

**Single Use Systems Workshop**  
*Speaker Biography Summary*

**Jeffrey Carter, PhD**

GE Healthcare Life Sciences

Dr. Carter has been a supplier to the bio/pharmaceutical manufacturing industry for the past eighteen years, and is currently serving as Director of Research and Development for filtration and single-use products at GE Healthcare Life Sciences. In this role, he has been responsible for directing product design initiatives, and has been leading in the areas of developing robust programs for extractables characterization, sterilization and microbial control, and rigorous application of Quality to the development and manufacture of customized single-use solutions. Prior to this position, he has been in Marketing and R&D capacities at GE and at Millipore, where he was active in the areas of sterile filtration and virus clearance. Dr. Carter received his PhD from the Pennsylvania State University, studying microbial genetic recombination, and he held a postdoctoral fellowship at the University of Colorado Health Sciences Center, where he performed research in the area of microbial DNA replication. He is active in external organizations, such as the Parenteral Drug Association and The BioProcess Systems Alliance, where he is an advocate for promoting the application of good scientific and business practices to the implementation of single-use biopharmaceutical manufacturing solutions.

**Tor Gråberg**

Medical Products Agency

Mr. Gråberg has been with the Medical Products Agency since 1996 as a Pharmaceutical Inspector with a focus on manufacturing of medicinal products both national and international. In 2004 he was appointed as Head of Drug Inspectorate.

Before joining the MPA Mr. Gråberg was working as a production manager during 13 years in the pharmaceutical industry. He holds a M.Sc. degree in Pharmacy from the University of Uppsala, Faculty of Pharmacy.

Mr Gråberg is the Swedish delegate at European Medicines Agency, GMDP Inspectors Working Group since 2004.

During 2010 and 2011 he was the Chairman of PIC/S (Pharmaceutical Inspection Co-operation Scheme). Mr Gråberg is also the Swedish delegate in the PIC/S Committee and he is member of the Executive Bureau.

Since April 2011 he is a member of PDA Science Advisory Board.

**Duncan Low, PhD**

Amgen Inc.

Duncan Low joined the Process Development Department at Amgen in 2003, where he is currently responsible for Materials Science. He leads cross-functional teams for materials and technology evaluation, technology development and Process Analytical Technology. He is a member of the ISPE Executive Committee for PAT, is a member of USP's Committee of Experts and chairs the ASTM E55.01 subcommittee developing consensus standards for Manufacture of Pharmaceutical Products. Prior to joining Amgen he held VP positions at Millipore and Pharmacia Biotech. He has extensive experience of the tools currently in use in upstream and downstream processing and has worked closely with applications development throughout the industry. He has an M.A. in biochemistry from the University of Cambridge and a Ph.D. in microbiology from the University of Glasgow.

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#### **Ingrid Markovic, PhD**

CDER, FDA

Dr. Ingrid Markovic currently serves as Expert Review Scientist for Extractables and Leachables in therapeutic biologic protein products in the Office of Biotechnology Products, CDER, FDA. She is also involved in the CMC review, development of agency-wide regulatory guidance documents, participation in the pre-approval and biennial inspections, and in the new reviewer training program. Prior to her current position, Dr. Markovic was a Staff Fellow in the Division of Monoclonal Antibodies at CBER, FDA. Ingrid trained in biochemistry, cell biology and chemical ecology. She received both her M.S. and Ph.D. degrees from University of Wisconsin-Madison and her post-doctoral work was completed at the National Institutes of Health in the Laboratory of Cellular and Molecular Biophysics.

#### **Jerold Martin**

Pall Life Sciences

Jerold Martin is Sr. Vice President, Global Scientific Affairs for Pall Life Sciences and Chairman of the Bio-Process Systems Alliance (BPSA) single-use bio-manufacturing trade association. He has over 32 years experience in the biotech and pharmaceutical industry and is a frequent speaker and author on filtration and aseptic processing, including co-authorship of numerous PDA Technical Reports, BPSA Guides and ASTM, ISO and ASME-BPE Standards. In addition to BPSA, he is an active member of ASME-BPE, ISPE and PDA, where he received the 2007 Distinguished Service Award. He holds an M. Sc. in Microbiology from the University of Toronto.



#### **Morten Munk**

CMC Biologics A/S

Mr. Morten Munk holds a degree in Chemical Engineering, is co-founder of CMC Biologics A/S, and is currently holds a Vice President position in Business Development at CMC.

Morten had a key role in the design, commissioning and qualification of CMC's contract manufacturing facilities. His key areas of expertise are: Downstream Process Development, Process Scale-up, Facility Design and Process Validation.

Morten is a member of the board of ISPE Nordic Affiliate and several subgroups under ISPE. Furthermore, Morten has participated in several PDA special task force groups writing Technical Reports covering Process Validation and other regulatory subjects. Morten is currently co-chair for a new PDA Technical Report on Single Use Systems.

Prior to founding CMC in 2001, Morten held a position as Principal Scientist specializing in protein purification development and facility design at Novo Nordisk A/S.



#### **Paul Priebe**

Sartorius Stedim Biotech

Mr. Priebe has more than 12 years experience in process filtration and single use technologies in the biopharmaceutical industry. Through his career, he has held positions in manufacturing, engineering, sales, product management and marketing. Mr. Priebe joined Sartorius in July of 2002 as a Product Manager for Sterilizing Grade Filtration Products. From December of 2004 to August of 2007, he was Head of Product Management for Process Filtration and Disposable Technology. Today he is the Director of Fluid Management Technologies for Sartorius Stedim Biotech, with responsibility for all single use fluid handling technologies in the Americas. Mr. Priebe is a published author on the subjects of membrane filtration selection, sterile filtration, single use



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#### Paul Preibe, continued

technology and the biotech and pharmaceutical industries. He is a board member of the BioProcess Systems Alliance (BPSA) and a member of the PDA, including active participation as a contributing author on the Single Use Task Force. Mr. Priebe holds a bachelor's degree in mechanical engineering from the University of Delaware.

#### Robert Repetto

Pfizer

Robert Repetto is Research Fellow, External Affairs Technical Advocacy function focused on industry and regulatory trends that enable the BioTherapeutics and Vaccine portfolio. Technical Advocacy Topics of interest include: Single Use Systems, QbD, Biosimilars, and Innovative new therapies.

Prior to this position Bob was Director of Technology and Innovation for Wyeth Biotech, where he was responsible for development of strategies focused on new technologies, innovation, risk management, process technology, and real time process monitoring. Robert has over 20 years of process development, manufacturing and clinical production experience. He holds a B.E. in Chemical Engineering from Manhattan College, M.S. in Bioengineering from Polytechnic University of New York, and a MBA from Iona College. Robert is currently Chairman of the PDA's Global Taskforce for Single Use Systems.



#### Robert Shaw

Ark Therapeutics

Robert is currently working with Ark Therapeutics. He spends the great majority of his time at their operational Gene Therapy manufacturing and development facility in Kuopio Finland. Robert has had an enjoyable career of some 39 years in the pharma industry. In the early seventies, Robert qualified as a pharmacist and chemical engineer from The School of Pharmacy University of London.

Robert worked for some twenty years in small molecule product development and manufacture. His expertise was stretched from oral dose forms to inhaled powders and wound-care products, with four years colour matching cosmetic products! However, the experience gained in understanding patient requirements, real quality attributes and the regulatory need for process consistency and control for the wide range of pharmaceutical dose forms has proven invaluable.

Robert worked with Medeva from 1998 until 2002, as the Ashton site director. He joined Ark in area of Gene Therapy manufacture in 2004, as the IMPD regulations in Europe became established. His time at Ark has seen the implementation of the EMA ATMP regulations, and he has been responsible as QP for Phase 3 supply of Cerepro in clinical trials throughout Europe. The development control and process validation of gene-therapy products in the full GMP environment has brought fresh challenges. The provision by Ark of Trinam for clinical trials in the USA has allowed Robert to establish a view of the regulatory environment in the USA. Ark's current products and partnerships in clinical supply of product for the EU and USA territories continues to stimulate and challenge.



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#### **Christopher J. Smalley, PhD**

Merck

Chris Smalley has recently joined Merck, where he has responsibility for innovative processes implementation and validation, including Single Use Systems, worldwide in the vaccine, pharmaceutical and biotechnology businesses of the organization. Previously, he had been Director of Quality Operations for Wyeth Pharmaceuticals for 12 years with responsibility for setting validation standards and conducting validation activities globally in the pharmaceutical, biotechnology, consumer health and nutritional businesses. His research experience includes responsibility for Quality in the U.S. operations of the Sanofi Research Division, and earlier he had worked for the Johnson & Johnson family of companies, where he was the Plant Manager for the Parenterals facility for Janssen Pharmaceutica. Chris retired from the United States Air Force as a LtCol where he practiced as a pharmacist and healthcare administrator, and is a graduate of the Philadelphia College of Pharmacy of the University of the Sciences in Philadelphia. His graduate education includes a MBA from Temple University Fox School of Business and a Masters of Science in Pharmaceutical Chemistry from Temple University School of Pharmacy.



Chris is a member of the PDA Board of Directors, as well as a member of the Science Advisory Board.

#### **Marion Traverse**

NNE Pharmaplan AG

Since 2011, Ms. Traverse is employed at NNE Pharmaplan Switzerland, as lead process engineer with major expertise in single use systems in cell culture pilot plant. Previously, she has been working for 4 years as process engineer at Roche, where she specialized in single use technology. Notably, she played a major role in the implementation of a process transfer platform based on single use bioreactors. She is currently heading a large single use bioreactor implementation project in a vaccine production facility.



#### **Russell Wong, PhD**

Bayer Healthcare

Russell Wong is a Senior Engineer with Bayer Healthcare in Berkeley, California. In his position in Manufacturing Sciences, he has technical responsibility for single use bioprocess systems. He is currently serving on the PDA Single Use Systems Task Force. Dr. Wong joined Monsanto Plastics in Springfield, Massachusetts in 1991 where he developed engineering thermoplastics for specialty industrial and medical applications. Following the acquisition of Monsanto Plastics by Bayer, he continued to focus on the medical application of plastics at Bayer. Dr. Wong holds a BE in Chemical Engineering from the Cooper Union and an MS from the University of Utah in Bioengineering where he began his interests in the medical application of polymers. He completed his PhD at the University of Tennessee in Polymer Engineering with research into biomedical polyurethanes used for cardiovascular implant applications.

