Panelist Biographies

Panel 1: Pilot Participants

David Armor

VP Quality & Regulatory Affairs
Pear Therapeutics

David Amor is the VP of Quality and Regulatory Affairs at Pear Therapeutics in San Francisco, CA where he manages quality assurance and regulatory groups focused on clinically validated, prescription digital therapeutics. Previously a biotech quality and regulatory consultant to over 40+ companies, David recently led quality management within Teva's digital health group and co-founded RemindTrac, a mobile health startup in the care management space. David is a Fellow Emeritus of the University of Minnesota's Medical Device Center, served as an adjunct professor at St. Cloud State University in the graduate quality/ regulatory program, and actively serves on several AAMI and other industry working groups.

Alex Bisignano

CEO
Phosphorus

Alexander Bisignano serves as the Chief Executive Officer for Phosphorus. Alex is responsible for long-term direction and development of Phosphorus diagnostic tests, software, and research initiatives. Before Phosphorus, Alex co-founded Recombine, a clinical genetic testing company, which was acquired by CooperSurgical in May of 2016. At Phosphorus and Recombine Alex helped develop novel genotyping and next-generation sequencing platforms for clinical genetics. Alex received his B.A. in molecular biology from Princeton University and is a member of Sigma Xi, the Scientific Research Society.

Larry Carrier

Head of Global Regulatory Affairs
Verily

Larry Carrier is a biomedical engineer with over twenty-six years' experience as a regulatory professional in the medical device industry managing global regulatory programs and teams. He is currently Head of Global Regulatory Affairs at Verily Life Sciences, LLC (South San Francisco, CA). Prior to Verily, Larry worked in Regulatory Affairs leadership positions at Claret Medical, Medtronic Cardiovascular, ProRhythm, Med-El Elektromedizinische Geraete, W.L. Gore & Associates, Ethicon Endo-Surgery, and other medical device companies. Larry is a graduate of Texas A&M University with a Bachelor's degree in Biomedical Engineering and holds an M.S. in Biomedical Engineering from the University of Texas at Austin.

Diane Johnson

Digital Health Policy Lead
Johnson & Johnson

Diane Johnson is responsible for regulatory policy shaping for North America for the Johnson & Johnson Medical Device Companies, as well as serving as the regulatory Digital Health Policy Lead. She is responsible for identifying key emerging regulatory policy issues and shaping the outcomes through continued interactions with HAs. She also supports government affairs in shaping legislation. Activities are

focused on laws, regulations, and guidance that will drive Business and Strategic Plans. She has over 30 years of experience in the device industry, specializing predominantly in Regulator Affairs. For five years, she was a senior scientific reviewer at FDA's CDRH, with a focus on cardiovascular devices. Her B.S. and MS. are in Materials Engineering.

Yong Jin Lee

Senior VP
Samsung

Yong Jin Lee is currently Senior Vice President responsible for developing health devices and algorithms at Samsung's Mobile Communications Business. He leads the development of health sensors and algorithms for flagship smartphones and wearables as well as the development of dedicated wearables and nearables for health and wellness. He also oversees clinical research programs involving digital health. Prior to Samsung, Dr. Lee was the CTO and SVP of Engineering at Salutron. Dr. Lee was the principal investigator for over a dozen research programs on physiological monitoring and wearable devices for NASA, DARPA, Office of Secretary of Defense, US Army Medical Research, Office of Naval Research, and Department of Homeland Security. Dr. Lee was also at Veeco and Texas Instruments. Dr. Lee holds BS, MS and PhD degrees in Electrical Engineering, AB in Economics, and MS in Engineering management, all from Stanford University. Dr. Lee is a recipient of F.E. Terman Award, and member of Tau Beta Pi, and Phi Beta Kappa honor societies.

Howard Look

CEO
Tidepool

Howard Look is President, CEO and Founder of Tidepool, a nonprofit, open source, diabetes data management platform. Previously, Howard was on the founder's team at TiVo where as VP of Software and User Experience he led the efforts that made TiVo as easy to use as it was disruptive. He was also VP of Software at Pixar, where he led the team developing Pixar's proprietary film-making system, and at Amazon where he ran a software projects for devices that leverage cloud services. At Linden Lab, he led the team that delivered the open-sourced Second Life Viewer 2.0 project. In 2015, Howard was awarded the White House Champions of Change award for Precision Medicine on behalf of Tidepool's work. In 2016, Howard participated in a panel discussion with President Barack Obama at the Precision Medicine Initiative Summit at the White House. Howard has a BS in Computer Engineering from Carnegie Mellon University. His teenage daughter has type 1 diabetes.

Danelle Miller

VP Global Regulatory Policy & Intelligence
Roche

Danelle Miller is Vice President, Global Regulatory Policy and Intelligence for Roche Diagnostics. In that role, she is responsible for guiding Roche Diagnostics' global regulatory policy efforts. Ms. Miller joined Roche Diagnostics in 2005, and served as Regulatory Counsel for Roche Diagnostics' Indianapolis-based affiliates, and later as Global Regulatory Counsel, where she counseled Roche Diagnostics worldwide on quality and regulatory issues. Prior to joining Roche

Diagnostics, she worked for the law firm of Baker & Daniels, where she was responsible for representing food, drug and medical device companies on regulatory and related issues involving the Food and Drug Administration and other federal and state agencies. Ms. Miller also has served as Regulatory Counsel for a major pharmaceutical firm. Ms. Miller holds a B.S. from the University of Tulsa, M.A. from Ball State University, and a J.D. with high honors from the University of North Carolina School of Law.

Jennifer Newberger	*Senior Legal Counsel* Apple	Jennifer Newberger works on Apple Health Special Projects as a member of the RA/QA team. In her role, Jennifer works with a variety of teams across Apple on health-related projects. Jennifer joined Apple in 2017 after spending 10 years in Washington, DC. During this time, she advised numerous companies in the areas of digital health, medical device regulatory strategy, and compliance. Jennifer holds a JD from University of Miami, an MPH from Emory University, and a BA from Washington University in St. Louis.
Adam Pellegrini	*General Manager* Fitbit	Adam Pellegrini is the General Manager of Fitbit Health Solutions and is tasked with helping Fitbit connect its products, information, data and insights in new and innovative ways into employers, health plans and hospital systems. Pellegrini brings more than 20 years of experience across multiple sectors of the healthcare industry including providers, insurers, health technology and non-profits. He joins Fitbit from Walgreens Boots Alliance, where he was the Vice President of Digital Health, responsible for revolutionizing how the global chain approached omni-channel digital healthcare, including advancing the company's integration with wearables, launching telemedicine and advancing their core digital pharmacy platforms. As part of his work with Walgreens, his team led the largest retail mHealth integration of more than 1 million connected devices and launched the company's first integration of wearables – including Fitbit devices – with its Balance Rewards program, which rewards customers for making healthy choices. Previous to WBA, Pellegrini worked on products like Microsoft HealthVault, HealthyCircles and lead online strategy for the American Cancer Society.

Panel 2: FDA Pre-Cert Pilot Core Team

Cathy Bahr	*Digital Health Expert Advisor* Office of the Center Director	Cathy Bahr is a Digital Health Expert Advisor in the Office of the Center Director in CDRH. She advises CDRH leadership and staff on digital health regulatory matters and leads policy development in digital health areas. One of Cathy's key roles is advising the digital health team in formulating regulatory policy aligned with the guidance published by the International Medical Device Regulator Forum Software as a Medical Device Working Group. She also advises the digital health team in rethinking FDA's regulatory oversight of digital

health technology in light of the 21st Century Cures Act and the Digital Health Software Precertification Program. Cathy joined the FDA after 37 years of experience at GE in various businesses and roles across the globe. Prior to joining the FDA, she was Senior Director of Global Regulatory Policy for GE Healthcare globally. Ms. Bahr holds a B.S. from the University of Pennsylvania and is a graduate of the General Electric Financial Management Program.

Adam Berger

Personalized Medicine Staff

Office of In Vitro Diagnostics and Radiological Health

Adam C. Berger, Ph.D. is part of the personalized medicine staff in the Office of In Vitro Diagnostics and Radiological Health at the U.S. Food and Drug Administration (FDA). In his role at FDA, Dr. Berger addresses a wide range of policy and regulatory issues related to precision medicine, next generation sequencing, real world evidence, and digital health. Dr. Berger previously served as a Senior Fellow to the Secretary of Health and Human Services, overseeing the development and implementation of the Precision Medicine Initiative, a precedent setting and transformational medical initiative to accelerate the development of disease treatments by taking into account patients' individual characteristics, across all operating and staff divisions of the Department of Health and Human Services. Prior to working in government, he was a Senior Program Officer and Director of the Roundtable on Translating Genomic-Based Research for Health in the Board on Health Sciences Policy at the Institute of Medicine (now the National Academy of Medicine). Dr. Berger received his doctorate from Emory University in the Biochemistry, Cell and Developmental Biology Program, his B.S. in Molecular Genetics from The Ohio State University, and completed his postdoctoral training at the National Cancer Institute of the National Institutes of Health.

Esther Bleicher

Senior Policy Advisor

Office of the Center Director

Esther W.B. Bleicher is Senior Policy Advisor in the Office of the Center Director in CDRH. She advises CDRH leadership and staff on legally complex strategic matters and leads policy development in high priority areas. One of Esther's key roles is advising the digital health team in rethinking FDA's regulatory oversight of digital health technology in light of the 21st Century Cures Act and the Pre-Cert Pilot Program. Prior to joining CDRH, Esther was Deputy Chief of Staff for the FDA Commissioner. Esther has held other roles at FDA, including Chief Implementation Manager of the FDA Food Safety and Modernization Act and attorney in FDA's Office of the Chief Counsel. She has her J.D. from Harvard Law School, M.P.H. from Harvard School of Public Health, and B.A. in philosophy from Dartmouth College.

Marisa Cruz

Senior Medical Officer

Office of the Center

Marisa Cruz is the Senior Medical Advisor for the Digital Health Unit in CDRH, providing a clinical perspective on policy and program development in cross-cutting and emerging areas. Prior to joining CDRH, Marisa served as a senior advisor to the Associate

	Director	Commissioner for Public Health Strategy and Analysis, and as a lead for the development of a framework to align risk-informed prioritization and decision-making with strategic planning, budget formulation and execution in the Office of Foods and Veterinary Medicine. She received her M.D. from the Johns Hopkins School of Medicine, completed an Internal Medicine residency and Endocrinology fellowship at the University of California, San Francisco, and continues active clinical care as an Assistant Clinical Professor at George Washington University.
Martin Ho	*Associate Director for Quantitative Innovation* Office of Surveillance and Biometrics	Martin Ho, MS, is the Associate Director for Quantitative Innovation at the Office of Surveillance and Biometrics in the Center for Devices and Radiological Health (CDRH) of the FDA. He has been leading the CDRH Quantitative Innovation Program (QuIP) since its creation in 2017. QuIP provides methodological leadership to use novel quantitative methods (such as user-generated data for regulatory purpose) to inform regulatory decision making. QuIP works with review teams across the Center to conduct reviews of submissions with innovative methods, develops good review practices for these methods, and builds review capacity to meet CDRH's long term needs. Prior to his current position, Mr. Ho was a statistical reviewer, team leader, and acting branch chief reviewing medical device submissions of various therapeutic areas for 8 years.
John Murray	*Expert Regulatory Review Scientist* Office of the Center Director	John F Murray Jr. is an "Expert Regulatory Review Scientist" at the US Food and Drug Administration. He is a member of the FDA Digital Health Team. His 24 years of FDA service includes 8 years in the Office of Science & Technology, 15 years in the Office of Compliance. John served in the United States Navy Nuclear Submarine Service. John was awarded his BS in Electronics Engineering from George Mason University and his MS in Computer Science from Rensselaer Polytechnic Institute (RPI).
Linda Ricci	*Health Scientist* Office of Device Evaluation	Linda Ricci 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 Digital Health within the Office of Device Evaluation. In this role, she leads the development and implementation of digital health policy within the Office of Device Evaluation. She has degrees in Electrical Engineering and Medical Engineering.
Francisco (Cisco) Vicenty	*Program Manager* Office of	Cisco Vicenty is currently the Program Manager for the Case for Quality (CfQ) within the Office of Compliance, Center for Devices and Radiological Health (CDRH), FDA. This effort is part of the CDRH

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Surveillance and Biometrics

strategic priorities for 2016 and 2017. This strategic priority will improve access and outcomes for patients by engaging industry, payers, providers, and patients to increase focus on the quality and performance of medical devices. Cisco began his career at FDA as a compliance officer in the Cardiac Rhythm and Electrophysiology Branch in the Office of Compliance at CDRH. He then worked as a project manager for the FDA's Case for Quality initiative. Prior to his current role, Cisco was the Branch Chief of the Respiratory, E/N/T, General Hospital, and Ophthalmic Devices Branch in the Division of Manufacturing and Quality, within the Office of Compliance. Prior to working with FDA, Cisco Vicenty was a Quality and Reliability Engineer with the Micro-Electronics Business Unit at IBM responsible for emerging server technology lines and network systems along with high volume gaming systems from Nintendo, Sony, and Microsoft.

Panel 3: Healthcare Stakeholders

Naomi Aronson

Executive Director

Blue Cross Blue Shield Association

Dr. Naomi Aronson leads BCBSA clinical effectiveness and policy engagement with government, regulatory agencies and policy consortia. Her areas of leadership include comparative effectiveness, patient centered research, safety surveillance, regulatory science and methodological standards. Previously, Dr. Aronson led the development of the BCBSA Technology Evaluation Center (TEC), now the Center for Clinical Effectiveness, as a nationally recognized technology assessment program and an Evidence-based Practice Center of the Agency for Healthcare Research and Quality (AHRQ). She has directed over 300 technology assessments and 20 evidence reports for AHRQ. Dr. Aronson is a member of the Methodology Committee of the Patient-Centered Outcomes Research Institute (PCORI). She also serves on the PCORI Board of Governors Research Transformation Committee and the PCORI Rare Diseases Advisory Panel. Dr. Aronson is a member of the Health Technology Assessment International Health Policy Forum, Institute of Medicine Genomics Roundtable, the National Business Group on Health Committee on Evidence-Based Benefit Design, and the New Drug Development Paradigms (NEW DIGS) initiative of the MIT Center for Biomedical Innovation, Steering Committee of the Quality Assurance Pilot for Cancer CDx. Dr. Aronson is a founding member of EXCITE International, Excellence in Clinical and Technology Evaluation. She serves on the EXCITE International Advisory Board, the Scientific Collaboration and is Chair of the Payer Advisory Committee. Dr. Aronson is a member of the Medical Device Innovation Consortium (MDIC) National Evaluation System for Health Technology (NEST) Governing Committee. Prior to joining TEC, Dr. Aronson was a member of the Northwestern University faculty, specializing in the sociology of science and medicine. She was a post-doctoral fellow in

the Science, Technology and Society Program at MIT and received research awards from the National Science Foundation and the American Council of Learned Societies. Dr. Aronson's academic research focused on how the organization of scientific specialties in biomedical and clinical research affects the process of scientific discovery.

Andrew Auerbach

Professor of Medicine

UCSF Center for Digital Innovation

Dr. Auerbach is Professor of Medicine in residence in the Department of Medicine at UCSF, Editor in Chief of the Journal of Hospital Medicine, Director of Innovation Research in the UCSF Center for Digital Innovation, and a practicing Hospitalist in the UCSF Division of Hospital Medicine where he leads research programs focusing on improving health systems using informatics tools. Dr. Auerbach also has a central role as the Chair of the committee which oversees electronic health tool development and implementation within UCSF's vendor EHR (Epic), and co-chairs the UCSF Digital Diagnostic and Therapeutic Committee, the group responsible for evaluating, testing, and implementing software such as those we are considering today into use at UCSF Health.

Kathleen Blake

Vice President

American Medical Association

Kathleen Blake, MD, MPH, is Vice President, Healthcare Quality, at the American Medical Association where she works to ensure that physicians have the information and tools they need to successfully participate in new payment programs. She chairs the Clinical Review Group of AMA's Integrated Health Model Initiative. From 2013 until 2016, Dr. Blake was Executive Director of the PCPI® which includes the National Quality Registry Network™ (NQRN™) and was responsible for its portfolio of over 350 performance measures. Dr. Blake is a member of the Governing Committee of the National Evaluation System for health technology (NEST) coordinating center hosted by the Medical Device Innovation Consortium under contract with FDA. NEST aims to make available real-world evidence throughout the total product lifecycle of medical devices. She is a past co-chair of the Health IT Policy Committee of the Department of Health and Human Services. Prior to joining AMA, she was Senior Research Director at the Center for Medical Technology, overseeing Public-Private Partnerships, Policy and Education and serving as advisor to two national clinical registries. Dr. Blake is a clinical cardiac electrophysiologist who received her education and training from the University of Chicago, Stanford University and the Johns Hopkins Bloomberg School of Public Health. From 1988 until 2011, Dr. Blake practiced at the New Mexico Heart Institute, where she also served as President. She is a part-time member of the Johns Hopkins University medical faculty.

Adam Brown

Senior Editor

diatribe/Close Concerns

Adam Brown serves as Head of Diabetes Technology & Digital Health at Close Concerns and Senior Editor at diaTribe.org. Adam brings 16 years of personal experience living with diabetes to all of

his work, especially in testing out new technology like glucose meters, CGMs, insulin pumps, automated insulin delivery, and mobile apps. He writes an acclaimed column for diaTribe, Adam's Corner, which has brought useful diabetes tips to over 600,000 people since 2013. Adam's first book, Bright Spots & Landmines: The Diabetes Guide I Wish Someone Had Handed Me, was published in May 2017 and received immediate praise for its actionable advice on food, mindset, exercise, and sleep. Adam has also brought a patient perspective to numerous public venues, including FDA and NIH meetings, scientific and industry conferences, and patient events. He graduated summa cum laude from the Wharton School of the University of Pennsylvania in 2011 pursuing concentrations in marketing and health care management & policy. He is passionate about exercise, nutrition, psychology, and wellness, and spends his free time cycling in San Francisco.

Cara Tenenbaum	*Senior Advisor* Office of the Center Director	Cara is a Senior Advisor in the Office of the Center Director, Center for Devices and Radiological Health. She provides policy analysis and serves as a liaison to external stakeholders regarding policy issues. She was previously a Senior Advisor in the Office of External Affairs in the Office of the Commissioner where she handled stakeholder strategy and outreach for policy issues at the Agency. Before joining the FDA, Cara served as Vice President for Policy and External Affairs at the Ovarian Cancer National Alliance (Alliance). At the Alliance for seven years, she was responsible for the public policy and educational efforts for the organization, including federal appropriations, legislation and regulations affecting women with ovarian cancer. She worked on laws and regulations related to health reform, safe and effective drug approvals and reimbursement practices. Additionally, Ms. Tenenbaum often served as the spokesperson for the Alliance, providing insight on important ovarian cancer issues to media outlets like the Wall Street Journal, New York Times and Fox Business News. Ms. Tenenbaum holds a Bachelor's Degree in Economics from the University of Maryland, College Park, a Juris Doctor from Case Western Reserve University and a Master's in Business Administration from Case Western Reserve University.

Panel 4: Digital Health Stakeholders

Asif Dhar	*Principal Chief Health Informatics Officer* Deloitte	Dr. Asif Dhar is a Deloitte Principal Chief Health Informatics Officer, and Therapeutic Area Transformation Solutions Leader. He is responsible for developing integrated capabilities that bring together ecosystems, exponential technologies, data, and analytics, to transform health care. These highly innovative solutions in disease areas such as diabetes and oncology may provide the market with approaches to radically change the way therapies are developed,

diseases diagnosed, and consumers engaged. He advises some of the World's most innovative companies and Governmental agencies tackling disease and public health. He is Deloitte's Lead Client Services Partner (LCSP) for the Firm's US Food and Drug Administration (FDA) account and responsible for all work Deloitte performs with and for the Agency. His perspectives on real world evidence, regulatory sciences, digital health, and innovation are sought by clients around the World. Dr. Dhar led Deloitte's Cancer XPRIZE team from Visioneering through initial prize design and ecosystem activation. This XPRIZE seeks to diagnose cancer anywhere for everyone, making treatment affordable and avoiding suffering for thousands around the World.

Anand Iyer

Chief Strategy Officer

WellDoc, Inc., Digital Therapeutics Alliance

Anand is a respected global digital health leader—most known for his insights on and experience with technology, strategy and regulatory policy. Anand has been instrumental in WellDoc's success and the development of BlueStar®. Prior to WellDoc, Anand served as the Director of PRTM's wireless practice and was the founder and immediate-past president of the In-Building Wireless Alliance. Anand teaches advanced wireless courses to senior officers in the US DoD at the Institute for Defense and Business. Anand holds an MS and a PhD in electrical and computer engineering, and an MBA from Carnegie Mellon University.

Michael Kirwan

Vice President

Continua

Personal Connected Health Alliance

Michael J. Kirwan is the Vice President of Continua, a division of the Personal Connected Health Alliance (PCHAlliance). Michael holds an MBA from the University of North Carolina, a BS in Industrial Technology from Northwest Missouri State University and is Program Management Professional certified. Michael works directly with PCHAlliance's Policy, Regulatory, International, Technical and Certification Committees and serves as Co-Chair of the IEEE 11073 Personal Health Devices Working Group. Other programs that Michael leads at Continua are Certification, Plugfests, Test Tool, Software SDK, CODE for Healthcare, source-code development (CESL and mCESL), Open-source, and the Interoperability program. Mr. Kirwan has over 20 years of experience in driving operations, certification and testing strategies within major organizations, such as Bluetooth SIG and several major airlines.

Anna Libman

Director of Regulatory Affairs and Business Development

Experien Group

Anna Libman is Experien Group's Director of Regulatory Affairs and Business Development. Anna, leads Experien Group's advances in SaMD and digital health technologies. She works with clients from product inception through commercialization. Since joining the firm in 2010, Anna has supported numerous clients in defining and executing regulatory strategies, submissions, Quality Systems, and device testing as the client's regulatory representative. She earned her BS in Biochemistry and Molecular Biology from UC Davis and her MBA from UCLA Anderson School of Management with concentration in new enterprise formation and finance.

Zach Rothstein

Associate Vice President for Technology & Regulatory Affairs

Advanced Medical Technology Association (AdvaMed)

Zach Rothstein is Associate Vice President for Technology & Regulatory Affairs at the Advanced Medical Technology Association (AdvaMed). In this position, Zach advocates for fair, efficient, and effective regulatory policies for medical devices. In particular, Zach's efforts are primarily focused on digital health, software, cybersecurity, medical device labeling, and postmarket surveillance. Prior to joining AdvaMed, Zach was Deputy Senior Counsel for Public Policy, at Samsung Electronics, where he was responsible for the company's medical device and healthcare regulatory and policy issues. Zach was previously an Attorney in the FDA and Healthcare practice at the law firm of Morgan, Lewis & Bockius LLP.

Panel 5: Learning from Excellence Models used in other Sectors

Tim Anderson

President

Anderson Leadership

Tim began his career in the Excellence field in 1992. He participated as an external assessor in his first Malcolm Baldrige based assessment in 1994 and the same year joined a team that used the EFQM Model to turn around an automotive supplier. He has lost count of how many assessments he has participated in. Typically, Tim is hired by C level executives to implement major change initiatives, often using Excellence models. His diversity of experience in 20 different industries brings a wide view of possibilities to his customers, and is recognized as an expert in Leadership, Performance Management, Innovation, and Business Transformation.

Kirk Holmes

President

Holmes and Associates

Kirk Holmes is President of Holmes and Associates, Inc. Kirk is a long-time operations and technology executive, a pioneer in the broadband Internet industry, and a leader in the growth of some key quality and best practice frameworks. As both an operator and a consultant in his 30-year career, Mr. Holmes has helped organizations save millions of dollars and improve business results, service delivery, operations management, and cost optimization through management intervention and best practices implementation. Employers have included IBM, SRA, and Comcast. Consulting clients have included Comcast, Time Warner Cable, AT&T, U.S. Department of Justice, National Institutes of Health, U.S. IRS, and the U.S. Army.

Howard Rohm

Co-Founder; President

Balanced Scorecard Institute

Howard Rohm is the Co-Founder and President of the Balanced Scorecard Institute. A performance management trainer, author, consultant, and technologist with over 40 years' experience, Howard developed the Institute's *Nine Steps to Success*™ scorecard excellence framework in 1997, now used in over 70 countries. In 2013, he co-authored *The Institute Way: Simplify Strategic Planning*

& Management with the Balanced Scorecard. As a Pioneer and member of the Association for Strategic Planning Board of Directors, Howard led the development of the Association's long-term strategy and strategic plan. He is one of the original authors of the Strategic Planning and Management Body of Knowledge, the international standard for the profession, and helped create the international certification program and examinations. Howard was a consultant with Booz, Allen Hamilton, and retired from government service as the Executive Director of the Advanced Nuclear Reactor research program at Department of Energy. He has engineering degrees from Iowa State University and George Washington University, and is a Presidential *1000 Points of Light* recipient.

George Zack

Co-founder; Principal

Two Harbors Consulting

George has been in leadership and contributor roles in information technology, software development and delivery, and process improvement over the past 20 years. George is Co-founder and Principal at Two Harbors, a firm focused on helping organizations achieve greater business value and performance results above compliance and regulatory expectations. George's recent efforts include helping medical device manufacturers connect with FDA CDRH in the Case for Quality's "Voluntary Medical Device Manufacturing and Product Quality Pilot." Prior to forming Two Harbors, George led McKesson's regulatory and quality compliance audit program which performed quality system audits for registered medical devices and pharmaceutical distribution centers in the US, Canada, and Europe. George's experience in process and continuous improvement also includes CMMI appraisal activities, value stream mapping engagements, Agile and other SDLC transformations, Six Sigma and enterprise tool implementations.

FDA Leadership

Bakul Patel

Associate Center Director for Digital Health

Office of the Center Director

Bakul Patel, MSEE, MBA, is Associate Center Director for Digital Health, at the Center for Devices and Radiological Health (CDRH), at the Food and Drug Administration (FDA). Mr. Patel is responsible for providing leadership, development, implementing, execution, management and setting strategic direction and regulatory policy and coordinate scientific efforts for digital health, software and emerging technologies. This includes responsibilities for mobile health, health information technology, cyber security, medical device interoperability, and medical device software. Mr. Patel is leading the effort for the agency in developing the precertification program in collaboration with all stakeholders. Prior to joining FDA, Mr. Patel held key leadership positions 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.

Jeffrey Shuren

Center Director

Center for Devices and Radiological Health

Jeffrey Shuren, MD, JD is the Director of the Center for Devices and Radiological Health (CDRH) at FDA. He previously served as Acting Center Director. Dr. Shuren has held various policy and planning positions within FDA from 1998 to 2009, including Acting Deputy Commissioner for Policy, Planning, and Budget; Associate Commissioner for Policy and Planning; and Special Counsel to the Principal Deputy Commissioner. Dr. Shuren is board certified in Neurology and served as an Assistant Professor of Neurology at the University of Cincinnati. In 1998, Dr. Shuren joined FDA as a Medical Officer in the Office of Policy. In 2000, he served as a detailee on the Senate HELP Committee. In 2001, he became the Director of the Division of Items and Devices in the Coverage and Analysis Group at the Centers for Medicare and Medicaid Services. From 1998 to 2003, he served as a Staff Volunteer in the National Institutes of Health's National Institute of Neurological Disorders and Stroke Cognitive Neuroscience Section supervising and designing clinical studies on human reasoning. Dr. Shuren returned to FDA as the Assistant Commissioner for Policy in 2003, and assumed his current position in September 2009.