



NAVIGATING THE HORIZON OF INDUSTRY CHANGE

ISPE 08

ANNUAL MEETING

26-29 OCTOBER | Boca Raton Resort | Boca Raton Florida | USA

Brochure current as
of 27 June 2008.

Table of Contents

Affiliate/Chapter Council Activities.....	27
Career Café.....	26
CPIP SM Workshops.....	26
Education Schedule.....	7
Education Sessions.....	4-25
Exhibit Information.....	26-27
Event Highlights.....	26-27
General Information.....	28
Hotel Information.....	31
Hotel Reservation Form.....	30
Keynote Session.....	3
Poster Presentations.....	6
Registration Form.....	29
Registration Information.....	28
Student Activities.....	27
Sponsorships.....	Back Cover

Dedicated to Joseph X. Phillips, Sr.



ISPE dedicates the 2008 Annual Meeting to the memory Joseph X. Phillips, Sr., ISPE International Regulatory Affairs Advisor — a friend to many; a visionary for all.

It was with such ease, a true concern for people, and an understanding of the value of interpersonal relationships, that Joe was able to unite

people with differing views, cultural backgrounds, and seniority. As he gave great time and commitment to the Society, even during his years with the FDA, others followed. His vision led to the creation of many of ISPE's most important initiatives.

Joe was pivotal in leading ISPE in its global mission and worked tirelessly to facilitate key relationships with regulators and industry leaders around the world. Joe passed away 13 April at the age of 73, but his vast and valuable contributions to ISPE will benefit Members, the industry, and Regulatory Authorities for many years to come.

Joe had a distinguished career with the US Food and Drug Administration for 44 years. He ended his career in the position of Deputy Regional Director of the Agency's Central Region. He was heavily involved in training of FDA Investigators and in planning and managing pharmaceutical programs including the Pre-Approval

Inspection program and the SUPAC (Scale-Up and Post Approval Changes) for field operations. Joe was a principal negotiator for the US/EU Mutual Recognition Agreement and was the FDA Lead to the International Conference on Harmonization (ICH) Expert Working Group for GMP Guidance for Active Pharmaceutical Ingredients (ICH Q7A).

Joe joined ISPE in 2003 as International Regulatory Affairs Advisor, the same year he was appointed as a special government employee to the FDA's Pharmaceutical Science Advisory Committee that is involved in the agency's *Risk-based Approach to Pharmaceutical cGMPs for the 21st Century* initiative. He was a founding member of ISPE's Product Quality Lifecycle Implementation (PQLI) initiative and was a strategic advisor to Society President/CEO Bob Best.

"I have long accepted the theory that no one is irreplaceable," said Bob Best. "Joe Phillips is an exception to that rule. I have never met a nicer, kinder human being than Joe. He was loved by people all over the world. And the list of his contributions, both as a long-time representative of the FDA, and later for ISPE, is impressive. This was truly a *great* man in every sense of that word."

Joe is survived by his wife, Dolores, and sons Joe and John. Joe Jr. followed in his father's footsteps and works for GlaxoSmithKline as Investigator, Chemical Development Pilot Plant Technical Support.

Keynote Speakers

Keynote Session, Monday, 27 October 08.30 – 12.00



Hans Rosling, MD, PhD

Professor of International Health, Karolinska Institute and Director of Gapminder Foundation, Stockholm, Sweden



Janet Woodcock, MD

Director, Center for Drug Evaluation and Research, U.S. FDA



Patrick Y. Yang, PhD

Executive Vice President, Product Operations, Genentech, USA

It's Easy to Register as an Education Delegate

1. Review this brochure or visit www.ISPE.org/annualmeeting to select the sessions you would like to attend.
2. Register by completing the Delegate and Hotel Registration Forms at the back of this brochure and return to ISPE with payment, or visit www.ISPE.org/annualmeeting to register on-line.

Exhibiting companies will receive confirmation packets and a badge registration form by e-mail.

The Keynote Session is just one of the many opportunities at ISPE 2008 Annual Meeting for pharmaceutical manufacturing science and biotechnology professionals to learn about emerging global industry trends and practices. The Meeting's content-rich education sessions also help professionals navigate the horizon of industry change providing critical information and interaction with industry experts and regulatory authorities.

Track Color Guide

Regulatory (100)
Innovation (200)
Manufacturing Operations (300)
Engineering Design (400)
Investigational Products (500)
Project Management (600)
Efficient and Effective Compliance (700)

Regulatory (100)

This track has critical information for all facets of our industry. Regulatory issues, changes, and uncertainties pervade the industry. This year's Regulatory track will focus on specific regulatory topics:

- Product Quality Lifecycle Implementation (PQLI) seeks to define a practical approach to global implementation of ICH documents. Attend the PQLI Global Updates Parts 1 and 2 to get the latest information
- Risk-MaPP addresses the use of risk-based techniques for managing cross contamination risks - the new ISPE *Risk-MaPP Guide* is imminent
- PAT application has matured, and discussion and case studies can move implementation of PAT forward as delegates learn from each other through case studies and discussion
- Biosimilars provides a forum for debating the issue from multiple perspectives to facilitate the creation of a regulatory pathway for product approval
- Quality control laboratories also face continuing challenges, learn the latest on some of these as well as an update on the development of this ISPE Guide

Track Program Chair

- Rebecca Waterbury, Regulatory Compliance, Abbott Vascular, USA

Innovation (200)

Our increasingly competitive environment, with its associated focus on improving operational efficiency and reducing cost, led us to be dissatisfied with incremental improvements. In seeking new methods of solving problems, we wish to create major gains in our own operations. One good way to innovate is to look at how others in our industry have or are planning to solve these problems. This track will look at several of the hot areas where major innovations are taking place.

All of the sessions in this track will make you think, will provide new perspectives, or provide new information. In this track, we address continuous and high throughput as well as downstream processing, science in technology transfer, and developments in vaccines and the field of nanotechnology. If you want to learn about the innovations taking place in the pharmaceutical industry, this track is for you.

Track Program Chair

- Michael Denault, Principal, Denault Associates, USA

Manufacturing Operations (300)

Manufacturing operations face challenges from multiple fronts:

- A vastly expanded global marketplace
- Increasing pressure on manufacturing efficiency to remain competitive in the world market
- Outsourcing
- New developments in barrier isolation and aseptic processing

This track offers sessions on all these challenges linked with topics on achieving manufacturing excellence and a specific focus from a supplier's perspective on emerging global opportunities. You will participate in sessions that are global, innovative, include generics, contract manufacturing, and issues important to big pharma. Attend this track to:

- Hear ideas that will expand your views
- Meet key players with broad perspectives that will challenge you to think creatively
- Participate in discussions and share your perspectives
- Take advantage of the vast experience represented by fellow delegates

This track will address both strategic and tactical issues, and will therefore be of interest to all levels, including executive level participants who need an ever-expanding range of views to make informative decisions.

Changes in the manufacturing environment as we know it are already occurring. This track presents the details that enable you to make the most informed decisions. Be informed on how you will be affected and on how to formulate the best course of action.

Track Program Chair

- Cheryl Tucker, Alliance Management, Eli Lilly & Co., USA

Engineering Design (400)

This track is focused on clarifying and broadening collective understanding. ISPE is a connector among topics, technical documents, buyers and suppliers, and many other parts of the industry. These sessions, which focus on:

- Critical interfaces
- Facilities
- Design standards

present an opportunity to see in two to three hours what you would need three to four months to learn. The Engineering Design track helps identify and define critical issues, and gives you an opportunity to discuss concerns that further the industry progress because you bring your knowledge to the table – and share it. Attend and hear about new approaches from all over the world as we all work toward increasing quality and reducing costs.

Track Program Chair

- Michelle Gonzalez, Retired, Amgen, Inc., USA

Investigational Products (500)

Participate in a dynamic track with a focus on innovation and strategic partnerships. Find out about industry success stories and increase your ability to deliver today and tomorrow. Share in the discussion of 'hot topic' issues facing Investigational Products (IP) professionals. Hear from industry experts on

topics such as:

- Protocol interpretation
- Comparator strategies
- Developing successful partnerships
- Business project management
- Updates on current regulatory issues

Track Program Committee

- Michael Arnold, RPh, Business Process Head, Global Supply Chain, Pfizer Inc., USA
- Michelle Foust, PharmD, Director New Product Development, Almac Clinical Services, USA
- Neal Gordon, Senior Director CMC-USA, Organon a part of Schering Plough Corporation, USA
- Kunal Jaiswal, Planning Committee Chair, Associate Director, Clinical Supplies, Schering-Plough Company, USA
- Paula Mastrangelo, Associate Director, Bristol-Myers Squibb, USA
- Robert Pizzie, PhD, Senior Director Global Clinical Supply Planning, Schering-Plough, USA

Project Management (600)

In order to meet the demand to deliver projects and programs on an accelerated schedule, effective application of project management methodologies is critical. Participate in this interactive track to analyze current real-world, applied innovations in project delivery, and take advantage of valuable insights from industry experts discussing how current and future trends can be used to transform current projects, and help shape future project success. Participate in discussions on successful project execution on a wide variety of project types. This innovative track will help new or veteran project managers improve their performance, and establish valuable knowledge to further their job success and career goals.

Track Program Chair

- Keith Gibbs, Corporate Manager Technical Services, C&Q, Yonkers Industries, USA

Efficient and Effective Compliance (700)

This track brings some key new guidance and standards from the 50,000 ft level down to real world implementation. It will help attendees by providing practical application of the new guidance and compliance standards which have emerged in the last year. Sessions will address Project Information Management (PIM), ASTM E2500, GAMP[®]5, ICH Q9 and the C&Q companion guide in progress.

It stresses efficiencies, which may be gained by adopting the new practices, and includes new, more efficient, risk-based concepts in play for focusing the efforts in qualifying or verifying systems.

Presentations will include case studies and interactive workshops to promote deeper understanding of both the advantages and pitfalls of the implementation of the concepts under discussion. Sessions will provide practitioners with tools and techniques to apply and manage the information in cooperation with vendors, engineering and validation to effectively deliver fit-for-purpose systems with minimal duplication of effort. The sessions are structured to provide an opportunity to:

- Benchmark your practices against peer companies' practices
- Identify better ways of working
- Avoid wasted and duplicated efforts
- Leverage tasks to meet multiple goals
- Understand how these new ideas can pay off in many ways including improving the bottom line

Sessions will benefit new practitioners to seasoned professionals.

Program Chair

- James John, Project Lead, Altus Automation, A ProPharma Group Company, USA

North American Education Committee and Annual Meeting Task Team

Call for Poster Presentations Due 31 July 2008

What is a Poster Presentation?

Posters present information pictorially and with written documentation. They are an effective means of sharing a new application or approach, a creative solution, or a collaboration that worked.

Benefits of Presenting a Poster

- Exposure to a global audience of 2,000 pharmaceutical industry professionals at the ISPE 2008 Annual Meeting
- Posters are displayed in a common area and will be viewed by a large number of attendees
- Poster presenters will present during two scheduled breaks in a less formal, interactive environment
- Select posters may be invited to be published in ISPE's *Pharmaceutical Engineering* (PE) magazine received by 25,000 ISPE Members, or considered for the *Journal of Pharmaceutical Innovation* (JPI)

Eligibility

Professionals from the pharmaceutical, biotechnology or medical device industry, and university faculty may submit abstracts for review. Abstracts are reviewed for sound technical content and avoidance of commercial intent. Submissions will be accepted from any ISPE Member or professional in the pharmaceutical industry and academia.

Review Criteria

Submissions will be reviewed for technical relevance, merit, organization, clarity, and avoidance of commercial intent.

How to Submit a Presentation

Download submission forms at www.ISPE.org/posterproposal, or at the Downloads page at the Annual Meeting Web site.

Deepak Agarwal
Director, Pharma Technology
Jacobs Engineering Group Inc., USA

Roger Brunkow
Director of Biologics Manufacturing
Cardiome Pharma Corp., USA

Mark Butterworth
Project Manager
GlaxoSmithKline, Canada

Nuala Calnan
Principal Consultant
PM Group, Ireland

Grace Chin
Senior Vice President, Science and
Technology
SNC-Lavalin Pharma, Canada

Paul Crissman
Principal
Biotechnical Solutions, USA
(NAEC Immediate Past Chair)

Berthold Duethorn
Director Validation Services
Robert Bosch GmbH, Germany

Joseph De Paul
Director Vertical Marketing, Pharma
Cypress Systems, USA

Michael Denault
Principal
Denault Associates, USA

Paul D'Eramo
Executive Director
Johnson & Johnson, USA

Michelle Foust, PharmD
Director of New Product Development
Almac Clinical Services, USA

Daniel Franklin
Regional Compliance Manager
Integrated Project Services (IPS), USA

Keith Gibbs
Corporate Manager Technical Services
C&Q Yonkers Industries, USA

Michelle Gonzalez, Retired
Amgen, Inc., USA

C.R. Green
Director Design Engineering
Fluor Daniel, USA

Gerard Guillorn
Vice President
Structure Tone, Inc., USA

Timothy Howard, PE
C&Q Business Lead
Commissioning Agents, Inc., USA
(NAEC Chair)

James John
Project Lead
Altus Automation, A ProPharma Group
Company, USA

Gary Knight
Project Manager
Commissioning Agents, Inc., USA

Jeffery Odum
Principal
NCBioSource, USA

Miguel Perez Colon
President
Water Management Associates, USA

Allan Pfitzenmaier
President
Vectech Pharma Consultants Inc., USA
(NAEC Co-Chair and Annual Meeting Task
Team Chair)

Manmohan Sihra
Principal Consultant
Sihra Consulting, USA

Cheryl Tucker
Alliance Management
Eli Lilly & Co., USA

James Vogel, PE
Principal
Process Facilities Services
Incorporated, USA

Rebecca Waterbury
Regulatory Compliance
Abbott Vascular, USA

Stephanie Wilkins, PE
President
PharmaConsult US Inc., USA

Patrick Yeung, PhD
President
PPY Pharma Services Pte. Ltd.,
Singapore

Schedule At-A-Glance

Education Sessions

SUNDAY, 26 OCTOBER	
13.00-17.00	PAT Implementation (101)
	High Throughput Processing (201)
	Hot Topic-China (207) CANCELLED
	Operational Excellence (301)
	Suppliers Summit (307)
	Critical Interfaces (401)
	Applied Risk Mgmt (601)
	PIM (701)

MONDAY, 27 OCTOBER	
08.30-12.00	Keynote Session
13.30-17.00	Risk-MaPP (102)
	Downstream Processing (202)
	Managing Innovation (208)
	Global Marketplace (302)
	Facility of the Year (402)
	IP Operations Track (501)
	IP Management Track (502)
	Capital Project (602)
	Validation Hot Topics (702)

TUESDAY, 28 OCTOBER	
08.15-11.30	PQLI Global-1 (103)
	Tech Transfer (203)
	Outsourcing (303)
	BioPharm Facility (403)
	IP-Delivering QbD, General Session <ul style="list-style-type: none"> • IP-Operations Track (501) • IP-Management Track (502)
	Small Scale Projects (603)
	ASTM E2500, C&Q Original & New Guide Transition (703)
14.15-17.15	PQLI Global-2 (104)
	Pandemic Flu Vaccine (HHS) (204)
	Advanced Aseptic (304)
	Green Design (404)
	IP Operations Track (501)
	IP Management Track (502)
	Confessions of a Project Manager (604)
	C&Q Transition Case Studies (704)

WEDNESDAY, 29 OCTOBER	
08.15-11.15	Follow On Biologics (105)
	Vaccine Mfg & Devt (205)
	Hot Topic: GMPs (209)
	Hot Topics Aseptic (305)
	Design Standards (405)
	Kilo & Pilot Plants (406)
	IP-Delivering QbD, General Session <ul style="list-style-type: none"> • IP-Operations Track (501) • IP-Management Track (502)
	Role of Integrator (605)
	CSV Session 1 (705)
	12.45-15.45
Nanotechnology (206)	
Platform Approaches (306)	
Clinical Projects (606)	
	CSV Session 2 (706)

Track Color Guide

Regulatory/PQLI/PAT (100)
Innovation (200)
Manufacturing Operations (300)
Engineering Design (400)
Investigational Products (500)
Project Management (600)
Efficient and Effective Compliance (700)

Can't attend everything?

Recordings with slides will be available for sale at a highly reduced cost to attendees.

Days and Times for Special Events

See the "Event Highlights" section on pages 26-27 of this brochure.

Regulatory

PAT Implementation Tools and Methods (101)

26 October 13.00-17.00

ISPE CEUs 0.4

This session will address questions, concerns and successes regarding PAT implementation including the use of thought-provoking case studies and discussion, the lifecycle of a typical Quality by Design project. Additional topics will likely include identification of potential projects, conceptual design, data monitoring, applying data to process improvement, transitioning to validated tools and methods, commissioning and qualification. Lessons learned and discussions will play a major role.

Product Quality Lifecycle Implementation (PQLI) and QbD concepts are being defined and PAT tools are being increasingly used. However, there are still more questions than answers on how to successfully implement these initiatives. The groundwork has now been laid. The intent of this session is not for any one person to teach the “answer,” but to encourage a discussion to find best practices.

How You Will Benefit

At the end of this session, participants will be able to:

- Research and develop process data gathering projects using PAT
- Determine a path forward for utilization of process data for process improvement
- Understand and determine the application of process improvement tools and methods in a validated environment

Who Should Attend

Process development, validation, quality, manufacturing, automation and engineering personnel, and everyone interested in Product Quality Lifecycle Implementation (PQLI)

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Biotechnology (Biotech), Commissioning and Qualification (C&Q), Process Analytical Technology (PAT), and Process/Product Development (PPD)

Leaders and Speakers to Date

- Nathan Temple, PAT Business Area Leader, Commissioning Agents Inc., USA (Leader)

ISPE's Risk-MaPP Baseline® Guide: Its Impact and Application (102)

27 October 13.30-17.00

ISPE CEUs 0.2

The need for dedicated facilities for the manufacture of certain classes of compound has been the subject of much debate in recent years. The rationale for separating certain compounds has not always been clear and regulators in the USA, Canada, and Europe are working on revisions to parts of their Good Manufacturing Practice (GMP) guidelines that would, if implemented, dictate groups of compounds for which dedication would be mandated.

This session will provide an abbreviated introduction to Risk-MaPP. Representatives from key regulatory agencies will present their perspective on use of risk-based techniques for making decisions associated with the handling of highly hazardous compounds.

Currently there are two new guides under development, an ISPE *Risk-MaPP Baseline Guide* and a *Science and Risk-Based Cleaning Guide*. This session will highlight the status of these two projects.

How You Will Benefit

At the end of this session, participants will be able to:

- Explain the purpose of Risk-MaPP and how it fits into a quality systems strategy
- Understand how regulatory agencies are applying the Risk-MaPP principles to their inspection strategies
- Analyze emerging regulatory issues worldwide that impact containment and Risk-MaPP
- Participate in a regulatory round-table/panel discussion on the issue of dedicated facilities

Who Should Attend

Quality, regulatory compliance, manufacturing, including contract manufacturers, engineering, operations, environmental health and safety, occupational toxicology, and cleaning validation

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Containment, Disposables, Heating, Ventilating, and Air Conditioning (HVAC), Oral Solid Dosage (OSD), Project Management (PM), and Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Stephanie Wilkins, PE, President, PharmaConsult US Inc., USA (Leader)

Regulators Invited

FDA, USA; AFSSAPS, France; ANVISA, Brazil; Health Canada, Canada; Medical Products Agency, Sweden; and MHLW, Japan

Regulatory

PQLI Global Update (103 and 104)

Part 1 (103), 28 October 08.15-11.30

Part 2 (104), 28 October 14.15-17.15

ISPE CEUs 0.2 for each

Product Quality Lifecycle Implementation (PQLI) is an industry-driven initiative, designed to develop a practical and pragmatic approach to implementing Q8, Q9, and Q10 ICH Guidance documents. In essence, PQLI provides the link between ICH guidelines, and the needs of those implementing them. PQLI provides a technical framework for the implementation of Quality by Design (QbD) based on sound scientific, engineering, and business principles. PQLI helps craft a pragmatic approach to implementing Q8, Q9 and Q10, using a risk-based approach to the lifecycle of a product – from regulatory submission, to end of life migration. Uniquely, PQLI involves worldwide regulators in the development and implementation of this critical thinking.

This session will provide an overview of PQLI and progress made to date; updates from current Task Teams (Legacy Products, Control Strategy, Design Space, and Criticality, plus Biotechnology); how PQLI topics are integrated; and the pathway forward for PQLI including plans for generation of technical documents and additional Task Teams. A special section on generics is also planned. Note: PQLI Update Parts 1 & 2 are not the same programs.

Part 1 (103) will focus on:

- Overview of PQLI and Integration Concept
- Design Space
- Criticality
- Control Strategy
- Regulatory Panel Discussion - US, Europe, and Japan invited
- Pathway Forward

Part 2 (104) will focus on:

- Overview of PQLI and Integration Concept
- Legacy Products
- Generics
- Biotechnology
- Regulatory Panel Discussion - US, Europe, and Japan invited
- The Future

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the views of senior regulators from USA, Europe, and Japan
- Help formulate your future by participating in this global initiative
- Understand how design space, criticality, control strategy, legacy products, and biotechnology are integrated
- Provide input into the future development of White Papers and technical documents for industry consideration

Technical Documents - www.ISPE.org/publications

Preliminary planning is underway on PQLI-related technical documents; watch for publications in the future

Who Should Attend

This will be of interest to a range of participants from senior leaders to project managers from regulatory, development, quality, and manufacturing who wish to facilitate the future framing of QbD

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Commissioning and Qualification (C&Q), Process Analytical Technology (PAT), Project Management (PM), and Process/Product Development (PPD)

Leaders and Speakers to Date, Session #103

- John Lepore, PhD, Senior Director, Commercialization, Merck and Co. Inc., USA
- Line Lundsberg-Nielsen, PhD, Director, External Pharmaceutical Programmes, AstraZeneca, UK
- Roger Nosal, Executive Director, Pfizer Inc., USA
- Christopher Potter, PhD, CMC Pharmaceutical Consultant, UK
- David Selby, PhD, Managing Director, Selby Hope International Ltd., UK
- Regulators from US, Europe, and Japan invited

Leaders and Speakers to Date, Session #104

- Ron Branning, President, Ron Branning and Associates, USA
- Christopher Potter, PhD, CMC Pharmaceutical Consultant, UK
- David Selby, PhD, Managing Director, Selby Hope International Ltd., UK
- Regulators from US, Europe, and Japan invited

Program elements and speakers subject to change.

Regulatory

Follow On Biologics – A Panel Discussion (105)

29 October 08.15-11.15

ISPE CEUs 0.2

Several smaller molecule biologics like Insulin and HGH, made using r-DNA technology, are already being marketed by multiple manufacturers. It is estimated that biologics worth \$10 billion will be off patent by the year 2010 and that by 2015 the market value of off patent biologics is expected to top \$20 billion. It is therefore no surprise that the market place is extremely interested in the fate of biogenerics, biosimilars or follow on biologics. This session is being offered to stimulate the healthy debate required to create a well thought out and defined pathway for Follow on Biologics without risking drug safety and efficacy.

The biogeneric manufacturers will have to face the unique challenges associated with replicating large molecule biologics. In addition, should they also be required to submit evidence of drug safety and efficacy, which may be even more stringent than that provided for the original?

As a part of this session the panelists will explore and debate:

- Economic and Financial Issues
- Legal/Patent Issues
- Technical Issues
- Regulatory Issues

The panel discussion format will not only create an opportunity to see the same issues explored from differing perspectives, but also allow the attendees to become active participants in the discussion.

How You Will Benefit

At the end of this session, participants will be able to:

- Develop a comprehensive understanding of issues and challenges associated with Follow on Biologics
- Explain differing views on the issues within the marketplace

Who Should Attend

Owners, developers and designers, of biopharmaceutical processes and facilities as well as regulatory and quality professionals involved in product and facility validation and approval/licensing processes

ISPE Community of Practice (COP)

Biotechnology (Biotech)

Leaders and Speakers to Date

- Deepak Agarwal, Director, Pharma Technology, Jacobs Consultancy, USA (Leader)
- Gerhard Klement, CEO and President-Biopharmaceuticals, Reliance Life Sciences, India
- Regulators from USA and Europe invited

Quality Laboratory Facilities Baseline® Guide: Your Roadmap to a Compliant, Cost-effective Lab (106)

29 October 12.45-15.45

ISPE CEUs 0.2

This session provides an update on the development of the new *Baseline® Guide for Quality Laboratory Facilities* including application of principles of risk assessment, efficient and cost-effective commissioning and qualification, and existing international regulations surrounding the quality laboratory. At the time of this printing, the document development team is responding to global industry review comments and updating a draft to forward to the U.S. FDA.

There it will receive a formal technical and legal review. The anticipated publication date is first quarter 2009. The session will feature:

- Laboratory Guide overview, philosophy used in creating the Guide, and quality and compliance benefits of use
- Regulatory philosophy as it relates to facility design of quality control labs
- Application of ICH Q9: Quality Risk Management including particular risks to your laboratory situation based on current practices/strategies of your company
- Compliance through the application of ASTM E2500 vs. traditional C&Q
- Panel discussion/question and answer with Guide Authors

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the major issues/updates to the Guide
- Describe regulatory challenges in laboratories
- Understand application of risk assessment in determining the quality strategies for your lab
- Analyze what risk assessment strategies you should consider for your laboratory

Who Should Attend

Laboratory, compliance and validation professionals, project engineers, architects, construction managers, and quality personnel

Leaders and Speakers to Date

- James O'Brien, President, NAMA Industries Inc., USA
- Fred Fricke, Director, Forensic Chemistry Center, FDA, USA invited
- Catherine Middelberg, Manager, Engineering, Wyeth Biotech, USA
- Kimberly Snyder, Senior Project Manager, NNE Pharmaplan US, USA
- Rebecca Waterbury, Regulatory Compliance, Abbott Vascular, USA (Leader)

Continuous and High Throughput Processing (201)

26 October 13.00-17.00

ISPE CEUs 0.4

This education topic will cover the technologies and methodologies emerging in the industry for continuous and high throughput processing modes of operation. Currently, there are a number of companies beginning to evaluate and implement continuous processing and lean methodologies to minimize non-value added processing steps into manufacturing operations. A short list includes a GlaxoSmithKline European operation and a Genzyme process operating at the multi-hundred ton scale with a significant focus on PAT implementation. Continuous and high throughput manufacturing can reduce cost of goods and improve product quality.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand continuous processing technologies
- Describe release strategies
- Analyze lean implementations that increase throughput and reduce cost

Who Should Attend

Scientists and engineers, process development and quality assurance professionals

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Biotechnology (Biotech), Process Analytical Technology (PAT), and Process/Product Development (PPD)

Leaders and Speakers to Date

Peter McDonnell, Senior Technical Director, Genzyme Ltd., UK (Leader)

Developments in Biotech Downstream Processing (202)

27 October 13.30-17.00

ISPE CEUs 0.2

In the last 10 years, biotechnology processes based on mammalian cell culture have seen tremendous increases in upstream titer (from a few hundred milligrams per liter to 5-10 grams per liter). There have been few significant increases in downstream processing efficiency and the downstream processing is now becoming a significant manufacturing bottleneck. This session will explore this issue and focus on recent developments and needs in this area.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand why downstream problems are developing
- Explain recent trends in DSP technology
- Articulate the newest improvements in DSP

Technical Documents - www.ISPE.org/publications

Biopharmaceutical Manufacturing Facilities Baseline® Guide

Who Should Attend

Research, process development, and process engineering

ISPE Communities of Practice (COPs)

Biotechnology (Biotech) and Process/Product Development (PPD)

Leaders and Speakers to Date

- Richard Schoenfeld, Principal, BioWorks Consulting, USA (Leader)
- Michiel Ultee, Senior Director, Process Sciences, Laureate Pharma, Inc.

The Position of Science in Technology Transfer (203)

28 October 08.15-11.30

ISPE CEUs 0.2

Review implications to traditional tech transfer, which PQLI introduces. QbD development will lead to an increased body of knowledge earlier in a product's or process's development. This knowledge needs to be efficiently transferred and manufacturing will need to apply this knowledge to further develop/improve the process/product. This puts additional requirements into the technology transfer process. Integration of new technologies and the expansion of process knowledge can aid in this process.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify issues related to PQLI and tech transfer, and discuss possible solutions
- Develop a case for revisions to traditional tech transfer approaches based on new body of process/product knowledge
- Understand how data and new technologies can aid in this arena

Technical Documents - www.ISPE.org/publications

ISPE Good Practice Guide: Technology Transfer

Who Should Attend

Development and manufacturing scientists and engineers, and quality assurance professionals

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Biotechnology (Biotech), Good Automated Manufacturing Practice (GAMP), Process Analytical Technology (PAT), and Process/Product Development (PPD)

Leaders and Speakers to Date

- Howard Levine, PhD, President, BioProcess Tech Consultants, Inc., USA
- Angel Morales, Pharmaceutical Chemist, Eli Lilly and Co., USA
- Gregory Needham, Senior Scientist, Eli Lilly and Co., USA

Challenges in Managing the Pre-Pandemic Influenza Vaccine Stockpile (HHS Perspective) (204)

28 October 14.15-17.15

ISPE CEUs 0.2

The U.S. Department of Health and Human Services (HHS) Pandemic Influenza Plan has invested almost \$1 billion in the purchase of Influenza bulk vaccines for pandemic preparedness. This course will review the status of current stockpile and the selection of virus strains for the stockpile. The course will also review the current status of Avian Influenza in the world and the various virus strains in circulation. The impact of the genetic shifts in Avian Influenza and their impact on virus strain selection and current pre-pandemic bulk vaccine will be discussed. The HHS program to extend the pre-pandemic Influenza bulk through the use of adjuvants will also be reviewed. Lastly, the life cycle cost analysis developed by HHS/ASPR/BARDA for the stockpile program will be presented.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify advances in vaccine technology development
- Describe scientific challenges still facing vaccine development and manufacture
- Describe scientific challenges still facing vaccine storage and stability
- Understand the value of the interface between immunology and vaccines for development breakthroughs

Who Should Attend

All persons interested in the department of Human Health and Services Pandemic Influenza Preparedness programs and their impact on the vaccine manufacturing community

ISPE Communities of Practice (COPs)

Biotechnology (Biotech), Containment, Disposables, Process/Product Development (PPD), Project Management (PM), and Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Armen Donabedian, Senior Program Manager, Vaccines, HHS/OS/ASPR/BARDA, USA
- Robert Huebner, Senior Program Manager, HHS/OS/ASPR/BARDA, USA
- Michael Perdue, Acting Director, HHS/OS/ASPR/BARDA, USA
- Robin Robinson, Director, HHS/OS/ASPR/BARDA, USA
- Thomas Warf, Program Manager, Department of Human Health and Services, USA (Leader)

Advances in Vaccine Discovery and Manufacturing (205)

29 October 08.15-11.15

ISPE CEUs 0.2

With all the advances in therapeutics, vaccines continue to represent the single most cost-effective medically delivered strategy for confronting the challenges involved in prevention of viral and bacterial diseases. The advancements in vaccine technology development are further hampered by the unique economic, legal, and regulatory issues faced by vaccines.

The desire to be able to create a shield against current and potential threats against the likes of HIV, potential flu pandemic and agents of bio-terrorism continues to fuel vaccine development in spite of all the challenges. As a matter of fact, there has been a tremendous resurgence in vaccine development activity after several decades of relative inactivity. This session intends to bring case studies of real projects to exemplify the current state of vaccine development.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify advances in vaccine manufacturing technology
- Describe scientific challenges still facing vaccine manufacturing development
- Understand the global manufacturing capacity challenges offered by a pandemic outbreak

Who Should Attend

Professionals working in vaccine development and processing

ISPE Communities of Practice (COPs)

Biotechnology (Biotech), Containment, Disposables, Process/Product Development (PPD), Project Management (PM), and Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Parrish Galliher, Founder and Chief Technology Officer, Xcellerex, Inc., USA (Leader)

Innovation

Nanotechnology (206)

29 October 12.45-15.45

ISPE CEUs 0.2

Nanotechnology promises a revolution in the field of medicine. Although there are a few nanoscale drug products currently on the market, there is an enormous amount of research being done in this area. From transdermals and oral dosage products to biologics, nanotechnology could transform the future landscape of the pharmaceutical industry. The field is, however, still in its infancy. New processing technologies need to be developed and the debate over the safety and environmental impact of nanoparticles should be addressed. This session will provide an overview of the latest “nano” developments in pharma as well as where we are likely to be heading in the future.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the current state of nanotechnology in the pharmaceutical and biologics industry
- Identify the risks to employee safety
- Describe some of the new processes being developed and used to create drugs at the nanoscale

Who Should Attend

Professionals from process development, engineering, validation, environmental health and safety

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Biotechnology (Biotech), Containment, Commissioning and Qualification (C&Q), and Process/Product Development (PPD)

Hot Topic China (207) CANCELLED

26 October 13.00-17.00

ISPE CEUs 0.4

Visit www.ISPE.org/annualmeeting for updates.

Managing Innovation for Profitable Growth: What the Pharmaceutical Industry Can Learn from Others (208)

27 October 13.30-17.00

ISPE CEUs 0.2

Innovation is a strategic tool to develop new products, improve manufacturing methods and achieve operational efficiencies. Managing innovation, however, can be a difficult and challenging problem. Decades of industrial research directed by the Center for Innovation Management Studies at NC State University's College of Management have shown that innovation management can be learned, practiced, measured and ultimately improved and managed. Mastering these elements is essential to achieving profitable growth and long term organizational health. Examples abound from different industries as to how the strategic needs of companies for new and improved products and services can be successfully matched with opportunities arising from new technical possibilities and scientific discoveries.

This session will examine some of the fundamentals of innovation, as practiced not only by the pharmaceutical industry but by other science and technology-focused industries that compete in the global marketplace.

Leaders and Speakers to Date

- Paul Mugge, Director, Center for Innovation Management Studies, N.C. State University, USA (Leader)

Hot Topic – In Search of the GMPs (209)

29 October 08.15-11.15

ISPE CEUs 0.2

The FDA received numerous comments from industry regarding the proposed revisions to the GMPs. Due to the number and content of those comments, the Agency removed the proposed revisions from posting and went back to the drawing board in April, 2008. What has happened since then and what does this mean to the industry? This session will explore the current state of revision, review some of the comments and hear from industry and regulators on how the GMPs will be impacted by events and other initiatives shaping the global marketplace today.

Manufacturing Operations

Supporting Strategic Initiatives with Operational Excellence (301)

26 October 13.00-17.00

ISPE CEUs 0.4

The pharmaceutical industry is currently undergoing a major business transformation driven by a combination of global regulatory requirements, operational constraints, and growing pressure to reduce the cost of pharmaceuticals to the public. Industry's transformation is affecting operations across the board.

Listen to case history presentations from your peers. These include enterprise knowledge management and a detailed case study of an ongoing operational excellence program. In this presentation, the journey to Class A includes the rollout of business process management, ownership of global processes, and process improvement of issues, which are identified through quarterly assessments using a variety of tools and methodologies. Additionally, review the implementation and deployment of a risk management and six sigma program with actual industry examples. Join in the panel's discussion on global market and business trends and how they impact development and manufacturing operations and performance. Challenges such as industry advancements in technology, the importance of such tools as Six Sigma and other strategic tools, as well as the significance of optimizing operations and business performance improvements in real time are also addressed.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand how operational and business excellence leads to strategic improvements
- Establish a real connection from the business to the plant while enabling process improvements
- Apply what professionals in the pharmaceutical, biotechnology, and other industries are doing
- Explain why knowledge management is important to Operational Excellence

- Understand how others are using tools and methodologies for implementation and deployment
- Describe examples of how others are creating value and strategically improving throughput, yields and quality while reducing costs and mitigating risks
- Understand how strategic initiatives support your business and lead to operational excellence

Who Should Attend

Pharmaceutical, biotechnology, contract and generic manufacturers, and anyone from the engineer to the vice president of quality or operations and supply chain should attend to learn how industry advances impact business, and how they can implement and sustain programs that support strategic initiatives and develop operational excellence

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API) and Biotechnology (Biotech)

Proposed Agenda

- Pharmaceutical Industry Strategy: Enabling Business Strategies (Case Study)
- More Than a Program for Integrating Control and MES (Case Study)
- Six Sigma: Friend or Foe (Case Study)
- Operational Excellence Strategic Initiatives (Case Study)

Leaders and Speakers to Date

- Janice Abel, Director, Pharma and Biotech, Invensys, USA
- Catherine Middelberg, Manager, Engineering, Wyeth Biotech, USA

Competing in the Global Marketplace (302)

27 October 13.30-17.00

ISPE CEUs 0.2

Challenge the current state of the pharmaceutical industry with these provocative questions. Join in this stimulating discussion as we tackle these questions with a panel of leaders.

- Is risk-adversity suicide in the face of competition? Change is essential, yet numerous companies avoid change because it comes with risk.
- Why build more and more elaborate facilities using more and more energy?
- Why use equipment and processes a baker in the 1900s would recognize?
- Why believe the regulator is the enemy?
- Why do we still find silos when quality, regulatory, toxicology, validation, and others rarely talk to each other?

The world cannot be changed in two and one-half hours, but the intention is to provoke thought, encourage discussion, and promote productive change.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the issues that delegates raise as most challenging
- Become open to possible new solutions
- Create change or at least start the discussion

Who Should Attend

Senior management and decision makers

ISPE Communities of Practice (COPs)

All COPs

Leaders and Speakers to Date

- Julian Wilkins, Vice President, PharmaConsult US Inc., USA (Leader)

Manufacturing Operations

Outsourcing: Friend or Foe? (303)

28 October 08.15-11.30

ISPE CEUs 0.2

Increased outsourcing to Contract Manufacturing Organizations (CMOs) for the manufacture of pharmaceuticals is raising very important questions for both the contractor and the pharmaceutical company.

- Are CMOs aware of regulatory and client audit requirements, particularly for high hazard compounds?
- From the CMOs' perspective, what do they need to offer in order to meet the expectations of the pharma company and to be the best that they can be?
- What are the issues at an operational level?
- Is the CMO route here to stay or is it about to change again?
- What new challenges are emerging in this increasingly popular manufacturing setting?

Gain insight on these questions and join in interactive discussion among speakers and delegates to understand both the issues above and others that will emerge from discussion. ISPE offers these special sessions as opportunities to create the common ground, which is vital for moving the industry ahead as it faces and articulates challenges in an open setting.

How You Will Benefit

At the end of this session, participants will be able to:

- Articulate contracting company goals and expectations when working with CMOs and vice versa
- Identify challenges that are currently arising in pharma/CMO projects
- Describe good practices and potential solutions to problems that other companies have experienced

- Outline new challenges that may be on the horizon with insight from the perspective of the CMO if pharma, and pharma if CMO

Who Should Attend

Management, operations, outsource procurers, CMOs, quality, regulatory and environmental health and safety professionals

ISPE Communities of Practice (COPs)

Containment and Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Jeff Campie, Senior Director, Commercial Quality Assurance, Gilead Sciences, USA
- Jeffrey Ellenburg, Head of Quality Control, Vetter Pharma-Fertigung GmbH & Co KG, Germany
- Julian Wilkins, Vice President, PharmaConsult US Inc., USA

Advanced Aseptic Processing (304)

28 October 14.15-17.15

ISPE CEUs 0.2

This session will focus on advanced aseptic processing topics and will feature case studies and discussion on important topics: Blow Fill Seal (BFS), Isolators, Restricted Access Barrier Systems (RABS), as well as question and answer/discussion.

How You Will Benefit

At the end of this session, participants will be able to:

- Explain updated technologies applicable to advanced aseptic processing using BFS, Isolators and RABS
- Understand what to do and what not to do from those who have done it before

- Answer questions on advanced aseptic processing issues

Technical Documents - www.ISPE.org/publications

Sterile Manufacturing Facilities Baseline® Guide

Who Should Attend

All aseptic processing professionals wishing to stay at the forefront of advanced aseptic processing technologies would benefit from this session

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Containment, Heating, Ventilation and Air Conditioning (HVAC), Process/Product Development (PPD), Project Management (PM), and Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Stewart Davenport, Senior Manager Technical Services, Pfizer Inc., USA
- Andrew Goll, Technical Sales Manager, Weiler Engineering Inc., USA
- Jack Lysfjord, Principal Consultant, Lysfjord Consulting LLC, USA (Leader)

Manufacturing Operations

Hot Topics in Aseptic Processing (305)

29 October 08.15-11.15

ISPE CEUs 0.2

Continuing technological advances and regulatory changes in aseptic processing requires professionals continually working to stay current. This session will pull some of the best concepts from the two-day Annual Aseptic Processing Symposium recently offered at the ISPE Conference in Tampa. If you did not attend that conference, attend this session for a summary of the best principles presented there.

Topics covered:

- Annex 1 implementation challenges
- Trends in the Disposable Technologies
- Multi-chamber containers for injectible drugs

How You Will Benefit

At the end of this session, participants will be able to:

- Outline key new developments/challenges in aseptic processing
- Identify trends in process design and current regulatory issues
- Describe innovative practices and how they can improve efficiencies and plant output

Technical Documents - www.ISPE.org/publications
Sterile Manufacturing Facilities Baseline® Guide

Who Should Attend

Professionals involved in managing, planning, engineering, operation, and qualification of compliant aseptic processes for production of sterile injectible projects

ISPE Community of Practice (COP)

Sterile Products Processing (SPP)

Leaders and Speakers to Date

- Jeffrey Ellenburg, Head of Quality Control, Vetter Pharma-Fertigung GmbH & Co KG, Germany
- Gordon Farquharson, Principal Consultant, Bovis Lend Lease, Technology Division, UK
- Jerold Martin, Senior Vice President, Global Scientific Affairs, Pall Life Sciences, USA
- Manmohan Sihra, Principal Consultant, Sihra Consulting, USA (Leader)

Platform Approaches to Streamline Development (306)

29 October 12.45-15.45

ISPE CEUs 0.2

The pharmaceutical and biotechnology industry have a lot to learn from other industries in which platform strategies have been applied with great success. With increasing pressures for cost-savings, efficiency, and speed to market, platform strategies will continue to develop in our pharmaceutical industry. This session provides the opportunity to compare actual case studies and participate in a forum for sharing best practices.

How You Will Benefit

At the end of this session, participants will be able to:

- Apply lessons learned from experienced users of platform technologies
- Identify the possible functions that can benefit from platform/standard strategies
- Recognize the pitfalls of implementation in order to perform a proper benefit analysis
- Understand the limitations of platform approaches

Technical Documents - www.ISPE.org/publications

Biopharmaceutical Manufacturing Facilities Baseline® Guide, and *Oral Solid Dosage Forms Baseline® Guide*

Who Should Attend

Development and manufacturing scientists, engineers, and managers

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Biotechnology (Biotech), Product Process Development (PPD)

Proposed Agenda

- Use of process platforms
- Use of equipment platforms
- Use of analytical platforms
- Standardization of other development activities

Leader and Speakers to Date

- Michiel Ultee, Senior Director, Process Sciences, Laureate Pharma, Inc. (Leader)

Manufacturing Operations

Suppliers Summit: Building Bridges to Better Performance and Accelerating Innovation Sharing Among the Pharma Manufacturing Community (307)

26 October 13.00-17.00

ISPE CEUs 0.4

We live in an increasingly outsourced world, where innovation is springing from all corners of the pharma manufacturing community, including pharma owners, consultants, contract manufacturers, solution-providing suppliers of packaged equipment and systems.

This Suppliers Summit is sponsored by ISPE's Suppliers Advisory Council. The SAC charter is to advise ISPE leadership on ways to promote and accelerate the contribution and impact of ISPE's supplier members. This group of consultants and solution-providing vendors and contractors hold a vital role to help ISPE be a Catalyst for Change for the pharma industry.

This session will bring together thought leaders from the manufacturing community to dialogue and identify practical paths to establish a broader platform of technical and commercial exchange that takes full advantage of innovation.

The session will address opportunities and barriers currently faced where commercial, risk management and regulatory realities threaten a stable and sustainable business climate. True partnerships can enhance opportunities currently available from the evolving supplier community. Owner companies are challenged to maximize contributions from outsourced activities, especially in manufacturing, which has traditionally been in-house. Effective partnering offers significant paybacks. This session will encourage open dialogue and identify issues for group discussion.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify trends and opportunities
- Recognize subject matter experts (SMEs) who may become future partners to expertly support your organization's strategic goals
- Better appreciate current obstacles to knowledge, innovation transfer, procurement practices, intellectual property issues, risk sharing and other issues
- Recognize opportunities to partner with suppliers as case studies present examples of cost reduction, improved flexibility and quality, and shared management of risk
- Understand the value of meaningful dialogue to collectively discuss challenges and suggest emerging solutions with new groups and from new perspectives

Who Should Attend

This session will be of significant interest to global manufacturers, emerging producers, mid-cap operators, consulting firms, architects, planners, design engineers, validators, and construction contractors. It will also be relevant to vendors/suppliers of integrated solutions for manufacturing, especially GMP pharma processing, packaging and finishing operations, as well as contract manufacturing organizations (CMOs). Senior operations management, facilities management, planning, designing, building, validating new and renovated facilities, owners, operators and maintainers of GMP facilities, specifiers, assemblers, and vendors/ integrators of complex, pharma processing equipment and systems will find this session invaluable. Professional business planners, project developers and strategic marketers will enjoy the visioning and future-oriented discussion directed towards identifying trends and opportunities.

ISPE Communities of Practice (COPs)

All

Agenda

- Frame the issues and opportunities
- Owner- and A/E-focused case studies and dialogue session
- Supplier-focused case studies and dialogue session
- Panel discussion/path forward

Leaders and Speakers to Date

- Andrew Signore, PE, CPIP, CEO, IPS, USA (Leader)

Engineering Design

Review of Critical Interfaces (401)

26 October 13.00-17.00

ISPE CEUs 0.4

The session looks at the part played by specialized transfer technologies, such as split butterfly valves, rapid transfer ports and bag trick connections to allow the transfer of materials from one closed system to another without compromise of the material or the environment. These systems are becoming increasingly critical as the trend to more highly hazardous compounds continues. One speaker will highlight a thoughtful and long term review of these systems presenting their merits and challenges. The potential impact of these systems to reduce costs and improve quality is important and will be explored in light of *ISPE's Risk-MaPP Baseline® Guide* and the trend to closed processing. Vendors will be invited to provide samples in "show and tell" opportunity featuring actual equipment so that participants can get hands on experience with help from vendor technical representatives. The session will conclude with a group discussion. Disclaimer: ISPE does not endorse these vendors who will be invited to attend at a premium. This session will have more of a commercial aspect to it than most ISPE education, but the benefit of being able to see the equipment and discuss advantages and disadvantages is an important part of this session.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the issues raised by these systems
- Explain how the varying systems work
- Discuss the critical issues raised by these devices when solving a problem or meeting a need
- Explain the pros and cons of various equipment options
- Analyze competing systems

Technical Documents - www.ISPE.org/publications

ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment, and the ISPE Baseline® Guide Series

Who Should Attend

Anyone contemplating closed processes for aseptic, occupational and product protection including those handling compounds of concern: hormones, cytotoxins, cytostatics, mutagens, teratogens, sensitizers and carcinogens. This session would be helpful for quality, regulatory, process engineering, aseptic, and operations professionals.

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API) and Containment

Leaders and Speakers to Date

- Paul Richards, Project and Technology Engineer, Pfizer Inc., USA
- Julian Wilkins, Vice President, PharmaConsult US Inc., USA (Leader)

2008 Facility of the Year Awards Winner Presentations (402)

27 October 13.30-17.00

ISPE CEUs 0.2

This session will feature project presentations by each of the Category Winners from the Facility of the Year Program (FOYA) for 2008. Immediately before this session, the Overall Winner will be announced in the morning Keynote Session. The 2008 Category Winners are:

- Boehringer Ingelheim Pharma GmbH & Co. KG
Winner in Facility Integration
- Bristol-Myers Squibb
Winner in Equipment Innovation

- IDT Biologika GmbH
Winner in Operational Excellence
- Pfizer
Winner in Process Innovation
- F. Hoffmann La Roche AG
Winner in Project Execution

ISPE, INTERPHEX, and *Pharmaceutical Processing* magazine support the FOYA program for projects that demonstrate global leadership by showcasing cutting-edge engineering, innovative new technology, or advanced applications of existing technology. This annual competition recognizes state-of-the-art projects that utilize new, innovative technologies to improve the quality of products, to reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery. This program is unique because it provides a platform for the pharmaceutical manufacturing industry to showcase its accomplishments in facility design, construction, and operation, while sharing the development of new applications of technology and cutting-edge approaches. However, the FOYA Program is about much more than just the science and technology of the facilities. More importantly, it is about recognizing the shared commitment and dedication of individuals working for different companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of all global consumers.

How You Will Benefit

At the end of this session, participants will be able to:

- Explain innovative approaches to solving facilities challenges and reduce costs
- Understand novel partnerships collaborating not only on a project, but the presentation of that project for this competition

Technical Documents - www.ISPE.org/publications
ISPE Baseline® Guide Series

Engineering Design

Who Should Attend

Vice presidents and senior vice presidents from owner companies, project managers, architects, engineers, members of construction companies, and vendors

ISPE Communities of Practice (COPs)

All COP members will benefit especially those from Project Management (PM) and the newly forming Sustainable Facilities.

Leaders and Speakers to Date

- Clive Mullins, Vice President, Foster Wheeler Corp., UK (Leader)

Planning the Successful BioPharm Facility Modification (403)

28 October 08.15-11.30

ISPE CEUs 0.2

As the biopharmaceutical industry has matured and evolved, owners and design service providers increasingly find themselves faced with the task of retrofitting existing operating manufacturing facilities. These projects may be to shore up aging infrastructure and mechanical systems as they near the end of their useful life, to increase throughput capacity, or perhaps re-purpose older facilities as new ones come on line. Limited capital may make retrofitting existing facilities a very viable choice to meet the needs of a product launch or production capacity increase. Others have gone this route to achieve 'Global Compliance' from a cGMP/Regulatory Compliance perspective in order to increase the potential markets for products produced within the facility.

Regardless of the project driver, the technical complexity and level of logistics planning involved with this undertaking can often overwhelm the design team if they are not adequately prepared and armed with the information necessary to achieve their end goal. Add to this the fact that the front-end/ conceptual design

and scope of a GMP/regulatory compliant facility needs a logical, step by step approach to the planning and pre-work associated with this uniquely challenging endeavor. Specific direction will be given identifying critical information to address regulatory compliance, risk mitigation, and construction logistics planning as well as building code and life safety issues. Potential barriers to success and stumbling blocks are included to eliminate unpleasant surprises during project implementation. A recent retrofit case study will be included.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand retrofit design process considerations
- Explain why a retrofit may be a viable choice rather than new construction
- List the front-end, conceptual considerations that will inform decision-making
- Identify potential barriers

Specific guidance will be given for the following:

- Identifying critical information to be gathered before initiating the design effort
- cGMP/regulatory compliance implications
- Risk mitigation
- Construction logistics planning
- Building code and life safety issues

Technical Documents - www.ISPE.org/publications

ISPE Baseline® Guide Series

Who Should Attend

Owners/facilities managers, design service providers, engineers, architects, planners, and project managers

ISPE Communities of Practice (COPs)

Sustainable Facilities and Project Management (PM)

Leaders and Speakers to Date

- Robert Allen, Technical Director Facilities Integration, Fluor Corporation, USA (Leader)
- Todd Dando, Construction Manager, Fluor Corporation, USA

- Timothy Jackson, Director, C&Q, Fluor Corporation, USA
- Alison More, Vice President, Hayward Manufacturing Operations, Amgen
- Ashely Taylor, Director of Hayward Facility Manufacturing, Amgen
- Scot Stofan, Technical Director, Construction, Fluor Corporation, USA

Green Design of Critical Utility Systems for Pharmaceutical Manufacturing and Related Industries (404)

28 October 14.15-17.15

ISPE CEUs 0.2

Focus on efficient design of water and steam purification and delivery systems. Topics include reduction in raw utilities, minimization of waste streams, reduction in chemical consumption, and energy minimization. As ancillary systems in the manufacture of pharmaceutical and biotechnology products, critical utility systems are a prime area for reduction in natural resources and pollution prevention. The topics covered will include new technologies and applications for waste minimization, water conservation and efficient design.

How You Will Benefit

At the end of this session, participants will be able to:

- Evaluate the inefficiencies with current processes and operating techniques
- Investigate energy reduction techniques for critical utility applications
- Explore options for green credits and green design techniques for CU applications
- Compare new efficient technologies
- Explain applications based case studies on water conservation, reclaim, and re-use

(Continued on page 20)

Engineering Design

Green Design of Critical Utility Systems for Pharmaceutical Manufacturing and Related Industries (404)

(Cont. from page 19)

Technical Documents - www.ISPE.org/publications

ISPE Baseline® Guide Series

Who Should Attend

Design engineers, process engineers, project managers, and utility/facility engineers

ISPE Communities of Practice (COPs)

Critical Utilities (CU) and Project Management (PM)

Leaders and Speakers to Date

- Mark Butler, General Manager Engineering, IPS, USA
- Andrew Collentro, Technical Director, Water Consulting Specialists, Inc., USA (Leader)
- Ed Helmig, Principal Project Engineer, Wyeth BioPharma, USA
- Phillip Sumner, Manager, Global Engineering, Pfizer Inc., USA

Design Standards for the Pharmaceutical Industry (405)

29 October 08.15-11.15

ISPE CEUs 0.2

Get involved with shaping the industry standards of tomorrow! Representatives from ISPE, ASME-BioProcess Equipment Standard, Pharmaceutical-3A, and more, are looking for your input to make the standards the best that they can be. Each representative will provide a brief description of the scope of their efforts, currently and on the horizon, and how these efforts relate to each other. There will be a special focus on facility standards and the new IBC L-Classification for

Laboratories in California, and soon to come to other jurisdictions. COP questions regarding standards will also be reviewed and the audience will participate in a moderated discussion on the general use of the standards, where each standard or guideline best applies, and what the industry needs from the standards in the future.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify current activities with ISPE, IBC, ASME and P3A on codes, standards and guidelines
- Describe new and developing standards and current trends that are emerging
- Apply the standards to their own jobs and company projects

Technical Documents - www.ISPE.org/publications

ISPE Baseline® Guide Series

Who Should Attend

People who want to understand standards and influence the industry such as design engineers, project managers, validation engineers, department managers, quality and regulatory staff

ISPE Communities of Practice (COPs)

All COPs

Leaders and Speakers to Date

- Reinhard Hanselka, PE, REA, Principal Chemical Engineer, IES USA
- William Huitt, Owner/President, W.M. Huitt, Co. USA
- Brian Rubin, Technical Consultant/Pharmaceutical Engineering, Abbott Laboratories, USA
- James Vogel, PE, Principal, Process Facilities Services Incorporated, USA (Leader)
- Richard Zinkowski, Manager, Products and Marketing, ITT Industries, Pure-Flo Solutions Group, USA

Kilo Labs and Pilot Plants: Bridges to the Future (406)

29 October 08.15-11.15

ISPE CEUs 0.2

This seminar features the latest developments in API Kilo Labs and Pilot Plants. It starts with the owner's perspective, such as reasons for building or renovating, and then continues through the planning, cost estimating, and scheduling of a Kilo Lab and/or Pilot Plant project. ISPE *API (Bulk) Baseline® Guide* authors will provide their perspectives and other presentations will feature trends and hot topics. Also address the marriage of process and building systems that must exist and be synergistic to have a successful Kilo Lab and/or Pilot Plant.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the functions and importance of Kilo Labs and Pilot Plants, and how they form an important bridge and component of the drug delivery pipeline
- Plan a Kilo Lab and/or Pilot Plant project
- Estimate the cost and schedule for a Kilo Lab and/or Pilot Plant project based upon benchmarked data

Technical Documents - www.ISPE.org/publications

API (Bulk) Baseline® Guide and *ISPE Baseline® Guide Series*

Who Should Attend

Anyone in planning, design, construction, commissioning, qualification, and operation and/or management of API Kilo Labs and/or Pilot Plants

ISPE Community of Practice (COP)

Active Pharmaceutical Ingredients (API)

Leaders and Speakers to Date

- Melody Armstrong, Senior Project Director, CE&IC, Inc., USA
- Ping Chang, Director, Schering Plough, USA
- Stanley Newberger, President, CE&IC Inc., USA (Leader)

Investigational Products

Investigational Products – Delivering Quality by Design

Operations Track (501) Management Track (502)

27 October 13.30-17.00

28 October 08.15-11.30 and 14.15-17.15

29 October 08.15-11.15

ISPE CEUs 1.0 each; Application for ACPE Accreditation is in process. Please visit www.ISPE.org for updates.

The ISPE Investigational Products Community of Practice (IP COP) is a unique global organization with a common global strategic vision that supports industry professionals worldwide by providing relevant, timely and cutting-edge information as well as access to solutions and resources in all aspects of the IP supply chain. In response to your feedback, a portion of this year's educational forum is segmented into two tracks to better meet the needs of the attendees. Although we will ask you to register for a particular track, attendees are free to engage in topics and sessions delivered in each of the tracks, based on your interest in topics.

- The Operations Track (501) will focus on tactical challenges industry professionals face in their day-to-day lives and how to overcome them
- The Management Track (502) will focus on strategic issues faced in managing an IP organization

The education forum kicks off with four workshops. Workshops are focused and interactive sessions where participants will have the opportunity to provide their own perspectives on each topic and takeaway actionable solutions.

Operations Track Workshop Themes

- Distribution Management
- Protocol Management

Management Track Workshop Theme

- Beginner and Advanced discussion on Business Process Management

Joint general sessions will continue to address the challenges of delivering in our global regulatory environment. Choices will be available in the tracks, topics to include:

Operations Track

- Management of trials in emerging markets
- Forecasting technology

Management Track

- Talent management
- Strategic decisions regarding emerging markets

Afternoon break-out sessions will provide the opportunity to delve deeper into these topics and gain from shared experience with your industry colleagues. Our popular Wildcard session allows you to bring forth the topic of your choice.

How You Will Benefit

At the end of this session, participants in the Operations Track will be able to:

- Relate challenges and risks faced in distributing clinical supplies and employ solutions/suggestions to mitigate these challenges and risks
- Examine tools/solutions for forecasting clinical supply needs
- Discuss challenges associated with comparator sourcing and controlled substances

At the end of this session, participants in the Management Track will be able to:

- Evaluate and assess benefits of business process management and how it applies to an Investigational Products (IP) group
- Discuss solutions on how to improve colleague training and retention in IP groups

- Engage in discussion on the benefits and risks of strategically going into emerging markets

At the end of this session, participants overall will be able to:

- Articulate real challenges and solutions in the IP community

Technical Documents - www.ISPE.org/publications

- *Comprehensive Guide to Clinical Materials*
- *ISPE Good Practice Guide: Development of Investigational Therapeutic Biological Products*

Who Should Attend

Investigational products professionals from all levels of the pharmaceutical and biotechnology industry—pharmaceutical companies, generics, and third party vendors

ISPE Communities of Practice (COPs)

Investigational Products (IP) and Packaging

Investigational Products Program Planning Committee:

- Michael Arnold, RPh, Business Process Head, Global Supply Chain, Pfizer Inc., USA
- Michelle Foust, PharmD, Director New Product Development, Almac Clinical Services, USA
- Neal Gordon, Senior Director CMC-USA, Organon a Part of Schering Plough Corporation, USA
- Kunal Jaiswal, Planning Committee Chair, Associate Director, Clinical Supplies, Schering-Plough Company, USA
- Paula Mastrangelo, Associate Director, Bristol-Myers Squibb, USA
- Robert Pizzie, PhD, Senior Director Global Clinical Supply Planning, Schering-Plough, USA
- FDA Invited

Project Management

Applied Risk Management – Addressing Cross Industry Challenges (601)

26 October 13.00-17.00

ISPE CEUs 0.4

Risk management is a process used within most areas of the pharmaceutical and biopharmaceutical industry - whether assessing risks in developing or manufacturing a new drug, or when building facilities to produce drugs. Within this industry, we have a vast array of potential risks, which we must identify, eliminate or mitigate, and ultimately control. Our goal is to take a risk-based approach to all aspects of the drug supply chain: from development to launch, and from launch to sustainable manufacture and sale. This session will introduce general principles of risk management, which are applicable across the industry and aims to be a practical workshop introducing different risk types and challenges:

- Quality (ICHQ9)
- Project (cost, time, scope risks)
- Operational (risks associated with health and safety, maintenance and quality)
- Business (supply chain and commercial/competitive risks)

Subject matter experts from various Communities of Practice (COPs) will be available to present concepts, tools and case studies and facilitate interactive sessions. These interactive sessions will give delegates hands-on practice on how to apply tools introduced during the seminar as well as to take them away for use within their own role.

How You Will Benefit

- At the end of this session, participants will be able to:
- Understand generic concepts of risk management – for example those which are as applicable to quality risk assessment as safety risk assessment
 - Apply a set of basic risk management tools
 - Demonstrate templates and sample model answers to interactive exercises presented

Who Should Attend

Project managers, engineers, and quality professionals

ISPE Communities of Practice (COPs)

Active Pharmaceutical Ingredients (API), Containment, Commissioning and Qualification (C&Q), Good Automated Manufacturing Practice (GAMP), and Project Management (PM)

Leaders and Speakers to Date

- Joerg Block, PS-TS-KM-Tech Compliance, Bayer HealthCare AG, Germany
- Patricia Melton, Managing Director, MIME Solutions Ltd., UK (Leader)
- Stanley Newberger, President, CE&IC Inc., USA
- Stephanie Wilkins, PE, President, PharmaConsult US, Inc., USA

Managing Innovation in a Capital Project (602)

27 October 13.30-17.00

ISPE CEUs 0.2

Analyze a case study focused on integration of an off-site construction philosophy within a traditional construction project of approximately \$100 million. This facility is designed to fill/finish a cytotoxic compound. Review the design, construction and start-up phase of the project and focus on the application of classic project management tools and methods. Interactive aspect of session allows for question and answer with presenters on best practices and lessons learned from this project.

How You Will Benefit

At the end of this session, participants will be able to:

- Apply best practices and lessons learned on like projects

Who Should Attend

Engineering, construction, and qualification project managers

ISPE Communities of Practice (COPs)

Containment, Heating, Ventilation and Air Conditioning (HVAC), and Project Management (PM)

Leaders and Speakers to Date

- William Bullock, Executive Vice President, Environmental Air Systems
- William Mahle, Senior Project Manager, CRB Consulting Engineers, Inc., USA
- Christopher McCann, Principal, McCann Construction Consulting, LLC, USA
- David Ross, Senior Project Manager, Yonkers Industries, USA (Leader)
- Sean Stringer, Facility Engineer, Eisai Inc., USA

The Real World of Project Management 1 – Capital Delivery Process for Small Scale Projects (603)

28 October 08.15-11.30

ISPE CEUs 0.2

Focus on delivery methodology for small-scale projects (under \$5 million). This program and methodology approach is innovative, fast track and immediately applicable. This session will be useful to you whether you are a student or a 20 year professional. Most companies who deliver small projects find unique challenges in following capital delivery processes developed to execute large-scale projects. This approach often delivers less than optimal results. The approach presented here will cut through the confusion and present a rational alternative. The new process uses the same basic principles, but tailors them appropriately. These “Real World” workshops have been highly rated by attendees.

How You Will Benefit

At the end of this session, participants will be able to:

- Discuss and analyze real world application of project management principles
- Share lessons learned with a like minded audience
- Take home tools and methods for application to their work

(Continued on page 23)

Project Management

The Real World of Project Management 1 – Capital Delivery Process for Small Scale Projects (603)

(Continued from page 22)

Who Should Attend
Project managers

ISPE Community of Practice (COP)
Project Management (PM)

Leaders and Speakers to Date

- Joseph De Paul, Director Vertical Marketing, Pharma, Cypress Systems, USA
- Keith Gibbs, Corporate Manager Technical Services, C&Q, Yonkers Industries, USA (Leader)
- John Honey, Senior Manager, Project Engineering, Genentech, USA

The Real World of Project Management 2 - Confessions of a Project Manager (604)

28 October 14.15-17.15

ISPE CEUs 0.2

Explore the trials and tribulations of project management, whether dealing with direct reports, vendors or project sponsors. This session is fast paced, highly interactive, and allows you to share with, and in return, learn from peers. Guided by highly experienced professionals.

How You Will Benefit

At the end of this session, participants will be able to:

- Know how to deal with and set expectations with executive sponsors
- Recognize underperformers within the owners (yours) or the contractor's project team and effective methods of working to better the situation
- Know how to effectively work with difficult subcontractor/vendors

Who Should Attend

Project managers and any other industry professionals

ISPE Communities of Practice (COPs)
Project Management (PM), and all others

Leaders and Speakers to Date

- Mark Butterworth, Project Manager, GlaxoSmithKline, Canada
- Keith Gibbs, Corporate Manager Technical Services, C&Q, Yonkers Industries, USA (Leader)

Managing Integration, Role of Integrator (605)

29 October 08.15-11.15

ISPE CEUs 0.2

Integration is a key component of a Capital Project and includes integrating controls, automation, and building management among other aspects. Facilitators will guide discussion on how to manage integration, deliverables, the implementation phase, effective C&Q of integrated systems, skills, knowledge, steps, and most importantly, the role the integrator plays in a project from design to construction, and turnover.

How You Will Benefit

At the end of this session, participants will be able to:

- Apply knowledge to execution of integration projects

Who Should Attend
Project managers

ISPE Community of Practice (COP)
Project Management (PM)

Leaders and Speakers to Date

- Timothy Alsin, President, QSPEC Solutions Inc., USA (Leader)
- Nuala Calnan, Principal Consultant, PM Group, Ireland (Leader)
- Aaron Corder, Senior Validation Specialist, NNE US Inc., USA
- Charles Crosier, Staff Engineer, Diosynth RTP Inc., USA

Managing Clinical Stage Projects (606)

29 October 12.45-15.45

ISPE CEUs 0.2

The process of getting a drug to market is a vast organizational effort for many drug companies these days and speed to market is imperative. As a product moves from late stage development through phase III clinical trial management and licensing, a focused project team and effort requires managing. Finding a way to successfully transfer a Biotechnology product in to full scale phase III manufacturing, validating that process, and ultimately licensing it with a focus on reducing cost, increasing speed, and maintaining compliance, is quite a project management challenge.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the process of moving a product from development to phase III to licensing, allowing for better internal customer appreciation
- Recognize universal tools that work for capital projects regardless of type (for example, design-build, construction, commissioning, vs. product development)
- Apply new tools to standard engineering projects

Technical Documents - www.ISPE.org/publications

ISPE Good Practice Guide: Technology Transfer, and *Biopharm. Manufacturing Facilities Baseline® Guide*

Who Should Attend

Project managers, engineers, process and development scientists, quality control, and quality assurance

ISPE Communities of Practice (COPs)

Biotechnology (Biotech), Investigational Products (IP), Project Management (PM), and Process/Product Development (PPD)

Leaders and Speakers to Date

- Amy Barnes, Project Manager, Global Project Management, Centocor USA
- Andrew Jones, Senior Manager, Global CMC QA, Global Biologics Supply Chain LLC., USA (Leader)

Efficient and Effective Compliance

Project Information Management (701)

26 October 13.00-17.00

ISPE CEUs 0.4

In the pharmaceutical industry, information about manufacturing asset design, fabrication, function and use is as important as the physical asset itself and in some cases, the absence of such information renders the asset unfit for use.

The Project Information Management (PIM) program supports information delivery and leverages trends such as increasing use of asset management technology tools, paperless asset delivery, and good engineering practice to provide a comprehensive program for asset information delivery and management.

The importance of assuring complete, accurate information for product, process, and equipment decision-making is a theme underscored throughout the ASTM E2500 standard and is fundamental to risk-based decision processes. The PIM program provides tools and processes to assure the timely delivery and ongoing management of accurate, complete asset information.

How You Will Benefit

At the end of this session, participants will be able to:

- Identify the fundamental components of a comprehensive project information management program
- Understand the importance of good engineering practices such as engineering change management and version control to maintaining information integrity
- Understand the benefits and challenges associated with asset information technology tools

- Examine their own project delivery programs and identify opportunities for improvement and for application of PIM principles and tools
- Understand the status of data and document standards development by ISPE C&Q COP Task Team

Technical Documents - www.ISPE.org/publications
Commissioning and Qualification Baseline® Guide

Who Should Attend

Professionals involved with capital project delivery including project management, Commissioning and Qualification, as well as validation, quality, maintenance, operations, IT, and process automation

ISPE Communities of Practice (COPs)

Commissioning and Qualification (C&Q), Project Management (PM), and Good Automated Manufacturing Practice (GAMP)

Leaders and Speakers to Date

- Dan Franklin, Regional Compliance Manager, Integrated Project Services (IPS), USA (Leader)
- David Kwilosz, Senior Project Engineer, Eli Lilly and Co., USA
- Dennis Naughton, Senior Project Engineer, Eli Lilly and Co., USA

Validation Hot Topics (702)

27 October 13.30-17.00

ISPE CEUs 0.2

Take this opportunity to hear from industry leaders on the latest guidance documents from the FDA as well as trends and issues arising from new Warning Letters and 483's issued by the FDA in 2008. In a constantly changing compliance environment, it is essential to stay up to date with the expectations of the regulators. The session will be very interactive, including panel question and answer. Visit www.ISPE.org/annualmeeting for session updates.

ASTM E2500, the Original C&Q Baseline Guide, and the New Science and Risk-based Approach for Specification, Design, Installation, and Verification for Facilities, Utilities and Equipment Baseline® Guide – Overview and Managing the Transition (703)

28 October 08.15-11.30

ISPE CEUs 0.2

The ASTM Standard defines at a very high level what is required under the new Verification Process to establish Pharmaceutical Facilities so that facilities are Fit For Use. The new *Commissioning and Qualification Baseline® Guide* in final development ("Volume 12 Science and Risk-Based Approach for the Specification, Design, and Verification of Facilities, Utilities and Equipment Systems") has begun the process of "how" to implement the verification process. The original *Commissioning and Qualification Baseline Guide* (Volume 5, Impact Assessment) continues to be an acceptable approach to qualification.

Receive an overview of different approaches to qualification and initial approaches and strategies being developed by the C&Q COP to assist industry in the transition from impact assessment to ICH Q9 risk-based approaches. A workshop at the end of session provides input and recommendations to the transition process. It will focus on the standard, Baseline Guides and Transition approach. Session 704 on Tuesday afternoon, 28 October, will present a series of case studies detailing transition approaches being implemented by owner companies. You may wish to attend both of these sessions for a fuller view of this topic.

Efficient and Effective Compliance

How You Will Benefit

At the end of this session, participants will be able to:

- Understand what is required by the ASTM E2500 standard
- Describe the verification process
- Describe the difference between the new and original C&Q Baseline Guides
- Understand the risk-based approach and how it is a different approach

Technical Documents - www.ISPE.org/publications
Commissioning and Qualification Baseline® Guide

Who Should Attend

All multi-disciplined project teams which are responsible for demonstrating that manufacturing elements are Fit For Use (i.e. qualified) to produce pharmaceutical products meeting quality requirements. This includes engineering, quality, SMEs, R&D, operations, among others.

ISPE Communities of Practice (COPs)

All COPs

Leaders and Speakers to Date

- Steven Wisniewski, Senior Associate Director of Compliance, Integrated Project Services (IPS), USA (Leader)

Science and Risk-based Approach (for C&Q): Application of the New Guide, Volume 12 Science and Risk-Based Approach for the Specification, Design, and Verification of Facilities, Utilities and Equipment Systems Transition Case Studies (704)

28 October 14.15-17.15

ISPE CEUs 0.2

Review a series of case studies showing initial industry approaches to transition from the original *C&Q Baseline Guide* approach using impact assessment to science

and risk-based approaches described in ASTM E2500 and the New *C&Q Baseline Guide*. Following the presentation, a speakers' panel will hold a discussion session with the audience to clarify points of interest. This session compliments session 703. You may wish to register for both if you are interested in this topic.

How You Will Benefit

At the end of this session, participants will be able to:

- Understand the transition from Impact Assessment to Risk-based approaches
- Have a better understanding of the verification process
- Understand the difference between the new and original *C&Q Baseline Guides*

Technical Documents - www.ISPE.org/publications
Commissioning and Qualification Baseline® Guide

Who Should Attend

All multi-disciplined project teams which are responsible for demonstrating that manufacturing elements are Fit For Use (i.e. qualified) to produce pharmaceutical products meeting quality requirements. This includes engineering, quality, SMEs, R&D, operations, among others.

ISPE Communities of Practice (COPs)

All COPs

Leaders and Speakers to Date

- Bob Adamson, Manager, Compliance and Validation, Foster Wheeler Energy Ltd, UK (Leader)

How good are your CSV practices? Benchmarking, Guidance, Case Studies - Two Sessions (705 and 706)

705 - 29 October 08.15-11.15

706 - 29 October 12.45-15.45

ISPE CEUs 0.2 each session

Assess your computer validation or verification system against best practices as described in *GAMP® 5*. This data will be collated and the feedback will be shared with

all delegates allowing them to identify specific areas for improvement. Presentations and workshops will then focus on the areas identified by attendees, which are in most need of improvement. Presentations will deepen understanding, and make practical suggestions for application upon return to work.

How You Will Benefit

At the end of this session, participants will be able to:

- Compare their CSV system with current good practices as reflected in *GAMP 5* and with those of other delegates
- Identify improvements that could be made to their CSV systems to reflect good practice
- Apply new ideas which can result in significant cost saving measures

Technical Documents - www.ISPE.org/publications
GAMP® 5: A Risk-based Approach to Compliant GxP Computerized Systems

Who Should Attend

Validation managers and practitioners from industry and suppliers, project managers, IT and controls engineers with responsibility for qualification, validation or verification

ISPE Communities of Practice (COPs)

Commissioning and Qualification (C&Q), Critical Utilities (CU), Good Automated Manufacturing Practice (GAMP), and Process Analytical Technology (PAT)

Leaders and Speakers to Date

- Kathleen Samways, Consultant, KAS Associates Ltd., UK (Leader)
- David Selby, PhD, Managing Director, Selby Hope International Ltd., UK (Leader)

Event Highlights

Monday, 27 October ISPE Community of Practice (COP) Night

Specific Times and Locations to be Announced
Price: visit www.ISPE.org/annualmeeting for specific prices, registration is open to all registered attendees; Age restrictions may apply

Plan to attend a Community of Practice (COP) Night event to network with your fellow COP members and other professionals with similar interests. It's a night for open dialogue, casual socialization, and enlightening industry updates. These customized COP gatherings allow you to make the most out of your networking opportunities while choosing the event that is of most interest to you. Watch www.ISPE.org/annualmeeting for registration and other important pricing information about these exciting networking events. Learn more about ISPE's rapidly growing COPs and other networking events at www.ISPE.org/COPs.

Sponsorship Opportunities

The COP Night will provide exclusive sponsorship opportunities. Contact Dave Hall at dhall@ispe.org, or Karen Newhouse at knewhouse@ispe.org for more information.

Tuesday, 28 October 11.45 – 13.45 Membership Luncheon and Awards Ceremony

Join ISPE leadership and colleagues in celebration of outstanding achievements. Special recognition awards will be presented to Members, Affiliates, Chapters, committees, companies, authors, and students. ISPE leaders provide their insight on Society accomplishments in 2008 and 2009 goals.

New Member/First Time Attendee Orientation Sunday, 26 October 11.00-12.30

During this informal, high energy lunch, new Members and first time attendees will have an opportunity to learn about the Society, how to navigate the Annual Meeting, and network with other attendees. Don't forget to bring plenty of business cards for the special networking activities! Event hosted by ISPE's Membership Services Committee (MSC). Please be sure to check this event on the 2008 Annual Meeting Delegate Registration Form.

Career Café

For job seekers, the ISPE 2008 Annual Meeting Career Café features job postings, the chance to post résumés on-line, and the opportunity to meet with prospective employers who are exhibiting at the event.

By posting a job for the Career Café, employers gain exposure to a highly-targeted and experienced audience – all 2008 Annual Meeting delegates, students, speakers, committee volunteers, and exhibitors. Positions will be posted on job boards and private interview space will be available to Featured Employers. To view employer packages, please visit www.ISPE.org/careers or contact Karen Newhouse, tel: +1-813-960-2105, Ext. 254.

Cyber Café

Sponsored by Austin AECOM

Access the Internet at the ISPE Cyber Café located in the Exhibit Hall - open during exhibit hours.

Certified Pharmaceutical Industry ProfessionalSM (CPIPSM) Workshops

These complimentary, one hour workshops provide an overview of the CPIP — an exciting, internationally recognized credential made available through the ISPE Professional Certification Commission. Topics include: a CPIP introduction, eligibility criteria, and the application and examination processes. Visit www.ISPE-PCC.org for

more information. Sign up for one of these workshops on page 29.

Monday, 27 October

13.30-14.30 and 15.00-16.00

Tuesday, 28 October

08.30-09.30, 10.30-11.30, and 14.00-15.00

Wednesday, 29 October

09.00-10.00

Showcase Your Products and Services at the Table Top Exhibition

The ISPE Annual Meeting Table Top Exhibition is your prime opportunity to gain access to and interact with key decision makers and buyers from the global pharmaceutical and biotech manufacturing industry. This year's exhibition will be centrally located adjacent to the Keynote Session.

The ISPE Annual Meeting attracts professionals from a wide range of disciplines, including facility engineers/managers, project engineers/managers, process engineers, manufacturing engineers, validation and quality professionals, as well as regulatory affairs, computer and process control personnel, scientists, operations, and investigational products professionals.

"Exhibiting at the ISPE Annual Meeting gave us the visibility to generate many new leads which resulted in a multimillion dollar proposal," said representatives from Brock Solutions.

The price for each table top is US\$2,750 and includes two complimentary exhibitor badges. The two complimentary exhibitor badges include access to continental breakfasts, refreshment breaks, the Monday lunch, and the Sunday Welcome Reception which will all be held in the exhibit hall. Additional exhibitor badges are available for purchase. Please contact Dave Hall, ISPE Director of Sales, tel: +1-813-739-2274, dhall@ispe.org or Karen

Event Highlights

Newhouse, Sales Executive, tel: +1-813-960-2105, Ext. 254, knewhouse@ispe.org to reserve a space.

Only registered exhibitors, committee members, speakers, or education delegates may walk through the exhibit hall. We no longer offer exhibit walk through badges.

Exhibit Hall Hours

Sunday, 26 October 17.00 – 18.30

Monday, 27 October 07.00 – 16.15

Tuesday, 28 October 07.00 – 11.00

The Sunday Welcome Reception, continental breakfasts, and breaks will be in the exhibit hall. Stop in for the opportunity to network with exhibitors and delegates.

Students Connect with Industry Professionals and Fellow Students at Annual Meeting

ISPE 2008 Annual Meeting offers many opportunities for you to meet and greet Industry Professionals and other Students, learn about industry trends, and make valuable connections to boost your career potential. If you are an ISPE Student Member, or are interested in becoming a Student Member and would like to attend, contact ISPE Customer Service by tel: +1-813-960-2105, or e-mail customerservice@ispe.org.

ISPE International Student Poster Competition

Student poster finalists from around the world showcase visual displays of their research or program highlights. These talented Student Members present their work before a panel of distinguished industry judges and attendees are able to view the posters throughout the meeting. ISPE announces the international graduate and undergraduate winners at the ISPE 2008 Annual Meeting Membership Luncheon and Awards Ceremony on Tuesday, 28 October.

Winners receive a monetary prize and recognition in ISPE publications. Participants have the opportunity to

publish an article based on their poster presentation in ISPE's *Pharmaceutical Engineering* magazine or the *Journal of Pharmaceutical Innovation*.

Visit www.ISPE.org/campusconnection for details.

Student Activity Schedule

Sunday, 26 October

- Student Lunch/Orientation with Industry Speakers 12.30 – 15.00

- Developing Job Interviewing Skills

- Student Poster Set Up 15.00 – 16.00

Monday, 27 October

- Student Poster Competition 13.30 – 17.00

Tuesday, 28 October

- Membership Luncheon and Awards Ceremony 11.45 – 13.45

- Student Poster Competition Winners Announced

- Student Chapter of the Year Announced

- Affiliate/Chapter/Student Chapter Workshops for North and South America/Europe/Asia Pacific

14.00 – 17.00

Affiliate/Chapter Council Activities

Monday, 27 October

Joint Affiliate Councils Meeting - North and South America/Europe/Asia Pacific 13.30 – 17.00

Tuesday, 28 October

- Membership Luncheon and Awards Ceremony 11.45 – 13.45

- North America South America Affiliate Council 08.30 – 11.30

- Asia Pacific Affiliate Council 08.30 – 11.30

- Affiliate/Chapter/Student Chapter* Workshops for North and South America/Europe/Asia Pacific 14.00 – 17.00

Downloads

Visit the Downloads Page at www.ISPE.org/annualmeeting to view registration forms, the delegate roster (available 20 October), presentation handouts, and exhibitor forms.

Academic and Industry Colloquium: Partners in Change Tuesday, 28 October 08.15 – 17.00

The necessity for industry and academic interaction on the research front is critical to the development of new products, processes and systems. This session creates an environment where collaboration among academic institutions, industry leaders, and regulators will lead to the establishment of an active global community of practice for academic affairs. Through participation in roundtables and workshops participants can:

- Establish global networks and relationships for new collaborations with other institutions and industry
- Explore opportunities for collaboration with human resources directors, vice presidents of research, and other industry leaders
- Examine the newest industry-regulatory-academic initiatives focused on education, including: nanotechnology, biotechnology, process analytical technology, Product Quality Lifecycle Implementation (PQLI), and Quality by Design
- Understand industry's perspective and expectations for skills and knowledge for professionals entering the pharmaceutical industry

Colloquium participants are invited to ISPE's Annual Membership Luncheon that includes an overview of ISPE's activities and opportunity to interact with industry.

The Full Academia Fee to attend the Colloquium is US\$665 Member, and US\$695 nonmember (includes ISPE membership). This discounted fee is available until 15 September. The Tuesday, One Day Fee is US\$450. Visit the Downloads Page at www.ISPE.org/annualmeeting to register.

General Information

How to Register

Education delegates, committee members, speakers, government and university faculty, and ISPE Student Members may register:

On-line: Visit www.ISPE.org/annualmeeting

Via Fax: Complete the registration form in this brochure and fax it to: +1-813-264-2816

Via Mail: Complete the registration form and mail it with payment to: ISPE Headquarters, 3109 W. Dr. Martin Luther King Jr. Blvd., Ste. 250, Tampa, Florida 33607 USA

Questions? Call ISPE Customer Service, tel: +1-813-960-2105, or e-mail: customerservice@ispe.org

Payment must be included with registration; complete credit card information is required for all registrations sent by fax. We accept American Express, VISA, or MasterCard/Eurocard. Payments made by check must be in US dollars and drawn on a US bank. Wire transfers are accepted—please contact ISPE for details. Hotel accommodations are not included in the registration fee.

Full conference registration includes access to all four days of conference educational sessions, continental breakfast, breaks, lunches (Monday – Wednesday), Sunday Welcome Reception and the Tuesday Navigating the Islands Party. You may also purchase a one-day pass to attend daytime events on Sunday, Monday, Tuesday, or Wednesday. The one-day pass does not include evening events, which may be purchased a la carte. Use the registration form included with the Annual Meeting Networking Brochure to register for the Spouse/Guest Package and to sign up for Optional Events.

Substitutions

Substitutions for education delegates are accepted and may be made by contacting ISPE in writing. Nonmembers substituting for Members are required to pay the difference in all the Member fees.

Exhibit Cancellations

Exhibit cancellations must be made in writing. Any cancellation made before 25 July 2008 will result in a US\$500 fee. Exhibitors are responsible for the full Table Top fees for cancellations made after 25 July 2008.

Education Program and Spouse/Guest Package Cancellations

Education program and spouse/guest cancellations will be accepted only in writing. If received by 28 September 2008, a full refund minus a US\$100 handling fee will be issued. No refunds after that time. Telephone cancellations will not be accepted.

Hotel Accommodations, Information and Reservations

See pages 30 and 31.

Airport Transportation

Airport taxi service is approximately US\$75

From Fort Lauderdale International Airport

Go Airport Shuttle; tel: +1-954-561-8888. This share-ride door-to-door transportation travels to and from Fort Lauderdale International Airport. 24-hour service is available, shuttles pick up every 30 minutes. Reservations are available at tel: +1-954-561-8888, or www.floridalimo.com. The one way trip is US\$18 per person.

From Palm Beach International Airport

Supershuttle; tel: +1-561-233-0500. Exclusive share-ride door-to-door transportation to and from Palm Beach International Airport. 24-hour service is available. Reservations are available at tel: +1-561-233-0500. The one way trip is US\$26 per person.

Dress is Business Casual

All ISPE Annual Meeting delegate functions are business casual. The spouse/guest, optional, and evening functions are casual. Typical autumn weather in Boca Raton calls for high temperatures around 82°F / 28°C and lows around 66°F / 19°C. Temperatures in meeting rooms tend to be cool so bring a light jacket or sweater.

Education Handouts

Registered Education Delegates will have on-line access to session handouts for a limited time before and after Annual Meeting. Reminders will be e-mailed. If you wish to take notes directly on handouts, we recommend you print handouts prior to your arrival.

Notice Regarding Speakers

Speakers selected to present programs are leading professionals in their fields. However, in rare circumstances, it may be necessary to make substitutions. Every possible effort will be made for a speaker with comparable qualifications. Agendas are subject to change without notice. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for information distributed or contained in the programs or for any opinion expressed.

ACPE CEUs

ACPE CEUs are awarded only for educational offerings that relate to Investigational Product topics. Application for these credits is pending. Please check www.ISPE.org/annualmeeting for updates.

ISPE CEUs and Accreditation

ISPE provides ISPE Continuing Education Units (CEUs). These nationally-recognized units of achievement have been designed for those individuals continuing their education in their chosen field or profession. Delegates will receive ISPE CEU certificates six to eight weeks following the program. ISPE has been named a continuing education provider by the Florida Board of Professional Engineers. Although ISPE is not an American Institute of Architects (AIA) continuing education provider, AIA members may submit their ISPE conference sessions by completing the Self-Report Form located on the AIA Web site, www.aia.org.

About Boca Raton

The product of a rich and fascinating history, Boca Raton, Florida once represented a bounty of natural resources. In the 1920s the sleepy town of Boca Raton began to change, as a group of Palm Beach and Northern investors headed by society architect Addison Mizner purchased oceanfront property. The town became the focal point of the area. Mizner set out to transform Boca Raton into his dream city, creating stylish homes and a gorgeous hotel.

ISPE 2008 Annual Meeting Education Delegate Registration Form

Attach Hotel Reservation Request Form, and submit both to ISPE. Photocopy to register additional people.

Please type or print clearly.

Check here if you were previously an ISPE Member. ISPE ID # _____

First Name _____ MI _____ Last Name _____

Informal Badge Name _____ Chapter/Affiliate _____

Job Title _____ E-mail Address _____

Company _____

Business Address _____ City _____

State/Province _____ Zip+4/Postcode _____ Country _____

Business Tel _____ Business Fax _____

ON-LINE: www.ISPE.org/annualmeeting

FAX: +1-813-264-2816

MAIL: ISPE, 3109 W. Dr. Martin Luther King Jr. Blvd., Suite 250, Tampa, Florida, 33607 USA

**Early Bird
15 Sept.**

[W]

Emergency Phone: Cell Phone _____ or Home Phone _____

FULL DAY EDUCATION FEES No refunds after 28 September	On or Before 15 Sept.	After 15 Sept.	TOTAL US\$
<input type="checkbox"/> Member	\$1,325	\$1,625	\$
<input type="checkbox"/> Nonmember*	\$1,525	\$1,825	\$
<input type="checkbox"/> Committee	\$ 725	\$ 725	\$
<input type="checkbox"/> Government	\$ 815	\$ 815	\$
<input type="checkbox"/> Academia Member	\$ 665	\$ 815	\$
<input type="checkbox"/> Student Member	\$ 450	\$ 450	\$

* Yes, I elect ISPE Membership. Visit www.ISPE.org/Membership, download, and complete an application. This is a 30-day limited offer.

FULL DAY EDUCATION MEAL FUNCTIONS

Full delegate registration includes all events listed below, plus the Sunday Welcome Reception, continental breakfasts, and breaks. Please check functions you plan to attend so that we can arrange for sufficient meals.

- I will not attend any meals, receptions, or parties
- Monday Lunch
- Tuesday Membership Lunch and Awards Ceremony
- Tuesday Navigating the Islands Party
- Wednesday Lunch

Special Meal Requirement Kosher Vegetarian Gluten Free

SINGLE DAY FEES* For Sun. to Weds., check days you will attend.	On or Before 15 Sept.	After 15 Sept.	TOTAL US\$
Half Day <input type="checkbox"/> Sunday	Member \$ 225 Nonmember \$ 265	Member \$ 275 Nonmember \$ 315	\$
One Day <input type="checkbox"/> Monday <input type="checkbox"/> Tuesday <input type="checkbox"/> Wednesday	Member \$ 450 Nonmember \$ 530	Member \$ 550 Nonmember \$ 630	\$
1 1/2 Day <input type="checkbox"/> Sunday/Monday	Member \$ 675 Nonmember \$ 795	Member \$ 825 Nonmember \$ 945	\$
Two Day <input type="checkbox"/> Monday/Tuesday <input type="checkbox"/> Tuesday/Weds	Member \$ 900 Nonmember \$1,060	Member \$1,100 Nonmember \$1,260	\$
2 1/2 Day <input type="checkbox"/> Sun/Mon/Tues	Member \$1,125 Nonmember \$1,325	Member \$1,375 Nonmember \$1,575	\$

SINGLE DAY EDUCATION MEAL FUNCTIONS

Single day fees include continental breakfast, lunch, and breaks for the days registered. The Tuesday Night Party must be purchased a la carte. Please check functions you plan to attend so that we can arrange for sufficient meals.

- I will not attend any meals, receptions, or parties
- Monday Lunch
- Tuesday Membership Lunch and Awards Ceremony
- Wednesday Lunch

<input type="checkbox"/> Tues Navigating the Islands Party	\$200	\$	\$
TOTAL US\$			\$

I wish to keep my data confidential and it is given only for use by ISPE and its local Chapters and Affiliates.

I do not wish my information to be printed in the Membership Listings.

I grant ISPE permission to record and/or copy my image and/or voice, and I grant ISPE all rights to use these sound, still, or moving images in any medium for education, outreach, promotional, or archival activities and other purposes of trade without limitation and/or compensation.

I'm a new ISPE Member.

I'm a first-time ISPE Annual Meeting attendee.

I will attend the New Member/First-time ISPE Annual Meeting Attendee Orientation on Sunday. See page 26 for details.

PAYMENT METHOD

Registrations only accepted with payment or credit card information. Please contact ISPE regarding wire transfers.

Substituting For _____
If you are a nonmember substituting for a Member, the nonmember registration fee is required in advance.

Check # _____
enclosed payable to ISPE (US Dollars only, drawn on a US bank) in the amount of \$ _____

Bill My Credit Card - Circle Type:

VISA MASTERCARD/EUROCARD AMEX

CARD NUMBER _____

EXPIRATION DATE _____

NAME OF CARDHOLDER (AS IT APPEARS ON CARD) _____

CARDHOLDER SIGNATURE _____

**Cancellations must be made in writing.
No registration refunds after
28 September 2008.**

Please send Annual Meeting registration and hotel reservation forms with payment to: ISPE Headquarters
3109 W. Dr. Martin Luther King Jr. Blvd., Suite 250
Tampa, Florida 33607, USA
Tel: + 1-813-960-2105, Fax: +1-813-264-2816
www.ISPE.org - FEI #59-2009272

PLEASE SELECT SEMINARS OF CHOICE

Select the sessions you will attend. Each is listed by track.

Keynote Session - Mon 08.30-12.00

CPIPSM Certification Workshops - 27-29 October (Complimentary)

Mon 13.30-14.30 Mon 15.00-16.00 Tues 08.30-09.30
 Tues 10.30-11.30 Tues 14.00-15.00 Weds 09.00-10.00

Regulatory Track (100)

101 PAT Implementation Sun 13.00-17.00

102 Risk-MaPP Mon 13.30-17.00

103 PQLI Global-1 Tues 08.15-11.30

104 PQLI Global-2 Tues 14.15-17.15

105 Follow On Biologics Weds 08.15-11.15

106 Laboratories Weds 12.45-15.45

Innovation Track (200)

201 High Throughput Processing Sun 13.00-17.00

202 Downstream Processing Mon 13.30-17.00

203 Tech Transfer Tues 08.15-11.30

204 Pandemic Flu Vaccines (HHS) Tues 14.15-17.15

205 Vaccine Mfg & Devt Wed 08.15-11.15

206 Nanotechnology Weds 12.45-15.45

~~207 Hot Topic China Sun 13.00-17.00 CANCELLED~~

208 Managing Innovation Mon 13.30-17.00

209 Hot Topic: GMPs Weds 08.15-11.15

Manufacturing Operations Track (300)

301 Operational Excellence Sun 13.00-17.00

302 Global Marketplace Mon 13.30-17.00

303 Outsourcing Tues 08.15-11.30

304 Advanced Aseptic Tues 14.15-17.15

305 Hot Topics Aseptic Weds 08.15-11.15

306 Platform Approaches Weds 12.45-15.45

307 Suppliers Summit Sun 13.00-17.00

Engineering Design Track (400)

401 Critical Interfaces Sun 13.00-17.00

402 Facility of the Year Mon 13.30-17.00

403 BioPharm Facility Tues 08.15-11.30

404 Green Design Tues 14.15-17.15

405 Design Standards Weds 08.15-11.15

406 Kilo & Pilot Plants Weds 08.15-11.15

Investigational Products Track (500)

501 IP-Operations Track Mon 13.30-17.00, Tues 08.15-11.30 and 14.15-17.15, and Weds 08.15-11.15 (Includes General Session)

502 IP-Management Track Mon 13.30-17.00, Tues 08.15-11.30 and 14.15-17.15, and Weds 08.15-11.15 (Incl. General Session)

Project Management Track (600)

601 Applied Risk Mgmt Sun 13.00-17.00

602 Capital Project Mon 13.30-17.00

603 Small Scale Projects Tues 08.15-11.30

604 Confessions of a Project Manager Tues 14.15-17.15

605 Role of Integrator Weds 08.15-11.15

606 Clinical Projects Weds 12.45-15.45

Efficient and Effective Compliance Track (700)

701 PIM Sun 13.00-17.00

702 Validation Hot Topics Mon 13.30-17.00

703 ASTM E2500, C&Q Original & New Guide Transition Tues 08.15-11.30

704 C&Q Transition Case Studies Tues 14.15-17.15

705 CSV Session 1 Weds 08.15-11.15

706 CSV Session 2 Weds 12.45-15.45

ISPE 2008 Annual Meeting Hotel Reservation Request Form

Hotel accommodations will book fast! Early registration is strongly recommended.

ON-LINE: www.ISPE.org/annualmeeting
 FAX: +1-813-264-2816
 MAIL: ISPE, 3109 W. Dr. Martin Luther King Jr. Blvd., Suite 250, Tampa, Florida, 33607 USA

In order to qualify for the discounted ISPE hotel rates, each delegate must be fully registered for the Annual Meeting as an education delegate, active committee member, speaker, or exhibitor. There are two ways to make a hotel reservation and **all hotel reservations must be made through ISPE (do not contact hotels directly):**

Option 1: On-line Reservation. Register on-line for the Annual Meeting at www.ISPE.org/annualmeeting. You will receive a confirmation page with a link to a hotel reservation page. We encourage you to complete this process immediately upon confirmation of your conference registration in order to secure a reservation since space at all hotels is limited.

Option 2: Fax or mail. Complete the meeting registration and hotel reservation forms at back of this brochure, including payment information, and return both to ISPE via fax or mail (FAX: +1-813-264-2816; MAIL: ISPE, 3109 W. Dr. Martin Luther King Jr. Blvd., Suite 250, Tampa, Florida, 33607 USA). Once your meeting registration has been completed, your room request will be submitted by ISPE to the hotel.

Once your hotel reservation has been made, you will receive an e-mail with your acknowledgement number listed, and we will advise you on the procedure for making changes to your reservation. **Please print this page for your records.**

Please do not call the hotel to verify your reservation until after the hotel cut-off date of 15 September. A confirmation e-mail will be sent by the hotel after 15 September.

Official Meeting Dates - Sunday, 26 October - Wednesday, 29 October

Name (print) _____ ISPE ID # _____

E-mail Address _____ Company _____

Please reserve one (1) room for _____ people for Arrival on _____ Departure on _____

Room Type Preferred: Handicapped Non-Smoking Smoking King Bed Double Beds Estimated Time of Arrival _____
Please notify us in writing if you have any special requirements.

Address _____

City _____ State/Province _____ Zip+4/Postcode _____ Country _____

Tel _____ Fax _____

Name(s) of person(s) sharing accommodations _____

Credit Card Type _____ Credit Card Number _____ Expiration Date _____

I authorize ISPE to charge my account for one night's deposit plus applicable taxes.

Signature _____

If you would like to pay by check, please contact ISPE Customer Service to make arrangements, tel: +1-813-960-2105, or e-mail customerservice@ispe.org.

Please understand that due to overwhelming responses, processing your reservations from ISPE into the hotel system will take a few days. Rest assured that if you have received confirmation already from ISPE, the hotel will honor your booking.

ISPE has negotiated discounted room rates at the hotels listed below, and detailed on the Hotel Accommodation Options information page in this brochure (page 31) for Annual Meeting delegates. Due to limited space at the hotels, please carefully review hotel details and select the hotel that best fits your needs. Complimentary transportation will be provided for delegates staying at Boca Raton Bridge Hotel and Boca Raton Marriott at Boca Center. **All attendees not staying at the resort hotel will have access to resort amenities at no additional charge.**

A deposit of one night is required to hold your room reservation and is non refundable after 15 September. Please complete the credit card information in full.

Resort Fee – A resort fee will be charged each night for attendees staying at Boca Raton Resort and Club. The resort fee is US\$16. This fee includes bellman gratuities, access to fitness center, high speed internet access in guestrooms and lobby, two bottled waters in guestrooms daily, 800 and local calls, shuttle busses to Mizner Park and Boca Raton Beach, daily newspaper, and coffee makers in room.

PLEASE SELECT HOTEL OF CHOICE		HOTEL RATE (Non refundable single night deposit after 15 September.)	TOTAL
Boca Raton Resort and Club ISPE 2008 Annual Meeting Headquarters Hotel <i>Four-night minimum stay required</i>	<input type="checkbox"/> 1st Choice <input type="checkbox"/> 2nd Choice <input type="checkbox"/> 3rd Choice	<input type="checkbox"/> US\$278.75 single/double (includes tax and US\$16 resort fee)	
Boca Raton Bridge Hotel <i>Two-night minimum stay required</i>	<input type="checkbox"/> 1st Choice <input type="checkbox"/> 2nd Choice <input type="checkbox"/> 3rd Choice	<input type="checkbox"/> US\$157.42 single/double (includes tax)	
Boca Raton Marriott at Boca Center	<input type="checkbox"/> 1st Choice <input type="checkbox"/> 2nd Choice <input type="checkbox"/> 3rd Choice	<input type="checkbox"/> US\$217.43 single/double (includes tax)	
Total US\$ _____			

ISPE 2008 Annual Meeting Hotel Accommodation Options

ISPE negotiated discounted room rates at the hotels listed below for Annual Meeting delegates. Due to limited space at the hotels, please review the hotel details carefully and select the hotel that best fits your needs. **Complete and submit to ISPE the Hotel Reservation Request Form on page 30 to make a reservation.** It is necessary to be fully registered for the Annual Meeting as an education delegate, active committee member, speaker, or exhibitor in order to qualify for a reservation. **One room per each registered delegate.** Questions? Call ISPE Customer Service, tel: +1-813-960-2105; e-mail: customerservice@ispe.org.

Hotel Options	Boca Raton Resort and Club	Boca Raton Bridge Hotel	Boca Raton Marriott at Boca Center
	Official ISPE 2008 Annual Meeting Headquarters Hotel 501 East Camino Real Boca Raton, Florida 33432 Tel: +1-561-447-3000; Fax: +1-561-394-3961 www.bocaresort.com	999 East Camino Real Boca Raton, Florida 33432 Tel: +1-561-368-9500; Fax: +1-561-362-0492 www.bocaronbridgehotel.com	5150 Town Center Circle Boca Raton, Florida 33486 Tel: +1-561-392-4600; Fax: +1-561-395-8258 www.marriott.com/pbibr
Pricing	<ul style="list-style-type: none"> • US\$278.75 single/double (includes tax and US\$16 resort fee) • Additional adults \$33 per night • Children under 16 free • Maximum in room – 4 • Non refundable one night deposit of US\$278.75 if cancelled after 15 September 	<ul style="list-style-type: none"> • US\$157.42 single/double (includes tax) • No charge for additional people • Maximum in room – 4 • Non refundable one night deposit of US\$157.42 if cancelled after 15 September 	<ul style="list-style-type: none"> • US\$217.43 single/double (includes tax) • No charge for additional people • Maximum in room – 4 • Non refundable one night deposit of US\$217.43 if cancelled after 15 September
Hotel Information	<ul style="list-style-type: none"> • 4 night minimum stay required • Check in: 16.00 • Check out: 11.00 	<ul style="list-style-type: none"> • 2 night minimum stay required • Check in: 15.00 • Check out: 12.00 	<ul style="list-style-type: none"> • No minimum stay • Check in: 15.00 • Check out: 12.00
Amenities	<ul style="list-style-type: none"> • Resort fee of US\$16 includes bellman gratuities, access to fitness center, high speed Internet access in guest rooms and lobby, two bottled waters in guestrooms daily, 800 and local calls, shuttle bus, daily newspaper, and coffee makers in room • On-site spa, golf, tennis, and shopping • Four pools • Shuttle to beach 	<ul style="list-style-type: none"> • Complimentary internet throughout the hotel • Walk to the beach • Fitness center with sauna • Pool • Includes Boca Resort amenities • All rooms with balconies and views of Atlantic or Intercoastal Waterway) 	<ul style="list-style-type: none"> • Complimentary internet in lobby • Internet in hotel rooms at US\$9.95 for 12 hours • Business center • Fitness center • Pool and hot tub • Includes Boca Resort amenities
Cancellation/Shortened Stay	<ul style="list-style-type: none"> • Cancel 14 days prior to check in or guests will be charged for their full stay • Guests will be charged a four-night minimum if they shorten stay • One night deposit is non refundable after 15 September 	<ul style="list-style-type: none"> • Cancel 30 days prior to check in or guests will be charged for their full stay • One night deposit is non refundable after 15 September 	<ul style="list-style-type: none"> • Cancel 72 hours prior to check in or guests will be charged for their full stay • One night deposit is non refundable after 15 September
Transportation (from Ft. Lauderdale or Palm Beach Intl. Airports)	<ul style="list-style-type: none"> • 24 miles/39 kilometers • Taxi approximately US\$75 • Shuttle details on page 28 	<ul style="list-style-type: none"> • 24 miles/39 kilometers • Taxi approximately US\$75 • Shuttle details on page 28 	<ul style="list-style-type: none"> • 25 miles/40 kilometers • Taxi approximately US\$75 • Shuttle details on page 28
Parking	<ul style="list-style-type: none"> • US\$26 overnight (unlimited in/out access) • US\$9 day time only (no in/out access) 	<ul style="list-style-type: none"> • US\$10 overnight with complimentary use of valet 	<ul style="list-style-type: none"> • Complimentary self parking • US\$10 for valet
Area	<ul style="list-style-type: none"> • Headquarters hotel • Complimentary shuttle to Mizner Park daily 	<ul style="list-style-type: none"> • Walk to the beach • 10-minute walk to headquarters hotel (complimentary shuttle also) 	<ul style="list-style-type: none"> • Nearby shopping and restaurants • Nightlife • Nearby spa • Complimentary shuttle to headquarters hotel • 10-minute drive to Boca Raton Resort and Club
Restaurants	Old Homestead, Cielo, Lucca, Bar Luna, Mizner's, and Monkey Bar	Watercolors Restaurant and Bar and Carmen's at the Top of the Bridge	Absinthe, on-site. Nearby: Big City Tavern, Cucina D' Angelo, Cheesecake Factory, Morton's, Opus 5, Uncle Tai's, and Sushi Ray



NAVIGATING THE HORIZON OF INDUSTRY CHANGE

Special Thanks to Our Current Sponsors

Platinum Sponsors:



Gold Sponsors:



Annual Meeting Sponsorships

Create Brand Awareness, Increase Visibility, and Develop New Business

Becoming an Annual Meeting sponsor guarantees your company wide exposure to key decision makers in pharmaceutical and biotech manufacturing with a minimum investment of your time and personnel. We offer a range of new sponsorship opportunities designed to build greater brand awareness, strengthen your company image, and increase your exhibit traffic. Sponsorships available include Platinum, Gold, Silver, and Bronze as well as specialty item sponsorships for tote bags, T-shirts, exhibit hall giveaways, room drops, and much more. We also offer on-site advertising opportunities.

A unique addition to this year's Annual Meeting will be the Community of Practice (COP) Night on Monday, 27 October when several ISPE COPs will hold additional networking activities providing sponsors with the opportunity to engage and interact with like-minded professionals. These networking events offer unparalleled exposure to a targeted audience providing cost-effective sponsorship. For more information please contact Dave Hall, ISPE Director of Sales, tel: +1-813-739-2274; dhall@ispe.org or Karen Newhouse, tel: +1-813-960-2105, Ext. 254; knehouse@ispe.org.