May 14-15, 2014 | Somerset, NJ-USA

Stability Program Conference 2014

Preliminary Program Topics:

- ICH Stability Requirements and Challenges
- Design of Protocols for Early Development Stability Studies
- Stability-Indicating Methods for Biotechnology Products
- Stability Challenges of Combination Products
- How to Make Risk-based Stability Testing Decisions for Drug Substance (DS) Batches after Changes
- Advanced modeling for accelerated stability determinations
- New Analytical techniques for stability testing of Biopharmaceutical
- The Future of Medical Products
- Stability programs for Leachable Impurities
- Applications of Reduced Study Designs for Stability Programs
- Excipients in Drug product stability
- Forced Degradation Studies
- Monitoring Stability of Fc Fusion Protein
- Stability challenges and rationale study design for biologics

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Distinguished Speaker

Dr. Geoff Carr

Director, Analytical Development
Patheon Inc.

Dr. Geoff Carr was appointed as Manager, Analytical Development at Patheon Inc, Ontario, Canada in 2000 and is now Director, Analytical Development. Prior to that, he held positions of Manager, Analytical Sciences at Celltech-Chiroscience, UK, Head of Analytical Development at Medgenix, Belgium and before that at Wyeth Research, UK. He originally started his career in pharmaceutical analysis at The British Pharmacopoeia Laboratory where he held several posts and was finally appointed Head of the Laboratory. His academic background is in Chemistry and he has a PhD from London University in Synthetic Organic Chemistry. He has been a Member of various British Pharmacopoeia Committees, a UK representative to Committees of the European Pharmacopoeia and Member of USP Committees and is currently a Member of the 2010-2015 Cycle USP General Chapters – Chemical Methods Expert Committee. He is the author of numerous papers and presentations at international conferences on various topics related to Pharmaceutical Analysis.

Dr. Wayland Rushing

Sr. Scientific Advisor at
ABC Laboratories

Dr. Wayland Rushing is a technical expert in CMC program design, analytical development and regulatory submissions. Over his career, Dr. Rushing has led CMC development programs for a wide array of biopharmaceuticals, including parenterals, inhalation drugs, and other pharmaceuticals with complex delivery systems.

Dr. Rushing is a subject matter expert in HPLC and GC method development and validation, extractables and leachables program design and regulatory submission requirements; has drafted multiple IND and NDA submissions; and assists ABC clients in responding to FDA deficiency letters. Dr. Rushing currently serves on Parenteral Drug Association (PDA) advisory committees for Technology Transfer and Elastomeric Closures and Seals Defects.

Distinguished Speaker

Dr. Chan Li

Senior Principal Scientist
Boehringer Ingelheim

Dr. Chan Li obtained her BS and MS degrees from Nanjing University, China and her Ph.D. from the University of Illinois at Urbana-Champaign. After two years of postdoctoral research at the University of California at Santa Barbara, Chan joined the Analytical Department of Boehringer Ingelheim Pharmaceuticals in Ridgefield, Connecticut, in 1993. Since then Chan has been involved with all stages of analytical development for drug substances and drug products; releasing of synthesis materials used for GMP manufacture of drug substances; CMC development strategy and documentation (CMC expert); SOP writing and training; and process improvement (she is a certified green belt of Lean Six Sigma). Chan is also taking an internship in Project Management working on a new biological development project. She represents Boehringer Ingelheim on the IQ Stability Working Group. Chan has published 29 scientific papers and given 19 national or international presentations.

Dr. Kenneth C. Waterman

President
Free Think Technologies

Dr. Ken Waterman received his B.S. degree with honors in chemistry from UCLA, his Ph.D. in physical-organic chemistry from UC Berkeley and conducted post-doctoral studies in physical chemistry as an NIH research fellow at Columbia University. Dr. Waterman worked 12-years at Polaroid (as a distinguished scientist) developing imaging products, then 13 years at Pfizer (as a Research Fellow) working on drug stability, drug delivery, biopharmaceutics and prodrugs. In 2011, he started FreeThink Technologies which is an R&D company developing new products in a number of fields. He is the author of over 70 publications and was made an AAPS Fellow in 2011.

Distinguished Speaker

Dr. Michael Drues,

President
Vascular Sciences

Dr, Michael Drues, Ph.D., is President of Vascular Sciences, an education, training, & consulting. Company offering a broad range of services to medical device, pharmaceutical & biotechnology Companies including (but not limited to): stimulating & innovative educational programming, brainstorming Sessions, prototype design, product development, benchtop & animal testing, innovative Regulatory strategy & completive regulatory intelligence, clinical trial design, FDA presentation Preparation & defense, reimbursement, clinical acceptance, business development & technology Assessment.

Dr. Drues received his B.S., M.S., and Ph.D. degrees in Biomedical Engineering from Iowa State University in Ames, Iowa. He has worked for and consulted with leading medical device, Pharmaceutical and biotechnology companies ranging in size from start-ups to Fortune 100 Companies. He also works on a regular basis for the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the Centers for Medicare and Medicaid Services (CMS) and other regulatory and governmental agencies around the world.

Dr. Drues is an internationally recognized expert and featured keynote speaker on cutting-edge medical technologies and Regulatory affairs. He conducts seminars and short-courses for medical device, pharmaceutical and biotechnology Companies, the U.S. Food and Drug Administration (FDA), Health Canada, the US and European Patent Offices, the US Centers for Medicare and Medicare Services (CMS) and other regulatory and governmental agencies around the world.

Finally, as an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology, Dr. Drues teaches graduate courses in Regulatory Affairs & Clinical Trials, Clinical Trial Design, Medical Device Regulatory Affairs & Product Development, Combination Products, Pathophysiology, Translational Medicine, Medical Technology & Biotechnology at several Universities & medical schools on-ground & on-line.

IPA Speaking Opportunities

Interested in presenting at one of our upcoming events?

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Tel: 416-410-7402 or enquiry@ipacanada.com

Distinguished Speaker

Dr. John C. Anders, Ph.D.

Sr Scientific Advisor
ABC Laboratories

Over the past three decades, Dr. John Anders has been instrumental in the development of scores of recombinant proteins, therapeutic antibodies, antisense oligonucleotides, biosimilars and genomic medical devices. A retired Major in the U.S. Amy Medical Research and Development Command, Dr. Anders served for many years at the Walter Reed Army Institute of Research and the U.S. Army Medical Institute of Chemical Defense at Aberdeen Proving Grounds, Maryland, where he pioneered numerous vaccines and drugs to fight parasitic disease, and helped develop countermeasures against chemical and biological threat agents. An accomplished researcher and publisher, Dr. Anders subsequently served as laboratory director for two contract research organizations supporting the development of biopharmaceuticals. Also as VP of lab operations at Gene Express Inc. he led a team in development of several genomic-based diagnostic and companion tests for subsequent approval as medical devices. Today, Dr. Anders is the resident Senior Scientific Advisor at ABC Laboratories for analytical support of biotherapeutics and assists clients in the development and regulatory requirements of biotherapeutic products worldwide.

Ms. Sylvia Wu

Scientist
OncoMed Pharmaceuticals

Ms. Sylvia Wu is a Scientist in Process Development at OncoMed Pharmaceuticals responsible for designing and performing in-house stability studies as well as formulation development. She has 20 years of experience in various areas of the biotechnology industry. Prior to OncoMed, she was at Abgenix/Amgen/Boehringer Ingelheim in the Analytical and Drug Product groups involved in assay development and supported drug product filling. At Genentech where she started her career, she was in the formulation/lyophilization group mainly responsible for lyophilization cycle development. Sylvia has a B.Sc. in Biology from UBC and attended graduate studies in Biomedical Engineering at UIC.

Swita Singh, Ph.D.

ImClone Systems, a wholly-owned subsidiary of
Eli Lilly & Company

Dr. Swita Singh is currently Senior Scientist, Formulation Development at ImClone Systems, a wholly-owned subsidiary of Eli Lilly & Company. Dr. Singh has more than ten years of experience in Biologics Formulation Development. Prior to joining ImClone Systems, Dr. Singh was a Formulation Scientist at Pfizer, Pearl River, NY. Dr. Singh obtained her Ph.D. in Pharmaceutical Sciences from University of Nebraska Medical Center, Omaha, NE. Dr. Singh's research work has been published in several peer-reviewed journals and presented at national and international meetings.

Preliminary Program Agenda

Day 1 – May 14, 2014

TIME	OUTLINE
8:30 am - 9:00 am	Registration, Networking and Continental Breakfast - Exhibition Opens
9:00 AM – 9:15 AM	Chair's Welcome Note
9:15 AM – 10:00 AM	ICH Stability Requirements and Challenges Performing stability studies is often considered a routine task in the development cycle even though this data can have significant impact on the Drug Product. Ineffective stability programs can lead to a shortened shelf life of the product and/or delays in regulatory approvals. This presentation will cover the ICH stability requirements and common challenges which can occur during these programs.
10:00 AM- 10:45 AM	Design of Protocols for Early Development Stability Studies The ICH Q1 series of guidelines are designed for stability programs leading to registration applications for marketing authorizations. However, there is also a need to conduct stability programs to support drug product development and the use of investigational drug products in clinical programs. This module will discuss the application of such studies and how they may be designed to provide the information required for these different circumstances. The types of studies that will be discussed includes drug excipient compatibility studies; applications of stability studies for experimental prototype formulations; designs for drug products intended for different stages of a clinical trial program; stability studies for clinical placebos and blinded clinical comparators.
10:45 AM – 11:00 AM	Mid-morning Refreshment Break - Exhibition viewing
11:00 AM - 11:45 PM	Stability-Indicating Methods for Biotechnology Products Critical Life-Cycle Elements of Stability-Indicating Methods for Biotechnology Products: Qualification, Validation, Transfer and Bridging Studies.
11:45 AM - 12:00 PM	Morning Panel Q & A
12:00 PM - 1:00 PM	Networking Lunch - Exhibition viewing
1:00 PM - 2:00 PM	Stability Challenges of Combination Products How do we combine drugs, biologics, medical devices and more? An estimated 30% of all new healthcare products under development today are combination products. But what is a combination product and how are they regulated? More importantly, why do some say combination products represent the future of medicine? What manufacturing and packaging challenges i.e., stability, sterility, shelf-life, etc. do combination products pose to manufacturers and how do we face them? Using a unique case study approach, all of these questions and more will be discussed during this thought-provoking presentation.

Preliminary Program Agenda

2:00 PM - 2:45 PM	How to Make Risk-based Stability Testing Decisions for Drug Substance (DS) Batches after Changes Historical DS stability dada and key findings • Risk analysis of manufacture process changes and effects on DS quality attributes • Identifying DS stability-related quality attributes (SRQA) • Making stability testing decisions based on risk analyses and identified SRQAs • Examples of stability testing protocols • Documenting risk analysis and stability testing decision (forms and report)
2:45 PM – 3:00 PM	Mid-Afternoon Refreshment Break - Exhibition viewing
3:00 PM – 3:45 PM	Advanced modeling for accelerated stability determinations
3:45 PM – 4:30 PM	New Analytical techniques for stability testing of Biopharmaceutical
4:30 PM - 5:00 PM	Afternoon Panel Q & A - Open Forum Discussions
5:15 PM	Conclusion of Day 1 Conference

Preliminary Program Agenda

Day 2 – May 15, 2014

TIME	OUTLINE
8:00 AM – 9:00 AM	Networking and Continental Breakfast - Exhibition Opens
9:00 AM - 9:05 AM	Chair's Welcome Note
9:05 AM – 10:05 AM	Stability challenges for future medical technology (future looking) What should manufactures be thinking about today to be ready for tomorrow? Future medical products will look very different than the products we use today. Technologies like bioprinting, personalized medicine (pharmacogenomics), tissue engineering (regenerative medicine), biomedical nanotechnology and others are much closer than many think. These technologies may not be suitable for traditional stability, sterility, shelflife and packaging the way we are used to. So what should manufactures be thinking about today to be ready for tomorrow? During this workshop, participants will be exposed to a wide range of examples of 'futuristic' products on the market, under development and on the drawing board emphasizing challenges to manufacturing and stability professionals.

Preliminary Program Agenda

10:05 AM – 10:45 AM	Stability programs for Leachable Impurities Leachables are impurities which originate from contact surfaces (typically the final container). Performing leachable stability studies can be challenging and is generally less understood than for typical drug product related impurities. ICH stability requirements are not directly applicable to leachables. This presentation will cover: what are leachables and where do they come from, what are the similarities and difference to drug product related impurities, what are the method and stability requirements.
10:45 AM – 11:00 AM	Mid-morning Refreshment Break - Exhibition viewing
11:00 AM – 11:45 AM	Applications of Reduced Study Designs for Stability Programs Stability programs represent a considerable expenditure of resources including human, equipment and financial. A registration study, for example one involving 3 strengths of a product in 3 different packaging configurations and conducted in triplicate will require 27 samples to be analyzed per pull point and for the first 6 months of the study this increases to 54 samples to accommodate both real time and accelerated conditions. Therefore any scientifically justifiable way of reducing the resulting analytical burden is very welcome to pharmaceutical companies conducting such programs. Reduced study designs employing bracket, matrix or combinations of these may be applied as described in ICH guideline Q1D as will be discussed in this session together with consideration of advantages and disadvantages of the different design approaches including their acceptability to regulatory agencies as well as any impact on the quality of the data generated.
11:45 AM - 12:00 PM	Morning Panel Q & A
12:00 PM – 1:00 PM	Networking Lunch - Exhibition viewing
1:00 AM – 1:45 PM	Excipients in Drug product stability
1:45 PM – 2:30 PM	Monitoring Stability of Fc Fusion Protein Fc fusion proteins display structural heterogeneity occurring during production and storage which ultimately affects shelf life. It is important to characterize these variants to identify product-related variants that must be controlled and monitor changes occurring during storage at intended and accelerated stability conditions. This study is focused on monitoring product-related variants of Fc fusion proteins on stability and the challenges in shelf life determination. The structural changes that have been observed with some Fc fusion proteins on stability and the analytical methods used in the characterization are described. Also described are the different approaches used in early clinical development to predict shelf life in these Fc fusion proteins. • Identify degradation products that affect stability • Describe analytical methods used to monitor important degradation products • Identify most appropriate assay for shelf life prediction • Describe different methods to predict shelf life of antibodies and Fc fusion proteins

Preliminary Program Agenda

2:30 PM - 2:45 PM	Afternoon Panel Q & A - Open Discussion
2:45 PM – 3:45 PM	Forced Degradation Studies "Forced Degradation Studies for Biotechnology Products: Why, When, and How?"
3:45 PM – 4:30 PM	Stability challenges and rationale study design for biologic
4:30 PM – 5:00 PM	Mid - Afternoon Panel Q & A Open Forum Discussions
5:00 PM	Conclusion of Conference

Who Should Attend

This two day conference is directed toward Directors, Managers, Supervisors, Analysts and Associates in the Pharmaceutical, Biotechnology, and allied industries with responsibilities in the following areas:

- Stability
- Analytical R&D
- Quality Control
- Quality Assurance
- Raw Materials Testing
- Product Development
- Formulation
- Chemistry, Manufacturing and Controls (CMC)
- GMP/GLP Compliance
- Pre-Clinical Research
- Regulatory Affairs
- Validation
- Product Submission
- Training
- Documentation and Technical Writing
- Contract Laboratories
- Consultants
- Contract manufacturing
- and other Compliance professionals

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Call the hotel directly at the above number and mention you are attending
IPA-AAPS meeting to receive the reduced room rate.

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REGISTRATION FORM

Stability Program Conference 2014

May 14 & 15, 2014 | Somerset, NJ-USA

Early Bird: Before February 25, 2014	USD $798
Discounted Price: February 26, 2014 to April 13, 2014	USD $898
Regular Price: April 14, 2014 to May 14, 2014	USD $998

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10% for a group of 3 or more from the same organization registering at the same time

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All cancellations are subject to a CAD $150.00/person processing fee. To receive cancellation credits for attendance at an upcoming course, IPA must be notified of the cancellation in writing (by email, mail or fax) up to 3 weeks prior to the program start date. Cancellations submitted less than 3 weeks prior to the event will not be qualified for refund or credit.

Substitution of delegate/s with the member/s of the same organization is permitted at any time with no penalty.

IPA reserves the right to postpone an event, prior to which time all the registered attendees will be notified a minimum of 2 weeks in advance. IPA shall not be responsible for any air fare, hotel or transportation costs incurred by registrant/s.