing high voltage and telemetry circuitry for implantable defibrillators. He then filled various leadership roles in his career with a focus on leading technical teams that served as the interface between engineering staff and physicians, preparing IDE and PMA submissions to FDA, as well as managing numerous IDE clinical studies. He joined FDA five years ago and now works in FDA's Office of Device Evaluation. He is responsible for pre-market regulation of cardiovascular devices, including pacemakers and defibrillators. He previously served in the Office of Compliance's Division of Enforcement, overseeing orthopedic and physical medicine devices. In addition to his routine duties, Ken has led and coordinated a number of cross-Center collaborative projects including the Entrepreneurs-in-Residence team focused on streamlining the path to reimbursement for innovative medical devices. Last year, he coordinated a productive public workshop in partnership with AdvaMed that was focused on the review and submission of manufacturing changes.
TOM SKOWERA, Staff Engineer, UL LLC

Tom Skowera is the Lead North American Regional Battery reviewer at UL LLC. He joined UL 30 years ago as an engineer in their engineering services department evaluating products for safety certification. For the past 15 years, he has evaluated cells and batteries to UL and IEC standards for ITE, medical, UN transport, UPS, cell phone, stationary energy storage, light electric vehicle, and electric vehicle applications. He has responsibility for technical input, determining technical competency criteria for UL staff and supporting UL’s certification programs for his categories of responsibility. Tom also has experience evaluating capacitors, plastics, corrosion of metals, piping, and flammable liquid storage tanks.

Tom is a licensed Professional Engineer in Illinois and has a Bachelor’s of Science degree in chemical engineering from the University of Illinois.

BHANDU SOOD, Director of Test Services and Failure Analysis Laboratory, University of Maryland

Mr. Bhanu Sood is the Director of the Test Services and Failure Analysis Laboratory at the University of Maryland's Center for Advanced Life Cycle Engineering (CALCE). Mr. Sood’s research areas at CALCE include developing analytical techniques for detecting failures in electronic products, materials characterization based strategies for counterfeit electronic parts detection and leading CALCE’s efforts in understanding failure mechanisms in electronic parts, batteries and printed circuit boards. Mr. Sood holds the US Patent on laser-based techniques for the transfer and embedding of electronic components and devices. He is a member of IEEE, SAE and ASM.


William Sovitsky is an AAMI Certified CBET, CRES. He has thirty years BMET experience with twenty as active duty Air Force.
CURT A. STRAUB, Non-Commissioned Officer In-Charge, National Maintenance Program, United States Army Medical Materiel Agency (USAMMA)

I was born and raised in Brunswick, Ohio and am the youngest of five children. I joined the US Army over 22 years ago and have always been a Medical Maintenance Technician. I worked in a variety of units from traditional hospitals to deployed medical units all over the world. I was assigned to four different hospitals and three field hospitals, each of which offered different challenges. I had the pleasure to travel all over the world and worked in amazing places with amazing people. I witnessed the transition of medical equipment from large, bulky devices to the modern, high technology equipment we use today. As I reach the end of my military career, I look forward to continued challenges in a large medical device/service company or a large hospital group.

MARY WEICK-BRADY, MSN, RN, Senior Policy Advisor, CDRH, FDA

Mary Weick-Brady is a senior policy advisor in the Office of the Center Director at the Center for Devices and Radiological Health. Ms. Brady joined CDRH over 20 years ago analyzing adverse events and later became a branch chief and deputy division director supervising staff that interpreted the reporting regulations. She has chaired a committee on the home use of medical devices since 2001 to develop policy for the safe migration of medical devices going into non-clinical environments. She has been working on device labeling policy for 3 ½ years.

LIKE XIE, PhD, Vice President, Chief Technical Advisor, Palladium Energy Inc

As Palladium's Vice President, Chief Technical Advisor, Dr. Like Xie brings almost 25 years of experience in battery technologies such as Lead acid, Ni-Cd, Ni-MH, Li Metal and Li-ion batteries, with extensive Li-ion battery expertise in cathode development, cell design, cell production, cell testing, battery design and battery testing. Like has extensive knowledge in all lithium-ion cell producers' production processes and builds on that expertise to select cells, test cells and audit cell suppliers for various applications to ensure safety and performance. He is a member of the UL Standards Technical Panel (UL 1642 and UL 2054) and part of a working group for IEEE1725, IEEE1625 and Telcordia Standard for Large Li Battery. Like holds a Ph.D. in Materials Science and Engineering, and conducted post-doctoral research in Li Polymer Battery technology.