AMDM 2016 Focus Meeting Speaker Bios

(Listed in Order of the Agenda)

Thursday Speakers

Elizabeth Hillebrenner, came to CDRH in 2002 with degrees in Biomedical Engineering from Tulane University. She reviewed coronary drug-eluting stents and other interventional cardiology devices for eight years in the Office of Device Evaluation, spent over two years on FDA's Medical Device User Fee Amendments (MDUFA) III reauthorization team, and completed a detail as Special Assistant to the Assistant Commissioner for Compliance Policy. Elizabeth joined OIR in 2012 to stand up and run the Pre-Submission program that was developed during MDUFA III negotiations. She also provided policy support for review staff on the IDE, 510(k), PMA, and CLIA programs. In 2015 Elizabeth became OIR's Associate Director for Programs and Performance.

Robert Di Tullio is the Senior Vice President of Global Regulatory Services at Beaufort, a global contract research organization specializing in the IVD industry with expertise in diagnostic clinical research, regulatory affairs, quality assurance and staffing services.

Mr. Di Tullio is an accomplished regulatory affairs professional with 42 years' experience in the in vitro diagnostics industry with the last 29 years in regulatory, clinical and quality management. Mr. Di Tullio provides vision, strategic insight and leadership to promote commercial success while assuring compliance with global regulations and initiatives. He is responsible for planning and managing engagements that involve regulatory issues in a manner that delivers the best solution for clients. Prior to joining Beaufort, he was Vice President of Global Regulatory and Clinical Affairs for Alere and held similar positions at ProteoGenix, Sequenom, Siemens Medical Solutions Diagnostics and Diagnostic Products Corporation. Mr. Di Tullio holds a bachelor's degree in biology from Saint Joseph's University. He is currently the President of Di Tullio Consulting, Inc. and a long-time member of the Regulatory Affairs Professionals Society (RAPS). Mr. Di Tullio was also the co-chair of the AdvaMed Diagnostics Task Force from 2007 to 2013, the industry liaison to the Clinical Laboratory Improvement Advisory Committee (CLIAC) from 2011 to 2015, and was an advisory board member for the Medical Device graduate degree curriculum at the University of Southern California.

Dr. Reena Philip currently holds the position of Director in the Division of Molecular Genetics and Pathology in the Office of In Vitro Diagnostic Devices and Radiological Health, at Center for Devices and Radiologic Health at the FDA. At the FDA, she has been involved in many diverse activities including premarket clearance/approval, manufacturer assistance, post market regulatory compliance actions, and the development of FDA Guidance on In Vitro Companion Diagnostic Devices. She has been an ongoing participant in FDA multi-center reviews in companion diagnostics including many that includes liquid biopsy. Dr. Philip received her Ph.D. in Molecular Biology from The University of Illinois at Urbana-Champaign.

Lesley Farrington currently holds the position of Director of Regulatory Affairs at Roche Sequencing Solution (RSS). Previous to RSS, she was the regulatory functional lead of the Genomics and Oncology group at RMS with a focus on Personalized Health Care. Lesley was the regulatory project lead for the cobas® BRAF V600 Mutation Test, which was approved as the CDx to Zelboraf. She also oversaw the approval of the cobas® EGFR Mutation Test which is the CDx to Tarceva for both tissue and plasma. Before joining the Genomics and Oncology group, she worked on blood screening products and was the regulatory project lead for the cobas® Taqscreen West Nile Virus Test at RMS.

Girish Putcha, is currently the Chief Medical Officer at Freenome, Director of Laboratory Science for Palmetto GBA's MolDX program, the founding Medical Director for Orion Genomics, and Managing Director at Personalized Medicine & Diagnostic Solutions.

Previously, Girish was the founding Laboratory Director and/or Chief Medical Officer at Ariosa Diagnostics, Crescendo Bioscience, Life Technologies, and VitaPath Genetics. Prior to this, he focused on investments across healthcare, from biopharmaceuticals and medical devices to diagnostics and services, at Panorama Capital and RiverVest Venture Partners, where he also served on the boards of several portfolio companies, including Presidio Pharmaceuticals, PowerVision, and Phenomix. He was also a founding team member at VeraCyte and a clinical development fellow at CardioDx, both venture-funded personalized medicine companies. Girish received a bachelor's degree from Rice University and master's degrees from the University of London and the Welcome Institute as a Marshall Scholar. He holds medical and doctoral degrees from Washington University School of Medicine, where he also completed a postdoctoral fellowship in molecular neuroscience. Girish completed his postgraduate medical training at the Stanford University School of Medicine, where he also served as adjunct clinical faculty, specializing in molecular genetic pathology.

Dr. Stefan Burde is an IVD Product Expert and QMS assessor in the In Vitro Diagnostics Notified Body at BSI Healthcare. He received his PhD in Pathology from the University of Rochester and did post-doctoral work at Los Alamos National Laboratory. He has over 13 years of experience in the In Vitro Diagnostics Industry in the development and manufacturing of IVDs for US, European and global markets in both large companies and startups. He joined BSI in 2014 as part of BSI's expansion of the IVD team to address the growing need for Quality and Technical assessments by the IVD Notified Body in response to the upcoming changes to the European In Vitro Diagnostics Regulation.

Erika Ammirati, RAC, MT(ASCP) is an independent regulatory consultant to industry located in Los Altos, CA. Ms. Ammirati specializes in the areas of clinical trials and product approvals for diagnostics and devices, with an emphasis on point-of-care (POC) and over-the-counter diagnostics. She is also well-versed in CLIA regulations and has brought several POC diagnostics through the CLIA waiver process. Prior to becoming a consultant 22 years ago, Ms. Ammirati gained over 10 years of industry experience in in-vitro diagnostic (IVD) firms, preceded by a 10-year career in the clinical laboratory as a medical technologist. Ms. Ammirati is a past Industry Representative on two FDA Advisory Panels is the author or co-author of numerous publications; she holds a BS degree in Genetics from the University of California, Davis, and current California State licensure in Medical Technology. She is also certified as a regulatory professional through RAPS (Regulatory Affairs Professional Society).

Dr. Jacqueline Francis is a pediatrician and medical officer at FDA. She began her career at FDA in the office of In-Vitro diagnostic devices where she worked in the microbiology branch as a clinical consultant. In her current home office, the Office of Device Evaluation in the Division of Surgical Devices, she specializes in policy, regulation and clinical protocol design of plastic and reconstructive surgery devices as well as pediatric surgical devices. She also serves as an Attending Physician with the KIDS mobile clinic (Georgetown/ Medstar Hospital) and the Hoya clinic that serves the shelter patients at DC General campus. A graduate of Cornell University in 1993, Dr. Francis continued on to Temple University School of Medicine where she earned a Medical Degree, Georgetown University for internship, residency (Pediatrics) and, fellowship (Clinical Pharmacology) then, completed her training at Johns Hopkins (Preventive Medicine Residency) where she also received a MPH.

April Veoukas is Director, Regulatory Affairs in Abbott Quality & Regulatory. During her more than twenty-five years at Abbott, she has held positions in regulatory affairs, technology acquisitions, and research and development. In her current position, she represents Abbott in industry associations, is responsible for regulatory intelligence, and formulates company responses to proposed regulatory policies.

April earned a juris doctorate from DePaul University College of Law and a bachelor of science in biology magna cum laude from Loyola University of Chicago. She holds a Certificate in Health Law from DePaul

University College of Law. April is a member of the Regulatory Affairs Professional Society (RAPS), the industry co-chair of the AdvaMed 510(k) Working Group, a member of the MDIC Clinical Diagnostics Steering Committee, Chair of the MDIC Contrived/Surrogate Samples Work Group, and the industry representative on FDA's Medical Devices Dispute Resolution panel advisory committee.

Rebecca Santorios is Director of Compliance at ByteGrid. In that role, she is responsible for ensuring compliance to GxP and HIPAA compliance within the ByteGrid organization, and for providing compliance services to ByteGrid's regulated clients. Prior to joining ByteGrid, Rebecca served as a compliance consultant to organizations throughout the GxP vertical, after having held senior compliance positions in medical device and pharmaceutical organizations. Rebecca has a background in biochemical engineering, with additional studies in system engineering, and over 15 years of experience implementing and validating computerized systems in the GxP space. Rebecca is an active member of ISPE and is an ASQ CQE.

Sergio Chavez, is a Compliance Officer with the US Food and Drug Administration and has been in the San Francisco District Office for 14 years.

Karen Heichman, PhD, Vice President, Director, PharmaDx Program; adjunct associate professor of pathology, University of Utah, is the Director of the PharmaDx program at ARUP and is an adjunct associate professor at the University of Utah School of Medicine. Her role at ARUP involves both developing and managing scientific and business collaborations, with a special emphasis on those involving the pharmaceutical industry. Dr. Heichman led the team that developed and received FDA approval for ARUP's two companion diagnostic tests. Dr. Heichman holds an AB in genetics from the University of California at Berkeley and a PhD in biological chemistry from the UCLA School of Medicine. She trained as a postdoctoral fellow in the field of cycle control at the Fred Hutchinson Cancer Research Center in Seattle. Dr. Heichman has more than 25 years of scientific experience in both corporate and academic institutions. Prior to joining ARUP, she spent several years at Myriad Genetics where she was the vice president of proteomic research and three years at the Huntsman Cancer Institute at the University of Utah as the director of cancer systems biology and resources.

Thomas Soriano, President and Chief Executive Officer, DOCRO, Inc. has been involved with the discovery, development, clinical evaluation, and commercialization of "standard of care" diagnostic biomarkers for more than twenty years. He has worked to improve the diagnosis, prognosis, and monitoring of patients afflicted with atherosclerosis, infectious diseases (including HIV, STD's, and Lyme Disease), obstetric and gynecologic maladies, and most prominently, those with solid and hematologic cancers. During the early 80's, he worked on an Army contract developing self-enclosed immunoassay systems for battlefield detection of biological warfare agents.

From 1988-1996, Tom was employed by DIANON Systems, Inc. and served with great distinction in a variety of positions in DIANON's R&D Department - all related to the discovery, development, clinical evaluation, and commercialization of new diagnostic biomarker technologies. Tom's group was responsible for DIANON's introduction of virtually all of the USA's "standard of care" oncology biomarker assays. Amongst their numerous successes at DIANON, Tom and his colleagues are inventors of five key clinical utility patents for the use of Free PSA and Total PSA. In 1996, Tom and his colleagues addressed the market opportunity for a specialized contract research organization (CRO) focused on meeting the needs of the medical in vitro diagnostics (IVD) industry and the allied fields of pharmaceuticals and biotech that use IVD products. Today, DOCRO is the leading CRO specializing in the commercialization of biomarker technologies emerging from proteomic and genomic discovery efforts. He is the President and Chief Executive Officer of DOCRO.
Since 1996, DOCRO has been party to more than one hundred and twenty (120) successful 510k, PMA, and PLA IVD submissions to FDA. Tom holds a degree in Biochemistry and another degree in Psychology from Cornell University, as well as a certificate in finance from Boston University.

Lawrence Worden, Vice President & Senior Partner, Market Diagnostics International, has over 35 years of experience in the field of medical/scientific market research with a primary focus on in vitro diagnostics. As a co-founder of MDxI, he consults with clients in the design and implementation of international market research studies, coordinates with MDxI's analytical staff to develop key findings/recommendations, and helps clients integrate these findings into their organizational goals and objectives. Prior to MDxI, he was a senior consultant and co-founder at CaseBauer & Associates, an international business development and research firm exclusively focused on in vitro diagnostics. He has held government affairs and market research positions with Becton Dickinson and Company, AdvaMed, Luning Prak Associates, and IMS Health. Larry has developed syndicated data services for the clinical diagnostics, diagnostic imaging, and medical/surgical markets, has authored numerous regulatory compliance manuals for the diagnostic and medical device industries and served as the biomedical industry liaison to the College of American Pathologists' Workload Recording Committee and is the current President of the Diagnostics Marketing Association.

Friday Speakers

Donna M. Roscoe, Ph.D., is the Branch Chief for the Molecular Genetics Branch in the Division of Molecular Genetics and Pathology in FDA's Office of In Vitro Diagnostic Device Evaluation and Radiological Safety. The branch is responsible for reviewing IVDs principally in the area of oncology with extensive experience in companion diagnostics. Prior to coming to the FDA, Dr. Roscoe worked for various CROs and the National Center for Biotechnology Information (NCBI) after completing a post-doctoral fellow in the clinical cancer research Laboratory of Molecular Biology at the National Cancer Institute (NCI) at NIH.

Dr. David Litwack received a B.S. in Chemistry from the University of Chicago, and a Ph.D. in Biology from MIT. After postdoctoral studies at the Salk Institute for Biological Studies, he joined the faculty of the University of Maryland School of Medicine as an Assistant Professor in the Department of Anatomy and Neurobiology and a member of the Program in Neuroscience. In that role, Dr. Litwack directed an NIH-funded lab that studied the role of transcription factors in neurogenesis in the mammalian brain and in human embryonic stem cells, and was a founding member of the School's Center for Stem Cell Biology and Regenerative Medicine. In 2010, Dr. Litwack was awarded an AAAS Science and Technology Policy Fellowship in NCI's Office of Biorepositories and Biospecimen Research. During this fellowship, he led several efforts to develop policy and programs to advance the use of biobanking for personalized medicine. In 2012, Dr. Litwack joined the Personalized Medicine Staff of the Office of In Vitro Diagnostics and Radiological Health at the FDA, where he develops policies to guide the review of investigational biomarker tests, companion diagnostics, and next generation technologies.

Irene Tebbs, Ph.D., Scientific Reviewer, Division of Chemistry and Toxicology Devices, Office of In Vitro Diagnostic Devices and Radiological Health, CDRH, US FDA. Dr. Tebbs works at FDA as a lead reviewer of premarket submissions and pre-submissions for chemistry, toxicology and diabetes devices. She also reviews Investigational Device Exemption (IDE) applications for clinical studies. Dr. Tebbs received her B.S. at The University of Virginia and her Ph.D. from Yale University.

Jeffrey N. Gibbs is a director in the Washington, D.C. law firm of Hyman, Phelps & McNamara, P.C. Before entering private practice, he was Associate Chief Counsel for Enforcement at the Food and Drug Administration. Jeff also served as a Special Assistant United States Attorney in the District of Columbia in the Civil Division.

Jeff assists in vitro diagnostic and medical device companies with a variety of regulatory issues, including FDA product clearance and approval, product labeling, clinical studies, promotional and marketing programs, appeals, regulatory strategy, and FDA enforcement actions. He has written extensively on FDA issues, including those involving diagnostic products, and has advised IVD companies on a wide range of FDA regulatory and strategic issues. He is Vice Chairman of the Food and Drug Law Institute in Washington, D.C., and is a lecturer on device law at George Washington University. In 2013, he received FDLI's Distinguished Service and Leadership Award. He was also named LMG Life Science's Medical Device Attorney of the Year in 2013, and received FDLI's Distinguished Service and Leadership Award. Jeff graduated from Princeton University and New York University School of Law.

Dr. Stefan Burde is an IVD Product Expert and QMS assessor in the In Vitro Diagnostics Notified Body at BSI Healthcare. He received his PhD in Pathology from the University of Rochester and did post-doctoral work at Los Alamos National Laboratory. He has over 13 years of experience in the In Vitro Diagnostics Industry in the development and manufacturing of IVDs for US, European and global markets in both large companies and startups. He joined BSI in 2014 as part of BSI's expansion of the IVD team to address the growing need for Quality and Technical assessments by the IVD Notified Body in response to the upcoming changes to the European In Vitro Diagnostics Regulation.

Pashmi Vaney is currently a Regulatory Affairs Specialist for NanoString Technologies, Inc. In this role, she supports regulatory activities for companion diagnostic investigational studies in the US, EU, and rest of world as well as regulatory sustaining activities for Prosigna, a multivariate gene expression breast cancer assay. She has experience with FDA preSubmissions, 510(k)s, EU Technical Files, Health Canada Device License submissions and amendments, development of labeling and promotional material, UDI barcode labeling, and product development team support. Recently, she led the FDA Unique Device Identification labeling implementation program for NanoString Diagnostics products using GS1 standards. Pashmi earned a Master of Science degree in Regulatory Affairs from the University of Washington and a Medical Degree from India. She was a practicing family physician in rural Delhi, India prior to coming to the United States, where she did research in hormone replacement therapy. Before joining NanoString, she was in laboratory research and worked on development of drug target identifiers.