

Mark Allen, PhD

Professor

University of Pennsylvania

mallen@seas.upenn.edu

Dr. Allen is a pioneer in the field of micro-electromechanical systems, or MEMS, and nanofabrication technology. His research allows the creation of structures, sensors and actuators that exploit the unique potential of the small scale. For example, such miniscule devices can sit at the intersection of the biological and the digital, sensing the physical and electrical signals found in the heart and in the brain and transmitting them to computers for processing.

Andrew Baumann, PhD

Mechanical Engineer

Food and Drug Administration (FDA)

Andrew.Baumann@fda.hhs.gov

Andy has a background in experimental and computational biomechanics. He enjoys investigating the structure-function relationships of biological tissues and how they interface with medical devices. At the FDA, Andy works with review teams to develop research that advances the mechanical performance evaluation of orthopaedic medical devices.

Stefano Bini, MD

Professor

University of California, San Francisco (UCSF) – Department of Orthopaedic Surgery

Stefano.Bini@ucsf.edu

Dr. Bini specializes in hip and knee replacement and is the Founder and Chair of the Digital Orthopaedics Conference, San Francisco (DOCSF). Current research interests include quantifying the impact of digital health on orthopedic care delivery, change management strategies in health care, and improving the results of total joint surgery.

Rickard Brånemark, MD MS PhD

Orthopaedic surgeon

University of California, San Francisco (UCSF)

Rickard.branemark@ucsf.edu

Rickard has been working in research, clinics and business development related to the field of percutaneous osseointegrated amputation prostheses for more than 25 years. He is currently involved in several IDE studies using implanted electrodes.

Seth D. Carmody, PhD

Cybersecurity Program Manager

Food and Drug Administration (FDA)

Seth.Carmody@fda.hhs.gov

Dr. Carmody is the Cybersecurity Program Manager for the Center for Devices and Radiological Health, serving as co-chair of CDRH's Cybersecurity Working Group. The Cybersecurity Working Group is an interdisciplinary team responsible for the FDA's final pre- and post-market cybersecurity guidances as well as incident response. Seth joined CDRH in 2011 as a medical device reviewer.

Joshua Chetta, PhD
Biomedical Engineer
Food and Drug Administration (FDA)
Joshua.Chetta@fda.hhs.gov

Josh Chetta is a biomedical engineer in the Clinical Trials Program in FDA's Office of Device Evaluation in CDRH. For the past year he has worked as part of an inter-office team developing processes and resources for staff to help CDRH implement the RWE Guidance Document.

Anton E. Dmitriev, PhD
Director, Division of Applied Mechanics
Office of Science and Engineering Laboratories (OSEL), CDRH, FDA
Anton.dmitriev@fda.hhs.gov

Dr. Dmitriev has nearly twenty years of experience working in the fields of applied orthopaedic and spinal research and regulation. Prior to joining the FDA, he served as Director of the Spine Research Center at the Walter Reed National Military Medical Center. Following his transition to the Agency in 2012, Dr. Dmitriev was branch chief for the Orthopaedic Joints and Anterior Spine Devices Branches. In 2014 he assumed his current role as Division Director in OSEL.

Lisa Ferrara, PhD
CEO
OrthoKinetic Technologies and OrthoKinetic Testing Technologies
lisa@orthokintech.com

Lisa has a background in spine, brain, and musculoskeletal biomechanics. Her dissertation work focused on the development of MEMs sensors for 'smart spinal implants' to measure fusion healing. She specializes in developing test strategies for the safety assessment of implants. She currently serves on multiple healthcare technical advisory boards, is a chairperson for NASS, ISASS, and serves on the Southeastern Regional Biotechnology Advisory Board for North Carolina.

Mark I Froimson, MD, MBA
Orthopedic Surgeon
Immediate Past President, American Association of Hip and Knee Surgeons
Principal, Riverside Health Advisors, LLC
mfroimson@riversideha.com

Mark has over 25 years of experience as an Orthopedic surgeon specializing in hip and knee replacement surgery. He has held significant health system executive leadership roles, including serving as hospital CEO within the Cleveland Clinic system and as Chief Clinical Officer for Trinity Health. He is an innovator and early adopter of APMs including Bundled Payments.

Vijay Goel, PhD
Distinguished University Professor and
McMaster-Gardner Endowed Professor in Orthopedic Bioengineering
Co-Director, Engineering Center for Orthopaedic Research Excellence (E-CORE)
Departments of Bioengineering and Orthopaedic Surgery
Colleges of Engineering and Medicine
University of Toledo

Vijay.Goel@utoledo.edu

Vijay is known worldwide for his pioneering research in the field of spinal disorders with multiple publications, peer-recognitions, and four life-time achievement awards. He is involved with the design and development of several spinal devices, a novel type Ca-P cement, a biosensor for detecting infection, and a procedure for nano-coating of the spinal implants.

Janice M. Hogan, JD

Partner

Hogan Lovells US LLP (Philadelphia)

Government Regulatory and FDA Medical Devices

Janice.hogan@hoganlovells.com

Janice Hogan has been involved in medical technology for over 25 years. From her engineering training at M.I.T. to work in the pharmaceutical industry, to her current practice representing medical device companies before the FDA, Janice has focused her career on the intersection of technology, regulation, and healthcare.

Joseph C. Kvedar, MD

Vice President, Connected Health

Partners HealthCare

Professor, Harvard Medical School

JKVEDAR@PARTNERS.ORG

Dr. Kvedar is creating a new model of healthcare delivery, moving care from the hospital or doctor's office into the day-to-day lives of patients. He has authored two books on the subject. At Partners Connected Health, he is leveraging technology to better manage chronic conditions, maintain health and wellness, and improve adherence, engagement and clinical outcomes.

Darren Lacey

CISO

Johns Hopkins University

dll@jhu.edu

Darren Lacey has been serving as Chief Information Security Officer and Director of IT Compliance for Johns Hopkins University and Johns Hopkins Medicine for the past fourteen years. He has been working in the technology sector, as a developer, attorney, consultant and executive for twenty-five years. He was the first Executive Director of the Johns Hopkins University Information Security Institute, a National Security Agency Center of Academic Excellence in Information Assurance. He is a graduate of Baylor and Harvard.

Jeffrey C Lotz, PhD

Professor and Vice Chair of Research

University of California, San Francisco (UCSF) – Department of Orthopaedic Surgery

jeffrey.lotz@ucsf.edu

Jeffrey C. Lotz, PhD, holds the David S. Bradford, MD, Endowed Chair in Orthopaedic Surgery and is vice chair for research. He has earned several awards for spine research, and serves as a deputy editor for the journal Spine. Dr. Lotz is the founding director of the UCSF Core Center for Musculoskeletal Biology in Medicine; the NSF-funded Center for Disruptive Musculoskeletal Innovations; and the NIDCR-funded Tissue Regeneration Resource Center, the

Center for Dental, Oral and Craniofacial Tissue and Organ Regeneration. He has expertise in spine biomechanics, intervertebral disc biology, and tissue engineering. His laboratory work focuses on identifying mechanisms of disc degeneration, developing novel diagnostics and therapies for low back pain, and the biomechanics of spinal instrumentation.

Michel Maharbiz, PhD
Professor
University of California – Berkeley
maharbiz@eecs.berkeley.edu

Dr. Maharbiz's research focuses on the extreme miniaturization of technology focused on building synthetic interfaces to cells and organisms. He is one of the inventors of "neural dust", an ultrasonic interface for vanishingly small implants in the body. His group is also known for developing the world's first remotely radio-controlled cyborg beetles. His long term goal is understanding developmental mechanisms as a way to engineer and fabricate machines.

Edward Margerrison, PhD
General Management
Food and Drug Administration (FDA)
Edward.margerrison@fda.hhs.gov

Ed is the Director of the Office of Science and Engineering Labs at FDA. Prior to joining the Agency in 2016, he worked in the orthopaedics industry for a number of multinational companies including Smith & Nephew and Zimmer Biomet. Most recently he was President and CEO of Ortho Regenerative Technologies, a biotech startup based in Montreal.

Colin O'Neill, MS
Biomedical Engineer
Food and Drug Administration (FDA)
colin.oneill@fda.hhs.gov

Colin is one of the co-organizers of this workshop. He has a background in orthopaedic biomechanics and mechanical testing. Colin joined CDRH over 9 years ago and has experience in both pre-market and post-market review of medical devices.

Michael Owens, MS
Biomedical Engineer
Food and Drug Administration (FDA)
MichaelC.Owens@fda.hhs.gov

Michael is one of the co-organizers of this workshop. He has a background in computational biomechanics and joint arthroplasty. Michael joined CDRH over 10 years ago and has experience in both pre-market and post-market review of medical devices.

Bakul Patel, MS MBA
Associate Director of Digital Health
Food and Drug Administration (FDA)
Bakul.Patel@fda.hhs.gov

Salwa Rafee, MS
WW Business Leader
Public Sector, IBM Security
srafee@us.ibm.com

Salwa is the Security Business Leader for Public Sector in IBM, managing its global business for Healthcare, Life Sciences, Government and Education. She has over 20 years of progressive leadership roles in Strategy Planning, eHealth Innovation, Security Services and Products, Consulting and Complex Program Management with a firm commitment to delivery excellence.

Linda Ricci
Biomedical Engineer
Food and Drug Administration (FDA)
Linda.Ricci@fda.hhs.gov

Linda began her career developing artificial intelligence solutions in the defense industry before moving to the medical device industry as a software engineer. She helped to develop several diagnostic cardiology devices and has participated in all phases of product life cycle development. Ms. Ricci moved to the FDA in 2005 and has had several roles including scientific reviewer and branch chief within the Division of Cardiovascular devices. Currently Ms. Ricci is the Associate Director for the Office of Device Evaluation focusing on Digital Health. In this role she, leads the development and implementation of digital health policy within the Office of Device Evaluation.

Shuvo Roy, PhD
Researcher / Professor
University of California, San Francisco (UCSF)
Shuvo.Roy@ucsf.edu

Dr. Shuvo Roy directs the Biodesign Laboratory at UCSF. He is also the Engineering Lead for Surgical Innovations, a joint initiative of the UCSF Departments of Surgery and Bioengineering & Therapeutic Sciences as well as founding member of the UCSF Pediatric Device Consortium, a FDA-funded program to accelerate the development of medical devices designed specifically for pediatric needs. His research focuses on the development of wearable and implantable medical devices using MEMS (Microelectromechanical Systems) and related nanotechnology strategies. He developed miniature sensors for wireless monitoring of orthopedic loads and evaluated biocompatibility of MEMS materials for medical applications.

Aenor Sawyer, MD, MS
Director, UCSF Skeletal Health Service and HITO (Health Innovation+Technology in Ortho)
Department of Orthopaedic Surgery, University of California, San Francisco (UCSF)
aenor.sawyer@ucsf.edu

Aenor is an Orthopedist at UCSF with over two decades of experience in health technology innovation in both device and digital health sectors. Across her career she has focused on assessing and optimizing functional abilities – as a Physical Therapist, an Exercise Physiologist and currently as an Orthopedist focused on Skeletal Health and Health Information Technology. Her innovation work is focused on developing methodologies to understand individualized function in real life settings. In an effort to support development of evidenced-based solutions she serves as Associate Editor of Nature's Digital Medicine Journal.

Constance Soves, PhD
Regulatory Advisor
Food and Drug Administration (FDA)
Constance.Soves@fda.hhs.gov

Connie is a biomedical engineer by training, with a background in orthopedic research. She began working at CDRH in 2011 as a premarket reviewer in the Division of Orthopedic Devices (DOD) prior to becoming a Regulatory Advisor in the Office of Device Evaluation. In her current position, she works closely with DOD on a variety of regulatory efforts.

Euan Thomson, PhD
Global Head R&D
Johnson & Johnson Medical Devices Companies
ethomso2@its.jnj.com

A medical physicist by training with over 30 years international healthcare experience, Euan leads the orthopaedics new product development teams. In addition, he is expanding the innovation focus of the business to deliver novel enabling technologies, personalized care and products and solutions that will deliver improved outcomes within our key disease focus areas.

Stephen Weber, M.D.
Orthopedic Surgeon
Food and Drug Administration (FDA)
Assistant Clinical Professor, Department of Orthopedics, the Johns Hopkins School of Medicine
Stephen.Weber@fda.hhs.gov
Stephen was a practicing Orthopedic Surgeon for 30 years, with a strong research interest in clinical problems in the shoulder, with multiple publications in open and arthroscopic shoulder surgery. At the FDA, he works in pre-market review of primarily orthopedic devices.

Beau Woods
Entrepreneur in Residence
Food and Drug Administration (FDA)
Gerald.woods@fda.hhs.gov
Beau has over a decade of work in cybersecurity, including defending hospital networks, performing device security research, consulting with device makers, and informing Congress. Beau is a Cyber Safety Innovation Fellow at the Atlantic Council, CEO of Stratigos Security, serves on the board of two non-profits, and has a Psychology degree from Georgia Tech.

Adolph J. Yates, Jr., MD
Orthopaedic Surgeon/Associate Professor
UPMC
yatesaj@upmc.edu
Dr. Yates earned his MD, and spent internship and residency at Johns Hopkins. He is an Associate Professor and the Vice Chairman for Quality Management within the UPMC Department of Orthopaedic Surgery. He is currently serving on the Surgical Committee for the National Quality Forum as well as CMS technical expert panels involving PhysicianCompare,

MACRA Measure Development, and MACRA Cost Measures. He previously served on the Device Panel for the FDA and MEDCAC.