2012 Pharmaceutical Cold Chain & Good Distribution Practice Conference
Speaker Biographies
As of November 13, 2012

Rafik Bishara, PhD

Chair, Pharmaceutical Cold Chain Interest Group (PCCIG)

Dr. Bishara has become one of the most respected figures in the pharmaceutical cold chain distribution sector, following a distinguished 35 year career with Eli Lilly & Co. as Director, Quality Knowledge Management and Technical Support.
Dr. Bishara received his Ph.D. from Purdue University, Indiana, USA, adding to his B.S. Pharmacy & Pharmaceutical Chemistry and an M.S. Phytochemistry from Butler University, Indianapolis, Indiana, USA. During his tenure at Eli Lilly and Company, Dr. Bishara was responsible for Quality Knowledge Management, Global Compendial Affairs, Stability and Distribution Excellence, Global Product Protection, Special Security Substances and Controlled Substances Administration. Dr. Bishara served on the Board of Directors of Sensitech, Inc., Kodiak Thermal Technologies, Inc., and Board of Advisors of Entropy Solutions, Inc.and CryoPort. He is a Temporary Adviser to the World Health Organization (WHO) since July, 2007. He has been acting as mentor & training adviser to the WHO/PDA "Pharmaceutical Cold Chain Management on Wheels." Dr. Bishara is a member of the Editorial Advisory Board of Pharmaceutical Outsourcing Journal; Life science Leader Magazine; and the Board of Advisors of BioConvergence, LLC, and MARKEN LLP. Dr. Bishara is the recipient of the PDA's 2007 Distinguished Service Award, IQPC's 2008 "Most Significant Contribution to Cold Chain Excellence," the 2008 School of Health Sciences, Purdue University, Distinguished Alumnus Award, and 2012 PDA's Michael S. Korcsynski Award for International Activities. Dr. Bishara has worked consistently towards harmonization of many global regulations and guidelines for the transportation of pharmaceutical and biotech products. He has chaired and presented at industry leading conferences. Dr. Bishara has authored numerous articles, and technically advised several organizations on Good Cold Chain and Temperature – Controlled Management.

Bob Celeste

GS1 Healthcare US

Bob Celeste is a Director of GS1 Healthcare US. Mr. Celeste has more than 25 years of experience in business process and supply chain management in the healthcare, pharmaceutical and a variety of other industries. GS1 Healthcare US focuses on driving the adoption and implementation of GS1 Standards in the healthcare industry to improve patient safety and supply chain efficiency.

Previously, Mr. Celeste lead the EPCglobal Inc. Healthcare and Life Sciences Industry Action Group focused on driving the adoption of Electronic Product Code™/Radio Frequency Identification (EPC/RFID) technology in the pharmacy, biologics, medical/surgical, and hospital sectors.

With GS1 Healthcare US, Mr. Celeste is responsible for working with the U.S. healthcare industry to help improve patient safety and increase supply chain efficiency through the adoption and wide-scale implementation of GS1® global standards to support visibility, traceability, and pedigree practices.

Prior to joining GS1 US, Mr. Celeste consulted to the retail, pharmaceutical, chemical, telecommunications, banking, investment, aerospace, manufacturing, research lab and utility industries on business process modeling and software development.

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Chris Chandler

US Veterans Health Administration

Dr. Chris Chandler is currently practicing as a Pharmacist Consultant for the United States Veterans Health Administration (VHA) Office of Informatics & Analytics Bar Code Resource. She completed her pharmacy training at the University of Illinois and has practiced at the Department of Veterans Affairs for the past 22 years in both patient care clinics, with the VHA Pharmacy Benefits Management Group and as a Quality Assurance Pharmacist with the National Office for the VHA Consolidated Mail Outpatient Pharmacy with an emphasis in the area of cold chain pharmaceuticals. She is also a member of the Parenteral Drug Association Pharmaceutical Cold Chain Interest Group Steering Committee and United States Pharmacopeia 2010-2015 Packaging, Storage, and Distribution Expert Committee.

Jay Crowley

Food and Drug Adminstration

Jay Crowley is Senior Advisor for Patient Safety in FDA's Center for Devices and Radiological Health. He is interested in developing and implementing new methods and techniques for identifying and resolving problems with the use of medical devices. Jay has held variety of positions over his 20 years at FDA. Currently, he has responsibility for implementing the Unique Device Identification requirements of the 2007 FDA Amendments Act. Jay holds a master's degree in risk analysis and a bachelor's degree in mechanical engineering.

Jean Pierre Edmond

Georgia Tech Research Institute

From 1992-2003 Dr. Emond was the Founder of the Food Engineering Program at Laval University and Head of the Air Cargo Transportation Research Group. From 2004-2010 he was a Professor with the Packaging Science Program at the University of Florida and the Co-Founder/Director of the UF/IFAS Center for Food Distribution and Retailing. From 2010-2012 he was a professor/Dean of the College of Technology and Innovation at University of South Florida. Since 2006 he is the CEO of Blueye LLC specialized in development of cold chain technologies. He is also currently the COO at The Illuminate Group, a company offering customized cold chain solutions.

He is currently the Principal Scientific Advisor for the Cool Chain Association (CCA) and was for 8 years the Scientific Advisor for perishable and pharmaceutical products with the IATA. He has done more than 50 research projects since 1993 mostly sponsored by the industry for more than $18 millions in the areas of packaging, transport and distribution.

Since January 1st, 2012, Dr. Emond is the director of Cold Chain Research in the Electro-Optical Systems Laboratory at Georgia Tech Research Institute. He is currently doing cold chain research activities in food/pharmaceutical distribution and retailing.

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Michael English

Merck

Michael has worked in the pharmaceutical industry for more than 23 years. Beginning with a position in Quality and moving to positions in Planning, Logistics, and Continuous Improvement, Michael landed in Packaging Technology where he has spent the last 12 years on Cold Chain packaging and shipping issues. Michael currently has responsibilities for not only qualifying new shipping systems but also for driving cold chain policy throughout the Merck network.

Charles Forsaith

Purdue Pharma LP

Chuck Forsaith joined Purdue Pharma LP in 2001, after 21 years of service as both a New Hampshire municipal and State Police officer - and also having formally directed security operations for a United States military installation.

His responsibilities with Purdue Pharma include managing all domestic and international supply chain security efforts, as well as regulatory compliance with all Federal supply chain security programs. He also acts as the Chairman of the Pharmaceutical Cargo Security Coalition (PCSC), a group from a wide variety of disciplines who monitor the security of pharmaceutical goods, in both transit and storage, all over the world.

He has lectured both domestically and internationally in the disciplines of Supply Chain and Site Security for such organizations as the Federal Bureau of Investigation, the US Food & Drug Administration, the Drug Enforcement Administration, the Department of Homeland Security, United States Customs, the Department of Justice, the United States Merchant Marine Academy, ASIS, TAPA, the HDMA, NADDI, NACDS, and the World Trade Group. He is an active member of the American Society of Industrial Security, the Transported Asset Protection Association, the Overseas Security Advisory Council, the National Association of Drug Diversion Investigators and the International Association of Chiefs of Police.

Maryann Gribbin

Johnson and Johnson

Maryann Gribbin currently holds the position of Director Quality Assurance, Johnson and Johnson with responsibility for Supply Chain Quality and Compliance. Maryann has held various positions in the industry in both Quality Assurance and Regulatory Compliance and served as a Drug Specialist with the Food and Drug Administration in the New Jersey District.

Karl Kussow

Fedex

Karl Kussow is the Manager of Quality and Validation for FedEx Custom Critical. Kussow leads the company's efforts to supply its customers with temperature-controlled shipping services and quality management assistance. He has more than 14 years of logistics experience in operations, safety, regulatory compliance and quality assurance. Kussow has extensive, practical experience with qualifying transportation equipment and shipping lanes for use in transporting temperature-sensitive pharmaceutical products. He has a Bachelor of Science in Mathematics from South Dakota State University.

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Neritan Mustafa

Genzyme Corporation

Neritan Mustafa is Associate Director at Genzyme A Sanofi Company. He is the leader of the Center of Excellence for Cold Chain Management (CoE for CCM) and oversees the Global Temperature Sensitive Distribution Program. Neritan's focus for the past 12 years has been understanding the requirements of the Global Cold Chain process, lead, manage and support key activities achieving business excellence aligned to strategy based on robust science, risk management while meeting global regulatory requirement.
Neritan received his Bachelors of Science in Chemical Engineering with a Minor in Chemistry from the University of Massachusetts Lowell, USA, and his Masters of Arts in Business Administration from Framingham State University, Framingham Massachusetts, USA.
Neritan is an active member of ISPE and PDA and contributing member of Industry Working Groups.

Bob Satek

Abbott

Bob Satek has worked for Abbott for 25 years. The last 7 years have been spent in Global Product Protection, where Bob has led various suppy chain initiatives to prevent cargo theft, diversion and counterfeiting of Abbott products. He has focused many of his efforts on improving transportation and warehouse security worldwide. In addition, Bob has also worked in Abbott Consulting Services, Distribution and Transportation planning and Corporate Customer Service. Prior to Abbott, Bob worked for General Motors for 9 years. Bob has a degree in Industrial Management from Purdue University and a MBA in Finance from Indiana University.

Robert Seevers, PhD

Eli Lilly and Company

Bob Seevers joined Eli Lilly and Company in January of 2002 after 8 years with the FDA. At Lilly his title is currently Principal Regulatory Consultant. He provides expertise in the areas of distribution and stability excellence as well as counterfeiting and knowledge and interpretation of regulatory and compliance expectations.

Bob is a member of the steering committee of the Pharmaceutical Cold Chain Interest Group of PDA and served as an editor of Technical Report 39, "Cold Chain Guidance for Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products through the Transportation Environment."

While he was with the FDA, Bob was a chemistry reviewer in the Divisions of Medical Imaging, Surgical, and Dental Drug Products, Metabolism and Endocrine Drug Products, and Reproductive and Urologic Drug Products and chemistry review team leader in the Division of Neuropharmacological Drug Products. During this time Bob also served on the Stability Technical Committee for several years, including 2 as Vice-Chair and 2 years as Chair. In that capacity, he was the editor of the 1998 Draft Stability Guidance.

Bob received his Ph.D. in Medicinal Chemistry from the University of Michigan in 1981.

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Mark Seitz

Eli Lilly and Company

Mark Seitz (Global Supply Chain/Logistics Advisor) supports Lilly's site and regional distribution operations and directly contributes to a variety of strategic logistics projects. He has an MBA in Supply Chain Management from Michigan State University. Mark has worked at Eli Lilly and Company for 25 years in a variety of manufacturing and management positions. Mark is a member of Lilly's Global Logistics Lead Team, and Anti-Counterfeiting Lead Team. He works closely with members of the company's Trade Relations and Government Affairs organizations in distribution related issues such as product serialization, importation, and emerging national and state product track-and-trace laws. He actively participates on a number of PhRMA (Pharmaceutical Research and Manufacturing Association) and HDMA (Healthcare Distribution Management Association) trade association committees and is a long time instructor of APICS Supply Chain certification courses. Mark also serves on the editorial board for Pharmaceutical Commerce magazine.

David Ulrich

Abbott Laboratories

Dave is the QA Director for Distribution and Logistics for Abbott's Global Pharmaceutical Operations (GPO) division. His responsibilities include standardization & optimization of supply chain quality systems (cGDPs), cold chain management, ePedigree/Track-n-Trace and import export compliance activities (FDA, USDA and EPA).

He was the clinical laboratory mgr at a Chicago hospital before coming to Abbott in 1987. He has been at Abbott 25 years, with the majority of time spent in bulk (API) manufacturing operations, manufacturing QA and plant maintenance, validation & engineering.

Tim Valko

Amgen, Inc.

Tim Valko has worked in Biopharmaceutical Supply Chain for over 20 years in positions in drug substance and drug product manufacturing, inspection and packaging, planning and inventory management, distribution and logistics, Import/export compliance and project management. Tim joined Amgen in 2007 as supply chain site head, at Amgen's Fremont California manufacturing facility. Tim's current role is Executive Director, Operations Risk Management, and leads a global team responsible for risk management, business continuity and brand protection based at Amgen corporate headquarters in Thousand Oaks, California. Prior to Amgen, Tim worked for Warner-Lambert/Parke-Davis and Pfizer, both based in Michigan.

Sally Wong

Merck & Company, Inc.

Ms. Wong has been with Merck and Co. since 1988 and with the Manufacturing Division Stability group for the last 12 years. The Stability group is responsible for Vaccine and Biological products from phase III to post approval. Ms. Wong manages the divisional vaccine sub-team within the Stability group responsible for formal stability studies, protocol design, expiry analysis, temperature excursion support, and regulatory filings / responses.