Center for Health Policy at BROOKINGS

# Promoting Continuous Manufacturing in the Pharmaceutical Sector

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## Biographies

**Clive Badman** took up the position of Vice President, Pre-Competitive Activities, in R&D, in October 2013 having previously been responsible for the supply chain for clinical trials worldwide and the scale up and transfer of products into manufacturing. Clive joined Beecham Pharmaceuticals in 1978 and has held positions of increasing responsibility in Development and Production both at site and in central functions before moving to R&D in 2002. From October 2013 he also took on a role in the Business Engagement Group at Strathclyde University where he is a Visiting Professor and Chairman of CMAC (Continuous Manufacturing and Crystallisation). Clive was awarded an OBE in 2012 for services to the Pharmaceutical Industry.

**Richard D. Braatz** is the Edwin R. Gilliland Professor of Chemical Engineering at the Massachusetts Institute of Technology (MIT) where he does research in systems and control technologies and their application to pharmaceutical and biologic drug manufacturing. He received an MS and PhD from the California Institute of Technology and was the Millennium Chair and Professor at the University of Illinois at Urbana-Champaign and a Visiting Scholar at Harvard University before moving to MIT where he leads the Quality-by-Design (QbD) and control systems activities in the Novartis-MIT Center for Continuous Manufacturing and in the development of the Integrated and Scalable Cyto-technology (InSCyT) Platform for Biopharmaceutical Manufacturing on Demand. He has consulted or collaborated with more than 20 companies including Novartis, Pfizer, Merck, Bristol-Myers Squibb, Biogen, and Abbott Laboratories. Honors include the AIChE PD2M Award for Outstanding Contribution to QbD for Drug Substance, the Technical Innovation Award from the International Society of Automation, IEEE Control Systems Society Transition to Practice Award, and the AIChE Excellence in Process Development Research Award.

**Eugene J. Choi** is a Technical Advisor for the Defense Advanced Research Projects Agency's (DARPA's) Biological Technologies Office and Defense Sciences Office in the areas of chemistry, materials and devices, manufacturing, and synthetic biology. Dr. Choi has extensive research experience in biomaterials, molecular biology, polymers and chemicals, and analytical instrumentation development. Dr. Choi is the technical lead for the DARPA Battlefield Medicine program, whose aim is to develop innovative, miniaturized pharmaceuticals and biologics manufacturing platforms capable of producing multiple drugs. The program is comprised of two integrated research thrusts, Pharmacy on Demand and Biologically-derived Medicines on Demand, that creates a more flexible, portable, and agile drug manufacturing and supply chain platform capable of producing drugs safely and reliably, at the point of care, in short time frames, and with real-time analytics verifying purity, potency, and quality.

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**Eliana Clark** is vice president of Global Manufacturing Sciences at Biogen. In this role, she leads the global network accountable for providing scientific and technical support for all process related aspects of clinical and commercial manufacturing of large and small molecules, and end to end manufacturing from raw materials to finished goods. Prior to Biogen, Eliana held positions of increasing responsibility at Genzyme, a Sanofi Company, where she led the Late Stage Drug Product Development organization, the Manufacturing Sciences and Technology group supporting both Drug Substance and Drug Product manufacturing at the Allston Landing Facility, and the CMC regulatory group, supporting all US manufacturing sites for Genzyme. Prior to Genzyme, Eliana was a professor and a leader at Tufts University. During her tenure at Tufts, Eliana was the Assistant Director of the Biotechnology Center and the Chair of the Chemical and Biological Engineering Department. Eliana holds a Ph.D. in Chemical Engineering with post doctorates from the University of Delaware and Worcester Polytechnic Institute.

**Gregory Daniel** is a Fellow in Economic Studies and Managing Director for Evidence Development and Innovation in the Center for Health Policy at the Brookings Institution. In this position, Dr. Daniel leads the Center's pharmaceutical and medical device policy portfolio that includes developing strategies for better post-market safety surveillance and comparative effectiveness research, improving regulatory science, fostering practical steps for implementing expedited drug development and review tools, improving biomedical innovation, and supporting payment reform. Dr. Daniel is also a senior advisor to the Reagan-Udall Foundation for the FDA. Prior to joining Brookings, Dr. Daniel was the Vice President of Government and Academic Research at HealthCore, Inc., a research subsidiary of Anthem, Inc. At HealthCore, he led a division responsible for research 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 with a minor in Epidemiology from the University of Arizona, an MPH specializing in biostatistics, an MS in Pharmaceutical Administration, and a BS in Pharmacy, all from The Ohio State University.

**Liam Feely** is AbbVie's Vice President of Manufacturing, Science and Technology. In this capacity he is responsible for the technology transfer of new products from R&D into commercial production and also the global technical support for currently marketed products. This covers drug substance, drug product, analytical methods and devices/combination products. He has a Degree in Pharmacy and a PhD in Pharmaceutics from the University of Nottingham in the UK and 28 years of experience within the pharmaceutical industry. He has held a variety of CMC roles throughout his career including Director of Pharmaceutical Development in R&D and Division Vice President of Regulatory CMC before assuming his current position.

**Alastair Florence** is Director of the EPSRC Centre for Innovative Manufacturing and Doctoral Training Centre in Continuous Manufacturing and Crystallisation. After graduating with a B.Sc. (Hons) Pharmacy (Strathclyde, 1991) he worked in pharmaceutical manufacturing with Organon before moving into research, gaining a Ph.D in Pharmaceutical Chemistry in 1997. He was appointed to a lectureship in the Dept of Pharmaceutical Sciences in 1998 and became Professor of Pharmaceutical Science in 2007. In this time he has attracted over £20M in research funding, establishing a leading pharmaceutical crystallisation and solid-state research programme. In addition to the EPSRC Centre, highlights include RCUK Basic Technology (Control and Prediction of the Organic Solid State; CPOSS) and EPSRC Science and Innovation Award in Physical Organic Chemistry programmes. He was awarded the Royal Pharmaceutical Society Science Medal in 2004, speaks regularly at national and international conferences and has published over 100 peer-reviewed papers and book chapters.

**Patricia Hurter** joined Vertex in 2004 as Head of Formulation Development, and currently leads CMC (chemical and formulation process development, materials characterization, analytical development) and preclinical development (preclinical safety assessment, drug metabolism and pharmacokinetics, and GLP bioanalysis). In the past four years, Vertex has filed and received approval for IncivekTM, KalydecoTM. , and Orkambi™. Kalydeco (ivacaftor) and Orkambi (a combination of ivacaftor and lumacaftor) are the first medicines to treat the underlying cause of cystic fibrosis. Both of these new chemical entities were granted breakthrough status by the FDA. In the CMC arena, fully QbD applications were submitted for all three, and for Orkambi a fully continuous drug product manufacturing process has been implemented and approved by both the FDA and the EMA. Prior to joining Vertex, Dr Hurter was Director of Formulation Development at Merck, from 2000-2004. Before joining the pharmaceutical industry, Dr. Hurter worked in the paper industry for 8 years. She has a Ph.D. in Chemical Engineering from M.I.T., M.S. in Mechanical Engineering from W.V.U. and a B.Sc. in Chemical Engineering from the University of Natal, Durban, South Africa.

**Johannes G. Khinast** studied chemical engineering at Graz University of Technology and finished his studies in 1995 with highest distinction. From 1998 to 2005 he was professor at Rutgers University in New Jersey, USA. Since 2006 he is head of the Institute of Process and Particle Engineering at Graz University of Technology and since 2008 the scientific director of the Research Center Pharmaceutical Engineering GmbH. Moreover, he held the Marie Curie Chair from 2005 to 2008 and was significantly involved in the development of the new master program "Chemical and Pharmaceutical Engineering" at Graz University of Technology. He received numerous awards, such as the STEP Award Category Products/Technology in 2012 or the Styrian Innovation Award (Fast Forward Award) in 2010. His main research interests lie in the fields of pharmaceutical engineering, chiral catalysis and the numerical analysis and simulation of complex systems. His publications involve 160 papers in refereed journals, more than 100 conference proceedings, more than 50 invited talks and more than 150 presentations and talks.

**Melvin V. Koch** is Principal Scientist with the Center for Process Analysis and Control (CPAC), at the University of Washington in Seattle, a global industry / university / government consortium. He received his BA in Chemistry and Mathematics from St Olaf College, MS in biochemistry, and PhD in Organic Medicinal Chemistry from the University of Iowa. Dr. Koch worked for The Dow Chemical Company in process research and analytical chemistry (including 4 years with the Italian Pharmaceutical firm Dow Lepetit), achieving the level of Global Director of Analytical Sciences. He is active in coordinating developments in the field of process analytical technology (PAT) and process optimization between industry, government laboratories, and academia. Presently, Dr. Koch is serving on the FDA advisory committee to the Office of Pharmaceutical Sciences.

**Konstantin Konstantinov** is responsible for the late stage bioprocess and technology development at Sanofi's Boston Hub. This includes all functions, spanning from cell banking to fill/finish. He got his Ph.D. in Biochemical Engineering from Osaka University, Japan, which was followed by a post doc assignment at DuPont and U of Delaware. Before joining Genzyme in 2007, Konstantin has worked for Bayer in Berkeley, California, for 14 years, advancing to the position of a Head of Process Sciences. He has published more than 60 peer reviewed papers in the field of bioprocess development.

**Markus Krumme** is Head of the Continuous Manufacturing Unit in Novartis' Technical R&D since June 1st, 2011. During his career at Novartis, Markus Krumme has had the responsibility to conceive and implement the Continuous Manufacturing Technology and Pilot Plant on the Basel Campus. Prior to joining Novartis, Markus Krumme worked for Lohmann Therapy Systems for 13 years in leading roles in Research and Development in the US and Germany, including Vice President Research and Development. Prior to LTS Markus worked as a lecturer at the University of Tuebingen, Germany, in Pharmaceutical Technology. Markus is a licensed pharmacist in Germany and has a PhD in Pharmaceutical Technology from the Free University Berlin.

**Mark McClellan** 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.

**Frank Montgomery** was awarded his PhD in Synthetic Organic Chemistry at Imperial College London and completed Post-Doctoral studies at Ohio State University. He then moved to Ciba Central Research in Discovery Chemistry then to AstraZeneca Process R&D. During that time Frank led projects from pre-clinical development through to lifecycle management and divestment of commercial products. Frank led the Process R&D team for AstraZeneca's project in the FDA's CMC pilot program for implementation of ICH Q8, leading subsequent consultations with PMDA, EMA & Health Canada. Frank moved from a technical role to Regulatory Affairs and is now Global Head Regulatory CMC for small and large molecules across AstraZeneca & Medimmune. Frank has presented at a number of International conferences on implementation of QbD including DIA, ISPE, PDA and more recently a major EMA/EFPIA workshop as a co-presentation with regulators and Industry from focusing on risk assessment and lifecycle management. Frank is now a member of ICH Expert Working Group (EWG) as EFPIA Expert for ICH Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management.

For the last 24 years, pharmaceutical product and process design has been **Fernando Muzzio's** main research and educational focus. His main research interests include continuous manufacturing, with additional focus on powder mixing, powder flow, segregation, compression, mixing and flow of liquids and suspensions, capsule filling, tablet dissolution, and tablet coating. He is the author of over 250 peer-reviewed scientific articles, book chapters and patents. He is a frequent participant at FDA events, and in 2010 he was appointed a voting member of the FDA committee on Pharmaceutical Sciences and clinical pharmacology, where he currently serves as a consulting member. Professor Fernando Muzzio is also the director of the National Science Foundation Engineering Research Center on Structured Organic Particulate Systems. The center, which has a total budget in excess of $10 million per year, focuses on pharmaceutical product and process design, with special emphasis on continuous manufacturing, particle engineering, and personalized medicine. FDA and 50 companies are currently members of the center, including 10 of the top 20 pharmaceutical companies in the world, and many technology suppliers in the equipment, instrumentation, software, and control industries. Professor Muzzio has been consultant to more than 50 companies, including brand and generic pharmaceutical companies, as well as many other industries, on topics including product and process design, use of statistical methodology for product and process optimization, materials characterization methods, and strategic research and development planning. He is also the Chief Scientific Officer of Acumen Biopharma, a specialty consulting firm focused on pharmaceutical IP litigation.

**Michael O'Brien** is the head of the PTx (small molecule) Pharmaceutical Sciences Technology & Innovation (T&I) Group and is a member of the Pharmaceutical Sciences Executive Leadership Team. Michael earned his Bachelors of Science degree from Ohio Wesleyan University, and in 1989 received his Ph.D. in Organic Chemistry from Case Western Reserve University under the guidance of Prof. Anthony J. Pearson. He joined Hercules Inc. in 1989, where as a member of a multi-disciplinary team in the Aerospace division, he investigated the use of organic materials for unique optical applications. In 1992 he joined Rhone-Poulenc Rorer / Aventis Pharma as a Research Scientist and in 1999 he became the US Head of Chemical Process Research. There he championed the use of automated parallel chemistry technologies as an integral tool

in process research and development. In 2001 Michael joined Wyeth Research Chemical Development in Pearl River where he was the Assistant Vice President of the Synthesis Research & Development group overseeing Process Chemistry, the Chemical Engineering Technologies group (CET) and the High Throughput Process Screening group. Michael joined Pfizer in 2010 following the Wyeth acquisition. As the T&I Head, he directs a group that oversees a range of functions, including informatics and technology strategy development. The group places a strong emphasis on leveraging Pfizer internal innovation & science to develop an ecosystem that is highly matrixed with external networks, focusing on the delivery of future and potentially disruptive technology advances and platforms.

**G.V. Rex Reklaitis** is Burton and Kathryn Gedge Distinguished Professor of Chemical Engineering at Purdue University and for the past nine years deputy director of the NSF ERC on Structured Organic Particulate Systems. At Purdue he has served as the Head of the School of Chemical Engineering and Director of the Computer Integrated Process Operations Center. His expertise lies in process systems engineering, the application of information and computing technologies to process and product design, process operations and supply chain management. Current research interests include applications of process systems methodology to improve pharmaceutical product design, development, manufacture and administration. He was educated at the Illinois Institute of Technology (BS ChE), received MS and PhD degrees from Stanford University, has held an NSF Postdoctoral fellowship (Zurich, Switzerland) and a Senior Fulbright Lectureship (Vilnius, Lithuania). He is a member of the US National Academy of Engineering, fellow of AIChE, past Editor-in-Chief of Computers & Chemical Engineering and currently is member of three editorial advisory boards. Among his recognitions, he has received the Computing in Chemical Engineering Award (AICHE), the ChE Lectureship Award (ASEE), the George Lappin and Van Antwerpen Awards (AIChE), the Long Term Achievements in Computer Aided Process Engineering Award of the European Federation of Chemical Engineering and Pruitt Award of the Council for Chemical Research. He has served on the Board of Directors of AICHE, the Council for Chemical Research and the CACHE Corporation. He has published over 250 papers and book chapters and edited/authored eight books.

**Robin Robinson** was appointed in April 2008 as the first director of the Biomedical Advanced Research and Development Authority (BARDA), and Deputy Assistant Secretary in the Office of the Assistant Secretary for Preparedness and Response within HHS. Dr. Robinson previously served from 2004-2008 as the Director for the Influenza & Emerging Disease Program within BARDA and its predecessor agency at HHS. Dr. Robinson was recruited by HHS from the vaccine industry in May 2004 to establish a program with scientific and technical experts to implement the strategic plans and policies for medical countermeasures outlined in the National Strategy for Pandemic Influenza. These measures included development, acquisition and establishment of national medical countermeasure stockpiles, and expansion of domestic manufacturing surge capacities for influenza vaccines, antiviral drugs, rapid diagnostics, and non-pharmaceutical countermeasures including respiratory devices. For his leadership in this role, Dr. Robinson was the recipient of the Department of Defense's Clay Dalrymple Award in 2008 and a finalist for the Service to America Medal in 2009. Dr. Robinson received a Bachelor's degree in Biology from Millsaps College in 1976, a Doctoral degree from the University of Mississippi Medical School in medical microbiology, and completed in 1983 a NIH postdoctoral fellowship with the State University of New York at Stony Brook in molecular oncology. As Director of Vaccines at Novavax, Inc., he developed patented platform vaccine technologies including virus-like particles and subunit protein vaccines for human pathogens including

malaria, human papilloma, hepatitis, and influenza and for prostate, melanoma, and cervical cancers. Dr. Robinson also serves on World Health Organization (WHO) international expert teams on pandemic influenza vaccines. Additionally, he continues to serve as an editorial board member and reviewer for several professional scientific and technical journals on virology, vaccines, public health, and biotechnology.

**Keith Roper** is the Program Leader for Engineering Research Centers and Network for Computational Nanotechnology in the Engineering Education and Centers Division of the Engineering Directorate at the National Science Foundation. He cultivates academic-industry-government partnerships to translate discovery to disruptive innovation. Dr. Roper also holds the Charles W. Oxford Chair of Emerging Technologies in Chemical Engineering at the University of Arkansas. He is a Fellow of the American Institute for Medical and Biological Engineering and a member of the Arkansas Academy of Science. From 2010-2013 he served as Assistant Director of Microelectronics-Photonics Graduate Program at the University of Arkansas. Previously, he was a faculty member at University of Utah, Chief Scientific Officer of Celux Scientific, Research Fellow at Merck Research Labs, and Research Engineer at Wiltec Research Corp. He received a B.S. degree (magna cum laude) from Brigham Young University and a Ph.D. from the University of Wisconsin-Madison. Dr. Roper's research examines electrodynamics and transport in nanomaterials and bio/electronic systems that impact optoelectronics, biomedicine, and advanced biomanufacturing. His recent advances have been in simulation, nanolithography, opto-electronic microscopy and spectroscopy of metamaterials and plasmon-enhanced van der Waals materials. He has developed processes for cell culture, fermentation, biorecovery, and analysis of polysaccharide, protein, DNA and adenoviral-vectored antigens at Merck & Co. (West Point, PA), extraction of photodynamic cancer therapeutics at Frontier Scientific, Inc. (Logan, UT), and virus binding methods for Millipore Corp (Billerica, MA). He was instrumental in development and clinical manufacture of 1 viral and 3 bacterial vaccine products, 16 cGMP process documents, and multiple bioprocess equipment designs. He has authored or coauthored 2 textbooks (1 in press at Wiley), 2 book chapters, 57 peer-reviewed archival journal articles, 30 proceedings, abstracts, and popular articles, 164 presentations, 4 patents, and 4 provisional patent applications. He is active in AIChE, ACS, AVS, CMOS ET, and SPIE.

**Janet Woodcock** is Director of the Center for Drug Evaluation and Research (CDER), at the Food and Drug Administration (FDA). As of January 2015, Dr. Woodcock also assumed the role of Acting Director of CDER's newly formed Office of Pharmaceutical Quality, (OPQ). Dr. Woodcock first joined CDER in 1994. For three years, from 2005 until 2008, she served FDA's Commissioner, holding several positions, including as Deputy Commissioner and Chief Medical Officer, Deputy Commissioner for Operations, and Chief Operating Officer. Her responsibilities involved oversight of various aspects of scientific and medical regulatory operations. Before joining CDER, Dr. Woodcock served as Director, Office of Therapeutics Research and Review, and Acting Deputy Director in FDA's Center for Biologics Evaluation and Research. Dr. Woodcock received her M.D. from Northwestern Medical School and completed further training and held teaching appointments at the Pennsylvania State University and the University of California in San Francisco. She joined FDA in 1986.

**Seongkyu Yoon** is the co-director of the Massachusetts BioManufacturing Center (MBMC) and the lead of Biomanufacturing Consortium, and an assistant professor in the department of Chemical Engineering and BMEBT (Biomedical Engineering and Biotechnology) program and Pharmaceutical Sciences, University of Massachusetts Lowell. Dr. Yoon's research area is Systems Biology. Research covers multiscale modeling of biologics and life sciences systems, development of next generation biopharmaceutical processes, systems biotechnology. Research aims at developing innovative systems technology to improve drug development efficiency and manufacturing productivity, and developing detection and diagnostic systems and tools for selected diseases. He is currently developing systems tool using genomics and metabolic flux analysis approach to explain variability to productivity and quality of CHO (Chinese Hamster Ovary) mammalian cell-culture product. Integration of medical devices with multivariate statistical method is also being explored to develop practical diagnostic tools.

**Lawrence X. Yu** is the Deputy Director, Office of Pharmaceutical Quality, Food and Drug Administration. He is also adjunct Professor of Pharmaceutical Engineering at the University of Michigan. Dr. Yu's research interests have centered on the prediction of oral drug delivery and the development of pharmaceutical Quality by Design. His compartmental absorption and transit (CAT) model has laid the foundation for the commercial software, GastroPLUSTM and Simcyp®, which are being widely used in the pharmaceutical industry. Dr. Yu is a fellow and the past section Chair of the American Association of Pharmaceutical Scientists and an Associate Editor of the AAPS Journal. Dr. Yu has authored/co-authored over 130 papers, and presented over 100 abstracts, and given over 200 invited presentations. He is a co-editor of the books entitled "Biopharmaceutics Applications in Drug Development" and "FDA Bioequivalence Standards".