



ENGELBERG CENTER for Health Care Reform at BROOKINGS

Measuring Pharmaceutical Quality through Manufacturing Metrics and Risk-Based Assessment

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Biographies



Barbara Allen, PhD, is Senior Director for Global Quality Systems for Eli Lilly and Company. Dr. Allen joined Eli Lilly and Company in 1991 in Ireland and has since held various assignments in API Manufacturing Technical Services, New Product Introduction, Quality Assurance, and Global Quality Systems, in Ireland and in the USA. In 2002, she began her current position in Global Quality Systems, where she is responsible for providing quality systems for Lilly manufacturing and for ensuring that Quality Systems are integrated across the corporation. Dr. Allen was a member of ICH Q10 EWG (Expert Working Group) representing PhRMA and currently serves as a member of IFPMA RPTS.



Ferdinando Aspesi, PhD, is the Senior Advisor to the Global Head of Quality at Novartis. Ferdinando has more than 35 years of experience in the Pharmaceutical Industry. He has worked in API and Drug Products Quality Assurance and Quality Control, in Pharmaceutical Research and Development and Analytical Development. Ferdinando joined Novartis in 2010 as Global Head of Pharma Development QA leading the Quality and Compliance Sustainability Program for Pharma Development and the re-design of the Pharma Development Quality organization. He became later the Global head of OTC QA. Since 2012, he is the Senior Advisor for the Novartis Global Quality Head. In his previous career, Ferdinando held positions as Global Head of Quality for Aventis and Wyeth Pharmaceuticals and led the Wyeth Global Regulatory Affairs Chemistry, Manufacturing and Controls organization. Ferdinando has worked in the United States, South Africa, UK, Germany, France and Italy and has extensive experience in interacting with all major Health Authorities. Over many years, Ferdinando has been active in external Industry initiatives. He engaged with the FDA on Process Analytical Technology and FDA 21st century GMP's initiative. He is currently involved in the FDA initiative on metrics and represents Novartis in the International Leadership Forum. Ferdinando has a degree in Organic Chemistry from the University of Milan/Italy.



Deborah M. Autor, Esq., is Senior Vice President, Strategic Global Quality and Regulatory Policy at Mylan, the world's third largest generics and specialty pharmaceutical company. In that role, Ms. Autor oversees Global Quality for Mylan. She works to advance Mylan's industry-leading efforts to establish high drug quality standards globally and to expand the world's access to high quality medicine. Prior to joining Mylan in 2013, Ms. Autor served for 11 years at FDA, most recently as Deputy Commissioner for Global Regulatory Operations and Policy. In that role, Ms. Autor supervised over 4,000 employees in FDA's Office of Regulatory Affairs (ORA) and the Office of International Programs (OIP), in their efforts to confront the challenges of globalization and import safety. Prior to assuming the role of Deputy Commissioner, Ms. Autor served for five years as Director of the Office of Compliance of FDA's Center for Drug Evaluation and Research (CDER). In that role, she led policy-making and enforcement for key public health programs for drugs including: current good manufacturing practices; human subject protection and bioresearch monitoring; marketed unapproved drugs; pharmaceutical import and export; Internet and health fraud; over-the-counter monograph compliance; adverse event reporting; registration and listing; risk evaluation and mitigation strategies; and drug recalls. Before joining FDA, Ms. Autor was a trial attorney for seven years in the Office of Consumer Litigation of the U.S. Department of Justice, where she litigated civil and criminal cases on behalf of FDA and other federal law enforcement agencies. She began her legal career practicing food and drug law at the firms of Weil, Gotshal & Manges and Buc Levitt & Beardsley. Ms. Autor's contributions to public health have been recognized many times. She was awarded the 2011 Meritorious Executive Presidential Rank Award and the 2011 Food and Drug Law Institute's Distinguished Service and Leadership Award; she also was a 2010 finalist for the prestigious Service to America Medal. In addition, the U.S. Department of Health and Human Services, FDA, CDER and DOJ decorated her with a total of more than 50 awards. At Mylan, Ms. Autor is continuing her work to improve drug quality and global access to safe, effective, high quality drugs.



Vinay Bhatt, PhD, is Vice President, Projects, at Zydus Pharmaceuticals (USA) LLC. Dr. Bhatt offers extensive experience in the areas of Quality and Regulatory Affairs with a focus on systems integration, improvement and simplification within pharmaceutical research and manufacturing environments. Chief Editor of a book entitled "GMP Compliance, Quality and Productivity: Achieving Synergy in Healthcare Manufacturing" published by CRC Press Inc., Vinay has worked for both PhRMA and GPhA member companies in Canada, USA, France and in India. Dr. Bhatt works out the NJ office and is the regulatory lead for organization's IND program; he also leads Quality and Regulatory functions for company's manufacturing operation based in USA.



Gregory Daniel, PhD, MPH, RPh, is a fellow in Economic Studies and managing director for evidence development and innovation in the Engelberg Center for Health Care Reform at the Brookings Institution. In this position, Dr. Daniel oversees and provides strategic direction regarding the Center's evidence development and biomedical innovation portfolio, including medical product safety surveillance, regulatory science and U.S. Food and Drug Administration (FDA) policy issues, comparative effectiveness research, and other biomedical innovation policies. Dr. Daniel was previously Vice President, Government and Academic Research at HealthCore (subsidiary of WellPoint, Inc.) where he led a division responsible for providing research services in the areas of pharmacoepidemiology; drug, vaccine, and biologic safety evaluations; comparative effectiveness research; and health economics and outcomes research. His research has utilized electronic health insurance claims data integrated with clinical data including laboratory results, electronic hospital data, paper-based and electronic medical record data, and registries. Dr. Daniel is a registered pharmacist and holds a PhD in pharmaceutical economics, policy, and outcomes research with a minor in epidemiology from the University of Arizona. He also holds an MPH specializing in biostatistics, a master's in pharmaceutical administration, and a BS in pharmacy, all from The Ohio State University.



Joachim del Boca, Chemical Engineer and Pharmacist, currently has the position of Vice President for Regulatory Affairs and Quality Compliance at Vetter Pharma-Fertigung GmbH & Co. KG in Ravensburg, Germany. Vetter is a leading CMO in the filling of sterile application systems like syringes, cartridges, and vials. Besides Regulatory Affairs issues, Mr. del Boca is responsible for all worldwide authority inspections and audits at Vetter including approximately 40 FDA inspections. Mr. del Boca started at Vetter in 1983 in the production department as a Director of Production, and changed to QA as a Vice President Quality Assurance.



Linda Evans O'Connor is the Vice President of Supplier Quality Management for Teva Pharmaceuticals, a position that she has held for one year. Linda is responsible for all external suppliers of GxP goods and services, as well as supply chain quality and external auditing. Prior to taking this role, Linda was responsible for Quality knowledge management on a global basis, as well as global quality metrics implementation. Linda has also held various quality roles on the local and regional levels within Teva. Linda holds an ASQ certification as Certified Manager of Quality /Organization Excellence. She is a member of various committees within ISPE. She is the Vice-Chair of the Manufacturing Technical Committee in PQRI and she is on the Board of Directors of RX-360. She has a BS in Biochemistry from Carnegie-Mellon University and an MBA in Marketing from Rutgers University.



Katy George, PhD, is a Director in McKinsey & Company's New Jersey office. Katy co-leads McKinsey's Global Manufacturing Practice. Katy is also a part of the leadership team of the Pharmaceutical and Medical Products Operations practice. An 18-year veteran of McKinsey, Katy's client service has focused on healthcare supply chain, manufacturing and quality, and Katy has also worked with healthcare companies on corporate strategy and commercial effectiveness. Katy has worked with pharmaceutical and medical device companies in setting operations strategy, defining and launching new operations organization structures and operating models, and optimizing supply and manufacturing performance to lower cost and improve service and market access. Katy leads McKinsey's Quality Roundtables in the pharmaceutical and medical device industries, helping to convene industry and regulators around common objectives. She has led multi-client benchmarking around quality and compliance efficiency, effectiveness, and risk-management. Katy also advises companies in the consumer, food and high-tech sectors on quality topics. In Katy's role as co-leader of the Global Manufacturing Service Line, Katy has focused on global macroeconomic changes, advanced manufacturing technologies, and how they will reshape manufacturing strategies and opportunities. Katy co-authored McKinsey's report "Manufacturing the future: The next era of global growth and innovation", a collaboration with McKinsey's Global Institute (2013). She also co-authored McKinsey's perspective "Next-shoring: A CEO's Guide" (2014). Katy has spoken at multiple conferences and with clients on advanced manufacturing technology adoption, digital manufacturing management, the role of advanced analytics in manufacturing, and regional manufacturing competitiveness. Katy also works with Episcopal Relief & Development, a non-profit organization that supports local, long-term initiatives addressing poverty, hunger, disease, economic development, and disaster response around the world. Prior to joining McKinsey, Katy worked as an associate analyst at National Economic Research Associates. She holds a high honors degree in economics and government from Oberlin College and a Ph.D. in business economics from Harvard University. Her doctoral work focused on factory management and supply chain improvements in assembly industries.



Donna S. Gulbinski, is Senior Vice President, Global Quality & Environment Health and Safety at Bristol-Myers Squibb. Donna provides quality and environmental health and safety (EHS) leadership to the Bristol-Myers Squibb (BMS) worldwide manufacturing and supply chain organization. She is a member of the Global Manufacturing & Supply Leadership Team as well as the Bristol-Myers Squibb Global Leadership Team. Her responsibilities span a broad range of quality, regulatory, and EHS activities. These include ensuring that the quality and EHS systems supporting BMS's global manufacturing and laboratory operations continue to meet or exceed applicable regulations and BMS standards. Under her leadership, BMS is continually assessing the evolving regulatory environment to establish and implement standards and processes that drive continued business success to ensure a reliable supply of quality products to patients. Donna began her career with Merck & Co., Inc., in 1985 where her responsibilities spanned a wide range of therapeutic areas, including research in bone biology, cardiovascular, anticoagulants, and protease inhibitors. She also had leadership roles in manufacturing operations and in quality (vaccine, biological, pharmaceutical non-sterile and aseptic operations). Donna joined Bristol-Myers Squibb in 2004 as Senior Director Worldwide Quality Policy & Compliance where she was responsible for worldwide quality standards and quality assurance and has since grown in responsibilities leading to her current role.



Paula Gurz, joined Premier as the Director Pharmacy Contracting, Generics in August 2011. In this position Paula is responsible for the management of all negotiation and administrative activities surrounding the Generic contracted portfolio. She has 20 years of experience in the generic pharmaceutical industry working with Sandoz, Dr. Reddy's Laboratories and Bedford Laboratories. During this time she functioned in various Pricing & Contracting or Marketing roles including Director Pricing & Contracts, Director of Marketing and Sr. Director Rx Marketing. Paula has extensive experience developing pricing strategies, negotiating pricing and contracts, marketing product portfolios, new product launches and product portfolio selection. Paula completed her undergraduate work at Daemen College receiving a BS in Marketing and graduate work at Canisius College in Buffalo New York with an MBA in Management. Paula resides in Lake Wylie, SC.



Mark McClellan, MD, PhD, is a senior fellow and director of the Initiative on Value and Innovation in Health Care at the Brookings Institution. Within Brookings, his work focuses on promoting quality and value in patient centered health care. A doctor and economist by training, he also has a highly distinguished record in public service and in academic research. Dr. McClellan is a former administrator of the Centers for Medicare & Medicaid Services (CMS) and former commissioner of the U.S. Food and Drug Administration (FDA), where he developed and implemented major reforms in health policy. These include the Medicare prescription drug benefit, the FDA's Critical Path Initiative, and public-private initiatives to develop better information on the quality and cost of care. Dr. McClellan chairs the FDA's Reagan-Udall Foundation, is co-chair of the Quality Alliance Steering Committee, sits on the National Quality Forum's Board of Directors, is a member of the Institute of Medicine, and is a research associate at the National Bureau of Economic Research. He previously served as a member of the President's Council of Economic Advisers and senior director for health care policy at the White House, and was an associate professor of economics and medicine at Stanford University.



Theresa M. Mullin, PhD, as Director of the CDER Office of Strategic Programs Dr. Mullin leads CDER strategic planning and directs the CDER international program, business informatics, drug data standards, program and strategic analysis. This includes leading FDA development of a drug benefit-risk assessment framework, Patient Focused Drug-Development initiative, and a new effort to establish the first formal pharmaceutical quality surveillance capability in CDER. In addition, Dr. Mullin heads the FDA delegation to ICH leading the US discussion of the future of ICH. She served as the FDA lead negotiator for the 2012 reauthorization of the Prescription Drug User Fee Act (PDUFA) providing an estimated \$700 million in annual fee revenues. She also served as lead negotiator for new user fees for biosimilar biological products authorized under the Biologics Price Competition and Innovation Act of 2009. Prior to joining CDER in September 2007, Dr. Mullin was Assistant Commissioner for Planning in the FDA Office of Commissioner where she led FDA user fee negotiations with the pharmaceutical industry for both the 2007 and the 2002 reauthorizations of PDUFA. Since joining FDA, Dr. Mullin has received a number of awards including the Senior Executive Service Presidential Rank Award for Distinguished Service in 2011 and Presidential Rank Award for Meritorious Service in 2006, as well as the FDA Commissioner's Award of Excellence. Prior to work at FDA, Dr. Mullin was a Senior Manager with The Lewin Group, specializing in health care consulting, and Principal Scientist at Decision Science Consortium, specializing in decision research and analysis. Dr. Mullin received her B.A. *magna cum laude* in Economics from Boston College, and Ph.D. in Public Policy Analysis from Carnegie-Mellon University.



Luisa Paulo, Chemical Engineer by training, joined Hovione in 1983 and has held several positions at the organization in different departments all related with quality units. As Senior Director of Compliance, Luisa is responsible for Hovione group Quality System, assuring its compliance with the newest regulations, company strategy plan and policies and is in force in all Hovione sites.



G.K. Raju, PhD, is Chairman and CEO of Light Pharma Incorporated, a consulting and technology company that is focused on the pharmaceutical and biotechnology industry, GK is also Executive Director for Manufacturing Initiatives at the Center for Biomedical Innovation (CBI) at MIT. He is Distinguished Fellow and Chairman of the Bio-Manufacturing Steering Committee at the Center for Biomedical Innovation (CBI) at MIT. He has been a Special Government Employee (SGE) of the U.S. Food and Drug Administration and has served on a number of FDA Advisory Committees for ten years. GK has also been Adjunct Professor of Industrial Pharmacy at Purdue University and Executive Director of the Consortium for the Advancement of

Manufacturing of Pharmaceuticals (CAMP) for about ten years. GK obtained his M.S. in Chemical Engineering from MIT in 1989, his MBA from the MIT Sloan School of Management in 1994 and Ph.D. in Chemical Engineering from MIT in 1998. G.K. has worked with or consulted for the U.S. FDA and most of the industry. His expertise is in defining the strategic role of pharmaceutical manufacturing and enabling its performance. He has benchmarked industry practices for a large number of years and has been involved in multiple organizational transformation efforts including at the U.S. FDA. His work focuses on innovation and transformation (and includes areas such as Regulatory Science, Quality by Design, Risk Management, Quality Management, Benefit Risk Analysis, Lean Six Sigma, Operational Excellence, Systems Dynamics, Organizational Learning, Process Analytical Technology, Data Analysis, Knowledge Management and Business Case Development). He is the author of several publications and book chapters and frequent speaker at international conferences.



Martin VanTrieste is the senior vice president of Quality at Amgen. He is responsible for all aspects of Quality Assurance, Quality Control, Compliance, Operational Excellence, Environment, Health and Safety along with Training at Amgen. Prior to joining Amgen, VanTrieste was with Bayer HealthCare's Biological Products Division as vice president of Worldwide Quality and Abbott Laboratories as the vice president of Quality Assurance for the Hospital Products Division. While at Abbott, VanTrieste held various positions in Quality, Operations, and Research and Development. He started his career at Abbott in 1983 after obtaining his

Pharmacy degree from Temple University School of Pharmacy. VanTrieste has been actively involved with various professional and trade organizations, including United States Pharmacopeia (USP), Pharmaceutical Quality Research Institute (PQRI), Pharmaceutical Research and Manufacturers of America (PhRMA), and AdvaMed, and he is the Chair Elect of the Parenteral Drug Associations (PDA). He is the founder and first Chairman of Rx-360 and is currently on their Board of Directors. Rx-360 is a nonprofit international supply chain organization that will enhance patient safety by increasing the security and quality of all parts of the supply chain. PharmaVoice in 2012 named VanTrieste as one of the 100 most inspiring people in the pharmaceutical industry and call him "a man with a mission".



Russell Wesdyk has over 25 years of experience in the pharmaceutical industry including the generic, biotech, and branded segments. Mr. Wesdyk received his BS in Chemistry from Seton Hall University before pursuing his MBA, integrating science and business components, a theme carried throughout his career. On the technical side, Russ has experience across a range of CMC areas with focus in Regulatory Affairs, Quality, Formulation, Manufacturing and Scale-Up. On the business side, Mr. Wesdyk's background includes corporate development, strategic planning, and life cycle management. His industry career has taken him through branded companies like Bristol Myers Squibb, and generic companies like

Apothecon and Lupin. During those roles Russ had responsibilities resulting in the successful domestic and international formulation, scale-up and technology transfer of a number of marketed products and served as a technical advisor to pharmaceutical equipment manufacturers as well as a reviewer for various industrial-pharmaceutics journals. Mr. Wesdyk has published actively in the areas of quality and formulation and manufacturing of controlled release dosage forms. His business accomplishments include securing funding for several start-up companies and serving as lead negotiator in transactions totaling in excess of \$10 Billion; additionally, Russ served as CDER's negotiator in the Generic Drug user Fee Act (GDUFA). Prior to joining FDA where he is currently employed as Scientific Coordinator in the Office of Strategic Programs, Mr. Wesdyk's last role in Industry was as Executive Vice President of Business Development for Cempra Pharmaceuticals, a recently IPOed bio-pharmaceutics firm focused on the development of anti-infective therapies.