Speaker Biography Summary

Anthony Andre, PhD

Interface Analysis Associates

Anthony Andre heads an award-winning human factors and ergonomics consultancy that specializes in health care safety, drug delivery device and instructional materials design, evaluation and testing, and regulatory process consulting. Interface Analysis Associates has a broad range of biotech, pharma and medical device clients and has been instrumental in obtaining approval of various drug delivery devices and combination products under the FDA's most recent human factors requirements. When not pulling rabbits out of a hat for his clients, Dr. Andre also serves as a Professor of Human Factors and Ergonomics at San Jose State University and the Associate



Director of their new "Human Factors in Health Systems" program. His other notable accomplishments include his recent term as President of the Human Factors and Ergonomics Society and his role as Organizer and Chair of the 2013 Symposium on Human Factors and Ergonomics in Healthcare, taking place next March in Baltimore, Maryland.

Harold Baseman

ValSource, LLC

Hal Baseman is a Principal and Chief Operating Officer for ValSource LLC. Mr. Baseman has held technical and executive management positions with several operating and consulting companies. He is a member and the Co-Chair of the PDA Science Advisory Board, the Co-Chair of the PDA Risk Management for Aseptic Processing Task Force, the Co-Chair of the PDA Technical Report #22 (Aseptic Process Simulation) revision team, Co-Leader of the PDA Process Validation Interest Group, and a member of the PDA TRI Faculty.



Mr. Baseman holds a Bachelor of Science Degree in Biology from Ursinus College in Collegeville, PA and a Masters in Business Administration in Management from La Salle University in Philadelphia, PA.

Kevin Constable

Terumo Medical Corporation

Mr. Constable joined Terumo Medical Corporation in January 2012 to lead the Technical Services team for the Global Pharmaceutical Division providing drug & device solutions to the pharmaceutical industry. Prior to Terumo Mr. Constable was employed by Pfizer working in the vaccines / biotechnology sector supporting technology transfer of new products, global launch of a pediatric vaccine, risk mitigation of supply, improved process solutions for filling and packaging, track and trace solutions, and global harmonization of practices for aseptic filling, inspection,



lyophilization, and packaging for pre-filled syringes and vials. Mr. Constable has over 20 years in the pharmaceutical industry and an additional 10 years in other manufacturing industries including clinical testing, nuclear power generation, and water / gas separation technology. In his spare time, Mr. Constable volunteers at the local high school teaching STEM concepts through robotic competitions within the structure of the FIRST organization (www.usfirst.org).

Brian Cooley

Eli Lilly & Company

Brian started his career in 1984 with Eli Lilly as a biochemical engineer responsible for the development and clinical trial supply of various biotech products including recombinant human insulins , antibiotics and mAbs. In 1990, Brian pursued an MBA and a career in marketing and sales. Since that time, Brian held a variety of US and international marketing leadership roles primarily in the therapeutic areas of Diabetes and Autoimmune. Brian has had significant experience developing and launching new



Speaker Biography Summary

Brian Cooley, continued.

products including Humalog in Europe, Actos in the US, Insulin Devices in Europe and the US, and the launch Byetta, the first GLP1-based therapy for the treatment of Type 2 Diabetes. Currently, Brian and his team are responsible for Drug Delivery New Product Planning to maximize drug delivery opportunities for Lilly's existing and emerging portfolio.

Dirk Daegele

Vetter-Pharma-Fertigung GmbH & Co.

Dirk Daegele studied biotechnology at University of Applied Science Mannheim, Germany. After joining the Development Service Department at Vetter Pharma-Fertigung in 2006 he has focused on the implementation of pharmaceutical processes for pre-filled liquid systems.



David Daily

Elcam Medical

David Daily is Director of R&D and BD, Injectable Drug Delivery Devices, Elcam Medical, and the CEO and co-founder of DALI Medical Devices, a R&D company focused on developing innovative drug delivery devices.



Most of these innovative drug delivery devices are being developed in partnership with Elcam Medical (www.elcam-medical.com), a world-class manufacturer of precision injection-molded disposable medical devices.

Before co-founding DALI (www.dalimed.com) in 2003, Daily worked as the Product Development Manager at Élan Medical Technologies (EMT, then a subsidiary of Élan Corporation, Ireland), where he was responsible for leading the development of a variety of disposable automatic injection and microinfusion systems from initial prototypes until registration.

Daily is a co-inventor on multiple international patents and patent applications.

He received a M.Sc. degree in Biomedical Engineering and a B.Sc. degree in Mechanical Engineering from the Technion (Israel Institute of Technology, Haifa), and a Master's degree in Business Administration (MBA) from the Hebrew University of Jerusalem (graduated with honors).

Barbara DeBaun

CMC Biologics A/S

Barbara DeBaun has over 30 years of experience in the field of infection prevention and quality improvement. She is currently an Improvement Advisor for Cynosure Health. In this role, she provides vision and leadership in the development, implementation and facilitation of performance improvement initiatives for healthcare organizations. Previously, she was an Improvement Advisor for BEACON, the Bay Area Patient Safety Collaborative, and was the Director of Patient Safety and Infection Control at California Pacific Medical Center in San Francisco. She is currently adjunct faculty at Dominican University of California. Barbara is a certified Infection Control



Practitioner and holds a Bachelor's degree in nursing from Pace University in New York and a Master of Science Degree in Nursing from San Francisco State University. She is an active member of APIC, the Association for Professionals in Infection Control and Epidemiology. Barbara currently serves as the chair of the 2012 APIC Annual Conference Committee and is a member of the APIC Education Committee and the APIC Practice Guidance Council. She is the APIC liaison to the CDC's Hospital Infection Control Practices Advisory Committee (HICPAC). She has lectured nationally and internationally on a variety of

Speaker Biography Summary

Barbara DeBaun, continued.

patient safety and infection control topics and has published over a dozen articles and several book chapters. In 2008, she was selected as *Infection Control Today's* Educator of the Year.

Garyen Denning

MedPro

Garyen Denning is the Executive Vice President for MedPro Safety Products. His primary focus is building partnerships with pharmaceutical companies and the MedPro technology. He previously served as Director, Program Management since joining MedPro in February 2006. Prior to that, he served as a sales manager for a consumer products distribution company. Mr. Denning received his undergraduate degree in economics from Wake Forest University and a master's degree from the Warrington College of Business Administration at the University of Florida.



Mariana Dimitrova, PhD

MedImmune, Inc.

Mariana N. Dimitrova is a group leader in the Formulation Sciences Department at MedImmune. Her current responsibilities include technical leadership in the formulation and fill/finish operations of biologics with a special emphasis on development of pre-filed syringe presentations for subcutaneous administration. Prior to MedImmune, Dr. Dimitrova was a member of the Drug Product and Device Development Department at Amgen Inc. where she assumed increasing responsibilities in the biophysical characterization of protein structure, stability, and degradation pathways. Between 1999 and 2003 Dr. Dimitrova was a postdoctoral



research fellow at National Institute of Health (NIH, NHLBI) in Bethesda, Maryland. She received her Ph.D. in Biophysics and Biological Sciences as a result of a joint research between National Institute of Advanced Industrial Science and Technology (AIST), MITI, Japan and Institute of Biophysics, Bulgarian Academy of Sciences.

Fabien Dubuc

BD Medical-Pharmaceutical Systems

He is currently leading a team responsible for developing, industrializing and promoting the BD Physioject™ disposable autoinjector platform. Among his many duties, he oversees product development, marketing, sales, regulatory, quality, and operations – ensuring resource alignment to meet customer needs.



Prior to this role, Fabien has had 4 years of experience as Project Leader for Global Industrial Operations where he started up a production unit of prefillable syringes in Hungary.

Before joining BD, Fabien was a consultant in Mergers & Acquisitions and Strategic Planning. He completed an MBA at the Collège des Ingénieurs Institute (Paris, France) and a Master degree in Aerospace Engineering at Supaero / ISAE (Toulouse, France).

Speaker Biography Summary

Bruce Eu, PhD

Amgen, Inc.

Bruce Eu received his Ph.D. in Macromolecular (Polymer) Science and Engineering from University of Michigan. He worked for Abbott Laboratories and Baxter HealthCare for research and development of in-vitro diagnostic and peritoneal dialysis devices. Bruce joined Amgen in 2005 and initiated the plastic pre-filled syringe program as a platform technology to eliminate silicone oil /tungsten induced protein aggregation and to avoid glass breakage. He developed a gold nano-particle staining method to visualize protein adsorption and silicone oil distribution in glass pre-filled syringes. He applied this method successfully to diagnose inconsistency in silicone oil



distribution that caused auto-injector failure. Bruce received 2009 best paper award by PDA for his work on characterization of silicone oil in glass pre-filled syringes. He is currently a Senior Principal Engineer and leads a group of engineers and scientists responsible for the development of new pre-filled syringes technology and integration with injection devices.

Chris Evans

West

Chris Evans brings more than 20 years of experience in product development, primarily in health care packaging and device development, to his role as Manager for West Innovation Concepts. He is the holder of 11 U.S. patents with several more pending. Chris was bitten by the innovation 'bug' while completing the pre-med program at University of Maryland, where he graduated with a B.S. in Biology in 1988. His first decade in the business found him concentrating on the manufacturing, engineering and commercialization of new products. Since then he has principally worked more on the 'front-end' of innovation, managing teams for discovery/user research, human-factors, conceptual and intellectual property development.



Mary Foley, RN, PhD

University of California San Francisco School of Nursing

Mary E. Foley RN, PhD is the Director in the Center for Nursing Research and Innovation at the University of California, San Francisco (UCSF). She has worked with the Center as Associate Director since 2004 in partnership with three Bay Area academic medical centers. Mary has worked with the Collaborative Alliance for Nursing Outcomes (CALNOC) since 2004, and in 2009 was appointed Director, Education Services for CALNOC. In that role, Mary has developed an area of expertise in nursing sensitive care measures, with special emphasis on medication safety. Mary is a past president of the American Nurses Association from 2000-2002 and the



National Student Nurses Association while she was a student in the 1970's. She has always been committed to hospital nursing, and while at Saint Francis Memorial Hospital in San Francisco she was a staff nurse, Director of Nursing, and Safety Officer.

A registered nurse for over 35 years, Foley has been active in the health care policy arena. She continues to write and lecture about health care policy, improving the workplace, and promoting safe care for workers and patients nationally and internationally. She completed a six-year term as a member of the National Patient Safety Foundation Board of Directors and is an advisory member of the Partnership for Patient Safety (p4ps). She is a member of the TMIT Patient and Family Advisory panel. In November, 2011 she was appointed a Nursing Co-Lead for the California Action Coalition to implement the IOM Future of Nursing report. She has also been elected the board of directors of the CGFNS International starting in 2012, and is Chairperson of the Safe in Common Campaign due to her passion for the topic of needle stick injury prevention.

Speaker Biography Summary

Mary Foley, continued.

Foley received her nursing diploma in 1973 from New England Deaconness Hospital School of Nursing, her BSN in 1976 from Boston University School of Nursing in Massachusetts, and her Master's of Science in Nursing Administration and Occupational Health from UCSF in 1994. She received her PhD in Nursing from UCSF 2010 with an emphasis on policy and occupational health.

Ed Geiselhart

Insight Product Development

Ed combines an education based on critical design thinking with over 20 years of experience in development consulting to help lead Insight project teams and to provide them with inspiration to achieve success.

Even before Ed began his design education, he believed that to create the most successful solution to any problem you must first appreciate and understand the interrelationship of each individual aspect of the problem.



He brings this passion to Insight today in appreciating how research, design, and engineering are inextricably linked, and how each has great potential for inspiring innovation. His experience helps give our teams the foresight to understand how to navigate the development process to best identify the right long-term strategy that aligns with the client's vision.

Ed is heavily involved in helping clients champion new methods to define and solve complex challenges that balance business goals, technical considerations, market influences, and user needs. He has published dozens of articles and has spoken on development and innovation topics at numerous engagements both domestically and internationally.

Ed graduated Magna Cum Laude from the University of Cincinnati with a BS in Industrial Design.

Aarti Gidh, PhD

GlaxoSmithKline

Aarti Gidh joined GlaxoSmithKline in September 2008 as Principal Scientist in the Biopharmaceutical Technologies group. She is currently an Investigator and is the technical lead for the formulation, product development, and technology transfer of early and late stage drug products. She was also the technical lead for the syringe first intent selection. Dr. Gidh worked as a Scientist at Amgen, Inc. for 2.5 years. She was the drug product team leader for a multi-billion dollar commercial product and has also worked on automatic visual inspection evaluation characterization and validation for syringes. She holds a MS and PhD degree in Chemical Engineering from



University of Mississippi, and a BE degree in Chemical Engineering from University of Bombay, India.

John Gosbee, MD

Red Forest Consulting, LLC

John Gosbee, MD, MS is a Human Factors Engineering (HFE) and Healthcare Specialist providing expertise to design of healthcare devices, software, and architecture. His clients include large medical device companies (e.g., Medtronic), healthcare delivery organizations (e.g., Northwestern University), professional societies (e.g., American College of Surgeons), federal government (e.g., FDA), and other countries (e.g., Sweden and Japan).



Dr Gosbee also works to develop and implement human factors engineering and patient safety ideas in academia at the University of Michigan Health System (UMHS) and elsewhere. He leads the patient

Speaker Biography Summary

John Gosbee, continued.

safety certification effort for all incoming UMHS residents. He has been visiting professor or given grand rounds at eleven universities in the past three years, including University of Maryland and Yale University. Dr Gosbee has been an advisory panel member or consultant to several patient safety programs, including those at Harvard Risk Management, Johns Hopkins, American Heart Association, and American Academy of Family Physicians.

Among other publications and recognition, Dr. Gosbee was guest editor for a 2004 series on patient safety

and human factors engineering for Joint Commission Journal on Quality and Safety. In 2005, he edited and was major contributor for the book, *Using Human Factors Engineering to Improve Patient Safety.* He received the "Cheers Award" for advancing medical device design in medication safety from the Institute for Safe Medication Practice (2005); and "Career Achievement Award" in medical device design from the Association for the Advancement of Medical Instrumentation (2002).

Dr Gosbee most recently worked at the U.S. Department of Veterans Affairs (VA) National Center for Patient Safety in Ann Arbor, MI (1999-2006). He led the development of patient safety and human factors engineering residency and medical school curriculum. He led the human factors engineering analysis of adverse events and close calls involving medical devices and software, including being the liaison to companies to rectify design issues. Prior to VA, Dr. Gosbee was Assistant Professor at Michigan State University College of Human Medicine (1992-9), was HFE consultant to several Fortune 500 medical device and software companies (1994-9), and worked at NASA on development of spacebased medical facilities (1988-92). He received his medical degree at University of Wisconsin in 1985, and masters degree training in aerospace medicine and human factors engineering at Wright State University in 1988.

Michael Gross, PhD

Chimera Consulting North America LLC

Michael Gross is the President of Chimera Consulting North America LLC, a consultancy specializing in quality, regulatory affairs and technical development strategy for drugs, biologics, medical devices and in particular drug delivery systems and combination products. Dr. Gross has worked in the medical products industry for over thirty years in senior quality and regulatory affairs roles.



Following post-doctoral training in biochemistry at the National Institutes of Health,

Michael joined the FDA as a research chemist engaged in regulating and inspecting biologic product manufacturers. Subsequently he joined the medical products industry, working for a number of large and small pharmaceutical and biotech companies and for a large medical device manufacturer. He is experienced in a variety of therapeutic areas (i.e., cardiovascular, neurological, pulmonary, urology, oncology, ophthalmology, dermatology, anti-infective drugs and blood products). Michael has worked with a variety of combination product types and understands the complex issues surrounding them. He is experienced in pre-clinical, clinical, manufacturing, quality, labeling, submissions and post-marketing compliance matters related to drugs, biologics, medical devices and combination products.

Dr. Gross has personally written and/or managed the submission of investigational exemption applications [IND, IDE], marketing applications [NDA, 505(b)(2) NDA, sNDA, ANDA, BLA], device registrations [510(k), PMA] and other FDA regulatory filings [RFD, DMF, BMF, MAF] and has also made counter-part filings to European Health Authorities. He has also held the senior compliance role for a large pharmaceutical manufacturer of plasma derived and recombinant plasma protein therapeutic products.

Speaker Biography Summary

Michael Gross, continued.

For more than 20 years, Michael has played an influential role providing an industrial perspective on the regulation of combination products. He is a frequent speaker on these topics at industry meetings and has presented testimony at FDA hearings on this subject.

M. Ryan Hawkins

Cook Pharmica

Ryan Hawkins is the Vice President of Drug Product Operations for Cook Pharmica, a contract biopharmaceutical manufacturer, located in Bloomington, Indiana. Beginning with Cook Pharmaceutical Solutions, followed by Baxter BioPharma Solutions, he has held positions of increasing responsibility in drug product contract manufacturing, including aseptic vial and syringe filling, automated inspection, and labeling and packaging operations. In 2007, Ryan re-joined Cook as Project Director leading the design and coordination of the Parenteral Manufacturing expansion project, consisting of over 120,000 square feet of newly developed space including



two high speed filling lines under barrier isolation and complimentary secondary manufacturing capabilities. With 14 years of industry experience, Ryan oversees Technical Services, Process Engineering and Production operations for the Drug Product business. Ryan holds a BS in Biology from the University of Wisconsin-Milwaukee and an MBA from Indiana Wesleyan University.

Tibor Hlobik

West Pharmaceutical Services

Tibor Hlobik has worked within the pharmaceutical packaging industry for over twenty-five years in areas of research & development, corporate quality, technical services and marketing primarily at West Pharmaceutical Services. He has extensive knowledge and experience with prefillable syringe systems and related technologies. Currently in his role as Director, Marketing for PFS Technologies at West Pharmaceutical Services, Tibor is responsible for defining new market requirements, launching new products, supporting business development plans, and overall execution of global marketing strategies for West.

Ronald G. Iacocca, PhD

Eli Lilly & Company

Ronald Iacocca received his B. S., M.S. and Ph.D. in Materials Engineering from Rensselaer Polytechnic Institute (RPI). For nine years prior to joining Lilly, he was a faculty member in the Department of Engineering Science and Mechanics at Penn State University. In November 2000, Ron joined Eli Lilly as a research scientist in Physical and Structural Characterization, Currently, he is a Senior Research Advisor in Analytical Sciences Research and Development, and is team leader of the Materials Science/Physical Characterization team. He has authored/co-authored over 65 journal articles, book chapters, and review articles, and has been granted 4 patents. He is a member of ASM International, ASTM, PDA, ACerS, and ISO.

Dr. Iacocca also served as an adjunct professor in the Department of Industrial and Physical Pharmacy at Purdue University from 2006-2009, and serves as a member of the editorial advisory board for

American Pharmaceutical Review, as a reviewer for the Journal of Pharmaceutical Sciences, as a key reader for Metallurgical and Materials Transactions A, and is head of the working group on laser diffraction for the International Standards Organization (Working Group 6, ISO TC24/SC4). In 2010, he was elected to the USP to serve on the Physical Analysis Expert Committee

Speaker Biography Summary

Sebastien Jouffray

BD Medical - Pharmaceutical Systems

Mr. Jouffray has been with BD Medical-Pharmaceutical Systems since 2001 in the R&D organization, first working in the sustaining engineering team, responsible for customer projects development and as well supporting customer technical demands. Most recently, in the Advanced Product Development group, he managed the team responsible for the Advanced Coating program.



Shawn Kinney, PhD

SiO2 Medical Products, Inc.

Shawn Kinney is the CEO of Supplier Sentinel Inc. (SSI), a newly founded company that provides supplier assessment/evaluation services to the biotech, pharmaceutical and medical device industries. Prior to co-founding SSI, Dr. Kinney was founder and CEO of Hyaluron Contract Manufacturing (HCM), a sterile contract manufacturing organization that was recently acquired. Dr. Kinney has significant experience in pharmaceutical formulation, scale up and sterile filling of drugs, proteins, and viscous products in syringes and vials. He holds patents in bubble free



filling, speaks frequently at industry conferences on sterile filling and prefilled syringes and he has numerous publications. Prior to founding HCM, Dr. Kinney was Vice President of Operation at Anika Therapeutics, where he was responsible for sterile manufacturing and filling of syringes for orthopedic and ophthalmic products.

Dr. Kinney holds a doctorate in Chemistry from the University of Massachusetts at Amherst, a Master of Science in Medicinal Chemistry from Northeastern University and a Bachelor of Science from Southeastern Massachusetts University. He is a member of the Parenteral Drug Association, and the American Association of Pharmaceutical Scientists. He is a regular speaker at pre-filled syringe conferences and holds patents in sterile syringe filling technologies.

Horst Koller

Schott Schweiz AG

Mr. Koller started his professional career in 1994 to work for a large pharmaceutical company in Germany managing the Process Engineering Group.

In 2000 he joined Schott in the business segment Pharmaceutical Packaging. He has been a key player in building the manufacturing unit for the Schott TopPac® polymer syringe within Schott AG. He held different positions including Quality Manager, Head of R&D, Manager Scientific Advisory and Manager Global Regulatory Affaris and Quality R&D. In his current position he is responsible for the global Technical and Quality Support syringes for Schott Pharmaceutical Packaging.



He is an active member as expert of ISO/TC 76/ working groups and a frequent speaker at extractables & leachables as well as Prefillable Syringe conferences.. He holds a degree as Dipl. Ing (FH) in Biotechnology.

Lee Leichter

P/L Biomedical

Lee Leichter has over 35 years' experience in the health care industry. He has been providing direct, hands-on assistance to domestic and international Pharmaceutical, Biotechnology and Medical Device companies for the last 15 years. Projects have encompassed a multitude of business, technical, regulatory and quality issues, mostly relating to drug delivery and combination products for marketing in the USA, Europe and Canada. He has worked with large multi-national companies and start-ups



Speaker Biography Summary

Lee Leichter

successfully navigating the challenges posed during the development, testing and marketing approval of products that merge pharmaceutical substances with high-tech device systems.

He serves as an independent expert on the ISO technical committees for Injection and respiratory products, infusion pumps, needles and catheters, and AAMI Injection and Infusion Devices and Human Factors committees, helping establish international standards for safety and performance of these products. He has also directly proposed and responded to FDA positions and proposals covering combination products, most recently as a consultant to the Combination Products Coalition.

He holds a Bachelor's degree from the State University of New York at Stony Brook and an MBA with Honors from Florida Gulf Coast University. He is certified in USA and EU Regulatory Affairs.

Lei Li, PhD

Eli Lilly and Company

Dr. Li has been with Eli Lilly and Company since 2009 in Global Packaging Technology and Development group, responsible for packaging evaluation laboratory and pilot plant operations. He leads a cross functional research team consisting of analytical scientists and packaging engineers to implement innovative pharmaceutical package testing capabilities in support of packaging development for Lilly's pipeline. Responsibilities include developing various techniques to characterize the physical and chemical properties of pharmaceutical packaging, with emphasis on product contact components, and applying them to enable material



selection, container closure system design and qualification, as well as packaging process development. He obtained his Ph. D. in Analytical Chemistry from West Virginia University and worked as a material characterization and analytical scientist at GE Plastics prior to joining Lilly.

Sheldon Moberg

Amgen, Inc.

Sheldon Moberg is vice president of Drug Delivery at Amgen. Sheldon joined Amgen in January 2011 to oversee the development of the company's broader drug delivery strategy. In this role, Sheldon is responsible for the execution of all device projects in Amgen's product portfolio, with extensive cross-functional collaboration within the company including R&D, Regulatory Affairs & Safety, Global Commercial Marketing, and Strategy & Corporate Development.



Sheldon has over 20 years of experience in the development and commercialization of innovative medical devices. Prior to Amgen, Sheldon held Research and Development leadership positions at Medtronic's Diabetes Division in Northridge, California, where he was responsible for managing research and development activities of drug delivery systems.

Sheldon earned a Master's degree in Mechanical Engineering from Purdue University and a Bachelor's degree in Mechanical Engineering from California Polytechnic State University, San Luis Obispo. Sheldon has been awarded 74 patents in the United States, with multiple patents pending.

Speaker Biography Summary

Kingman Ng, PhD

Novartis Vaccines & Diagnostics

Kingman Ng received a doctorate in biophysical sciences from University of Minnesota. Dr. Ng had more than 15 years of biologics formulation development experience with Eli Lilly and Company prior to join Novartis Vaccines and Diagnostics as Head of Pharmaceutical Sciences in Jul 2011, where he is leading and setting up the department of pharmaceutical sciences responsible for vaccine formulation and analytical development in US. In addition, Dr. Ng is also building a center of excellence for primary packaging development with special focus on prefilled syringe.



Soren Bogvad Petersen

NNE Pharmaplan

Søren has been with NNE Pharmaplan for 2 years as a senior consultant, where he has been managing a Tolerance Review project on Novo Nordisk prefilled insulin pen - FlexTouch®. With more than 12 years of experience within applied manufacturing science, Søren has a broad back ground with projects spanning from high volume production, over pilot production to early device development. A key part of his work has been practical application of statistical methods; developing costumer specific tolerance analysis solutions, conducting DoE as part of process and device development and implementing Statistical Process Control for a number of, mainly Danish, medical device manufacturers.



Heino Prinz, PhD

Wilco AG

Heino received his education as a Chemist at the University of Ulm with the main focus of Physical Chemistry within high resolution infrared and microwave spectroscopy. His PhD in 1990 in infrared laser spectroscopy and did research work in France, Austria, USA and Australia. From 1991 Heino served as Head of the department Theoretical Chemistry at Zentrum für Solar Energy and Hydrogen Research in Ulm. In 1995 he joined the Chamber of Commerce in Ulm as Technology Consultant. From 1997 at Uhlmann Pac-Systeme GmbH & Co. KG in Laupheim, and is responsible for the introduction of NIR-Spektroscopy into the packaging process. He



was a co-founder of Uhlmann VisioTec GmbH in 2000 where he became Head of R&D. He expanded the R&D department towards PAT and Consulting.

In August 2010 he joined Wilco AG, a world market leader in process quality systems for container integrity testing, in charge for research and development.

His profound knowledge of the pharmaceutical industry and his expertise in NIR spectroscopy helped the companies to develop high-speed Inspection systems which are used in numerous applications in the pharmaceutical manufacturing process as PAT tools. His expertise in in physics and chemistry helps customers around the world to deeply and better understand pharmaceutical processes, thus improving quality and dramatically reducing QC costs such as rework. Dr. Prinz also develops specifications for existing processes and provides consulting for pharmaceutical clients to achieve goals like Six Sigma processing, Right First Time Manufacturing and Quality by Design standards, and this also in conjunction with the technological developments under his responsibility.

Speaker Biography Summary

Brigitte Reutter-Haerle

Vetter Pharma International GmbH

Ms. Brigitte Reutter-Haerle is the Director of Corporate Marketing for Vetter, a leading contract development and manufacturing organization that serves the global pharma/biotech industry. She has held her current position since 2004 and is responsible for the company's international marketing activities and product and service management. In 2009, she led the communications program for Vetter's U.S. expansion. Ms. Reutter-Härle joined Vetter in 1996, serving in the company's sales and marketing function, and transferred to corporate marketing three years later. She began her career in 1983, holding various positions in the sales organizations of firms including Hilton International and TNT Express Worldwide.



Ms. Reutter-Haerle earned a B.A. and a degree in business administration from Baden-Wuerttemberg Cooperative State University. She has served as leader of the Prefilled Syringe Interest Group/Europe of the Parenteral Drug Association since 2007.

Philipp Richard

Ypsomed AG

Philipp Richard has been with Ypsomed AG since 2009 managing commercialized products and working with pharma and biotech partners to bring to market new innovative self-injection systems. Ever since joining the company, Philipp has been active in the area of human factors engineering.



He studied electrical engineering (MSc ETH EE) and has worked in product development, project management and international sales of technical products in other industries before joining Ypsomed and the world of medical devices

Andrea Sardella, PhD

Nuova Ompi-Stevanato Group

Degree in Physics at the Padua University in 1989, master in Nuclear Engineering in the 1990. As researcher at the National Research Council (C.N.R.) he developed several optoelectronic and nuclear scientific instruments for Magnetically Controlled Fusion Research setting up international collaboration with UWA Madison (Usa) and Garchin IPP (De). After 10 years of activity in research he moved to the industrial sector developing optical and vision controls for industrial application as CEO of a Tattile srl subsidiary. This experience drove him into the pharmaceutical field where he started to develop several control applications with vision and spectroscopy tools.



After several years he joined Brevetti C.E.A spa as R&D Manager and he developed the latest inspection technology currently on BCEA machines.

Since 2008 he has been with Stevanato Group as R&D Manager to develop new automation and inspection products dedicated to the pharmaceutical customers of the group.

Speaker Biography Summary

Klaus Schrieber

Robert Bosch GmbH

Klaus Schreiber has been with Robert Bosch since 1994. He started in the sales department of the Pharma Liquid plant at Crailsheim/Germany where he was managing various export markets in Europe, Latin America and the Asia Pacific region.

In 2004 he became head of the Product Management Group until August last year. His main tasks were strategic portfolio planning, optimization of sales tools and product specific marketing and communication.



Since 2012 Klaus Schreiber is responsible for Business Development of 3 smaller Leadplants within the Business Unit Pharma of Bosch Packaging Technology

Corinna Sonderegger, PhD

Sandoz International

Corinna Sonderegger received her PhD in biochemistry and molecular biology at the University of Innsbruck/Austria in 1998. As a post-doc at The Scripps Research Institute in San Diego/California she developed high-throughput cell-based drug-screening assays and performed cancer research applying virology and cell biology. In 2002 she joined Sandoz Biopharmaceuticals, being responsible for cell culture derived drug substance upstream process development including QbD process characterization and process validation concepts. Since 2010 Corinna is leading the development of biosimilar drug products at Sandoz Biopharmaceuticals Austria as Head of Pharmaceutical Development.

Ian Thompson

Ypsomed

Ian Thompson is Vice President of Business Development, Delivery Systems, at Ypsomed AC, where he has been working for over 10 years with pharma and biotech partners to develop and bring to market innovative and reliable injection systems for self-administration. Ian has over 20 years' experience in the selling and marketing of technical products, the last 14 of which have been spent in the field of medical devices. He has a degree in Biochemistry, a masters in Biotechnology and an MBA from Henley Management College, UK



Robbert van Meerwijk

ARTE Corporation

Robbert van Meerwijk joined Philips Duphar (later Solvay Pharmaceuticals) in 1976. He was responsible for Third Party Contract Manufacturing at Solvay Injectables since 1990. In 2009 he joined ARTE CORPORATION Japan, as Marketing & Sales Director Europe and North America, for their Prefillable Syringe line.

Christopher Weikart, PhD

Director, Research & Development

Christopher Weikart is the Director of Plasma Coating Systems at SiO2 Medical Products, is responsible for development of plasma coatings processes to support product development. Mr. Weikart directs development activities of the in house technical staff and external consultants. Mr. Weikart has a Ph.D. in Chemical Engineering from the University of Missouri. Prior to joining SiO2 Medical Products, was an R&D Manager for the Energy and Materials Business at the Dow Chemical Company, where he served for 11-years. During his tenure at Dow, Mr. Weikart worked in the plasma development group. Mr. Weikart was based in Midland, MI at



Speaker Biography Summary

Christopher Weikart, continued.

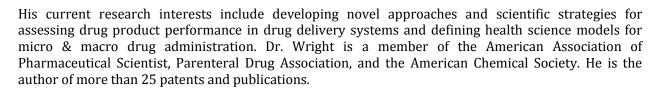
Dow Chemical, Central Research and Development.

Justin Wright, PhD

BD Medical - Pharmaceutical Systems

Dr. Wright is Director of Pharmaceutical Development for BD-Medical Pharmaceutical Systems. In his current role he serves as BD's lead technical interface for the Biotech, Vaccine, and Pharmaceutical industries in developing and commercializing complex and sensitive drug products in parenteral delivery systems.

Over the past two years he has served as an expert witness in numerous forums including the National Academies of Sciences (IOM), National Vaccine Program Office, and Biomedical Advanced Research Development Authority (BARDA) where he provided expert testimony for the US National Vaccine Plan and the National Pandemic Plan.



Prior to joining BD, Dr. Wright spent seven years at Merck & Co., Inc in roles of increasing responsibility across new product development, product commercialization, and franchise management.

Dr. Wright earned a PhD in Bio-Organic chemistry from Clemson University and completed a post-doctoral research fellow at Harvard Medical School.

Scott Young, PhD

West Pharmaceuticals

Dr. Young has more than 20 years of extensive expertise in the area of medical device design and materials development. Previous industrial experience includes employment at American Cyanamid, Shell Chemical Company, and WL Gore.

Dr. Young is currently responsible for the development and commercialization of the Daikyo Crystal Zenith Platform including syringes, vials, API containers, and novel delivery systems.



Dr. Young holds a B.S. degree in Chemical Engineering from West Virginia University, a M.S. and Ph.D. degree in Chemical Engineering from University of Pittsburgh, and an M.B.A. from the University of Delaware.

Dr. Young is an active member of the American Chemical Society and the Society of Plastic Engineers, and has authored more than 25 publications and conference presentations.

Speaker Biography Summary

Joerg Zimmerman, PhD

Vetter Pharma-Fertigung

Jörg Zimmermann studied pharmacy in Freiburg, Germany and Cardiff, Wales. He joined Vetter in 1994 as assistant head of production. His first responsibilities were process development and new product introductions with a focus on lyophilization process development. For the last 10 years, Jörg was responsible for the Vetter Site in Langenargen as Director of production, a site with 5 filling lines for aseptically prefilled injection systems. In September 2010 he changed back into the role of Director Process Development and Implementation.



Menachem Zucker, PhD

Elcam Medical

Dr. Menachem Zucker is currently acting as VP of Elcam Medical, Head of the Injectable Drug Delivery Devices unit, and act as the Chief Scientist of the company.

In the recent years Dr. Zucker is focusing on the area of Drug Delivery Devices specially designed for the new Biologics and injectable drugs, he is leading Elcam's efforts in this area and as a result a new portfolio of auto-injectors for drugs in Vials and in Prefilled syringes are now available for the Pharmaceutical market.



In the previous years Dr. Zucker was Elcam's VP for business development and marketing. Dr. Zucker received the BSc and MSc degrees from the Technion in Haifa Israel and received his Ph.D. from the Imperial College, University of London in 1990.

In 1991 Menachem received one of the most prestige's award from the government of Israel for Technology achievements.

Dr. Menachem Zucker has vast experience in several clinical arenas: Cardiology & Interventional cardiology, Intensive care and Heart by-pass surgery, where he was engaged in different technology projects very successfully.