



2011 Annual Meeting of the Midwest Chapter of the International Society for Lyophilization – Freeze Drying

Speaker Biographies

Michael J. Pikal, Ph.D. (University of Connecticut)

Dr. Mike Pikal is currently Professor and Distinguished Chair in Pharmaceutical Technology at the University of Connecticut. He received his Ph.D. in physical chemistry in 1966 from Iowa State University and was a Postdoctoral Research Fellow with the Lawrence Livermore Laboratory from 1966-1967. Prior to joining Lilly Research Laboratories in 1972, he was assistant professor of chemistry at the University of Tennessee. His current research activities include the solid state chemistry of pharmaceuticals, particularly the stability of amorphous materials, characterization of solids by calorimetry, and the science and technology of freeze drying with a focus on optimization of formulation and process for labile proteins. Dr. Pikal is a member of the ACS and AAPS. He was the recipient of the Ebert Prize in 1977 and the PDA's "best paper of the year" award in 1989. He received the Eli Lilly & Co. "Presidents Award" in 1996. Dr. Pikal was the Busse Lecturer at University of Wisconsin in 1983 and the Enz Lecturer at University of Kansas in 1998. Dr. Pikal is a Fellow of the AAPS, and received the AAPS Research Achievement Award in Pharmaceutical Technologies in 2001, and the Crioforma award in Freeze Drying in 2006. Dr. Pikal is the 2009 recipient of the AAPS Distinguished Scientist Award.

Miquel Galán (Telstar Technologies)

Miquel Galan is Director of Innovation and R&D of Telstar Technologies. He has been with Telstar for over 25 years. He is an expert in pharmaceutical engineering, as well as vacuum technology and leak detection. He has held a position as a Process Engineering Manager and has managed many large freeze-drying projects. He holds degrees in Chemical Engineering from the Instituto Químico de Sarrià (IQS) and Industrial Engineering from the Universitat Ramon Llull. He is an active member of ISPE (International Society of Pharmaceutical Engineering), PDA (Parenteral Drug Association), and of ISL-FD (International Society of Lyophilization – Freeze Drying). He is also a member of PHSS (The Pharmaceutical and Healthcare Sciences Society –formerly Parenteral Society), and AAPS (American Association of Pharmaceutical Scientists). He has chaired several freeze drying conferences, and lectured at many freeze drying courses, conferences, and workshops, as well as on other topics about pharmaceutical and high vacuum related subjects over the past fifteen years.

Ed Trappler (Lyophilization Technology, Inc.)

Ed Trappler is founder and president of Lyophilization Technology, Inc. a contract research, technical services and clinical material manufacturing firm dedicated to freeze drying. He has over 30 years experience in lyophilization that ranges from product development to equipment application engineering. He received his Bachelor of Science degree in chemistry at The College of New Jersey. His experience in the pharmaceutical industry includes product development, toxicology supply preparation, clinical manufacturing and parenteral production. Ed has authored and presented numerous papers and courses in freeze drying in the United States, Europe, Japan and China. He is an active member of the PDA, currently teaches at the PDA-TRI, heads the Lyophilization Interest Group, and recently chaired the inaugural Pharmaceutical Freeze Drying Workshop in San Diego in November, 2010.

Michael Gills (West Pharmaceutical Services)

Mike Gills is a Technical Customer Support Process Engineer at West's Lionville, PA office. He provides technical support to R&D and Marketing in the development and commercial launch of new products. He also supports customers with fill & finish process related issues, develops relationships with key equipment manufacturers and engineering or consulting firms, and develops additional customer services.

Over the last seven years, Michael has been responsible for fill / finish operations at major pharmaceutical / biological drug manufacturers. He has experience with vial and syringe filling using conventional aseptic processes, RABS and Isolator technologies of sterile pharmaceuticals (liquids and powders) and vaccines. He also has experience with manufacturing lyophilization products and has been involved with lyophilizer commissioning and qualification. Mike is West's primary technical contact for Lyoseal in the Americas.

Anton Mangold (iQ-mobil Solutions)

Anton Mangold is the founder and managing director of iQ-mobil Solutions. He is an engineer and studied business at the University of Munich. iQ-mobil's core competence is the development of wireless sensor systems, software, and customized sensor designs. Their patented technique has been adapted to the pharmaceutical application of lyophilization and has been used by leading biotech and pharmaceutical companies worldwide.

Madhav Kamat, Ph.D., R. Ph. (Bristol-Myers Squibb)

Dr. Madhav Kamat is a Director in Global Drug Product Manufacturing Technology for sterile and liquid products at Bristol-Myers Squibb Company in New Jersey. Dr. Kamat has significant experience in product/process development, both small molecule and biologicals, of over 22 years involving formulation development, scale-up/technology transfer, process validation, and sterile manufacturing of more than 20 injectable products. He is well recognized for his expertise in lyophilization, nano-suspension technology, pharmaceutical isolators processing, aseptic technology, and other sterile manufacturing processes. He is active in various initiatives by US-FDA and American Association of Pharmaceutical Scientists (AAPS). His recent interests are formulation and process development of IV injectable products of water insoluble drugs. Dr. Kamat received his Bachelors of Pharmacy and Masters of Pharmacy from Bombay University and Ph.D. from the College of Pharmacy at University of Kentucky, USA. Before joining Bristol-Myers Squibb Company in 1995, Dr. Kamat worked at Centocor and Johnson & Johnsons. Dr. Kamat is a Registered Pharmacist in the States of Pennsylvania and New Jersey.

Serguei Tchessalov, Ph.D. (Pfizer)

Dr. Serguei Tchessalov is a Principle Scientist at Pfizer Pharmaceutical R&D in Andover, Massachusetts. He received his Ph.D. from Institute of Applied Biochemistry in Moscow on development of novel methods for formulation and process control during lyophilization. For the past 20 years in Russia and US he has worked on formulation and lyophilization process development of bacterial and viral vaccines, proteins, and different biological materials. His current research is focused on lyophilization process scale up as well as processing of parenteral dosage forms, including filtration, filling, and freezing and thawing.

Tim McCoy (Ben Venue Laboratories)

Tim McCoy is a Senior Formulation Scientist with Ben Venue Laboratories. Tim works within the Manufacturing Science and Technology (MST) department where his focus is to develop, optimize, scale up and transfer lyophilization cycles. In his career to date, Tim has experience working with small molecules, vaccines, and proteins in both aqueous and co-solvent systems. Tim also focuses on system understanding, where he works on modeling heat and mass transfer of bench and commercial freeze dryers to simplify cycle development and assess scalability. Tim's responsibility is also to examine potential improvements to the lyophilization cycle step, where he works with Ben Venue pilot laboratory and manufacturing groups to implement value added process improvements. Tim has been actively involved in the ISLFD for many years along with holding memberships with the AAPS and the PHSS (UK).