International Consortium for
Innovation and Quality
in Pharmaceutical Development

2011 IQ SYMPOSIUM

CAMBRIDGE, MASSACHUSETTS

MARRIOTT CAMBRIDGE

Wednesday, 30 November 2011

AGENDA

Tuesday, November 29, 2011

5:30 – 7:30 PM	Check-in, Posters and Cocktail Reception	MC^2

Wednesday, November 30, 2011

8:00 – 8:30 AM	Check-in and Breakfast	2nd Floor Corridor / Salon 4
8:30 – 8:40 AM	***Welcome*** **Gordon Hansen** Vice President, Analytical Sciences Boehringer Ingelheim IQ Symposium Organizing Committee Chair	Salons 1-3
8:45 – 9:10 AM	***Emergence of IQ*** **Terrence Tougas** Highly Distinguished Fellow Boehringer Ingelheim IQ Consortium Chair	Salons 1-3
9:15 – 11:15 AM	***Innovation*** **Bink Garrison** President & Founder Bink, Inc.	Salons 1-3
11:20 – 11:40 AM	Break and Posters	2nd Floor Corridor
11:45 – 12:20 PM	***Green Chemistry Innovations*** **Richard Williams** President Environmental Science & Green Chemistry Consulting Speaking on behalf of the American Chemical Society Green Chemistry Institute®	Salons 1-3
12:25 – 1:40 PM	Lunch	Salon 4

1:45 – 2:35 PM	***Innovation Happens at the Vertices:*** How Collaboration Across Traditional Boundaries Drives Excellence and Innovation in Pharmaceutical Development **Patricia Hurter** Senior Vice President Global Pharmaceutical Development Vertex	Salons 1-3
2:40 – 3:15 PM	***Collaboration and Innovation for Early Stage Development*** **Steven King** Divisional Vice President GPRD Development Sciences Abbott	Salons 1-3
3:20 – 3:40 PM	Break and Posters	2nd Floor Corridor
3:45 – 4:20 PM	***Innovation in Biologics Manufacturing*** **Jorg Thommes** Vice President Global Engineering Biogen Idec	Salons 1-3
4:25 – 5:10 PM	**Panel Discussion** Moderator: **Pierre Boulas** Director Pharmaceutical Development Biogen Idec Panel: **Patricia Hurter** Senior Vice President Global Pharmaceutical Development Vertex **Jorg Thommes** Vice President Global Engineering Biogen Idec **Steven King** Divisional Vice President GPRD Development Sciences Abbott **Richard Williams** President Environmental Science & Green Chemistry Consulting	Salons 1-3
5:15 – 5:30 PM	***Closing Remarks*** **Lewis Kinter** Senior Director, Regulatory Toxicology AstraZeneca IQ Consortium Vice Chair	Salons 1-3

Gordon Hansen

Vice President, Analytical Sciences,
Boehringer Ingelheim

Mr. Hansen has over 25 years of experience at Boehringer Ingelheim Pharmaceuticals. He began his career at BI as a laboratory scientist in the Analytical Sciences Department and currently is Vice President of Analytical Development. He has a BA degree in Chemistry from New York University, an MS degree in Analytical Chemistry from the University of Delaware and has authored or co-authored over 20 publications in the field of Analytical Chemistry.

Throughout his career, Mr. Hansen has played a leadership role in a number of influential Industry collaborations and initiatives, all focused on addressing pharmaceutical and regulatory quality issues. He currently serves as chair of the Analytical Leadership Group of the International Consortium for Innovation and Quality in Pharmaceutical Development (IQ). Mr. Hansen has served as past chair, Steering Committee of the Product Quality Research Institute (PQRI) and past chair, Board of Directors of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS), the CFC Consortium and the HFA-134a Consortium.

Terrence Tougas, PhD

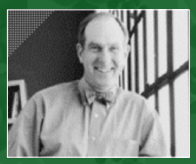
Highly Distinguished Fellow
Boehringer Ingelheim

Dr. Terrence Tougas has been employed for over 19 years in various capacities related to analytical chemistry and pharmaceutical development. He currently heads the Stabilty, Submission Documents and Information Systems Group. At Boehringer Ingelheim, he has been a major contributor to the CMC sections of many NDAs including pulmonary (MDI, inhalation solutions and nasal sprays) and antiviral products.

Dr. Tougas holds a BA (SUNY, Plattsburg) and a PhD in Chemistry (1983, University of Massachusetts, Amherst) and held a faculty position at the University of Massachusetts, Lowell.

Dr. Tougas is an active member of the International Pharmaceutical Aerosol Consortium on Regulation and Science (IPAC-RS) where he serves as a member of the Board of Directors and is a past chair. He has led or participated in a number of IPAC-RS working groups. Dr. Tougas is a past member of the Steering Committee of the Product Quality Research Institute (PQRI) and is the past chair of the PQRI Drug Product Technical Committee. More recently, Dr. Tougas has been elected to the USP General Dosage Forms Expert Committee where he serves as vice-chair and a member of the Aerosol subgroup. In addition, he has been involved in the formation of a new industry consortium – The International Consortium on Innovation and Quality in Pharmaceutical Development (IQ) and is serving as the first chair of its Board of Directors.

Dr. Tougas has authored numerous publications and presentations related to the CMC aspects of drug development, Analytical Chemistry and Quality Control statistics. He has contributed chapters to books on chromatography and leachables/extractables testing of inhalation products.



Bink Garrison

President & Founder
Bink Inc.

Nuclear weapons officer. Advertising agency CEO. Consultant to consultants. Biotech organizational catalyst. And back to consulting. That pretty well sums up **Bink Garrison**'s career trajectory.

After a stint in the U.S. Navy, Bink began his advertising years as a copywriter with Quinn & Johnson in 1977. In 1981, he became President & CEO, and led the acquisition of Ingalls Associates to form Ingalls, Quinn & Johnson, one of Boston's leading agencies. He left the agency after its sale in 1999.

Leaving advertising behind, Bink leveraged his years of CEO experience to create Bink Inc.-- a consulting business focused on organizational strategy, innovation, growth and team development. In 2005, one of his clients, Vertex Pharmaceuticals, hired Bink as a member of the executive team to work with their scientists and doctors. As SVP and Catalyst, he helped Vertex innovate, improve team performance, and nurture a remarkably inventive culture.

Bink left Vertex in 2009 and restarted Bink Inc. His clients have included McKinsey, Deloitte, J. Walter Thommespson, MIT, Liberty Mutual, Novartis, Pfizer, Simmons College, and Wesleyan University.

Bink attended Deerfield Academy and Princeton University. He lives in Boston with his wife, Weezie. They have three sons with normal names – Dan, Tom and Nick.

Richard Williams, PhD

President of Environmental Science &
Green Chemistry Consulting

Richard Williams recently authored a book chapter ("Environmental Science and Green Chemistry; Guiding Environmentally Preferred Manufacturing, Materials, and Products") and briefed the US Congress on green chemistry. Prior to forming his company, Rich achieved the most senior research position as a member of Pfizer's Chemistry R&D Department within Pharmaceutical Sciences. In 2001, Rich became founding chair of Pfizer's Green Chemistry team in Groton, CT and facilitated the development of similar teams across Pfizer. His team authored a U.S. Presidential Green Chemistry Challenge Award winning nomination, changed colleague behavior, and improved environmental and economic performance. Rich chaired, or was a member of, several senior Pfizer technical, management, and policy teams. He participated on PhRMA teams for over 15 years. Rich chaired a SETAC team of over 40 international experts and edited the resulting book evaluating the adequacy of environmental risk assessment science. He worked at Harvard Medical School early in his career. Rich holds a PhD in microbiology/ecology from the University of Minnesota (conducted research on biotransformations of biomass, biodegradation, and water quality), a M.A. in biology from Washington University, and a B.A. in microbiology/zoology from the University of New Hampshire.

Patricia N. Hurter, PhD

Senior Vice President, Global Pharmaceutical Development Vertex Pharmaceuticals, Inc.

Patricia Hurter has a PhD in Chemical Engineering from M.I.T., a M.S. in Mechanical Engineering from W.V.U. and a B.Sc. in Chemical Engineering from the University of Natal in Durban, South Africa. Dr. Hurter joined Vertex Pharmaceuticals in June 2004, as the Director of Formulation Development, and has been responsible for leading Pharmaceutical Development (comprising Chemical, Formulation, Analytical and Materials development from Discovery through development of the commercial process and product) since late 2006. Vertex is fully committed to applying fundamental scientific principles to drug substance, drug product and analytical method development, and has recently submitted two "fully QbD" NDAs in the space of a year, the first of which has been approved.

Before joining Vertex, she was Director of Formulation Development at Merck, from 2000-2004. Prior to joining the pharmaceutical industry, Dr. Hurter worked in the paper industry for 8 years, where she was considered an expert in paper physics. She has published several papers and been an invited speaker at international conferences on a variety of topics, ranging from fractal analysis, to molecular modeling of block copolymer micelles, to paper physics, and more recently on pharmaceutical topics such as polymorphism, pharmaceutical manufacturing, and application of QbD to spray-drying, formulation development and prediction of chemical stability of a drug product.

Steven A. King, PhD

Divisional Vice President Development Sciences in Global Pharmaceutical R&D
Abbott Laboratories

Steven King received a PhD in 1988 from Stanford University and performed postdoctoral research at Princeton University. He joined the Process Research Department at Merck in 1990 and moved to the Process R&D group at Abbott in 1995. In 2004, Steve became Divisional Vice President, Process R&D.

In 2007, Steve took on a larger role and is currently responsible for four GPRD functions: Process R&D, Preclinical Safety, DMPK-BA (Drug Metabolism, Pharmacokinetics, and Bioanalysis) and Global Data Management and Statistics. During this same period GPRD has more than doubled throughput in its R&D pipeline.

Steve lives in Gurnee, IL with his wife, Sarah, and has two children, Brian and Audrey.

Jorg Thommes, PhD

Vice President of Global Engineering
Biogen Idec

Dr. Jorg Thommes oversees all aspects of engineering for all Biogen Idec manufacturing facilities world wide and is responsible for Biogen Idec Facilities world wide as well as for Environmental Health & Safety, Security, and Infrastructure and Capital Management. Dr. Thommes holds a Doctorate in Chemistry from University of Bonn, Germany (with a thesis in mammalian cell culture technology), and an advanced University Teaching Degree (Habilitation) in Biochemical Engineering from University of Dusseldorf, Germany.

Previous positions include Vice President of BioPharmaceutical Development at Biogen Idec, Senior Director of Process Biochemistry at Biogen Idec, Associate Director of New Technologies at IDEC Pharmaceuticals, a Research and Teaching position at University of Dusseldorf in Germany, and a Research Scientist position at Pharmacia Biotech in Uppsala, Sweden (now GE Healthcare). He is the author of more than 60 peer reviewed publications and serves as board member of the Recovery of Biological Products conference series. He has served on the organizing committee and chaired sessions at a multitude of national and international meetings (American Chemical Society BIOT Division, Recovery of Biological Products, Society of Biochemical Engineering, CAP, GAB, PDA).

Pierre Boulas, PhD

Director of Analytical Development
Biogen Idec

Dr. Pierre Boulas is Director of Analytical Development at Biogen Idec in Cambridge, MA. Prior to joining Biogen, Dr. Boulas led the analytical group at Vertex Pharmaceuticals. He received a PhD in Analytical Chemistry from the University of Houston, Texas and a graduate degree in Physics and Chemistry from L'Ecole Supérieure de Chimie et Physique de Bordeaux, France. For the last 15 years, he has been involved in all aspects of analytical support of pharmaceutical development programs (orals, parenterals, semi-solid dosage forms, transdermal drug delivery systems). His main interests are in fostering change and innovation in analytical operations. His current focus is in the implementation of Quality-by-Design principles, innovation in manufacturing process controls and development of bio-relevant characterization methods. Dr. Boulas represents Biogen Idec on the Board of Directors of the IQ Consortium, an international association of pharmaceutical and biotechnology companies aiming to advance innovation and quality in the development of pharmaceutical products through scientifically-driven best practices and standards.

Lewis B. Kinter, PhD, D.A.B.T.

Senior Director: Regulatory Toxicology, and Head: Toxicological Operations, Safety Assessment (US)
AstraZeneca Pharmaceuticals

Dr. Lewis Kinter manages preclinical safety programs conducted in support of AstraZeneca's pharmaceutical clinical development activities in the US. Dr. Kinter has been engaged in pharmaceutical research and development and comparative physiology/medicine for 30 years and is an internationally recognized expert in cardiovascular-renal physiology, pharmacology, and toxicology.

Dr. Kinter received his doctorate in Medical Physiology from Harvard University (1978) where he initiated his professional interests in cardiovascular/renal physiology and pharmacology. Since 1981 he has held positions of increasing responsibility in pharmaceutical R&D with Smith Kline & French, SmithKline Beecham, Sterling Winthrop, Nycomed Amersham, Astra Merck, and AstraZeneca. Dr. Kinter is a Diplomat of the American Board of Toxicology, Fellow of the Academy of Toxicological Sciences, Professor of Physiology (Adjunct), University of Pennsylvania School of Medicine, and has authored over 100 research manuscripts and book chapters in basic and applied physiology, pharmacology, and toxicology. He is an active on the Editorial Board, Journal of Pharmacology and Experimental Therapeutics and regularly reviews research manuscripts for several pharmacology and toxicology journals. Dr. Kinter is a Founder and Past President of the Safety Pharmacology Society and the first recipient of the Society's Career Distinguished Service Award, Past-Chair of the PhRMA Preclinical Safety Leadership Committee (formerly DruSafe), inaugural member of the PhRMA Clinical and Preclinical Development Committee, PhRMA Topic Leader for the International Conference on Harmonization S10 (Phototoxicity) Expert Working Group, and a founder and Vice-Chair of the International Consortium for Innovation and Quality in Pharmaceutical Development

Dr. Kinter has also held leadership positions on Boards of Directors and Trustees of local community not-for-profit organizations.

ABOUT THE IQ CONSORTIUM

The International Consortium for Innovation and Quality in Pharmaceutical Development (IQ), formed in 2010, is a not-for-profit organization of pharmaceutical and biotechnology companies with a mission of advancing science-based and scientifically-driven standards and regulations for pharmaceutical and biotechnology products worldwide.

www.iqconsortium.com

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