

AGENDA - AT - A - GLANCE

20th Annual Product Show

Wednesday, October 5, 2011



**Boston Area
Chapter**

8:30 am – 7:30 pm

Registration and Information Desks Open

Location: East Clubhouse, Club Level, Top of Escalator

9:00 am – 12:00 pm

Nine Educational Programs:

E.L.S.I.E. Symposium long program and four sets of concurrent, shorter programs. See the adjacent agenda for times and session listings.

Location: East Clubhouse (Red Level and Blue Level) and West Clubhouse (Southwest Lounge)

11:00 am – 12:00 pm

Lunch:

Please note, tickets must have been pre-purchased to attend the lunch. Tickets will not be sold onsite.

Location: West Clubhouse (Southwest Lounge)

12:00 pm – 7:30 pm

Show Floor and Career Center Opens:

Visit over 300 Exhibitor Tables and Booths and Career Center

Location: East Clubhouse, Club Level and Red Level

3:30 pm – 4:45 pm

Keynote Address:

Hear from Jonathan Kraft, President, The Kraft Group

Location: West Clubhouse, Club Level, Center Atrium

6:00 pm – 7:00 pm

Young Professionals/Student Reception:

Location: West Clubhouse, Northwest Lounge Outside Balcony

7:30 pm – 9:30 pm

After Party Networking Reception

Appearance by Jerod Mayo, New England Patriots Football Linebacker

Don't forget to pick up your attendance wristband from an exhibitor!

Location: CBS Scene Restaurant and Bar, Patriot Place

EDUCATIONAL PROGRAMS

20th Annual Product Show

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Boston Area Chapter

9:00 am – 12:00 pm	9:00 – 10:00 am CONCURRENT SESSIONS	
<p><i>E.L.S.I.E. Symposium:</i></p> <p><i>Practical Solutions to Address the Impact of Extractables and Leachables on Materials, Manufacturing Processes and Packaging</i></p> <p>Speakers: Douglas J. Ball, MS, D.A.B.T., Pfizer, Inc.</p> <p>Lewis B. Kinter, Ph.D., D.A.B.T., Fellow A.T.S. , AstraZeneca Pharmaceuticals</p> <p>Daniel L. Norwood, Ph.D., Boehringer Ingelheim Pharmaceuticals, Inc.</p> <p>The Extractables and Leachables Safety Information Exchange (ELSIE) is developing a database containing safety information on E&L compounds and extraction profiles obtained using standardized protocols for a range of materials utilized for drug products, medical devices, and manufacturing processes. The ELSIE database seeks to facilitate early identification of safety issues at the initial stages of the development process, when materials are being screened and selected.</p> <p>Location: West Clubhouse, Club Level, Northwest Lounge</p>	<p><i>Biotech 101: Trends in Facility Design</i></p> <p>Speaker: Marc Pelletier, CRB Consulting Engineers</p> <p>Location: East Clubhouse, Red Level, R10</p>	<p><i>Risk Management: Next Steps Incorporating Risk Management into the Biopharmaceutical Quality System</i></p> <p>Speaker: Emma Ramnarine, Roche</p> <p>Location: East Clubhouse, Red Level, R17</p>
	9:45 – 10:45 am CONCURRENT SESSIONS	
	<p><i>Cold Chain Distribution: Ensuring Product Integrity to the Patient</i></p> <p>Speaker: Anthony (TJ) Rizzo, Cold Chain Technologies</p> <p>Location: East Clubhouse, Blue Level, B10</p>	<p><i>Every Gold Medal Winner Has a Coach and Mentors: Accelerating Your Leadership Career</i></p> <p>Panelists: Daniel (Dan) Button, BS, Ph.D. Kathy Freitas, BA, SPHR, Draeger Medical Armando Llorente, HRe-sources, LLC Kerry Harrison, BBA, SPHR, CCP, MIT Lincoln Laboratory Tawnya Johnson, Boston Red Sox Joe Maressa, Fitzgerald, Stevens & Ford/OI Partners</p> <p>Location: East Clubhouse, Red Level, R16</p>
	10:30 – 11:30 am CONCURRENT SESSIONS	
<p><i>Introduction to Validation</i></p> <p>Speaker: Jack Campion, Genzyme Corporation</p> <p>Location: East Clubhouse, Red Level, R10</p>	<p><i>Future Manufacturing & Packaging Challenges: How to Avoid them with the FDA</i></p> <p>Speaker: Michael Druess, Ph.D., Vascular Sciences</p> <p>Location: East Clubhouse, Red Level, R17</p>	
11:00 – 12:00 pm CONCURRENT SESSIONS		
<p><i>Rouge: Monitoring, Measuring and Remediating in Water and Steam Systems</i></p> <p>Speaker: Daryl Roll, P.E., Astro Pak Corporation</p> <p>Location: East Clubhouse, Blue Level, B10</p>	<p><i>Thriving at the Intersection of Science and Business: How to Transition from Geeky to Business Savvy</i></p> <p>Speaker: Gwen Acton, Ph.D., Vivo Group</p> <p>Location: East Clubhouse, Red Level, R16</p>	

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

ELSIE Symposium: 9:00 AM – 12:00 PM

Practical Solutions to Address the Impact of Extractables and Leachables on Materials, Manufacturing Processes and Packaging

By industry-working group ELSIE – Extractables and Leachables Safety Information Exchange

Room – West Clubhouse, Main Club Level

Abstract

Compounds that may leach into drug products from packaging/device or during manufacturing can pose safety and or quality concerns. Performing extraction studies on these materials prior to use can provide chemical profile information to assess safety and compatibility. Assessing the safety of extractables and leachables (E&L) is an essential element of the development and manufacturing process for pharmaceuticals, biologics, and medical devices. If an issue related to E&L is not detected until the later stages of the development process, a company may experience substantial delays in product development, regulatory review, market introduction, and most importantly patients' access to new treatments. A solution to prospectively de-risk E&L issues early in the development process and manage or eliminate them using Quality by Design concepts is to have readily available extractables profiles of materials used in biopharmaceutical processing, packaging and medical device applications as well as safety information on extractable and leachable compounds.



The Extractables and Leachables Safety Information Exchange (ELSIE) is developing a database containing safety information on E&L compounds and extraction profiles obtained using standardized protocols for a range of materials utilized for drug products, medical devices, and manufacturing processes. The ELSIE database seeks to facilitate early identification of safety issues at the initial stages of the development process, when materials are being screened and selected.

This symposium will provide: (i) an introduction to fundamentals concepts with respect to E&L, their impact on patient safety and regulatory significance; (ii) a discussion of best practices for E&L evaluations on materials; (iii) toxicological assessments of E&Ls; and (iv) background on ELSIE and a demonstration of the ELSIE database.

Do you need additional skills and knowledge? Attend the ISPE Professional Development Training in Norwood on October 6-7. For more information click here:

<http://www.ispe.org/2011norwoodtraining/pharmwaterstorage>

Speakers

Douglas J. Ball, MS, D.A.B.T.

Research Fellow, Regulatory Strategy and Compliance, Drug Safety Research & Development, Pfizer, Inc.

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

Mr. Ball obtained his B.S. and M.S. in Biology from St. John's University, Jamaica, N.Y. in 1977 and 1980, respectively, and became board certified in general toxicology (DABT) in 2003. Mr. Ball was involved in the Product Quality Research Institute (PQRI) L&E work group that generated the PQRI Best Practices Recommendations for Evaluation of Orally Inhaled and Nasal Drug Products (2006). Mr. Ball serves as a co-chair for the PQRI work team for L&E evaluation in Parenteral and Ophthalmic Drug Products (PODP) and is chairman of the Extractables and Leachables Safety Information Exchange (ELSIE).

Lewis B. Kinter, Ph.D., D.A.B.T., Fellow A.T.S.

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

Dr. Kinter has been engaged in pharmaceutical R&D and comparative physiology/medicine for 30 years and is an internationally recognized expert in cardiovascular-renal physiology, pharmacology, and toxicology. He received his Ph.D. in Medical Physiology, Harvard (1978). 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, author of over 100 research manuscripts and book chapters, and active on the Editorial Board, Journal of Pharmacology and Experimental Therapeutics. 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. He is also a founder and vice-chair of the International Consortium for Innovation and Quality in Pharmaceutical Development.

Daniel L. Norwood, Ph.D.

Distinguished Research Fellow and Section Leader, Structural Analysis Section
Boehringer Ingelheim Pharmaceuticals, Inc, Ridgefield, CT

Dr. Norwood received his Ph.D. in Environmental Chemistry from the University of North Carolina and has held senior pharmaceutical industry positions at Magellan Laboratories, Inc. and the Glaxo Research Institute. He was Medical Research Assistant Professor at Duke University Medical Center and Adjunct Assistant Professor at the University of North Carolina. He chaired the PQRI (Product Quality Research Institute) Working Group on Leachables and Extractables in Orally Inhaled and Nasal Drug Products, and has served on several IPAC-RS technical teams related to pharmaceutical impurity and packaging issues. He is a member of the PQRI Working Group on Leachables and Extractables in Parenteral and Ophthalmic Drug Products, and on the Board of Directors of ELSIE (The Extractables Leachables Safety Information Exchange). He also serves on the USP Packaging, Storage and Distribution Expert Committee and chairs their subcommittee on extractables and leachables, and is a member of the PhRMA LDKIT on Genotoxic Impurities. Dr. Norwood received the Glaxo CEO's Award in 1994, the Boehringer Ingelheim President's Award in 2007, and the PQRI Excellence in Research Award (2009).

Event Chairs

Keyur Doshi, Validation Engineering, Xcellerex Inc.

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

Co-Chair, Education Program Committee, ISPE Boston Chapter

Chuck Gillingham, Process Sales Leader, Rockwell Automation
Member, Education Program Committee, ISPE Boston Chapter

Seminars: 9:00 AM – 10:00 AM

1. Biotech 101: Trends in Facility Design

Room: TBA

Abstract

The biopharmaceutical industry has witnessed an escalation in the cost of manufacturing facilities over the past several decades, while it has also reached a point where process risk is well understood, equipment integrity is sound and verifiable, and the environment has little or no influence on product quality. In this session, we will present typical bioprocess unit operations, and give the attendees an opportunity to evaluate the integrity of these systems and to study the potential impact of cleaning, sanitization, human intervention and of the environment. We will discuss risk mitigation of adulteration of product from external influences, and compare improved system integrity cost to that of implementing and operating a clean room. We will provide a roadmap for strategic planning of process manufacturing streams and the environments housing these processes; a roadmap to designing smarter and higher value manufacturing facilities. We will also share insights into safeguards for consistent and reproducible manufacturing.

Speaker

Marc Pelletier

Director, Strategic Consulting, CRB Consulting Engineers

Vice Chair, Design Committee, ASME BPE

Committee Member, Main & General Requirements Committees, ASME BPE

Marc provides strategic planning, conceptual design, process engineering, risk assessment, compliance and validation for the Life Technologies sector at CRB. Prior to joining CRB, Marc was President of MPP BioDesigns, a consulting group also specializing in Bioprocessing.

Trained in biochemistry, Marc has worked as a process engineer for most of his 25+ year career, all in the food and pharmaceutical and biotechnology sectors as an end user developing bioprocesses. His roles included project management, fermentation and downstream process design, equipment and facility design, risk assessment and validation. In addition to his service on ASME BPE, Marc has served as adjunct professor at the University of Manitoba, Canada and Bemidji State University, MN, and a frequent lecturer for the AAPS, ASME CEI and ISPE.

Event Chair

Cory Siddons, Process Engineer, CRB Consulting Engineers, Inc.

Member, Young Professionals Committee, ISPE Boston Chapter

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

2. Risk Management: Next Steps

Incorporating Risk Management into the Biopharmaceutical Quality System

Room: TBA

Abstract

There have been a handful of changes to the regulatory landscape regarding Risk Management over the past year. Companies must go further than ad-hoc use of risk management tools within individual groups or activities such as Commissioning and Qualification, and the existence of perhaps one internal risk SOP. Risk Management is a dynamic system, not static, and your company's Quality System (using a Product Life-cycle approach) must be designed to handle the dynamic nature of Risk Management. This session will discuss how this should be approached, what are the potential pitfalls and share some lessons learned.

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<http://www.ispe.org/2011norwoodtraining/biopharmmanuffacilities>

Speaker

Emma Ramnarine, Associate Director
Head, Global Quality Risk Management, Roche

Emma is the Head of Global Quality Risk Management for Roche Pharma Technical Operations. She leads the design, deployment, and governance of a harmonized QRM Program including implementation of global standards, processes, and tools for consistent QRM application, and providing leadership for complex network QRM strategies. She is also active in influencing the development of industry QRM best practices, including leading QRM activities for the PDA and providing QRM training to regulatory authorities and at industry forums like PDA, ISPE etc.

Prior to joining Genentech in October 2005, Emma worked at Guidant Corporation, Cardiovascular division and ALZA Corporation/ Johnson & Johnson. Emma has an M.S. in Pharmaceutical Sciences from the University of Connecticut, an M.S. in Medicinal and Pharmaceutical Chemistry and a B.S. in Pharmacy, both from the University of Indore, India.

Event Chair

Dr. Mike Long, MBB, Director Consulting Services, ValSource, LLC
Member, Education Program Committee, ISPE Boston Chapter

Seminars: 9:45 – 10:45 AM

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

3. Cold Chain Distribution

Ensuring Product Integrity to the Patient

Room: TBA

Abstract

An increasing amount of medicinal products today have special temperature storage requirements. Heightened regulation both in the US and internationally continue to add pressure to manufacturers and distributors to maintain these requirements during both storage and distribution. The complex distribution network for medicinal products makes this task extremely difficult and many considerations must be considered when designing shipping solutions and planning shipments. This session will provide an overview on cold chain distribution as well as discuss the latest trends and best practices for thermal qualification of shipping solutions. A review of industry guidance documents including Parenteral Drug Association (PDA) Technical Report 39 and 46 will be covered.

Speaker

Anthony (TJ) Rizzo

Director of Sales, Cold Chain Technologies

TJ is responsible for Cold Chain's sales and customer service and continued growth initiatives. Previously he managed key accounts as a Strategic Account Engineer for Cold Chain. TJ has direct contact with clients, as well as corporate responsibilities. TJ is also extensively involved in industry groups including the PCCIG "Last Mile" task force and "Risk Management for Temperature Controlled Distribution" task forces. TJ has a strong understanding of industry requirements including USP 1079, PDA Technical Report 39, and FDA regulations as well as logistics as they pertain to the pharmaceutical and biotech sectors. TJ graduated from Pennsylvania State University with a bachelor's degree in Mechanical Engineering and is pursuing his M.B.A. from the University of Massachusetts.

Event Chair

Shelly Henderson, Vice President, HCA

Member, Education Program Committee, former Board Member, ISPE Boston Chapter

4. Every Gold Medal Winner Has a Coach and Mentors

Coaching and Mentoring: Accelerating Your Leadership Career

Room: TBA

Abstract

An accomplished panel of leaders will describe the role coaching and mentoring has played in their career experiences. This information and discussion will benefit individuals in leadership positions or aspiring to a leadership career.

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

- The case for having a leadership development coach and mentors in one's professional development and career
- The critical elements of effective leadership development coaching and mentor relationships
- Setting expectations, goals and measurement

Panelists

Daniel P. (Dan) Button, BS, PhD

Early Stage Executive, several local ventures in CleanTech and Advanced Materials

Dan is an early stage executive in high growth manufacturing industries spanning CleanTech, displays, LEDs and printed electronics. He has had broad success in leading, launching, and growing new businesses that now anchor sustained market leadership in technology, global share and profitability at Fortune 500 companies (DuPont, Corning) and MIT Start-ups (E Ink, QD Vision). Through design-in with top consumer electronics manufacturers, he has repeatedly established materials-based products as new industry standards. He currently advises a number of early stage companies in CleanTech and advanced materials. Dan has a BS in engineering from Cornell University and a PhD in Materials Science from MIT. He also has been a grateful benefactor from the wisdom and support of numerous mentors throughout his career.

Kathy Freitas, BA, SPHR

HR Director, Draeger Medical

Kathy is a senior Human Resources leader with significant experience in all aspects of Human Resources. She has successfully met HR objectives at both the strategic and tactical levels in a broad range of industries, including medical devices, biotechnology, and professional services. She has provided significant input and values-driven, cost effective solutions to execute staffs on a broad range of issues. She is currently the Director of Human Resources at Draeger Medical, a global medical device company. Her experience also includes the HR Director at Zycos, a biotechnology startup. She has a B.A. from the University of Massachusetts and is a Certified Senior Professional in Human Resources (SPHR).

Armando Llorente

Principal Consultant, HRe-sources, LLC

Armando Llorente is Principal Consultant @ HRe-sources, LLC. He is a bilingual (Spanish) business leader who has global human resources management experience in a variety of industries: high technology, research & development, equipment & product engineering, corporate finance & legal and consulting.

Throughout his career, he has partnered with colleagues and clients to develop HR strategy and metrics. Additionally, he has managed the integration of benefits, payroll and policies/ procedures for acquired

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

companies. Through the use of several assessment tools, he has provided feedback and coached associates - from team leads to senior executives.

Armando graduated from Wofford College (SC) and obtained his MBA from Plymouth State University (NH). He has completed The Partnership Inc. (Boston) "Fellows Program" and is a member of NEHRA, where he co-chairs the AIM Initiative.

Kerry A. Harrison, BBA, SPHR, CCP
Assistant Department Head, Human Resources, MIT Lincoln Laboratory

Kerry provides senior level leadership and guidance at MIT Lincoln Laboratory as the Assistant Department Head of Human Resources. She oversees a broad spectrum of HR services including Employee Education and Development, Benefits, Compensation and Human Resources Information Systems. One of her recent major initiatives at the Laboratory has been the implementation of several formal mentoring programs.

Kerry holds a BBA from University of Massachusetts, Amherst and professional certifications from the HR Certification Institute and World at Work (formerly the American Compensation Association). She is also a member of the Society of Human Resources Management.

Tawnya Johnson
Head HR (Interim), Boston Red Sox

Tawnya has over 15 years of experience in human resources management which includes biotechnology, pharmaceutical, medical services, and medical device industries. She has provided support to all levels within an organization from the shop floor to the board room. She has worked with start-ups, mergers and acquisitions, company closures and both public and private organizations of all sizes.

Tawnya holds a Certificate in Human Resource Management from Bentley College and is a member of both NEHRA and SHRM. She can be reached via email at tjmack@charter.net.

Joseph J. Maressa
Vice President, Fitzgerald, Stevens & Ford/OI Partners, a global talent management firm

Joe has been a leadership, organizational development and career transition coach in high stakes situations, including life science companies, start ups, and joint ventures. He has a BS in Chemical Engineering and an MBA from Northeastern University, and a MLS from Boston University. He has worked with faculty members of Harvard University's Graduate Schools of Business and Education. He can be reached at: jmaressa@fsandf.com.

Moderator and Event Chair
Dan Gee, Principal, gTechBio

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

Member, Member Services Committee, ISPE Boston Chapter

Seminars: 10:30 AM – 11:30 AM

5. Introduction to Validation

Room: TBA

Abstract

Validation provides documented evidence that a system used in the manufacture of a pharmaceutical reliably and consistently produces a product with acceptable quality. Validation has evolved over decades since it was originally mandated by the FDA. Regulatory requirements have been both under-interpreted and over-interpreted. In the former case, the pharmaceutical producer is at risk for product quality, regulatory non-compliance or both. In the latter case, the producer has spent too much and possibly lost business in the marketplace. Finding the validation “sweet spot” – neither too little nor too much – is the imperative in today’s highly competitive yet highly regulated environment. This seminar will provide the basics of validating pharmaceutical systems to efficiently ensure both product quality and regulatory compliance.

Do you need additional skills and knowledge? Attend the ISPE Professional Development Training in Norwood on October 6-7. For more information click here:

<http://www.ispe.org/2011norwoodtraining/processvalidation>

Speaker

Jack Champion

Manager of Project Controls, Genzyme Corporation, Allston Landing
Co-Chair, Education Program Committee, former Board & Treasurer, ISPE Boston Chapter

Jack Champion has held positions in process design, design-build project management, validation, and validation management for twenty-four years.

He led the commissioning, qualification and process validation program for MassBiologics' 100,000 square foot cell culture and aseptic fill-finish facility in Mattapan. In this role, Jack applied the ISPE Baseline Guide for Commissioning and Qualification, saving countless labor hours and weeks of schedule through careful system definition and elimination of redundant testing. Jack was also a member of the design team and was responsible for system turnover and acceptance from the construction manager.

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

Jack holds a BA in chemistry from the College of the Holy Cross and an MS in Chemical Engineering from Tufts University. He is a registered Professional Engineer in Massachusetts.

Event Chair

Aarash Navabi, Validation Specialist, Genzyme Corporation
Member, Young Professionals Committee, ISPE Boston Chapter

6. Future Manufacturing & Packaging Challenges: How to Avoid them with the FDA

What has worked in the past may not in the future!

Room: TBA

Abstract

When it comes to conducting clinical trials, manufacturing and packaging are often the last things on people's minds. Issues like shelf-life and sterility may not seem related to safety and efficacy but packaging issues can be critical to the success (or failure) of a new product, especially in clinical trials. If problems are discovered with a product in a clinical trial or after it is on the market, how do we know if these problems are caused by the product itself or by improper packaging or product handling? When it comes to the more complex products of the future, like biologics and combination products, these challenges become even more significant.

This seminar will provide a view to the future of manufacturing and packaging challenges for future products and advice on working with the FDA to avoid them. During this interactive workshop, participants will be exposed to multiple examples and case studies of products currently on the market, under development and on the drawing board.

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<http://www.ispe.org/2011norwoodtraining/applyingthegmps>

Speaker

Michael Druess, Ph.D.
President, Vascular Sciences

Michael offers a full range of consulting services to medical device, pharmaceutical and biotechnology companies including prototype design, product development, testing and evaluation, animal and clinical trials, business development, strategic planning, technology assessment and regulatory affairs. Michael received his Ph.D. in Biomedical Engineering from Iowa State University. He works for and consults with leading medical companies and also works on a regular basis for the U.S. Food and Drug Administration (FDA). Michael is an Adjunct Professor of Medicine, Biomedical Engineering & Biotechnology teaching graduate courses in pathophysiology, biotechnology, regulatory affairs and

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

clinical trials. He conducts seminars and short courses for medical device, pharmaceutical and biotechnology companies, the European Patent Office and the FDA.

Event Chair

John Sheridan, Managing Principal, PMA Consultants LLC
Member, Education Program Committee, ISPE Boston Chapter

Seminars: 11:00 AM – 12:00 PM

7. Rouge: Monitoring, Measuring and Remediating in Water and Steam Systems

Room: TBA

Abstract

Product contact surfaces containing rouge are found in a wide variety of systems in pharmaceutical and biotechnology manufacturing facilities. Contamination in high purity process equipment and piping systems from particulate content or metallic oxides (rouge) can be devastating; however, the risk can be easily assessed and controlled. This presentation covers the techniques available to measure and monitor rouge, as well as how to remediate contamination caused by rouge by developing a science-based approach to derouging and passivating. The development of a rouge monitoring program based on outlined objectives will be discussed that will include determining sampling criteria, establishing a baseline and initiating an audit program. Quantitative results of case studies comparing particulate and metal oxide content pre- and post derouging process is also illustrated, thereby further validating the process.

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<http://www.ispe.org/2011norwoodtraining/pharmwaterstorage>

Speaker

Daryl Roll, P.E.

Science and Quality Officer, Astro Pak Corporation
Member, Surface Finish and Materials of Construction Subcommittees, ASME BPE
Lead Contributor, Rouge and Passivation Task Groups, ASME BPE

Daryl leads the development and management of corporate technology objectives, safety and training, and monitoring of government compliance requirements. He serves as the primary technical advisor to clients and employees for corrosion, surface chemistry and stainless steel passivation. Previously Daryl served as Division Chemist and Division Engineer at Halliburton Company. He has over 30 years in chemical processing, including design of process cleaning equipment, chemical process technology, and precision cleaning of ultra-high purity systems.

ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011

Daryl is an active member of ISPE, Los Angeles, and conducts seminars and training. Mr. Roll has published in MICRO and Chemical Engineering on passivation and rouge control. He holds a B.A. in Chemistry and Earth Science from the California State University of Fullerton and a P.E. license from of California.

Event Chair

Robert Lucas, Biopharmaceutical Industry Professional, MBA Candidate, Boston University Member, Education Program Committee, ISPE Boston Chapter

8. Thriving at the Intersection of Science and Business

How to Transition from Geeky to Business Savvy

Room: TBA

Abstract

In order to be successful, pharmaceutical companies require that highly technically trained experts and business professionals work together productively. Scientists, engineers and business people often have different priorities and training, and sometimes face challenges understanding one another. Further, leadership in a life science environment often requires different skills and approaches from typical industry settings. Strategic thinking and leadership skills enable engineers and scientists to navigate more effectively in this distinct environment, improving their ability to achieve business and operational excellence. Case studies will illustrate how strategic leadership skills can be acquired and used productively by engineers and scientists so that they can thrive at the intersection of technology and business, or in any situation where disparate disciplines must work together.

Speaker

Gwen Acton, PhD
CEO, Vivo Group

Gwen is an expert on strategic leadership at the intersection of science and business. As CEO of Vivo Group, she leads her team in working with companies to increase the productivity and innovation of technically trained experts, as well as improve the ability of scientists and engineers to successfully navigate the life science and technology industries. Prior to this, Gwen was Director of Scientific Development at the Whitehead Institute/MIT Center for Genome Research where she oversaw operations of a \$40 million dollar research program. She received a Ph.D. in Biology from M.I.T. and served as a faculty member in Molecular and Cellular Biology at Harvard University. Gwen is author of the book *The Bluffer's Guide to Genetics* (<http://www.ovalbooks.com/bluff/Genetics.html>) published by Oval Books.

Event Chair

Bob Urbanowski, Business Development, Invensys Operations Management Board Member & Chair, Member Services Committee, ISPE Boston Chapter

SPECIAL THANKS TO:

**ISPE Boston Area Chapter
Product Show: Education Seminars
October 5, 2011**

Product Show Seminar Organizers

Joyce Chiu, CPIP, Senior Project Leader, Honeywell Safety Products
Member, Education Program and Member Services Committees, ISPE Boston Chapter

John Sheridan, Managing Principal, PMA Consultants LLC
Member, Education Program Committee, ISPE Boston Chapter