AGENDA - AT - A - GLANCE

21st Annual Product Show
Wednesday, October 3, 2012

ISPE Connecting a World of Pharmaceutical Knowledge | Boston Area Chapter

10:00 am	Registration Open	
10:30 am – 11:45 am	**FDA Inspection Observations - The FDA-483 and Beyond** David Chesney, Vice President and Practice Lead, Strategic Compliance Services, PAREXEL Consulting Location: East Clubhouse, Red Level, Room R10	**Bioprocess Engineering and the ASME** Reinhard Hanselka, PhD, REA Location: East Clubhouse, Blue Level, Room B10
12:00 pm – 7:30 pm	**Show Floor and Career Center Open:** Visit over 300 Exhibitor Tables and Booths and Career Center Location: East Clubhouse	
12:00 pm – 1:15 pm	**The Global Hub:** **An overview of Massachusetts Life Science Real Estate Market** Peter McManus, Principal, Murphy & McManus Location: East Clubhouse, Red Level, Room R10	**Integrated Commissioning and Qualification, Saving Time and Money Without compromising Quality** Jack Greene, Director, Process Development and Manufacturing, Allena Pharmaceuticals Location: East Clubhouse, Blue Level, Room B10
3:30 pm	**Keynote Address:** **Turning Ideas Into Medicines – Biologics Manufacturing 2013 and Beyond** Peter Moesta, PhD, Senior Vice President, Biologics Manufacturing and Process Development, Bristol-Myers Squibb Location: West Clubhouse, Center Atrium	
5:00 pm – 7:00 pm	**Young Professionals Equipment Showcase** See equipment samples and learn first-hand with live product demonstrations Location: West Clubhouse, Northeast Lounge	
7:30 pm – 9:30 pm	**After-Show Networking Reception** **with an Appearance by Jerod Mayo, New England Patriots Football Linebacker** Location: Bar Louis, Patriot Place	

Session Descriptions

21st Annual Product Show and Educational Seminars

Wednesday, October 3, 2012

Connecting a World of Pharmaceutical Knowledge

Boston Area Chapter

10:30 am – 11:45 am

Session Title: FDA Inspection Observations - The FDA-483 and Beyond

Session Description: This presentation will review the history and purpose of the FDA-483, the rules FDA has established for what is a reportable observation and what is not, and agency guidance for evaluating the significance of FDA-483 observations resulting from drug GMP inspections. The presentation will explain the process followed internally by FDA in deciding whether or not to escalate to a Warning Letter or other follow up action. In addition, the presentation will offer tips for crafting an effective and timely written response to an FDA-483, and steps to take to ensure the corrective actions were effective.

Speaker: David Chesney, Vice President and Practice Lead, Strategic Compliance Services, PAREXEL Consulting

Speaker Biography: Mr. David L Chesney, Vice President and Practice Lead, Strategic Compliance Services for PAREXEL Consulting, works with PAREXEL clients in the pharmaceutical, biologics and medical device industries worldwide. He also directs PAREXEL Consulting's Strategic Compliance Services group. Prior to joining PAREXEL Consulting, he served 23 years with the FDA. Mr. Chesney advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, he was appointed the District Director, San Francisco District Office, where he served until joining PAREXEL in 1995.

His expertise includes GMP, GCP, GLP, QSR and MDR compliance consulting and auditing. Mr. Chesney is highly experienced in the FDA enforcement process and specializes in helping clients avoid or mitigate enforcement sanctions. He has extensive experience providing adjunct services to client legal counsel, including FDA communication strategies, conduct of internal investigations, due diligence assessments and other privileged matters. Recently Mr. Chesney has completed corporate quality organization effectiveness assessments for major pharmaceutical companies, biotech companies, and virtual companies.

Mr. Chesney frequently conducts briefing and training sessions for senior managers and executives in compliance topics and FDA inspection readiness. He is an experienced public speaker and has published articles in several industry publications such as *Pharmaceutical Technology*, *Biopharm*, RAPS *Focus*, and FDLI *Update*. He has authored or co-authored two book chapters, one in the current FDLI *Practical Guide to Working with the Food and Drug Administration*, and another on application of GMP to the production of investigational medicinal products. He has taught PDA TRI courses in inspection readiness and quality and compliance management for virtual companies.

Mr. Chesney received his BA in Biology from California State University, Northridge. He subsequently completed postgraduate study in biology there and at California State University, San Diego, and has also received a Certificate in Health Care Compliance from Seton Hall University School of Law. He is an active member of the Parenteral Drug Association where he serves on the faculty of the PDA Training and Research Institute (TRI), the Food and Drug Law Institute, and the Regulatory Affairs Professionals Society.

Meeting Manager: Robert Lucas, Consultant, Validant

10:30 – 11:45 am

Session Title: Bioprocess Engineering and the ASME

Session Description: The ASME BPE (Bioprocess Equipment) Standard is a comprehensive document developed for the Bio Process Industry. The document was developed by Bio Process users, vendors, consulting engineers and Industry experts for the purpose of setting minimum standards for safe and effective operation. Initial efforts were devoted to stainless steel welding, dimensional standards and simplistic system construction. The document has since evolved to the extremely comprehensive 2012 Edition, which is now the definitive Worldwide Industry Standard.

The 2012 ASME BPE has evolved into a document which describes and specifies Stainless steel systems, corrosion resistant alloys, thermoplastic systems, vessels, system designs filters and various significant components. System effectiveness and designs for sterility are exposed in the manual.

Additionally the State of California has adopted the ASME BPE into the Building Code at the insistence of several large Bio Pharmaceutical Firms. This State legal adoption endorses the BPE as a part of the California System. The States of Arizona and Washington also have adoption plans in place. Ultimately all of North America will embrace the BPE.

This Presentation will summarize the requirements and practices expounded by the 2012 ASME Bioprocess Equipment Standard. Questions and discussion are encouraged.

Speaker: Reinhard Hanselka, PhD, REA

Speaker Biography: Reinhard Hanselka has over 35 years of project experience providing consultation on issues of Hazardous Materials, Fire and Building Codes to numerous jurisdictions and industry. He has specialized in Life Science and Advanced Electronic Industries. Reinhard has also instructed clients on Fire and Building Codes, Plastic Piping, Process Piping, High Purity Piping, and High Purity Water Production as well as lectured on subjects related to Codes and Materials of Construction to ISPE. He has also lectured on Hazardous Materials, Toxic Gases, Materials, Fire and Building Codes. He has been a consultant to the U.S. Environmental Protection Agency, The Department of Energy and Department of Defense, and numerous local Agencies and Jurisdictions. Reinhard is an ASME Board member.

Meeting Manager: Robert Lucas, Consultant, Validant

12:00 – 1:15 pm

Session Title: The Global Hub: An overview of Massachusetts Life Science Real Estate Market

Session Description: Ground zero for global life sciences is considered by many to be Cambridge, Massachusetts. But it is more than just the Cambridge area that makes the Boston region a focus of innovation. A well-developed ecosystem encapsulates the urban streets and suburban freeways of the area, stretching far beyond Cambridge and into the suburban corridors featuring leading research hospitals and big name biopharmaceutical companies.

These days if you follow the money, you might get lost bouncing between Cambridge, Boston, and the surrounding suburbs. With the life sciences industry continuing to permeate the entire metropolitan area, an understanding of what is happening in the local market is essential for companies to properly plan for capital expansions.

The presentation will focus on what is occurring in the Boston/Cambridge regional life science market as it pertains to real estate and how these market dynamics might influence future real estate endeavors at life science firms. The presentation will include information on the following topics:

- Market Lease Rates / Trends
- Planning considerations
- Build out Costs
- Future Space Demand

The presentation format will allow for interactive discussion with the session's audience.

Speaker: Peter McManus, Principal, Murphy & McManus

Speaker Biography: Pete is a Principal with the firm of Murphy & McManus in Needham, MA. Pete has a BS in Civil Engineering from Union College, an MS in Civil Engineering/Construction Management from the University of Missouri, a Master of Business Administration from the Amos Tuck School, Dartmouth College and is a Professional Engineer and Licensed Construction Supervisor.

Murphy & McManus is a full service developer of Healthcare, Life Science and Nano Technology Facilities for Institutional and Corporate Clients. Over the past two decades Murphy & McManus has delivered projects totaling in excess of 4,000,000 SF and with a total project value in excess of 2.0 billion dollars.

Examples of Murphy & McManus projects include:

Genzyme Science Building, Framingham, MA
Genzyme Biologics Support Center, Framingham, MA
Genzyme GMP Warehouse, Northborough, MA
Shire/TKT Laboratories, Cambridge, MA
Dana-Farber/Brigham & Women's Cancer Center at the Milford Regional Medical Center, Milford, MA
Children's Hospital Research Facility at the Center of Life Sciences, Boston, MA

Meeting Manager: Jim Grunwald, President, SciTech Builders, LLC

12:00 – 1:15 pm

Session Title: Integrated Commissioning and Qualification, Saving Time and Money Without compromising Quality

Session Description: Use of Integrated Commissioning and Qualification models offers a rare opportunity – a chance to deliver projects that meet user and product needs, with the full documentation package required by regulatory authorities, and do it on time and within budget.

However, having your cake and eating it too requires a departure from the traditional approach. This program will lay out a series of C&Q models, explain how they work (or do not work) and use first hand case studies to highlight the benefits and risks of each. This workshop will present various models and chronicle their history and then address how to set up integrated C&Q programs. Bring your questions and do not hesitate to interrupt in this interactive session!

Speaker: Jack Greene, Director of Process Development and Manufacturing, Allena Pharmaceuticals

Speaker Biography: Jack Greene has over 15 years of Commissioning and Qualification, Plant-Wide Automation Design, Continuous Improvement and Compliance experience in the biologic API, oral solid dosage and parenteral drug product area.

Jack's extensive background and experience in the Pharmaceutical industry includes previous positions as QC Chemist, PLC/DCS Architect and Quality Engineer. He is an expert in helping scientists and engineers express complex issues such that they can be understood by non-technical people. He has worked at Eli Lilly& Co, Alnara Pharmaceuticals, Altus Pharmaceuticals, Alkermes, Genzyme and Ares-Serono.

He is currently the Director of Process Development and Manufacturing for Allena Pharmaceuticals.

Meeting Manager: Dan Ramsey, Director of Operations New England, Commissioning Agents, Inc.

3:30 – 4:30 pm

Keynote Address: Turning Ideas Into Medicines – Biologics Manufacturing 2013 and Beyond

Peter Moesta, PhD, Senior Vice President, Biologics Manufacturing and Process Development, Bristol-Myers Squibb

Session Description: Peter will discuss the key industry trends at that are impacting the biologics manufacturing business today. He will review the major implications that current regulatory, scientific and industrial trends will have on biologics manufacturing. He will describe how Bristol-Myers Squibb plans to adjust its Biologics Manufacturing strategy to provide high quality products reliably at affordable cost to patients in need of biologics medicines.

Speaker Biography: Peter Moesta, Ph.D. is the Senior Vice President, Biologics Manufacturing and Process Development for Bristol-Myers Squibb (BMS). Joining BMS in early 2011, Peter leads the broad based technical activities between R&D and Manufacturing organizations to support the successful clinical development, registration, manufacturing and commercialization of biologics products.

Peter has extensive experience in biologics manufacturing, including process development, clinical and commercial manufacturing and supply chain across global operations. Before joining Bristol-Myers Squibb, he served as Division Vice President, Biologics Manufacturing for Abbott Laboratories where he guided the manufacturing process and led the CMC effort to obtain approval for Humira. He also led the design, start-up and registration of the company's large scale biologics manufacturing plant in Puerto Rico.

Earlier in his career, Peter worked for BASF for 17 years, both in Germany and the US. He held positions of increasing responsibility before becoming Vice President, Process Development and Operations for BASF Bioresearch Corporation in Worcester MA. While at BASF, he planned and executed the construction of a combined research and biologics production facility for BASF, then built a successful multi-disciplinary team to develop and manufacture therapeutic proteins at the facility.

Peter earned his Master's degree in Chemistry and a PhD in Biochemistry from the University of Freiburg in Germany. He completed post-doctoral fellowships at the University of Freiburg and at UCLA.