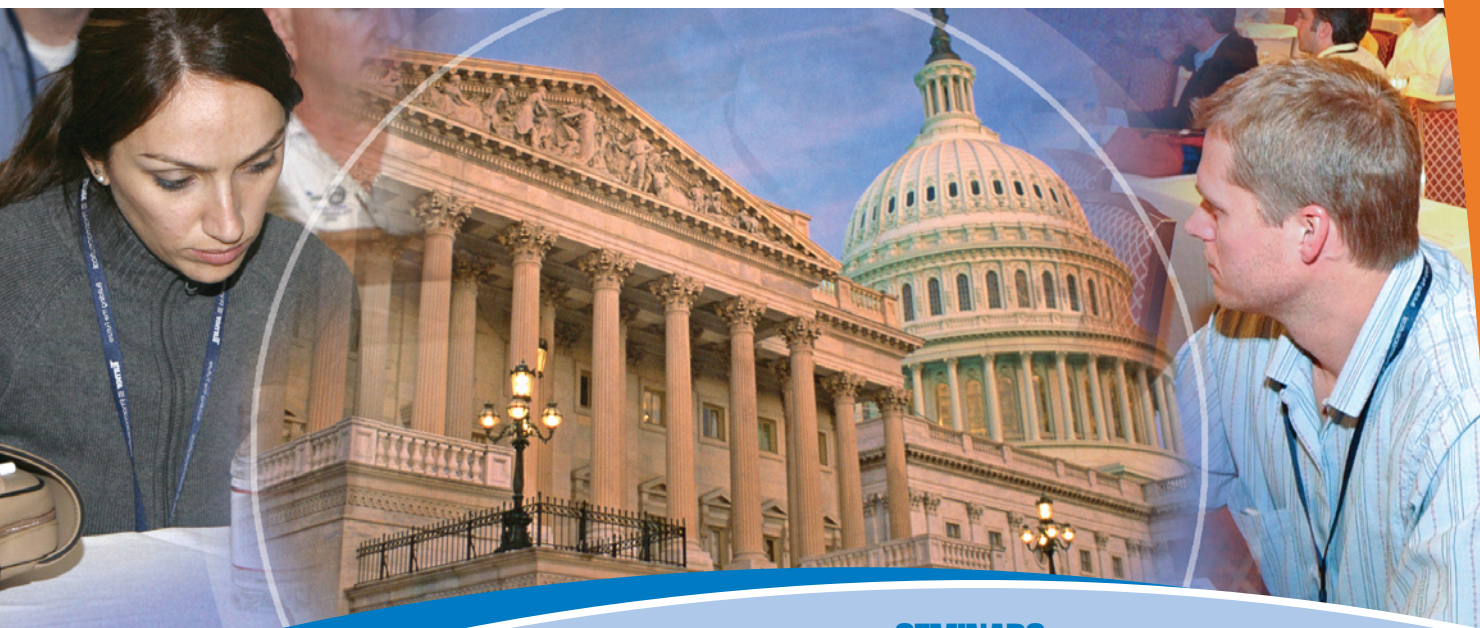


ISPE 2010 WASHINGTON CONFERENCE


Applying Risk-Based Approaches



7-10 June
JW Marriott
Washington, DC, USA

FDA Regulators
Invited to Present

TRAINING COURSES:

-  Process Validation in Biotechnology Manufacturing
- Cleaning Validation Principles

SEMINARS:

- Barrier Isolation Technology Forum: Innovation, Updates, New Case Studies
- PQLI®: Case Studies in QbD for Biotechnology and Small Molecule Product Realization
- Science and Risk-Based Commissioning and Qualification: Transitioning and Transforming
- Critical Utilities: Best Practices in Managing Risk and Cost
- Science and Risk-Based Validation: Practical Approaches Across Projects by Breaking Down Implementation Silos
- **FDA-ISPE Collaboration:** Pharmaceutical Quality Systems
- GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems - **NA Guide Launch**
- Sustainability: Best Practice Case Studies and Legislation Impact
- Trends in Biologics Manufacturing - with MedImmune Tour of Therapeutic Protein Facility
- GAMP® Good Practice Guide: Manufacturing Execution Systems - **Guide Launch**
- Practical Answers to Common HVAC Questions: An Introduction to the HVAC Good Practice Guide

Sponsorship and Table Top Exhibit Opportunities Available

www.ISPE.org/2010WashingtonConference

ENGINEERING PHARMACEUTICAL INNOVATION



2010 WASHINGTON CONFERENCE: Applying Risk-Based Approaches

ISPE 2010 Washington Conference At-A-Glance

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Career Café

Visit the Career Café to see the latest positions available from leading pharmaceutical and biotechnology employers and suppliers. Visit www.ISPE.org/careers for more details.

New Member/First Time Attendee Orientation

Monday

New Members and first time attendees are cordially invited to this special networking breakfast hosted by the Membership Development Committee (MDC). Meet fellow Society Members and Washington Conference attendees to foster new relationships, learn how to make the most out of your ISPE membership, and to ask questions. Bring plenty of business cards for networking.

 The mouse symbol indicates that the course includes a Webinar, a pre-recorded, online session that provides a review of the basics prior to the classroom or training course.

7-10 June 2010 JW Marriott, Washington, DC, USA

Monday, 7 June	Tuesday, 8 June	Wednesday, 9 June	Thursday, 10 June
Exhibits Open 17.00 – 18.30	Exhibits Open 07.30 – 16.00	Exhibits Open 07.30 – 16.00	
Barrier Isolation Technology Forum: Innovation, Updates, New Case Studies (E01)		Science and Risk-Based Validation: Practical Approaches Across Projects by Breaking Down Implementation Silos (E05)	
PQLI®: Case Studies in QbD for Biotechnology and Small Molecule Product Realization (E02)		FDA-ISPE Collaboration: Pharmaceutical Quality Systems (E06)	
Science and Risk-Based Commissioning and Qualification: Transitioning and Transforming (E03)		GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems - NA Launch (E07)	
Critical Utilities: Best Practices in Managing Risk and Cost (E04)		Sustainability: Best Practice Case Studies and Legislation Impact (E08)	
	GAMP® Good Practice Guide: Manufacturing Execution Systems - Guide Launch (D01)	Trends in Biologics Manufacturing - with MedImmune Tour of Therapeutic Protein Facility (E09)	
Process Validation in Biotechnology Manufacturing (T32)			
Cleaning Validation Principles (T17)			
Opening Reception in Exhibit Hall 17.00 - 18.30	Practical Answers to Common HVAC Questions 17.15 - 18.30 (F01)	Networking Reception 17.00 - 18.30	

ISPE Communities of Practice

ISPE Communities of Practice (COPs) provide enhanced connectivity through an interactive online community offering global networking opportunities and access to a community-specific Body of Knowledge. COP members are able to:

- Have the opportunity to share knowledge and experiences with other like-minded professionals through convenient global networking forums
- Access tools and resources that enhance productivity
- Stay current with industry trends and developments
- Foster a greater sense of professional commitment and enhance professional reputation

To join or learn more about COPs, visit www.ISPE.org/cops

Certified Pharmaceutical Industry Professional™ (CPIP™) Workshops

Introduction Workshops - Monday and Wednesday, 08.00 - 09.00

These complimentary, one hour workshops provide an overview of the CPIP — a pharmaceutical industry focused, international, competency-based credential made available through the ISPE Professional Certification Commission. Topics include: CPIP introduction, eligibility criteria, and the application and examination process.

www.ISPE-PCC.org

How-to Workshops - Tuesday 08.00 - 09.00 and Thursday 07.00 - 08.00

These complimentary, one hour workshops explain how to submit an eligibility application and prepare for the examination. Topics include: obtaining a university transcript, completing the professional experience forms, using the CPIP Study Guide, and organizing study groups. www.ISPE-PCC.org

Knowledge Elements Reference Chart

Technical Knowledge Competency Areas	1	Product Development	A	Formulation, clinical phases, and manufacture
			B	Technology transfer
			C	Production scale-up and optimization
	2	Facilities and Equipment	A	Design and construction/installation
			B	Commissioning and qualification as a risk management strategy
			C	Operation and maintenance
			D	Controls and automation
	3	Information Systems		
	4	Supply Chain Management	A	Materials management
			B	Operational economics
			C	Warehouse and distribution management
	5	Production Systems	A	Production unit operations - drug (small molecule) and biologics
			B	Production management
			C	Production control
6	Regulatory Compliance (Drugs, Environmental, Health, and Safety)	A	Government regulations	
		B	Standards, practices, and guides	
7	Quality Systems	A	Risk management and Quality Management System (QMS)	
		B	Systems validation	

Washington Conference Seminars or Training Courses	Technical Knowledge Competency Areas																	
	1			2				3	4			5			6		7	
	A	B	C	A	B	C	D		A	B	C	A	B	C	A	B	A	B
Barrier Isolation Technology Forum: Innovation, Updates, New Case Studies	X			X		X						X						
PQLI®: Case Studies in QbD for Biotechnology and Small Molecule Product Realization	X	X	X									X		X	X	X	X	X
Science and Risk-Based Commissioning and Qualification: Transitioning and Transforming				X	X	X	X									X	X	
Critical Utilities: Best Practices in Managing Risk and Cost				X	X	X	X										X	
Science and Risk-Based Validation: Practical Approaches Across Projects by Breaking Down Implementation Silos		X	X		X		X					X			X	X		X
FDA-ISPE Collaboration: Pharmaceutical Quality Systems	X	X							X	X	X			X			X	
GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems - NA Guide Launch						X		X										X
Sustainability: Best Practice Case Studies and Legislation Impact				X	X	X	X								X	X		
Trends in Biologics Manufacturing - with MedImmune Tour of Therapeutic Protein Facility	X		X									X						
GAMP® Good Practice Guide: Manufacturing Execution Systems - Guide Launch (Knowledge Elements in the Guide)		X					X	X	X			X	X			X	X	X
Cleaning Validation Principles														X				



All Washington Conference seminars (and one training course) contain knowledge related to the seven technical knowledge competency areas for the CPIP™ certification program, an international credential made available through the ISPE Professional Certification Commission. Completion of any of these seminars does not guarantee successful completion of the certification exam. Visit www.ISPE-PCC.org for details.

Seminar Content Level



This seminar presents developing technology and regulatory perspectives for barrier isolation, especially in regard to advanced aseptic processing, restricted access barrier systems (RABS), and isolators. Case studies bring the latest applications in the field. Content includes multiple case studies and interactive workshops on topics of global importance. Content includes background on four technology updates and seven case studies. Three interactive workshops provide access to discussion topics of global importance. Hear from speakers from Europe and North America, and participate in an FDA question and answer session.

In its 19th year, this seminar will feature a variety of topics including robotics, E-beam sterilization of syringe tubs, measurement of hydrogen peroxide, biological sensitivity to hydrogen peroxide, clinical trial materials produced in an isolator, a biotech facility using isolator, and several contract manufacturing examples using these techniques.

This seminar features information that is generally between intermediate and advanced levels; however, it is very suitable for less experienced professionals as well.

Leaders

- Jack Lysfjord, Principal Consultant, Lysfjord Consulting, LLC, USA
- Michael Porter, Director, Technical Operations, Merck & Co Inc., USA

Communities of Practice (COP)

Sponsoring COP: Sterile Products Processing
Related COPs: Biotech, C&Q, Containment, Disposables, Investigational Products, and Product Process Development

Related Technical Documents, Articles, and Publications

- *ISPE Baseline® Guide: Sterile Manufacturing Facilities*
- *ISPE Good Practice Guide: Assessing the Particulate Containment Performance of Pharmaceutical Equipment*
- *ISPE Knowledge Brief: Risk-Based Approaches to Cross Contamination*

How You Will Benefit

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

- Describe updated technologies applicable to advanced aseptic processing using BFS, RABS, and barrier isolation
- Describe how robotics can improve clinical manufacturing
- Understand protein sensitivity to hydrogen peroxide
- Interpret regulatory agency perspectives to streamline your regulatory submission and approval process
- Participate in peer discussion groups on advanced aseptic processing issues
- Understand what to do and what not to do from those who have done it before
- Apply best practices from case studies

Speakers to Date

- Dr. Dieter Bachmann, Head Quality Validation, Cilag AG, SWITZERLAND
- Dieter Bandtel, Product Manager, Bosch Packaging Technology, GERMANY
- Sarah Doshna, Director, Clinical Manufacturing, Bristol-Myers Squibb, USA
- Richard Friedman, Director, Mfg & Product Quality, FDA/CDER, USA, invited
- Tara Goen, LT, PHS, Compliance Officer, FDA/CDER/DMPQ, USA, invited
- Ryan Hawkins, Manufacturing Manager, Cook Pharmica, USA
- Thomas Huber, Sales Director and Deputy of the CEO, Skan AG, SWITZERLAND
- Sterling Kline, RA, Director, Project Development, IPS, USA
- Mathias Kreher, Product Manager, Bosch Packaging Technology, GERMANY
- Patrick Poisson, VP Manufacturing, Fill/Finish, United Therapeutics, USA
- Robert Sausville, Supervisory Consumer Safety Officer, FDA/CBER/OCBQ/DCM, USA, invited
- Barry Starkman, Director of Operations, Genentech, USA
- Christopher Wacinski, Director of Engineering, Jetalon, USA
- Dr. Michael Walsh, Sr. Research Scientist, Eli Lilly and Company, USA
- Sokhorn Yim, Pharma & Packaging Engineer, Genentech, USA

Who Should Attend

All aseptic processing professionals wishing to stay at the forefront of barrier isolation technologies.

Seminar Content Level



Is Quality by Design (QbD) applicable to biotechnology? Yes, and by participating in this two-day Product Quality Lifecycle Implementation® (PQLI®) workshop you will understand and discuss the A-Mab case study, which is the latest thinking in the application of QbD to biotechnology. This workshop provides the ideal forum to understand and take away practical examples of how principles of QbD can be applied to biotechnology, product development, and manufacturing. To complement the biotech approach and for comparison, a second case study developed by a PQLI team (a core component of a forthcoming ISPE Good Practice Guide on product realization) will be presented that explains QbD principles for a small molecule drug substance and drug product. Through these case studies and discussion you will better understand tools and processes to identify critical quality attributes and process parameters, as well as how an integrated control strategy can be developed. Additionally, the regulatory implications of what has been proposed can be discussed.

Leader

- Ranjit R. Deshmukh, PhD, Senior Director, Pfizer, USA
- Beth Junker, Senior Science Director, Merck & Co., Inc., USA

Related Technical Documents, Articles, and Publications

A-Mab Case Study accessible on the PQLI Web site, www.ISPE.org/PQLI

How You Will Benefit

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

- Understand the application of both simple and advanced Quality by Design principles with emphasis on biotechnology products, including small molecule applications
- Apply tools and processes to identify critical quality attributes and process parameters
- Explain how integrated control strategies can be developed
- Discuss regulatory implications of application of QbD

Program Committee

- John Berridge, PhD, CChem, FRSC, Pharma Quality & Regulatory, ISPE Advisor, UNITED KINGDOM
- Christopher Potter, PhD, CMC Pharmaceutical Consultant, ISPE Advisor, UNITED KINGDOM

Who Should Attend

Development, manufacturing, operations, technical services, quality assurance, quality control, process engineers, regulatory affairs, senior management, and life sciences professionals

Communities of Practice (COPs)

Sponsoring COPs: Biotech, PAT, and Product Process Development

Related COPs: API, OSD, and Sterile Products Processing

Science and Risk-Based Commissioning and Qualification: Transitioning and Transforming (E03)

7 - 8 June
1.2 CEUs

Seminar Content Level




Outlining science and risk-based methodologies for planning and implementing a project through the entire lifecycle, this seminar includes case studies and workshops to help you gain a working knowledge of the ISPE Baseline® Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment.

The seminar will outline science and risk-based methodologies for planning and implementing a project through the entire life cycle. The two-day seminar will feature the newest concepts and exemplify their applications in a way that you can use in your company.

- How to incorporate Quality Risk Management (QRM) principles (e.g., QbD, risk assessments, control strategies, product/process knowledge, etc.) into C&Q activities and deliverables (e.g., requirements definition, design review, C&Q planning, verification, test and release)

- Real-world implementation of risk-based approaches to fit your company's needs (efficient use of GEP commissioning data and vendor documentation based on identified risk factors)
- Managing and documenting engineering/project change
- Verification processes for demonstrating fit-for-intended use
- Understanding, defining, and assigning roles and responsibilities for a risk-based project, and building confidence in the process

Come and participate in discussions with the Guide writers, case study presenters, and your colleagues who also intend to implement this new approach. For those less experienced, an introductory webinar will be made available to you at no additional charge, upon request, so that you can better take advantage of this intermediate to advanced seminar. 

Leaders

- Scott Hamm, Consultant Engineer (C&Q), Eli Lilly & Co., USA
- Steven Wisniewski, Senior Associate Director of Compliance, IPS, USA

How You Will Benefit

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

- Understand and apply QRM principles to C&Q
- Deliver projects more efficiently using lean risk-based applications
- Understand how to apply risk-based principles within your organization based on knowledge obtained through case studies and workshops
- Understand regulatory perspectives and expectations
- Analyze applications through case studies and how this knowledge can be applied to your company
- Gain insights into problem solving by applying concepts in the Guide

Program Committee

- Nicholas Andreopoulos, Senior Manager, Pfizer, USA
- Dr. Joerg Block, PS-TS-KM-Tech Compliance, Bayer HealthCare AG, GERMANY
- Vincent Cebular, Vice President Compliance Ops, IPS, USA
- Rose Mary Dollard, Manager, Commissioning and Qualification Services, Johnson & Johnson, USA
- Petter Gallon, Risk Analyst, AstraZeneca AB, SWEDEN
- Gert Moelgaard, Vice President, Consulting, NNE Pharmaplan, DENMARK

- Frank Van Der Steen, Validation Manager, Synco Bio Partners B.V., NETHERLANDS

Who Should Attend

C&Q crosses over most pharma manufacturing professionals but will be especially important for Commissioning and Qualification (Validation) professionals as well as design GAMP practitioners, engineers, project managers, construction managers, and quality managers who need to understand and follow GEPs in order to design and deliver projects utilizing risk-based approaches

Communities of Practice (COP)

Sponsoring COP: C&Q which is a cross-functional COP in that it applies to many subject matter areas that other ISPE COPs represent. As a result, consult the agenda to see which case study subject matter areas will be addressed in this seminar.

Related COPs: GAMP and Project Management

Related Technical Documents, Articles, and Publications

- *ISPE Baseline® Guide: Volume 5 – Commissioning and Qualification*
- *ICH Q9* • *EU GMP Guide, Annex 15* • *ASTM E2500-07*

Critical Utilities: Best Practices in Managing Risk and Cost (E04)

7 - 8 June
1.2 CEUs

Seminar Content Level



How can you best maintain and upgrade existing systems and optimize water, steam, and process gas systems in the midst of changing risk environments, risk expectations, documentation requirements, and cost reduction challenges? The challenge is universal whether it is for existing or new critical utility systems. Water and steam are very expensive and important critical utilities necessary to all manufacturers. Attend this seminar to hear best practices from the proposed revision of the *ISPE Baseline® Guide: Water and Steam Systems*, and review real time case studies. Solicited from ISPE Members and peer-reviewed, the case studies offer attendees the best solutions from the field. For information on submitting case studies to be considered for presentation, visit www.ISPE.org/COP and download the Call for Proposals in the Critical Utility COP section.

Leaders

- Andrew Collentro, Technical Director, Water Consulting Specialists, Inc., USA
- Brian Severson, Senior Principal Engineer, Baxter Healthcare Corp., USA

How You Will Benefit

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

- Identify strategies on how to reduce company expenses for critical utilities especially process water, steam, and gases

- Apply risk-based design experience from others through case studies
- Apply FDA 21st Century Initiatives (QbD, PAT, Risk-based approaches, Sustainability)
- Compare different design configurations, operational, and sanitization methods

Program Committee

- Nissan Cohen, Industry Sales Manager, IN USA, USA
- George Gsell, President, MECO, USA
- Joseph Manfredi, President, GMP Systems Inc., USA
- Cameron Sipe, Principal Project Engineer, Pfizer, USA
- Brian White, Business Development Manager, CDI-Life Sciences, USA
- Gary Zoccolante, Pharma Tech Director, Siemens Water Technologies Corp., USA

Who Should Attend

Facilities and maintenance engineers, project managers and project/process engineers, systems designers and design engineers, and facilities management

Communities of Practice (COPs)

Sponsoring COP: Critical Utilities

Related COPs: C&Q, Product Process Development, Project Management, and Sustainable Facilities

Related Technical Documents, Articles, and Publications

ISPE Baseline® Guide: Volume 4 – Water and Steam Systems

Science and Risk-Based Validation: Practical Approaches Across Projects by Breaking Down Implementation Silos (E05)

9-10 June
1.2 CEUs

Seminar Content Level



Science and risk-based approaches to qualification and validation, introduced with ICH Q9, have been with us for several years now. The promise of more flexible facilities and processes entices, but how do you apply these concepts successfully on your project? This seminar will examine the latest developments and practical examples of application of science and risk-based approaches in the qualification of a new greenfield aseptic fill and packaging site, as well as in cleaning, sterility, pharmaceutical water systems, and clean-room HVAC applications. Hear from the FDA how science and risk-based approaches are incorporated in the new FDA Guidance on Process Validation. Ask questions, participate in interactive workshops, learn and bank the experiences of our presenters and your colleagues to streamline and customize your projects and your company challenges.

Leader

- Mark Hannon, Senior Compliance Specialist, Genentech, USA
- Nicholas Haycocks, Principal Engineer, Amgen, USA

Program Committee

- Robert Chew, PE, President, Commissioning Agents, Inc., USA
- Michael Denault, Principal, Denault Associates, USA
- Armen Nahabedian, Director, Commissioning/Qualification, Pfizer, USA

- Frank van der Steen, Validation Manager, Synco Bio Partners B.V., NETHERLANDS
- Mujtaba Ali, C&Q Consultant, USA

How You Will Benefit

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

- Apply effective science- and risk-based validation approaches across applications
- Understand the implications of the new FDA Guidance at your company
- Analyze how separate entities at your company could work together to streamline your company's validation challenges
- Interpret protocols to understand the outcome needed

Who Should Attend

Validation professionals, development engineers, process engineers, QA and QC professionals, automation engineers, and project managers

Community of Practice (COP)

Sponsoring COPs: C&Q, HVAC, OSD, and Sterile Products Processing

Related COPs: Biotech, Critical Utilities, Investigational Products, and Product Process Development

Related Technical Documents, Articles, and Publications

- Webinars on Process Validation found at www.ISPE.org/OnlineLearning
- See articles in the November/December 2009 issue of *Pharmaceutical Engineering*
- *ASTM E2500*

FDA-ISPE Collaboration: Pharmaceutical Quality Systems (E06)

9-10 June
1.2 CEUs

Seminar Content Level



As part of FDA's Pharmaceutical cGMP for the 21st Century Initiative, the Agency, along with industry leaders and regulatory agencies from other countries, have identified key components of a modern pharmaceutical quality system in ICH Q10. This two-day seminar will provide a special forum for the exchange of information between the FDA and the pharmaceutical industry and will focus on pharmaceutical quality systems and the implementation of elements that enhance its effectiveness. This is a special opportunity for interaction of FDA and industry to discuss the practical application of ICH Q10. Topics will include Technology Transfer, CAPA, Knowledge Management, Batch Release, PAT, and Practical Scale-Up Considerations. We will also discuss process performance and product quality monitoring as an additional direction that PQLI is addressing. Co-sponsored by the FDA, these highly-interactive sessions

will provide a forum for an exchange of ideas, and an interface between regulators and industry. Above the standard Q&A sessions, there will be a "Town Hall Forum" for you to pose your questions to the regulators and receive their candid assessment of your concerns. This session will include content of global interest.

Leaders

- Joseph Famulare, Senior Director, Quality and Compliance, Genentech Inc., USA
- Grace McNally, Consumer Safety Officer, FDA, USA

How You Will Benefit

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

- Explain key components of a modern pharmaceutical quality system
- Examine the significance of ICH Q10 guidance and its impact regionally and globally
- Illustrate how modern pharmaceutical quality systems enhance

an understanding of drug products and drug manufacturing processes, and facilitate continual improvement of products and processes

- Describe how concepts associated with modern pharmaceutical quality systems are giving direction to regulatory initiatives
- Understand end-to-end lifecycle management of a product through implementation of the process performance and product quality enabler Q10 using the “Product Stewart” model

Program Committee

- Paul Balcer, Special Assistant to Division Director/COTR, CDER/Office of Compliance, Division of Manufacturing and Product Quality, FDA, USA
- Paul D’Eramo, Executive Director, Johnson & Johnson, USA
- Rick Friedman, Director, Division of Manufacturing and Product Quality, FDA, USA
- Tara Goen, LT, PHS, Compliance Officer, FDA/CDER/DMPQ, USA

- Grace McNally, Consumer Safety Officer, FDA, USA
- George Millili, PhD, Senior Director, Pharma Commercialization Tech, Merck & Company Inc., USA
- Diane Raccasi, DHHS, FDA, CDER/OC/DMPQ, USA

Who Should Attend

Quality and compliance professionals, supply chain, regulatory affairs professionals, pharma manufacturing professionals engaged in risk management activities, PAT, formulators of drug delivery systems, CMOs, and tech transfer professionals

Communities of Practice (COP)

Examples for industry will probably be from these sectors: API, Critical Utilities, OSD, PAT, and Product Process Development

GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems - NA Guide Launch (E07)

9-10 June
1.2 CEUs

Seminar Content Level



Business process, technical support, and quality are a partnership. This seminar is about cooperation and frustration-prevention requiring that these three groups work together to achieve the best explanation of what is needed so that a technical support organization can support these goals most effectively. It is about effective communication among the parties:

- Technical support can benefit by understanding expectations better, how to listen effectively to what is needed – the first time.
- Business can benefit by understanding how to describe what they need, and what regulations they are trying to satisfy, so that technical support understands the outcome needs – the first time.
- Quality can benefit by learning how to ensure that this process happens to the overall benefit of the company and thus Quality can better deliver compliance.

You can apply this to your particular organization structure, no matter the title of the responsible group. It would be ideal if companies could send teams representing each part of this process partnership. FDA invited.

In content terms, this seminar will address the longest phase of the System Life Cycle – the operation phase – which requires the implementation, management, and monitoring of a number of interrelated processes to demonstrate that computerized systems remain in a state of control and in compliance with company policies and regulatory requirements. We will take the “O” or

Operations appendices from GAMP® 5 and explain them in detail, indicating where they are scalable to the criticality of the system to which they are applied. Further, we will exemplify how text, RACI (responsibility, accountability, consulting, informed) tables, and flow charts all are tied together. The roles in RACI are tied to the roles in GAMP® 5, and pivotally there are charts that indicate how one process can trigger others.

From handover at the end of the project phase, to system retirement / data migration at the end of a system’s useful life, these management processes and the evidential records they generate must be complete and subsequently used to indicate the level of care and identify any issues or trends in the performance of the systems. Depending upon the system’s criticality the processes can be scaled to an appropriate level – the risk-based approach – and a determination made of which processes are necessary for which systems.

Typically, processes to be considered are: Handover, Support Services and SLAs, Performance Monitoring, Incident Management and CAPA, Change and Configuration Management (including Repair), Periodic Review, Business Continuity (including Disaster Recovery and Back Up & Restore), and Systems Administration, and data migration and system requirement.

Leaders

- Kate Samways, Consultant, KAS Associates, UNITED KINGDOM
- Winnie Cappucci, PS Compliance IT Sys NA, Bayer Healthcare, USA

How You Will Benefit

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

- Analyze their company's processes and relationships to the benefit of effective and efficient technical support of business processes
- Identify areas of their company's processes that need improvement by benchmarking against others
- Apply good practices as defined in the guidance -- within your own company's culture

Speakers to Date

- Randy Perez, PhD, Executive Expert, QA, Novartis Pharmaceuticals Corporation, USA
- Christopher Reid, Director, Integrity Solutions, UNITED KINGDOM
- Michael Rutherford, Quality Consultant - Lab Informatics, Global Quality Labs, Eli Lilly & Co., USA
- Yves Samson, Senior Consultant/Director, Kereon AG, SWITZERLAND
- Dr. Robert Stephenson, Regulatory Systems Team Leader PGMIT Pfizer Global Mfg., UNITED KINGDOM
- Robert Tollefsen, Consumer Safety Officer, FDA, USA invited
- Charlie Wakeham, Project Manager, Pall Europe Ltd., UNITED KINGDOM
- Sion Wyn, Director, Conformity Ltd., UNITED KINGDOM
- David Selby, Managing Director, Selby Hope Intl., Ltd., UNITED KINGDOM

Who Should Attend

Engineers (or Engineering Compliance Auditors), compliance auditors, automation and IT professionals who need to understand the philosophy behind the "Why do they care about this?" Quality, validation, and general compliance professionals. This is helpful to very large, as well as smaller companies, consultants, and third party support organizations (stop driving your IT people crazy and understand why they are asking for what they ask for).

Community of Practice (COP)

Sponsoring COP: GAMP

Related COPs: GAMP relates to most ISPE Communities of Practice

Related Technical Documents, Articles, and Publications

GAMP® 5: A Risk-Based Approach to Compliance GxP Computerized Systems

Sustainability: Best Practice Case Studies and Legislation Impact (E08)

9-10 June
1.2 CEUs

Seminar Content Level



Learn from industry colleagues who have implemented innovative measures to achieve fiscal, energy, and environmental benefits. This two-day seminar will feature best practice case studies solicited from the industry that addresses the question, "How has your company approached sustainability and what innovative solutions have you implemented?" Case studies will be selected for presentation by the ISPE Sustainable Facilities Community of Practice Steering Committee to assure the best peer-to-peer learning opportunities. This will be a prime opportunity to discover the sustainable solutions your colleagues have executed and to discover potential applications for your company.

This seminar will also address the H.R.2454 - American Clean Energy and Security Act of 2009, known as the Waxman-Markley comprehensive energy bill, or ACES, that includes a cap-and-trade global warming reduction plan designed to reduce economy-wide greenhouse gas emissions 17 percent by 2020. Other provisions will include new renewable requirements for utilities, studies, and incentives regarding new carbon capture and sequestration technologies, energy efficiency incentives for industrial buildings, and grants for green jobs.

Leaders

- David Mellon, Associate - Science & Technology Sector, Arup, UNITED KINGDOM
- Gregory Butler, Director, Global Supply Chain Stewardship, BD, USA

How You Will Benefit

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

- Apply proven energy efficiency measures at your company
- Identify potential sustainable measures for implementation at your facility that may provide fiscal, energy, and environmental benefits
- Understand implications of the American Clean Energy and Security Act of 2009
- Understand how the pharma industry is fulfilling its obligations to global climate change legislation
- Appraise what is actually in the GMPs vs. what we have all assumed

Speakers to Date

- Gregory Butler, Director, Global Supply Chain Stewardship, BD, USA
- Mathew Edwards, Mechanical Engineer, CRB Consulting Engineers Inc, USA
- Michael Elliott, Instrument Plant Lean Leader/Operations, BD Diagnostics - Diagnostic Systems
- Axel Erhard, Principal, A T Kearney, Inc., USA
- Norman Goldschmidt, Principal, VP Engineering, Genesis Engineers Inc, USA
- Anthony Haskell, Project Manager, Shire HGT, USA
- Jeff Holmes, Principal Engineer, Genzyme Corporation, USA
- Farley Hunter, Novartis, USA
- Mac Kendall, Engineer, Biogen Idec, USA
- Nigel Lenegan, Managing Director, Energy & Carbon Reduction Solutions Ltd., UNITED KINGDOM
- James McGlade, Project Manager, O'Brien & Gere, USA
- David Rielly, Global Energy Manager, Novartis Institutes for BioMedical Research, USA
- Ronald Slember, CFM, CEM, Pfizer, USA
- Walt Tunnessen, Industrial Sector, Manager, U.S. Environmental Protection Agency, USA
- Michael Wise, IS Director, Smith & Nephew Inc, USA

Who Should Attend

Owner company's CFOs, engineering directors, engineers from owner companies and supply chain, sustainability officers, architects, facility managers, CMOs pushing sustainability to their partners in corporate responsibilities (and expressing this to their investors), and energy and project managers

Communities of Practice (COPs)

Sponsoring COP: Sustainable Facilities
Related COPs: Critical Utilities, Engineering Standards, Benchmarking, and HVAC

Related Technical Documents, Articles, and Publications

H.R.2454 - American Clean Energy and Security Act of 2009
<http://www.opencongress.org/bill/111-h2454/show>
Energy Star Program www.energystar.gov

Trends in Biologics Manufacturing (with MedImmune Tour of Therapeutic Protein Facility) (E09)

9-10 June
1.2 CEUs

Seminar Content Level



Just added to the lineup of seminars offered at the Washington Conference, this two-day seminar provides a leading edge look at the latest trends in the manufacture of recombinant proteins and pandemic vaccines, and will include a tour of a commercial monoclonal antibody production facility. The registration fee includes a half day tour of Medimmune's MAb manufacturing facility in Frederick, MD.

In the past ten years the number of recombinant bio-pharmaceutical products has more than doubled to over a hundred. During this time the titer of cell culture products has increased by nearly two orders of magnitude. As a result, the rate-limiting step in manufacture has changed from bioreactors to purification. Improvements in purification operations will be the focus of the recombinant proteins portion of this session.

In 2009 the pandemic preparedness of our society was put to test by the H1N1 Flu. Case studies will be presented by several vaccine manufacturers who responded to this pandemic need. This required a revamp of their manufacturing facilities, operations, and supply chain. The manufacturing and supply

chain response, whereas a success story overall, was not without challenges. Lessons learned from this experience will highlight what worked well, what did not, and what they may do differently the next time.

This timely and in-depth look at the most pertinent issues associated with production of biologics will provide valuable insights to those involved in the manufacture, release, and supply of therapeutic proteins and vaccines.

Leaders

- Deepak Agarwal, Director, Pharma Technology, Jacobs Consultancy, USA
- James Bouressa, Director, BRD Manufacturing, Pfizer, USA

Community of Practice (COP)

Sponsoring COP: Biotech

Seminar Content Level



This seminar will launch the new GAMP® Good Practice Guide: *Manufacturing Execution Systems, A Strategic and Program Management Approach*, which features how to develop and implement an integrated systems program based on a technology-independent structure and methodology. Attend this one-day seminar to learn how a company can apply a functional strategy to specify, verify, and manage all relevant system/application capabilities through the ISA hierarchy instead of a single-application approach. See how a company can assess the current state and define the manufacturing-related systems domain using existing and/or new systems/applications to contribute to lean design and a higher assurance of compliance. A panel discussion among speakers and attendees will allow for an interactive exchange of ideas. This is a Good Practice Guide launch; registrants will receive a copy of this guide.

Attendees will see practical industry examples that help decrease risk, and have the potential to save money by optimizing current resources and system functionality. This one-day seminar will walk through a methodology to assess what you have and what you want to accomplish -- before investing in expanded or new technical capabilities.

Leaders

- Paul Irving, Director, Aptitude UK Ltd., UNITED KINGDOM
- Gregory Ruklic, Pfizer Global Engineering, Pfizer, USA

How You Will Benefit

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

- Understand how to produce and document a computer integrated manufacturing strategy that will ensure that the user organization has an efficient, compliant, environment that will establish a steady state in the company
- Plan an effective program ensuring that effective MES support governance is in place including risk and configuration management
- Describe EPR (Electronic Production Records such as Electronic Batch Record and Electronic Device History Record), Review By Exception (RBE), and Electronic Work Instructions
- Establish a functional design path from the existing state to future derived state to drive technical development

Who Should Attend

Program and project managers, senior stakeholders responsible for strategy, engineers, IT, operations and quality personnel involved with specifying or verifying systems functionality affecting manufacturing, or linking the enterprise and laboratory systems to the shop floor

Communities of Practice (COPs)

Sponsoring COP: GAMP®

Related COPs: Critical Utilities, Engineering Standards, Benchmarking, and HVAC

Related Technical Documents, Articles, and Publications

- *GAMP® 5: A Risk-Based Approach to Compliant GxP Computerized Systems (Fifth Edition, February 2008), Appendix S2*
- MES article PE May/June 2008, deSpautz and Ruklic

Practical Answers to Common HVAC Questions – An Introduction to the HVAC Good Practice Guide (F01)

8 June
17:15 - 18:30
Free

Become familiar with the NEW ISPE Good Practice Guide: *Heating, Ventilation, and Air Conditioning*, and how to apply the Guide's best practices. The Guide contains all the basics to help non-engineers understand the scientific principles and industry accepted practices for HVAC in pharmaceutical, biotech, and medical device industries, as well as detailed discussions of advanced topics in HVAC for the seasoned professional.

The session will feature an interactive panel. Bring your HVAC questions and your most intractable HVAC problems to discuss with a panel of senior HVAC engineers with decades of experience in design, construction, commissioning, and qualification of HVAC systems.

Presenters

- Norman Goldschmidt, Principal, VP Engineering, Genesis Engineers Inc., USA
- Nicholas Haycocks, Principal Engineer, Amgen, USA
- Other Authors of the HVAC GPG

How You Will Benefit

At the conclusion of this session, participants will have an appreciation of the Guide content with a special focus on misunderstood and often overlooked issues, as well as the ability to get an expert opinion on issues they have.

Guide content includes:

- HVAC basics – demystifying HVAC, a comprehensive introduction to HVAC: its language, its principles, and its practices

- Key principles of good HVAC design – design process, principles, and debunking of common misconceptions
- Common HVAC applications by facility type
- Cleanroom theory – critical factors in cleanroom design, such as filter mechanics, dilution versus displacement, airflow versus air change (ventilation) rates, and how they relate to product protection
- Cross-contamination control – common potent compound handling evaluation techniques and equipment and how they relate to cross-product contamination
- Energy savings and sustainable design – discuss methods for conserving energy and the associated risks and rewards
- Going beyond appearance, strengths and mistakes – discuss and provide examples of common issues in equipment selection, materials of construction, and installation

- Risk assessment – cutting through the traditional red tape to focus documentation on bringing the greatest benefits to patient and public

Who Should Attend

Pharmaceutical manufacturing professionals from these disciplines: biopharmaceuticals, biotechnology, generics, engineering/architecture, consulting, validation, commissioning and qualification, construction services, facilities and equipment maintenance, contracted professionals, suppliers, public authorities/government, health/safety environment, maintenance, operations/manufacturing, process control/automation, project management, quality assurance/control, and technical services/product support.

Process Validation in Biotechnology Manufacturing (T32) Training Course

7 - 8 June
1.5 CEUs

Course Content Level



Validation for the biotechnology industry is substantially different from that of traditional pharmaceutical manufacturing, because of the complexity and inherent uncertainty of using living organisms as production systems to manufacture complex, biologically active proteins. Uncontrolled and untested changes in the manufacturing process, including both known and unknown raw materials, can impact the activity and antigenicity of the protein by inducing subtle changes in its structure or conformation. Therefore, controlling the manufacturing process using well-defined operating parameters and raw materials is critical to assuring the safety, potency and consistency of the product. Process validation provides a critical mechanism for understanding and controlling these vital manufacturing parameters.

This course provides an overview of the validation effort as applied to clinical and commercial biotechnology manufacturing. Topics include the general approach to validation, a review of important biotechnology manufacturing processes, and the strategies and requirements for their validation. Specific topics include validation of buffer/media preparation systems, upstream processes such as fermentation and cell culture, and downstream processes such as centrifugation, filtration, and chromatography. Other topics include: master plan development and execution, cleaning validation, analytical methods requirements, protocol writing and execution, and handling of deviations.

In addition to the classroom lecture, participants will take part in several interactive exercises and discussions that allow application of learned content to a typical biotechnology manufacturing process. Participants should have a basic understanding of commissioning, qualification and validation, and also at least a basic familiarity with biotechnology manufacturing processes and unit operations.

Important Course Notes

This course includes a pre-recorded web-based session that provides a review of the basics prior to the classroom course.

Take Back to Your Job How To...

- Define key validation activities for biotechnology pharmaceutical manufacturing
- Develop and execute validation master plans and validation protocols
- Discuss validation documentation requirements
- Apply strategies and fundamental components of cleaning validation, media and buffer preparation validation, and process validation for upstream and downstream clinical and commercial manufacturing processes
- Understand requirements for analytical methods used for validation
- Describe how deviations are handled

Who Should Attend

Process development engineers, validation personnel, manufacturing supervisors and managers, quality assurance specialists, and management personnel. Other professionals with commissioning, qualification, and validation experience who need a fundamental understanding of process validation for biotechnology manufacturing.

Instructor

Mark Witcher, PhD, Consultant, Pro Re Nata, Inc.

Communities of Practice (COP)

This training course is of particular interest to existing and future members of the ISPE Biotechnology and Process/Product Development Communities of Practice.

Course Content Level



As cleaning technology and detection methodology advance, so do the challenges associated with establishing, managing, and maintaining a scientifically sound cleaning validation program. FDA's risk-based regulatory initiatives focus new attention on the risks of cross-contamination. The solution is to understand life cycle management techniques for an effective cleaning validation program.

This course will cover elements of a cleaning validation program from start to finish, exploring such concepts as the determination of residues to be targeted, selection of analytical and sampling methods, determination of appropriate limits in various pharmaceutical and biotechnology processes, and establishment of scientific rationales acceptable to regulatory inspectors. For mature cleaning validation programs, concepts such as understanding process control, capability, learning to effectively self-audit a cleaning validation program, and documentation will be essential takeaways.

Take Back to Your Job How To...

- Identify and characterize potential residues including product, processing aids, cleaning agents, and adventitious agents
- Apply appropriate analytical methodology for selected residues
- Determine suitable sampling techniques and the selection of sampling locations that present a challenge for the cleaning process
- Calculate residue limits that meet all necessary regulatory requirements
- Create scientifically sound rationales, validation protocols, and reports
- Manage the challenges of multi-product facilities in the establishment of limits, determination of validation strategies, and maintaining the validated state
- Understand campaign-based production strategies for effective and scientifically sound validation
- Differentiate the requirements for cleaning validation when using manual, semi-automatic, and automatic cleaning technologies
- Determine scientific grouping or bracketing approaches
- Comprehend the pitfalls inherent in cleaning after the production of biopharmaceutical and pharmaceutical products
- Accomplish analytical method validation and recovery study requirements in cost-effective studies that provide the necessary assurance of an analytical system
- Evaluate cleaning practices, limit calculations, scientific rationales, and validation documents through internal self-audits to ensure compliance with ever-changing regulatory needs
- Practice hands-on exercises designed to reinforce core competencies and job-focused skills

Who Should Attend

- Professionals responsible for all aspects of cleaning validation programs, including development, deployment, and maintenance
- Quality assurance specialists, quality control technicians, regulatory affairs professionals, pharmacologists and toxicologists, validation scientists, and validation service personnel
- Manufacturing supervisors, technical support personnel, and engineers responsible for evaluating cleaning systems, reviewing equipment, and supporting the cleaning validation program on the plant floor
- All levels of management who need to understand the science of cleaning and cleaning validation including the aspects of residue selection, sampling method and analytical detection method validation, limits determination, and strategies for managing multi-product facilities

Instructor

Rebecca Brewer, Director, Validation & GMP Compliance, Dober Group

Communities of Practice (COP)

This training course is of particular interest to existing and future members of the ISPE Biotechnology and Process/Product Development Communities of Practice.

Knowledge Competency Elements

This course contains knowledge related to the CPIP™ technical knowledge competency element Production Systems. For complete information concerning the knowledge elements or the CPIP Credential, please visit www.ISPE-PCC.org.

ISPE 2010 Washington Conference

JW Marriott, Washington, D.C. • 7-10 June 2010

Registration Form

Please type or print clearly.

ISPE ID # _____

ONLINE: www.ISPE.org/2010WashingtonConference

FAX: +1-813-264-2816

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



Check here if you were previously an ISPE Member.

First Name _____ MI _____ Last Name _____

Informal Badge Name _____ Chapter/Affiliate _____

Job Title _____ Email Address _____

Company _____

Business Address _____

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

Business Tel _____ Business Fax _____

Emergency Phone For Last Minute Meeting Updates:

Cell Phone _____ or Home Phone _____

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 Directory or on Conference Attendee Listings.

First Time Attendee New Member New Member/First Time Attendee Orientation

HOTEL: Hotel accommodations and hotel fees are separate from Conference registration fees. For room reservations at the Conference venue, JW Marriott, call tel: 1-800-266-9432 or +1-506-474-2009 or visit <https://resweb.passkey.com/go/ispe2010washdc>. When making your reservation by phone, mention ISPE for a discounted rate of \$299 single/double. This rate is good until 7 May 2010, or until the room block is full, whichever comes first. Please contact the hotel as early as possible to make your reservations to ensure you are in the headquarters hotel.

SPECIAL LUNCH REQUIREMENT — Vegetarian Kosher Gluten Free

PAYMENT METHOD — REGISTRATIONS REQUIRE PAYMENT ATTACHED

Substituting for _____

(NONMEMBERS SUBSTITUTING FOR A MEMBER MUST PAY THE DIFFERENCE IN FEES)

Check enclosed payable to ISPE # _____ in the amount of \$ _____

(MUST BE DRAWN ON A US BANK)

Bill credit card (circle type): VISA MC AMEX Card number _____

Exp. date _____ Name of cardholder _____ (AS IT APPEARS ON CARD)

Cardholder signature _____

Registration is confirmed only when payment is received. Please send registration form 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 FEIN #59-2009272 • www.ISPE.org
Conference Cancellations - Cancellations must be made in writing. If cancellations are received by 17 May 2010, a full refund, minus a 10% handling fee (maximum of \$100), will be issued. After that time, no refunds will be granted.

If you are unable to attend, substitutions will be accepted. However, nonmembers substituting for a Member must pay difference in fees prior to the start of the event. ISPE is not responsible for lost airfare due to cancellations.

Pick Your Seminar(s)		Seminar Fees					Training Courses and Fees*		Total
** Early bird (lower fee) on or before 10 May; higher fee after 10 May		First Two-day Seminar Fee**	Second Two-day Seminar Fee**	One-Day Seminar** D01 GAMP GPG: MES 8 June	F01 GPG HVAC 8 June Free	T32 Process Validation in Biotechnology Manufacturing 7-8 June**	T17 Cleaning Validation Principles 7-8 June**		
7-8 June	<input type="checkbox"/> E01 Barrier Isolation Technology Forum	Member	<input type="checkbox"/> \$1,075 <input type="checkbox"/> \$1,375	<input type="checkbox"/> \$860 <input type="checkbox"/> \$1,100	<input type="checkbox"/> \$540 <input type="checkbox"/> \$690	<input type="checkbox"/> \$0	<input type="checkbox"/> \$1,510 <input type="checkbox"/> \$1,810	<input type="checkbox"/> \$1,410 <input type="checkbox"/> \$1,710	\$
	<input type="checkbox"/> E02 A-Mab: Case Study and PQLI [®] Next Steps	New Member	<input type="checkbox"/> \$1,290 <input type="checkbox"/> \$1,590	<input type="checkbox"/> \$1,030 <input type="checkbox"/> \$1,270	<input type="checkbox"/> \$755 <input type="checkbox"/> \$905	<input type="checkbox"/> \$0	<input type="checkbox"/> \$1,725 <input type="checkbox"/> \$2,025	<input type="checkbox"/> \$1,625 <input type="checkbox"/> \$1,925	\$
	<input type="checkbox"/> E03 Science and Risk-Based C&Q	<input type="checkbox"/> I elect ISPE membership. New Member fee includes a one-year membership, a \$215 value.							
	<input type="checkbox"/> E04 Critical Utilities	Nonmember	<input type="checkbox"/> \$1,355 <input type="checkbox"/> \$1,670	<input type="checkbox"/> \$1,080 <input type="checkbox"/> \$1,335	<input type="checkbox"/> \$795 <input type="checkbox"/> \$950	<input type="checkbox"/> \$0	<input type="checkbox"/> \$1,810 <input type="checkbox"/> \$2,125	<input type="checkbox"/> \$1,705 <input type="checkbox"/> \$2,020	\$
9-10 June	<input type="checkbox"/> E05 Science and Risk-Based Validation	Student Member	<input type="checkbox"/> \$150 <input type="checkbox"/> \$150	<input type="checkbox"/> \$150 <input type="checkbox"/> \$150	<input type="checkbox"/> \$150 <input type="checkbox"/> \$150	<input type="checkbox"/> \$0	<input type="checkbox"/> \$755 <input type="checkbox"/> \$905	<input type="checkbox"/> \$705 <input type="checkbox"/> \$855	\$
	<input type="checkbox"/> E06 FDA-ISPE Collaboration	Government	<input type="checkbox"/> \$690 <input type="checkbox"/> \$690	<input type="checkbox"/> \$690 <input type="checkbox"/> \$690	<input type="checkbox"/> \$345 <input type="checkbox"/> \$345	<input type="checkbox"/> \$0	<input type="checkbox"/> \$755 <input type="checkbox"/> \$755	<input type="checkbox"/> \$705 <input type="checkbox"/> \$705	\$
	<input type="checkbox"/> E07 GAMP [®] GPG: GxP Systems	Committee	<input type="checkbox"/> \$540 <input type="checkbox"/> \$540	<input type="checkbox"/> \$540 <input type="checkbox"/> \$540	<input type="checkbox"/> \$270 <input type="checkbox"/> \$270	<input type="checkbox"/> \$0	<input type="checkbox"/> \$1,510 <input type="checkbox"/> \$1,810	<input type="checkbox"/> \$1,410 <input type="checkbox"/> \$1,710	\$
	<input type="checkbox"/> E08 Sustainability	Academia/ Emerging Economy	<input type="checkbox"/> \$540 <input type="checkbox"/> \$690	<input type="checkbox"/> \$540 <input type="checkbox"/> \$690	<input type="checkbox"/> \$270 <input type="checkbox"/> \$345	<input type="checkbox"/> \$0	<input type="checkbox"/> \$755 <input type="checkbox"/> \$905	<input type="checkbox"/> \$705 <input type="checkbox"/> \$855	\$
	<input type="checkbox"/> E09 Vaccines						* Second Two-day Seminar Fee discounts do not apply to Training Courses.		

WASHCONF10-Broch1

General Information

How to Register

Online: Visit www.ISPE.org/2010WashingtonConference

Via Fax: Complete the registration form 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., Suite 250, Tampa, Florida 33607 USA

Questions? Call ISPE at tel: +1-813-960-2105, or email: ask@ispe.org

Written confirmation will be sent to you after your registration is processed (time permitting). In order to be listed in the official delegate roster, you must be registered and paid by 24 May.

Conference Fees Include

Exhibit Hall access, continental breakfasts, refreshment breaks, lunches, and networking receptions. Hotel accommodations and hotel fees are separate from conference registration fees.

For room reservations at the Conference venue, JW Marriott, Washington, D.C., call tel: +1-800-266-9432 or +1-506-474-2009 or visit <https://resweb.passkey.com/go/ispe2010washdc>. When making your reservation by phone, mention ISPE for a discounted rate of \$299 single/double (total with tax \$342.34). This rate is good until 7 May or until the room block is full, whichever comes first. Please contact the hotel as early as possible to make your reservations to ensure you are in the headquarters hotel. We thank you for staying at the Marriott as this enables ISPE to meet contract requirements.

Conference Schedule

The registration desk will be open: Sunday 15.00 - 17.00; Monday - Wednesday 07.30 - 17.30; and Thursday 07.30 - 16.00. Seminars are scheduled to begin at 09.00 and conclude at 17.00 from Monday to Wednesday. Thursday seminars begin at 08.00 and conclude at 16.00. Morning and afternoon breaks are scheduled daily. F01 on Tuesday will begin at 17:15 and conclude at 18:30. Lunch will be served each day. A la carte lunch tickets may be purchased separately onsite.

Conference Cancellations

Cancellations must be made in writing. If cancellations are received by 17 May, a full refund, minus a 10% handling fee (maximum of \$100), will be issued. After that time, no refunds will be granted. If you are unable to attend, substitutions will be accepted. However, nonmembers substituting for a Member must pay difference in fees prior to the start of the event. ISPE is not responsible for lost airfare due to cancellations.

Accreditation

ISPE provides continuing education units (ISPE CEUs). ISPE CEUs are nationally recognized units of attendance that identify those individuals continuing their education in their chosen field or profession.

Special Requirements

If you require special accommodations to participate, such as a wheelchair-accessible room or a sign language interpreter, please attach a written description of your needs to your registration form. If you have questions, please contact ISPE at tel: +1-813-960-2105 or email: ask@ispe.org. Please mark vegetarian, gluten free, or kosher, if needed, in the Special Meal Requirement box on the registration form.

ISPE Bookstore

Visit the ISPE Bookstore at Washington Conference to stock up on the latest technical publications from ISPE. Members receive a 20 percent discount onsite.

Notice

ISPE leaders and speakers are leading professionals in their fields. However, in those rare circumstances where we find it necessary to make substitutions, every possible effort is made to provide speakers with comparable qualifications. Agendas are subject to change without notice. Every precaution is taken to ensure accuracy, but ISPE cannot accept responsibility for the accuracy of information distributed or contained in these seminars or for any opinion expressed. Delegates' names and addresses may be given as part of a list to other organizations for purposes related to the field of pharmaceutical manufacturing. If you do not wish to receive other related information, please notify ISPE.

Know Before You Go - Access to Handouts

Visit www.ISPE.org/2010WashingtonConference prior to attending the Conference for all you need to "Know Before You Go." You will receive an email one week prior to the event with updated details, a delegate roster, access to handouts, and more.

Exhibit and Sponsorship Opportunities

The Table Top Exhibition is a popular marketing and business development tool that guarantees excellent exposure for your company. Don't miss out on this opportunity to meet face-to-face with key decision makers in the pharmaceutical and biotechnology manufacturing industries.

Exhibit set up will be on Monday, 7 June from 12.00 - 16.00. The exhibits will open on Monday, 7 June from 17.00 - 18.30 with the Opening Reception. Continental breakfast and refreshment breaks will be held in the Exhibit Hall on Tuesday and Wednesday.

The fee to exhibit is \$2,300 and includes two exhibitor badges per exhibit table. The table top exhibition is limited to 65 companies.

Exhibit cancellations made in writing prior to 19 April will result in a \$1,000 cancellation fee. There are no refunds for exhibit cancellations made after 19 April.

Contact John Phillips at jphillips@ISPE.org, or Valerie Adams at vadams@ISPE.org (813) 739-2274.

Sponsorships

ISPE Conference Sponsorships offer your company unique opportunities to build and reinforce name recognition, create top-of-mind brand awareness, and develop new business. These sponsorships provide an opportunity for you to connect with a targeted, unique, and global audience, promote the latest technical advancements, and demonstrate your company's commitment to the education of pharmaceutical and biotechnology manufacturing industry professionals. Host, Platinum, Gold, Silver, and Bronze Top Tier Sponsorships are available as well as cyber café, lanyards, and hotel keycards. Onsite advertising opportunities are also available. Contact John Phillips at jphillips@ISPE.org, or Valerie Adams at vadams@ISPE.org for details.



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New ISPE Publications Featured at Washington:

- *ISPE Baseline® Guide: Science and Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment*
- *GAMP® Good Practice Guide: A Risk-Based Approach to Operation of GxP Computerized Systems - NA Launch*
- *GAMP® Good Practice Guide: Manufacturing Execution Systems - Launch*
- *Answers to Common HVAC Questions: An introduction to the HVAC Good Practice Guide*

ISPE Members receive a 20% discount on all ISPE technical documents onsite (excludes CPIP™ Study Guide).

ISPE Membership: Knowledge, Community, Profession, and More

Find out what becoming an ISPE Member can do for you. New Member registration fees include a one-year ISPE membership. Visit www.ISPE.org/join to learn more about the many benefits of ISPE Membership.

Sponsorship and Table Top Exhibit Opportunities Available!

For details, see page 15 of this brochure or contact John Phillips at jphillips@ISPE.org, or Valerie Adams at vadams@ISPE.org for more information.