



Wireless Test Beds

W O R K S H O P

03.31.2015
Washington, DC

This workshop is part of the ongoing FDA/FCC collaboration and leadership in promoting innovative, connected medical technologies, and is being organized by the Connect2HealthFCC Task Force, the FCC Office of Engineering and Technology, and the FDA Center for Devices and Radiological Health.



- During the workshop, we encourage you to tweet using #testbeds and #C2HFCC.
- Follow us on Facebook at www.facebook.com/fcc and www.facebook.com/fda.
- You may submit questions to the session participants via Twitter (#testbeds) or email (livequestions@fcc.gov).
- BYOL: Information about nearby restaurants is available at the registration table.
- Public Wi-Fi Access: The FCC provides wireless hotspot network service for FCC visitors to its headquarters facility. Use the following access key: FCC23771. The policies that govern public use of the network are available at the registration table.

Promoting Medical Technology Innovation — The Role of Wireless Medical Test Beds

A Joint FCC-FDA Workshop

“The Commission’s top priority must be to make networks work for everyone.”

Chairman Tom Wheeler, FCC

“We must ensure the safety and effectiveness of the medical products that Americans rely on every day, and also facilitate the scientific innovations that have the potential to save patients’ lives.”

Dr. Jeffrey Shuren, Director, CDRH, FDA

2015 Wireless Test Bed Workshop Planning Committee

Heather Agler (FDA); Ben Bartolome (FCC); Michele Ellison (FCC); Chris Gibbons (FCC); Roger Goldblatt (FCC); Katie Gorscak (FCC); Shannon Hyatt (FCC); Ira Keltz (FCC); Deborah Klein (FCC); Julius Knapp (FCC); Nina Miller (FCC); Karen Onyeije (FCC); Bakul Patel (FDA); Seth Seidman (FDA)

ABOUT THE WORKSHOP

The Federal Communications Commission (FCC) along with the Food and Drug Administration (FDA) are pleased to co-host this public workshop on the role of wireless test beds and their influence on the development of converged medical technology for clinical and non-clinical settings.

As the rapid pace of innovation blurs traditional boundaries between consumer health technology, medical devices, and communications, the agencies seek to better understand how wireless test beds can be used and configured to meet the challenges and to take advantage of the opportunities this convergence presents. The workshop will discuss the use of best practices in designing and implementing wireless health technologies that operate in crowded and interference-prone spectrum environments.

This joint workshop is another step in the ongoing FDA/FCC collaboration and leadership in promoting innovative medical technologies and is being organized by the Connect2Health^{FCC} Task Force, the FCC Office of Engineering and Technology, and the FDA Center for Devices and Radiological Health.



The Federal Communications Commission regulates interstate and international communications by radio, television, wire, satellite and cable in all 50 states, the District of Columbia and U.S. territories. An independent U.S. government agency overseen by Congress, the Commission is the United States' primary authority for communications law, regulation and technological innovation. The mission of the FCC Office of Engineering and Technology is to manage the spectrum and provide leadership to create new opportunities for competitive technologies and services for the American public. Learn more at www.fcc.gov.



The Food and Drug Administration, an agency within the U.S. Department of Health and Human Services, protects the public health by assuring the safety, effectiveness, and security of human and veterinary drugs, vaccines and other biological products for human use, and medical devices. The agency also is responsible for the safety and security of our nation's food supply, cosmetics, dietary supplements, products that give off electronic radiation, and for regulating tobacco products. The FDA's Center for Devices and Radiological Health (CDRH), in particular, assures that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. CDRH facilitates medical device innovation by advancing regulatory science, providing industry with predictable, consistent, transparent, and efficient regulatory pathways, and assuring consumer confidence in devices marketed in the U.S. Learn more at www.fda.gov.



Connect2Health^{FCC} (C2HFCC) is a senior-level, multi-disciplinary Task Force created by Chairman Tom Wheeler to move the needle on broadband and advanced health care technologies. Recognizing that technology innovations in clinical practice and care delivery are poised to fundamentally change the face of health care, the Task Force is charged with exploring the intersection of broadband, advanced technology, and health. C2HFCC is also working to further chart the broadband future of health and care – serving as an umbrella for all FCC health-oriented activities to help enable a healthier America. Learn more at www.fcc.gov/health.

WELCOME TO THE FCC

Dear Workshop Participants:

On behalf of the FCC Chairman and Commissioners, the Connect2Health^{FCC} Task Force, the FCC's Office of Engineering and Technology, and our friends at the Food and Drug Administration, I want to welcome you to the FCC. Today's workshop, *Promoting Medical Technology Innovation — The Role of Wireless Test Beds*, has its roots in longstanding efforts by many of you and many others in various corners of academia, industry, science and technology innovation, government, and clinical practice. Our theme: "Innovation, Coexistence and Safety" reflects the diverse and critical goals at stake, and we are delighted that you share our passion for making tangible progress toward solving these challenges for now and the future.



It almost goes without saying, that technology is transforming the way we live, work, and play, not to mention how we get and stay well. In fact, if you're a Star Trek fan, you've been waiting a long time for one announcement at SXSW this month, namely, that at last we may have a working medical tricorder. The prototype was designed to diagnose 15 different medical conditions and monitor vital signs for 72 hours. It reportedly also conducts lab tests for conditions like diabetes, pneumonia, tuberculosis, and more. And, it includes a lipstick-sized attachment that serves as an otoscope or spirometer. Like the intrepid Dr. McCoy (or "Bones" to true Trekkies), some of us may be skeptical or even wary, but the future is here and now. Even beyond futuristic inventions of Star Trek fame, on an almost daily basis, new wireless medical technologies are giving clinicians and consumers alike more (and often, better) tools for diagnosing illness and monitoring health.

However, to deliver on the true promise of health tech, wireless medical devices must work as intended. They must reliably, safely and securely transmit the data they collect. And, they must play well in the sandbox with each other. It sounds deceptively simple, but it isn't. Thankfully, the challenges ahead will be met and surmounted by visionaries and technologists who are more than up to the task. I salute all of you.

When the Chairman launched the Connect2Health^{FCC} Task Force, he painted a powerful, yet simple vision of making sure that networks work for everyone. And, that's what this workshop is about — ensuring seamless coexistence so that health innovation can flourish. As we say at Connect2Health^{FCC}, we must connect everyone, everywhere through broadband and advanced technologies to the people, services and information they need to get well and stay healthy. And, this workshop is a tangible step in that direction, taking the baton from the mHealth Task Force and also acting on the recommendations of the FCC's Consumer Advisory Committee.

I also want to salute our federal partners — the Food and Drug Administration and the Office of the National Coordinator for Health IT — for their laser focus on coexistence and interoperability issues. In 2010, the FCC and the FDA formally agreed to work proactively to serve the national interest in finding innovative solutions to America's health care challenges. The FDA's Center for Devices and Radiological Health, under the able leadership of Dr. Jeffrey Shuren and Dr. William Maisel, as well as the FCC's Office of Engineering and Technology through its Chief, Julius Knapp, have done much to deliver on that promise. I am proud to join with them today in taking another step forward.

Thank you for choosing to join the FCC and FDA in today's endeavor. We appreciate your support and anticipate your valuable contributions.

With warmest regards.

P. Michele Ellison
Deputy General Counsel, FCC; Chair, Connect2Health^{FCC} Task Force

WORKSHOP AGENDA

Welcome and Greetings

9:00 - 9:15am



FCC Chairman Tom Wheeler

FCC Commissioner Mignon Clyburn

Dr. William Maisel, Deputy Director, Center for Devices and Radiological Health, FDA

FCC and FDA Overview

9:15 - 9:30am

Overview of FCC and FDA Ongoing Collaborative Efforts and Interest in Wireless Test Beds for Converged Medical Devices



Julius Knapp, Chief, Office of Engineering and Technology, FCC

Bakul Patel, Associate Director for Digital Health, Center for Devices and Radiological Health, FDA

SESSION ONE

9:30 - 10:45am

Defining the Need for and Scope of Wireless Medical Device Test Beds



What issues and potential problems arise as medical devices go wireless? What are the potential implications of medical devices using unlicensed spectrum? Are there current programs examining wireless medical device coexistence in hospitals and other health care facilities? Are there different

needs for pre-deployment testing and post-installation monitoring? Are medical device test beds needed, and if so, why? What is the desired output or outcome of using wireless test beds? How do they help protect patient safety? Are there any challenges and/or limitations from using a test bed? Are new issues emerging that make the need for these test beds more or less important (e.g., hospital to home; broader consumer use outside medical facilities; mBANS, more connected devices/Medical IoT)?

Moderators:

H. Stephen Berger, President, TEM Consulting; Chair, ANSI ASC C63 Subcommittee 7 on Spectrum Etiquette; Chair, ANSI C63.27 Working Group on Wireless Coexistence Testing; Co-Chair, AAMI Medical Device Wireless Committee

Dr. Julian Goldman, Medical Director, Biomedical Engineering, Partners HealthCare System; Attending Anesthesiologist, Massachusetts General Hospital/Harvard Medical School; Director, Medical Device Interoperability Program; Co-Chair, AAMI Interoperability Working Group

Discussants:

Shawn M. Jackman, Director, Strategic Planning, Network Services, Kaiser Permanente

Kerry McDermott, Vice President, Public Policy and Communications, Center for Medical Interoperability; former Director of Healthcare, FCC

Phil Raymond, Wireless Architect, Philips Healthcare; Chair, Wi-Fi Alliance, Healthcare Marketing Task Group

Rick Tevis, Senior Director, Clinical Engineering, Geisinger Health System

Donald Witters, Biomedical Engineer, Center for Devices and Radiological Health, FDA

Break

10:45 - 11:00am



Tweet with the hashtags #TESTBEDS and #C2HFCC and continue the workshop dialogue online.

WORKSHOP AGENDA

SESSION TWO

11:00 - 12:00pm

Overview of Current Public and Private Wireless Medical Device Test Bed Programs and Initiatives



What are some of the current, most innovative public and private wireless medical device test bed programs today, and where are they housed (e.g., hospitals, non-hospital settings, homes, universities, etc.)? What components and characteristics comprise these test beds? Are there different types of medical device test beds (e.g., hardware, software, etc.)? Where do these devices operate in the radio frequency? Is there a central repository of test results/data that the medical community and other stakeholders can access? What types of medical devices and innovations are being tested? How are tests and simulations being conducted in these settings? What testing standards, if any, are being applied for current wireless medical device test beds? Who are the primary users of wireless medical device test beds (researchers, manufacturers, doctors, innovators, entrepreneurs) and what knowledge can be gleaned from them?

Moderators:

Dr. Wendy Nilsen, Health Science Administrator, National Institutes of Health; Program Director, National Science Foundation

Seth Seidman, Senior Electrical Engineer, Center for Devices and Radiological Health, FDA

Discussants:

Greg Bowden, Senior Reliability Engineer, Medtronic, Inc

Mick Conley, Development Manager Industry Programs, Underwriters Laboratories Inc.

Dr. Hazem Refai, Associate Professor, University of Oklahoma; Founder and Director of the Wireless Electromagnetic Compliance and Design Center

Michelle Jump, Principal Regulatory Affairs Specialist, Stryker Corporation

Dr. William Young, Senior Engineer, National Institute of Standards and Technology

Lunch Break

12:00 - 1:00pm

SPOTLIGHT

1:00 - 1:30pm

The Future of Healthcare and Medical Device Innovation



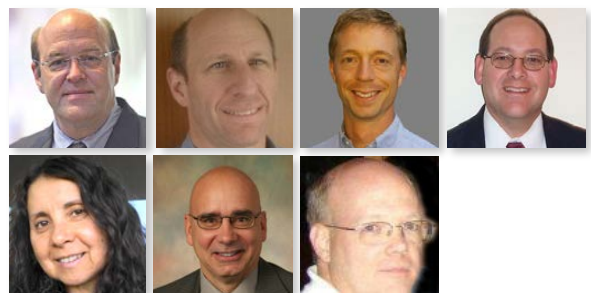
Featuring:

Dr. Harry Greenspun, Director, Center for Health Solutions, Deloitte Services LP

SESSION THREE

1:30 - 2:45pm

Identifying and Prioritizing Key Features, Functions and Gaps in Wireless Medical Device Test Beds



What would a wireless medical device test bed ideally look like? What can be done to enable more efficient testing? Are there gaps in the availability of test beds, test equipment, and/or test subjects? Are there gaps in standards for wireless medical devices that inhibit testing? What are the impacts of wireless test beds on patient care? Are the necessary features and functions, and any gaps in wireless medical test beds different for small versus

WORKSHOP AGENDA

large players? What should be the role of the federal government, and more specifically the FCC and FDA, in promoting these test beds? What, if any, changes should be made in the regulatory process to enable more efficient testing? How can the development of wireless medical device test beds be accelerated? What are the roles of medical device manufacturers, hospital IT departments, technology developers, and networking infrastructure providers?

Moderators:

Ed Cantwell, Chief Operating Officer, Center for Medical Interoperability

Ira Keltz, Deputy Chief, Office of Engineering and Technology, FCC

Discussants:

Dr. Steven Baker, Senior Principal Engineer, Welch Allyn

Rick Hampton, Wireless Communications Manager, Partners Healthcare System

Fanny Mlinarsky, President, octoScope, Inc.

Chris Riha, Senior Director, Technology Services Group, Carilion Clinic Health System

Ed Wyatt, Senior Systems Engineer, Ruckus Wireless, Inc.

What is the future of wireless health and connected health? As care moves from the clinical setting to the retail or home setting, how is coexistence affected? How are the coexistence issues similar or dissimilar between those settings? In light of the ongoing health care transformation, how can medical devices be future-proofed? What is next on the horizon for wireless test beds in clinical and non-clinical settings? How can relevant stakeholders develop a learning environment for wireless medical technologies so that information can be shared while balancing proprietary interests? What are some strategies to evaluate, catalog, and disseminate knowledge related to intelligent integration of medical devices into wireless systems in various settings. Are there other models (beyond or in conjunction with) wireless test beds to consider?

Moderators:

Dale Hatfield, Senior Fellow, Silicon Flatirons Center for Law, Technology and Entrepreneurship, University of Colorado at Boulder; former Chief, Office of Engineering and Technology, FCC

Robert Havasy, Vice President, Personal Connected Health Alliance; Executive Director, Continua

Discussants:

Surjit Ahluwalia, Director, Advanced Services, Cisco Systems

Dipankar (Dipu) Ganguly, Chief Executive Officer, AkibaH, Inc.

Scott Gresbach, Program Leader, GE Healthcare Global Services

Robert Jarrin, Senior Director, Government Affairs, Qualcomm Inc.

Jeffrey Tri, Section Head, Information Technology, Mayo Foundation for Education and Research

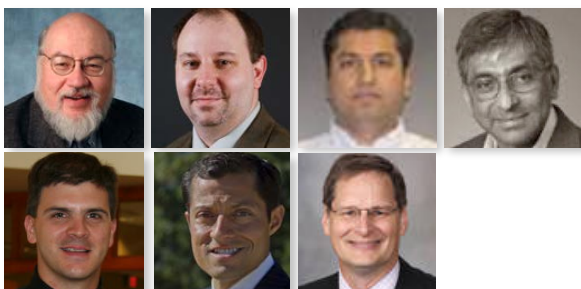
Break

2:45 - 3:00pm

SESSION FOUR

3:00 - 4:15pm

Driving Innovation and Safe Coexistence of Wireless Medical Devices



Closing

4:15 - 4:30pm

FEATURED SPEAKERS



Chairman Tom Wheeler
Federal Communications Commission

Tom Wheeler became the 31st Chairman of the Federal Communications Commission (FCC) on November 4, 2013. Chairman Wheeler was appointed by President Barack Obama and unanimously confirmed by the United States Senate.

For over three decades, Chairman Wheeler has been involved with new telecommunications networks and services, experiencing the revolution in telecommunications as a policy expert, an advocate, and a businessman. As an entrepreneur, he started or helped start multiple companies offering innovative cable, wireless, and video communications services. He is the only person to be selected to both the Cable Television Hall of Fame and The Wireless Hall of Fame, a fact President Obama joked made him “The Bo Jackson of Telecom.”

Prior to joining the FCC, Chairman Wheeler was Managing Director at Core Capital Partners, a venture capital firm investing in early stage Internet Protocol (IP)-based companies. He served as President and CEO of Shiloh Group, LLC, a strategy development and private investment company specializing in telecommunications services and co-founded SmartBrief, the internet’s largest electronic information service for vertical markets. From 1976 to 1984, Chairman Wheeler was associated with the National Cable Television Association (NCTA), where he was President and CEO from 1979 to 1984. Following NCTA, Chairman Wheeler was CEO of several high tech companies, including the first company to offer high speed delivery of data to home computers and the first digital video satellite service. From 1992 to 2004, Chairman Wheeler served as President and CEO of the Cellular Telecommunications & Internet Association (CTIA).

Chairman Wheeler wrote *Take Command: Leadership Lessons of the Civil War* (Doubleday, 2000) and *Mr. Lincoln's T-Mails: The Untold Story of How Abraham Lincoln Used the Telegraph to Win the Civil War* (HarperCollins, 2006). His commentaries on current events have been published in the Washington Post, USA Today, Los Angeles Times, Newsday, and other leading publications. Presidents Clinton and Bush each appointed Chairman Wheeler a Trustee of the John F. Kennedy Center for the Performing Arts, where he served for 12 years. He is also the former Chairman and President of the Foundation for the National Archives, the non-profit organization dedicated to telling the American Story through its documents, and a former board member of the Public Broadcasting Service (PBS).

Chairman Wheeler is a proud graduate of The Ohio State University and the recipient of its Alumni Medal. He resides in Washington, D.C.

FEATURED SPEAKERS



Commissioner Mignon Clyburn
Federal Communications Commission

Mignon L. Clyburn served as Acting Chairwoman of the Federal Communications Commission, following her appointment by President Barack Obama on May 20, 2013. As Commissioner, she is serving a second term as a Democrat on the Commission, for which she was sworn in on February 19, 2013 following her re-nomination by the President and confirmation by the United States Senate.

Clyburn began her service at the FCC in August, 2009, after spending 11 years as a member of the sixth district on the Public Service Commission (PSC) of South Carolina. She served as its chair from July 2002 through June 2004.

Prior to her service on the PSC, Clyburn was the publisher and general manager of The Coastal Times, a Charleston-based weekly newspaper that focused primarily on issues affecting the African American community. She co-owned and operated the family-founded newspaper for 14 years.

A longtime champion of consumers and a defender of the public interest, Commissioner Clyburn considers every Commission proceeding with an eye toward how it will affect each and every American. She is a strong advocate for enhanced accessibility in communications for disabled citizens, and works closely with representative groups for the deaf and hard of hearing. She has fought to promote strong competition across all communications platforms, believing that the more robust and competitive the marketplace, the less need there is for regulation.

However, when the market is not adequately addressing consumer concerns, Clyburn is an outspoken champion for smart, targeted regulatory action. She has pushed for media ownership rules that reflect the demographics of America, affordable universal telephone and high-speed internet access, greater broadband deployment and adoption throughout the nation, and transparency in regulation. Commissioner Clyburn is a member of the Federal-State Joint Board on Universal Service, Federal-State Joint Board on Separations, and the Federal-State Joint Conference on Advanced Services, all of which she chaired for three years during her first term at the FCC.

Clyburn is a graduate of the University of South Carolina, and holds a Bachelor of Science degree in Banking, Finance and Economics.

FEATURED SPEAKERS



William H. Maisel, MD, MPH

Chief Scientist and Deputy Center Director for Science, Center for Devices and Radiological Health
Food and Drug Administration

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 with more than 15 years of clinical experience as a Board-certified cardiologist.

He is former Chair of the FDA Circulatory System Medical Device Advisory Committee 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.



Harry Greenspun, MD

Director of the Deloitte Center for Health Solutions

Harry Greenspun, M.D., is the Director of the Deloitte Center for Health Solutions (DCHS), part of Deloitte LLP. He has held a diverse range of clinical and executive roles, and is now responsible for helping Deloitte's health care, life sciences, and government clients address key health information technology (IT) and clinical transformation issues. Prior to joining Deloitte, he served as Chief Medical Officer for Dell Inc.,

after serving as Chief Medical Officer for Northrop Grumman Corporation. Distinguished co-author of "Reengineering Health Care: A Manifesto for Radically Rethinking Health Care Delivery," Dr. Greenspun is recognized as a leader in the health care industry and has been named one of the "50 Most Influential Physician Executives in Healthcare" by Modern Healthcare. He serves on the World Economic Forum's Global Agenda Council on Digital Health, WellPoint External Advisory Council on Health Inequities, and the advisory boards for Georgetown University, the Global Medical Microtechnology Association (GMMA), and Wireless-Life Sciences Alliance (WSLA). He has served on advisory boards for the Healthcare Information and Management Systems Society (HIMSS), Tufts University, George Mason University, and Bloomberg/BNA.

As the Chairman of the HIMSS Government Relations Roundtable and as co-chair of the HIMSS task force responsible for creating the white paper entitled, "Enabling Healthcare Reform Using Information Technology," Dr. Greenspun has made recommendations to the Obama Administration and U.S. Congress on the importance of health care IT investment to the nation.

Dr. Greenspun received his bachelor's degree from Harvard University, his medical degree from the University of Maryland, and completed his residency and fellowship at the Johns Hopkins University Hospital in Anesthesiology and Critical Care Medicine, serving as chief resident. As a cardiac anesthesiologist, he has practiced in major academic medical centers, as well as community hospitals.

FEATURED SPEAKERS



Bakul Patel

Associate Director for Digital Health, Center for Devices and Radiological Health
Food and Drug Administration

Bakul Patel is Associate Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel leads regulatory policy and scientific efforts at the Center in areas related to emerging and converging areas of medical devices, wireless and information technology. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software.

Mr. Patel is the FDA liaison between the Federal Communications Commission (FCC) and the Office of the National Coordinator (ONC). Since its inception in 2013, Mr. Patel chairs the International Medical Device Regulators Forum (IMDRF) “software as a medical device” working group, a global harmonization effort.

Before joining FDA, Mr. Patel held key leadership positions working in the 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.



Julius Knapp

Chief, Office of Engineering and Technology, Federal Communications Commission

Julius Knapp is Chief of the FCC’s Office of Engineering and Technology (OET). OET is the Commission’s primary resource for engineering expertise and provides technical support to the Chairman, Commissioners and FCC Bureaus and Offices.

Mr. Knapp has been with the FCC for more than 40 years. He became Chief of OET in 2006. Mr. Knapp previously served as a Deputy Chief of OET from 2002 - 2006. Prior to that he was the Chief of the Policy & Rules Division where he was responsible for FCC frequency allocation proceedings and for proceedings amending the FCC rules for unlicensed radio frequency devices. Mr. Knapp was Chief of the FCC Laboratory from 1994 – 1997 where he was responsible for the FCC’s equipment authorization program and technical analyses.

Mr. Knapp received a Bachelor’s degree in electrical engineering from the City College of New York in 1974. He has received the FCC’s Silver and Gold medal awards for distinguished service at the Commission. He was the 2001 recipient of the Eugene C. Bowler award for exceptional professionalism and dedication to public service and was the 2010 recipient of the Federal Communications Bar Association Excellence in Government Service Award. He was also the recipient of the WCAI 2010 Government Leadership award and 2014 National Spectrum Management Association Fellow Award. In 2013 he received the Presidential Distinguished Rank Award for exceptional achievement in the career Senior Executive Service of the United States of America.

BIOGRAPHIES

SESSION ONE



H. Stephen Berger
TEM Consulting, Georgetown TX

Stephen Berger has 30 years of experience in standards development, product compliance, and technology development. He was the founder and first chairman of the IEEE Standards Coordinating Committee 41, Dynamic Spectrum Access Networks; served as president of iNARTE (International Association of Radio and Telecommunications Engineers); and is a lab assessor for ANAB. He currently chairs the ANSI C63.27 working group on wireless test methods and the AAMI SM-WG6 working group on wireless coexistence evaluation of medical devices.

Prior to becoming President of TEM Consulting, Mr. Berger worked with Siemens Information and Communications Mobile, the Thomas-Conrad Corporation, the Electro-Mechanics Company (EMCO) and Datapoint Corporation in various engineering, management and project management capacities. Mr. Berger holds a B.S. in Physics from the University of Wisconsin and has been awarded a number of patents relative to wireless communication and networking.



Dr. Julian Goldman
Medical Director, Biomedical Engineering, Partners HealthCare; Attending Anesthesiologist, Massachusetts General Hospital, Boston MA

Dr. Julian Goldman is Medical Director of Biomedical Engineering for Partners HealthCare System, a practicing anesthesiologist at the Massachusetts General Hospital, and Director of the Program on Medical Device Interoperability at MGH and CIMIT (Center for Integration of Medicine and Innovative Technology). Dr. Goldman founded the federally funded, multi-institutional Medical Device "Plug-and-Play" (MD PnP) Interoperability research program in 2004 to promote innovation in patient safety and clinical care by leading the adoption of patient-centric integrated clinical environments.

Dr. Goldman completed anesthesiology residency and fellowship training at the University of Colorado. He departed Colorado in 1998 as a tenured associate professor to work as an executive of a medical device company. Dr. Goldman joined Harvard Medical School and the Department of Anesthesia, Critical Care, and Pain Medicine at the Massachusetts General Hospital in 2002 as a staff anesthesiologist, where he served as a principle anesthesiologist in the MGH "Operating Room of the Future." Dr. Goldman co-chaired the FCC mHealth Task Force, the HIT Policy Committee FDASIA Workgroup regulatory subgroup, and the FCC Consumer Advisory Committee healthcare working group. He currently serves in leadership positions in several medical device standardization organizations.

Shawn Jackman

Director, Strategic Planning, Network Services
Kaiser Permanente, Walnut Creek CA



Shawn Jackman is responsible for network design standards and establishes new product offerings for Kaiser Permanente. In his tenure at Kaiser Permanente, he has established the wireless test bed for Kaiser Permanente that certifies infrastructure and devices for safe and effective production use for all wireless deployments. Mr. Jackman is also co-chair of the AAMI Wireless Strategy Task Force; Lead author for the CWDP, Certified Wireless Design Professional official study guide; co-author of CWSP Certified Wireless Security Professional official study guide; co-author of mHIMSS Roadmap; and is a Certified Wireless Network Expert #54.

Kerry McDermott, MPH

Vice President, Public Policy and Communications,
Center for Medical Interoperability, Washington DC



Kerry McDermott is Vice President of Public Policy and Communications for the Center for Medical Interoperability. The Center is a 501(c)(3) member organization led by hospitals and health systems, and is committed to leveraging the market presence and expertise of its members to demand plug-and-play interoperability of medical technologies and improve the safety, quality and affordability of health care. Prior to joining the Center, Ms. McDermott was Senior Director, Healthcare Technology Policy for West Health. Previously, she was Director of Healthcare for the FCC, where she focused on advancing wireless health technologies and expanding broadband connectivity for healthcare providers. She co-authored the healthcare section of the National Broadband Plan, advised the White House Health IT Task Force, and served as the FCC's liaison on healthcare issues. She has testified before Congress on rural health challenges and participated in World Economic Forum mobile health initiatives. She holds a Masters Degree in Public Health from Yale University

Phil Raymond

Wireless Architect, Philips Healthcare, Andover MA



Phil Raymond is the Wireless Architect and Senior Global Network Product Manager in Philips Healthcare Connected Care Solutions business unit and currently serves as the Chair of the Wi-Fi Alliance Healthcare Marketing Task Group and Co-Chair of the AAMI Wireless Strategy Task Force. Mr. Raymond continues his involvement in the connectivity standards development space including IEC/ISO 80001-1 and served as the Co-Chair for the IEC/ISO 80001-2-3 Wireless Guidance Technical Report team. Mr. Raymond is a global speaker regarding wireless connectivity best practices focused in the healthcare space.

BIOGRAPHIES



Richard Tevis

Senior Director, Clinical Engineering, Geisinger Health System, Scranton PA

Richard ("Rick") Tevis, Senior Director of Clinical Engineering, is part of the one-hundred plus member team providing Clinical Engineering and Technology Management for the Geisinger Health System. Mr.

Tevis has over 35 years in the Clinical Engineering field which includes experience with in-house, vendor, R&D, and ISO programs. He is a certified clinical engineer with a background in Physics/Electrical Engineering, and is an active member of AAMI, ACCE, and HIMSS. He is responsible for regulatory compliance, fiscal management, and the delivery of best-in-class service to help provide the best patient care possible using the appropriate technology in the most cost efficient manner. As part of the technology management process, Mr. Tevis and his IT counterparts have developed an outstanding CE/IT relationship and have partnered to provide all aspects of device integration which include wireless medical device applications.



Donald Witters

Biomedical Engineer, Center for Devices and Radiological Health, FDA, Silver Spring MD

Donald ("Don") Witters is a senior Biomedical Engineer/Regulatory Review Scientist in the Office of Science and Engineering Laboratories, CDRH. He has over 30 years of experience in the areas of medical

devices electromagnetic compatibility (EMC) and wireless technology, and microwave calibration. He also performs laboratory research, publishes technical papers, and is an FDA technical expert liaison for national and international standards dealing with EMC of active medical devices such as implantable neurostimulators and pacemakers, powered wheelchairs, and hearing aids. Mr. Witters is the primary author of the FDA Guidance for RF Wireless Medical Devices, and chairs the CDRH EMC and wireless work group. He is also co-chair of the AAMI work group SM/WG-06 on Wireless Medical Device Coexistence.

SESSION TWO



Dr. Wendy Nilsen

Health Science Administrator, National Institutes of Health; Program Director, National Science Foundation, Washington DC

Wendy Nilsen, Ph.D., is a Program Director for the Smart and Connected Health program at the National Science Foundation. Her work focuses on the

intersection of technology and health. This includes a wide range of methods for data collection, data analytics and turning data to knowledge. More specifically, her efforts in mobile and wireless health (mHealth) research include: serving as the lead for the NSF/NIH Smart and Connected Health announcement, convening meetings to address methodology in mobile technology research; serving on numerous federal technology initiatives; and leading training institutes. Dr. Nilsen is also a Health Scientist Administrator at the NIH Office of Behavioral and Social Sciences Research (OBSSR).



Seth Seidman

Senior Electrical Engineer, Center for Devices and Radiological Health, FDA, Silver Spring MD

Seth Seidman is a Senior Electrical Engineer with over 10 years experience at the FDA. He performs regulatory reviews, research, and has authored papers in the areas of medical device EMC and wireless coexistence. He is a U.S. representative to International Standards Organization (ISO) and International Electrotechnical Commission (IEC) Joint Technical Committee 1, Subcommittee 31 on automatic identification and data capture techniques; an FDA representative to the Association for Automatic Identification and Mobility (AIM); Co-chairman to the Association for the Advancement of Medical Instrumentation (AAMI) EMC Committee for Pacemakers and ICDs; and Vice Chair to the American National Standards Institute (ANSI) C63 Subcommittee 7 on Spectrum Etiquette. He earned both his bachelors and masters degrees in electrical engineering from the University of Maryland.



Gregory Bowden

Senior Reliability Engineer, Medtronic, Inc., Northridge CA

Gregory ("Greg") Bowden has been employed in the medical device industry for 20 years and is currently a Senior Reliability Engineer at Medtronic Diabetes in Northridge, California. His primary duties include: planning and executing product validation and verification testing; root cause analysis and corrective action implementation; cross-functional team member for risk management; and EMC testing.



Mick Conley

Development Manager Industry Programs, Underwriters Laboratories Inc., Fremont CA

Mick Conley is an industry expert on certification and interoperability testing programs for wireless technologies. As Development Manager Industry Program for UL, he is responsible for establishing certification and interoperability programs deploying wireless technologies. Prior to UL, he was the Executive Director Technical Operations for the Wi-Fi Alliance (WFA). He is a member of Wi-Fi Alliance, Thread Group, NFC Forum, Wireless Broadband Alliance, OIC and multiple Connected Car, IoT and Wearable study groups. He holds multiple leadership positions with many of these groups.

BIOGRAPHIES



Michelle Jump

Principal Regulatory Affairs Specialist, Stryker Corporation, Kalamazoo MI

Michelle Jump has worked in various aspects of regulated industry for over 15 years. She holds a Master of Science in Regulatory Science from the University of Southern California, and a Master of

Science in Biotechnology from California State University. She is also RAC certified. Her current role is in Regulatory Affairs at Stryker Corporation, specializing in software and connected devices. She participates in a variety of standard development work, including such topics as interoperability, software, wireless, cybersecurity, and software quality. As a member of the AAMI SM-WG 06 group, she has been actively involved in the development of a new Technical Information Report on Wireless Coexistence. At Stryker, she chairs corporate working groups in both interoperability and software, as well as consults with teams in regulatory strategy for software and emerging technology.



Dr. Hazem Refai

Associate Professor, University of Oklahoma; Founder and Director of the Wireless Electromagnetic Compliance and Design Center, Tulsa OK

Dr. Hazem Refai is the Williams Professor for Telecommunication and Networking at the University of Oklahoma (OU) school of Electrical and Computer Engineering (ECE) Telecommunication Program in Tulsa, Oklahoma. He is founder and director of the Wireless Electromagnetic Compliance And Design (WECAD) Center at OU-Tulsa. WECAD's mission is to conduct basic and applied research examining medical device coexistence with various RF wireless systems and technologies, as well as validating electronic and electromagnetic compatibility. Dr. Refai has published more than 160 referred papers for national and international conferences and Journal articles. His fields of interest include the development of physical and medium access control layers to enhance wireless coexistence, the characterization of hospital RF environment for medical electronics, and cognitive radios and networks. He is past IEEE ComSoc Tulsa Chapter President and served as the organization's North American Distinguished Lecturer Tour Coordinator.



Dr. William Young

Senior Engineer, National Institute of Standards and Technology, Boulder CO

Dr. William Young's fifteen years of experience in wireless communication systems includes diversity antenna design, radio frequency (RF) propagation measurements, multiple-input, multiple-output (MIMO) system applications, electromagnetic interference testing, and wireless network security analysis. He has developed RF laboratory measurement techniques adopted in the 2013 revision of the National Fire Protection Association 1982 standard. He is currently involved with the ANSI C63.27 project, which is focused on wireless coexistence test methodologies. Dr. Young holds a M.S. from Washington State University, and a Ph.D. from the University of Colorado, both in electrical engineering. From 1998 to 2010 he was with Sandia National Laboratories, and joined the NIST technical staff in 2010. He has co-

authored over thirty-five technical reports, conference papers, and journal articles covering aspects of wireless systems, electromagnetic propagation and MIMO technology. His recent efforts are focused on spectrum sharing in the new NIST Communications Technology Laboratory.

SESSION THREE

Ed Cantwell

Chief Operating Officer, Center for Medical Interoperability, Nashville TN



Ed Cantwell is chief operating officer of the Center, providing membership recruitment and strategic and tactical leadership. He was previously lead of the medical grade wireless utility at the West Health Institute. Before joining the Institute, he served as director of 3M Corporation's Wireless Business Unit and as chairman, president, and chief executive officer of InnerWireless, which he founded in 2000. His wireless experience began while working for Texas Instruments, where he led a number of high technology businesses and successfully obtained spectrum allocations from the FCC. This started as an incubator project then became SpectraPoint Wireless, where he was president and CEO. Before founding SpectraPoint, he held several positions within Texas Instrument's Defense Systems and Electronics Group, where he helped to develop a variety of communications systems. He also served as an Air Force fighter pilot for 12 years. Mr. Cantwell graduated from the University of Michigan's executive training program and is a graduate of the Air Force's fighter weapons school. He holds a B.S. in Mechanical Engineering from Duke University.

Ira Keltz

Deputy Chief, Office of Engineering and Technology, FCC, Washington DC



Ira Keltz is Deputy Chief of the FCC's Office of Engineering and Technology (OET). In this role, he assists in managing several divisions of engineers, attorneys and economists in the development of telecommunications policies for spectrum use in the United States. Mr. Keltz is responsible for balancing complex engineering, policy, economic and public interest issues to implement national spectrum policy. This includes allocating spectrum for licensed services, setting technical rules for unlicensed devices, and implementing procedures for equipment certification. Mr. Keltz previously served as Chief of OET's Electrical Compatibility Division and Deputy Chief of its Policy and Rules Division. In addition, he has been a Senior Technical Advisor in the Wireless Bureau's Public Safety and Private Wireless Division. Mr. Keltz has been with the FCC since 1994. Prior to the FCC, Mr. Keltz held positions with Loral Advanced Projects and LSA, Inc. Mr. Keltz holds a Masters Degree in Electrical Engineering from the George Washington University, and a Bachelors Degree in Electrical Engineering from the University of Michigan.

BIOGRAPHIES



Dr. Steven Baker

Senior Principal Engineer, Welch Allyn, Beaverton OR
Steven Baker is a Sr. Principal Engineer at Welch Allyn, where he developed and deployed the first enterprise-wide, standards-based patient telemetry solution. His work in 802.11 medical-grade wireless networks has continued for sixteen years, allowing him to contribute

to CEN/ISO IEEE 11073, 80001-1:2010, and co-author the 80001-2-3 Wireless Guidance TR. He serves on the AAMI Horizons editorial board, the AAMI Wireless Strategy Task Force, and is a senior member of the IEEE. He graduated magna cum laude from Utah State University and earned a Ph.D. in electrical engineering from Cornell University.



Rick Hampton

Wireless Communications Manager, Partners Healthcare System, Boston MA

Rick Hampton is the Wireless Communications Manager for Partners HealthCare System, Inc., Boston, MA. He is responsible for the overall coordination of activities relating to the safe, effective

and secure use of all wireless communications technologies at Partners HealthCare and its affiliates. This includes selecting and designing state-of-the-art systems, educating staff on wireless technologies, resolving electromagnetic compatibility, interference and health issues, addressing cybersecurity issues and developing policies and procedures. He also works with patient safety, industry and regulatory bodies to develop responses to these issues and is heavily involved in safety and risk management standards for wireless medical devices. Mr. Hampton has a B.S. in Biomedical Engineering from Wright State University. His healthcare experience includes fifteen years as a paramedic and nearly 30 years as a clinical engineer in large healthcare companies. His wireless background includes over 40 years working with military, commercial, amateur, consumer and medical systems.



Fanny Mlinarsky

President, octoScope, Inc., Littleton MA

Fanny Mlinarsky is President of octoScope, a wireless test platform manufacturer. Her background includes hands-on product development and R&D management. Prior to octoScope, Ms. Mlinarsky was Founder and CTO of Azimuth Systems, a wireless test equipment vendor. She has been an active contributor

to the wireless standards being developed at 802.11 and 3GPP. She also has published numerous articles, white papers and test reports on wireless technologies and standards and has delivered presentations and online webinars.

Chris Riha

Senior Director, Technology Services Group, Carilion Clinic Health System, Roanoke VA

Chris Riha has been in the medical technology workforce for over 30 years. He is currently a Senior Director in the Technology Services Group for the Carilion Clinic Health System in Roanoke, Virginia.

Along his career path, Chris has been affiliated with or provided consulting services to the following organizations: U.S. Army Medical Department, West Health Institute, American College of Radiology, BJC Health System, and the World Health Organization. Mr. Riha is a certified Clinical Engineer, Health Information Management Professional, Project Management Professional and Certified Health Information Technology Specialist, with a physics based undergraduate degree, and MS Degree in Health Sciences.



Ed Wyatt

Senior Systems Engineer, Ruckus Wireless, Inc., Sunnyvale CA

Ed Wyatt — after spending 2 years as a contracted technical sale rep for BreezeCOM — was hired in 1999 as the first field engineer for North America working on in-building wireless networks before the Wi-Fi standard was ratified. He spent the next several years training resellers and Wireless ISPs on the complexities of wireless broadband in a Point to Multipoint configuration. He spent the next 5 years as a product manager working with Alvarion in their WiMAX licensed portfolio deploying fixed and mobile networks throughout north America and the Caribbean. For the last 4 years he has been working with Wi-Fi again, this time for Ruckus Wireless as the technical lead for the Mobile Network Operator team in North America.



SESSION FOUR

Dale Hatfield

Senior Fellow, Silicon Flatirons Center for Law, Technology and Entrepreneurship, University of Colorado at Boulder; former Chief, Office of Engineering and Technology, FCC, Boulder CO

Dale N. Hatfield is currently a Senior Fellow at the Silicon Flatirons Center for Law, Technology, and Entrepreneurship and an Adjunct Professor in the Interdisciplinary Telecommunications Program – both at the University of Colorado at Boulder. Prior to joining the University of Colorado, he was the Chief of the Office of Engineering and Technology at the FCC and, immediately before that, he was Chief Technologist at the same Agency. He retired from the FCC and government service in December 2000. Before joining the FCC in December 1997, he was CEO of Hatfield Associates, Inc. Before founding the consulting firm in 1982, he was Acting Assistant Secretary of Commerce for Communications and Information, and Acting Administrator of the National Telecommunications and Information Administration (NTIA). Before moving to NTIA, Mr. Hatfield was Chief of the Office of Plans and Policy at the FCC.



BIOGRAPHIES

Mr. Hatfield has over fifty years of experience in telecommunications policy and regulation, spectrum management and related areas. He holds a BS in electrical engineering from Case Institute of Technology and an MS in Industrial Management from Purdue University. In May 2008, he was awarded an Honorary Doctor of Science degree by the University of Colorado for, inter alia, his commitment to the development of interdisciplinary telecommunications studies. Until recently, he was the Executive Director of the Broadband Internet Technical Advisory Group (BITAG). He is currently serving on the FCC's Technology Advisory Council (TAC) and on the Commerce Department's Spectrum Management Advisory Committee (CSMAC) and has served as an independent Director of Crown Castle International Corp. since July 2001.



Robert Havasy

Vice President, Personal Connected Health Alliance; Executive Dir., Continua, Arlington VA

Robert Havasy is a Vice President at the Personal Connected Health Alliance (PCHA) and the Executive Director of Continua. The PCHA is a first-of-its-kind collaboration between Continua, mHealth Summit, and HIMSS, focused on engaging consumers with their

health via personalized health solutions designed for user-friendly connectivity (interoperability) that meet their lifestyle needs. Prior to joining the PCHA, he was the Corporate Team Lead for Product and Technology Development at the Center for Connected Health (CCH), part of the Partners HealthCare System in Boston, Massachusetts. At CCH, he led the team that integrated the Center's remote patient monitoring technology with Partners' enterprise clinical systems. Mr. Havasy holds a B.S. in Environmental Science from Keene State College, and an M.S. in Health and Medical Informatics from Brandeis University. An electronics and computer enthusiast, Mr. Havasy also holds a General Class Amateur Radio Service license and a General Mobile Radio Service license.



Surjit Ahluwalia

Director, Advanced Services, Cisco Systems, San Jose CA

Surjit Ahluwalia leads the Global IOE Healthcare Solutions and Services Practice organization within the Advanced Services organization in Cisco. The focus of the organization includes architectures and solutions-based services for Connected Health offerings; specifically security, mobility, datacenter and collaboration. The service offerings cover planning, building and managing spectrum, including assessment, implementation, and optimization services. Mr. Ahluwalia has been with Cisco for 8 years and has spent 15 years working at Intel in a variety of operations and engineering leadership roles. He also has CISM (Certified Information Security Manager) and CRISC certifications from ISACA.



Dipankar (Dipu) Ganguly

Chief Executive Officer, AkibaH, Inc., San Jose CA

Dipankar ("Dipu") Ganguly is a serial entrepreneur with more than 25 years experience developing industry-first Class I/II/III medical products. He is also CEO or CTO of several early stage medical device companies.

He was the original inventor/developer of BladderScan that has become the standard of care of bladder management. Mr. Ganguly has nine issued patents and multiple graduate degrees in Physics at the University of Wisconsin, and in Electrical Engineering and Biomedical Engineering at the University of Southern California.

Scott Gresbach

Program Leader, GE Healthcare Global Services, Milwaukee WI



Scott Gresbach is a Program Leader at GE Healthcare, Milwaukee, Wisconsin, for the Global Service Organization. He leads the development of new product and service offerings at GE Healthcare. For the past 17 years, he has worked in various roles at GE Healthcare related to system integration and project management. Prior to joining GE Healthcare, he worked 8 years in Design Engineering at Criticare Systems, in Waukesha, Wisconsin, developing medical devices. Mr. Gresbach has a Masters degree in Networking and Communication from Keller Graduate School of Management of DeVry University, and recently achieved the PMP certification at the Project Management Institute.

Robert Jarrin

Senior Director, Government Affairs, Qualcomm Inc., Washington DC



Robert Jarrin is a Senior Director of Government Affairs for Qualcomm Incorporated. He represents Qualcomm on U.S. regulatory matters relating to wireless health and life sciences. His areas of responsibility include Food and Drug Administration regulation of converged medical devices, Federal Communications Commission healthcare efforts, Centers for Medicare and Medicaid Services telehealth reimbursement, Office of the National Coordinator regulation of health IT and healthcare legislative affairs. Mr. Jarrin holds a B.A. in Government and Politics from the University of Maryland at College Park, and a Juris Doctor degree from Northeastern University School of Law

Jeffrey Tri

Section Head, Information Technology, Mayo Foundation for Education and Research, Rochester MN



Jeffrey ("Jeff") Tri completed his undergraduate Electrical Engineering degree from North Dakota State University, and his Master's Degree in Electrical Engineering from the University of Minnesota. He has worked for Mayo Clinic for 28 years in multiple capacities. He has authored 7 papers, many regarding Electromagnetic Interference of cellular telephones and medical devices. He has designed and coordinated the installation of internal antenna and DAS systems for several Mayo facilities. He coordinates all Mayo FCC licensing. He has been involved with the management of wireless frequencies, RF policies and the investigation of suspected RF interference at Mayo Clinic for 27 years. Mr. Tri currently manages the teams responsible for Mayo Clinic's Enterprise Data Network supporting over 250,000 network ports.

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