2012 ISPE
ANNUAL MEETING

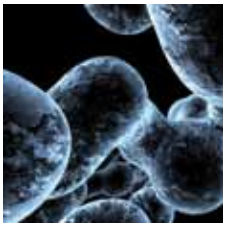
11 – 14 November
San Francisco, California

GLOBAL GMP SOLUTIONS

Through Innovation and Transformation






www.ISPE.org/2012AnnualMeeting

pharmaceutical professionals from around the world and across the product lifecycle gathering to share knowledge and engage in stimulating, meaningful dialog with the regulatory community

table of contents

ISPE **4-5**

program by topic **6-7**

8 plenary

schedule **9-11**

education schedule at-a-glance **12-13**

education program **14-33**

training **34**

networking events **36-40**

onsite services **41**

general info **45**

exhibit hours **42-43**

hotel info **46**

exhibitor information **44**

registration info **47**

connecting a world of

Lead

ISPE strives to be the leading voice for industry issues, technical and regulatory affairs through strategic relationships and collaboration.

Succeed

ISPE continually develops relationships with companies that have the ability to commit resources, for their teams, improve manufacturing efficiencies and enhance quality of life for patients.

Learn

ISPE is committed to bringing together top-level industry and regulatory voices for candid discussions of the pharmaceutical industry's challenges across the entire product lifecycle as well as offering the learned tools Members need to succeed.

pharmaceutical knowledge

Grow

ISPE presents solutions to your company's immediate goals and career-advancing opportunities through collaboration, education and certification.

Connect

ISPE is dedicated to leading the advancement of ideas and sharing expertise to provide you with a forum for career growth and meaningful participation.

Transform

ISPE is working to change the face of the pharmaceutical and biotechnical industry with through dedicated professionals who have expert knowledge and a passion for patient safety.

NEW! Executive Series and International Regulatory Summit

Do not miss these exciting new sessions featuring industry and regulatory leaders in candid discussions about the industry, today's market and what the future looks like.

International Regulatory Summit

Monday, 12 November
13.15 - 14.45

In our global economy, the interaction between industry and regulators is crucial. This summit will bring together high-level regulators from North America, Europe, Asia and Latin America to discuss regional regulatory challenges and examine those challenges within the context of a global regulatory environment.

Executive Series

Monday, 12 November
15.30 - 17.15

Based on the Global Positioning Strategy, developed by the International Leadership Forum (ILF), this series explores areas of critical importance for the future.

Comprehensive education sessions and discussion groups will offer best practices, applications, technology innovation and an opportunity to engage with global regulatory agencies.

executive series

Based on the Global Positioning Strategy, developed by the International Leadership Forum (ILF), this series explores areas of critical importance for the future.

EX1: Next Generation Processes, Equipment and Facilities
EX2: Biotechnology
EX3: Supply Chain Management
EX4: Enterprise Risk Management
EX5: Sustainability
EX6: Organizational Development

emerging markets

Learn how to achieve the most from GMP operations in emerging markets.

104: Manufacturing Facility Design for Global Organizations
204: Practical Experiences of Manufacturing Projects in Emerging Markets
404: Latin America Regulatory Compliance Forum
504: Compliance and Technology in Emerging Markets

facilities and equipment

Improve operations and design with fast-track techniques.

101: Case Studies of a Greenfield Site's Positive FDA-PAI Experience with Maintenance and Reliability
102: The Challenges of Bringing New Products into Existing Facilities
201: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 1)
202: Facility of the Year Awards (FOYA) 2012 Category Winners (Part 1)
209: HVAC and Sustainability Communities of Practice (COPs) Present: Quality Doesn't Have to Cost the Earth (Part 1)
301: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 2)
302: FOYA 2012 Category Winners (Part 2)
304: Biotechnology Manufacturing
309: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 2)
401: Practical Application of C&Q Applied Risk Management
402: Ultraviolet Applications and Dose Calculation for Pharma Water Treatment

quick glance by topic

501: Facility of the Future, Impact of Innovative Technology and Continuous Manufacturing
502: Design and Operation of Water and Steam Systems

clinical/ investigational products

Comprehensive program for professionals engaged in the manufacture and supply of materials for clinical investigation.

7001: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 1)
7002: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 2)
7003: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 3)
7004: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 4)
7005: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 5)

manufacturing operations

Develop and manage issues facing manufacturers today including supplier partnerships, automated systems, operational excellence and single-use technologies.

105: The Challenges Facing Disposable Technology and Their Solutions
107: Back to Basics: Good Documentation to Facilitate Compliance and Electronic Batch Record Implementation
205: GAMP® Part 1 - Information Security in the Global Market
305: GAMP® Part 2 – The Regulatory Focus on Data Integrity
405: Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships
409: Bridging the Compliance and Operational Excellence Gap
505: Improving Manufacturing Through Innovation: Continuous Processing and Process Control

project management

The Project Management Community of Practice (COP) is partnering with five different Communities of Practice to bring you a series of five distinct project case studies, highlighting different types of projects and distinct project phases.

108: Project Initiation and Business Case Development
208: Early Phase Project Planning for Process Development
308: Design Management in the Capital Project Lifecycle
408: Project Implementation of IT Infrastructure Projects
508: Managing Project Closeout, Product Approval, Product Launch

technology

Choose from a variety of subjects, including nanotechnology, sterile products and strategies.

106: Nanotechnology in the Pharmaceutical Industry
206: Innovation in Laboratory Operations
306: Strategies for Raw Material Variability
406: Sterile Products Processing Update
506: A Strategic Approach to Containment Systems: An Integrated Process from Concept to Use
509: Advanced Aseptic Processing

international regulatory

In a global economy, industry must adhere to varying regulatory requirements. Regulators are working to harmonize, but challenges remain and dialog continues.

International Regulatory Summit
103: C&Q Risk Task Team Forum IV
109: Process Analytical Technology: Near Infra-Red (NIRS) Implementation
203: New GMP Regulations and Inspection Programs in Asia Pacific Countries
303: Regulatory and Industry Perspectives of QbD
403: Process Validation: A Lifecycle Approach with Biotech Applications
503: Implementing PQS Elements

plenary

Monday, 12 November 08.30 –12.00

Nancy S. Berg
CEO, ISPE, USA

Nancy Berg will welcome delegates to San Francisco and discuss how ISPE is leading Members and industry in finding solutions to technical and regulatory complexities in today's business environment.

Charlotte Enghave Fruergaard, PhD
2013 ISPE Chair, Director of Technology, NNE Pharmaplan, Denmark

Dr. Enghave Fruergaard will discuss the important role of ISPE Members in driving change and technological innovation. As 2013 Chair of the ISPE International Board of Directors, some of her top priorities include stimulating ISPE's culture to reflect its diverse, global membership and engaging Young Professionals in the Society's programs and initiatives.

Murray Aitken
Executive Director, IMS Institute for Healthcare Informatics, USA

Top Priorities and Trends for the Pharmaceutical Industry

Hear cutting-edge research in the pharmaceutical market and learn how to address those changes and what your company should be focusing on next. IMS will release quantifiable data which will provide a global analysis of the industry and forecast top priorities and trends through 2016. Exclusive information will also be released to Annual Meeting attendees only.

Stephen P. Spielberg, MD, PhD
Deputy Commissioner for Medical Products and Tobacco, FDA, USA

How the FDA is Advancing Regulatory Science Through High Quality Collaboration

When Commissioner Hamburg created the position of Deputy Commissioner for Medical Products and Tobacco, she envisioned that it would "provide high-level coordination and leadership across the Centers for drug, biologics, medical devices, and tobacco products." This executive-level presentation will demonstrate how the FDA is addressing regulatory strategies and international collaboration.

2012
Facility of the Year Awards
Awarded by ISPE, INTERPHEX, Pharmaceutical Processing

Facility of the Year Awards (FOYA)

Learn about the innovative projects from the 2012 Facility of the Year Awards Category Winners. Be among the first to learn which project will be named the 2012 Facility of the Year Awards Overall Winner. The FOYA Program recognizes state-of-the-art pharmaceutical manufacturing projects utilizing new and innovative technologies to reduce the cost of producing high cost medicines.

schedule
by day

Full Conference

Sunday, 11 November

12.30 – 15.00 Young Professionals/Student Luncheon and Orientation

13.00 – 17.00 Optional Tour: San Francisco Highlights

13.00 – 19.00 Exhibit Hall Open

13.30 – 17.00

101: Case Studies of a Greenfield Site's Positive FDA – PAI Experience with Maintenance and Reliability
102: The Challenges of Bringing New Products into Existing Facilities
103: C&Q Risk Task Team Forum IV
104: Manufacturing Facility Design for Global Organizations
105: The Challenges Facing Disposable Technology and Their Solutions
106: Nanotechnology in the Pharmaceutical Industry
107: Back to Basics: Good Documentation to Facilitate Compliance and Electronic Batch Record Implementation
108: Project Initiation and Business Case Development
109: Process Analytical Technology: NIRS Implementation

15.00 – 15.45 Networking Break

16.00 – 17.00 New Member/First-Time Attendee Orientation

17.00 – 19.00 Welcome Reception in Exhibit Hall

Monday, 12 November

06.00 – 07.00 Charity 5K Run/Walk

07.00 – 17.00 Exhibit Hall Open

07.00 – 08.15 Continental Breakfast in Exhibit Hall

07.15 – 08.15 New Member/First-Time Attendee Networking Breakfast

08.30 – 12.00 Plenary Session

10.00 – 14.30 Optional Tour: Magical Marin

10.00 – 11.00 Networking Break in Exhibit Hall

12.00 – 13.00 Lunch in Exhibit Hall

13.15 – 14.45 International Regulatory Summit

13.30 – 17.00

7001: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 1)

14.45 – 15.30 Networking Break in Exhibit Hall

15.30 – 17.15 ISPE Executive Series

EX1: Next Generation Processes, Equipment and Facilities
EX2: Biotechnology
EX3: Supply Chain Management
EX4: Enterprise Risk Management
EX5: Sustainability
EX6: Organizational Development

17.30 – 19.00 Communities of Practice Night General Reception

19.30 – 22.00 Young Professionals Dinner

Tuesday, 13 November

06.00 – 07.00 ISPilates

07.00 – 08.00 Continental Breakfast in Exhibit Hall

07.00 – 08.00 Certified Pharmaceutical Industry Professional™ (CPIP™) Information Workshop

07.00 – 08.00 Young Professionals Meet and Greet

07.00 – 16.00 Exhibit Hall Open

08.00 – 11.30

201: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 1)
202: FOYA 2012 Category Winners (Part 1)
203: New GMP Regulations and Inspection Programs in Asia Pacific Countries
204: Practical Experiences of Manufacturing Projects in Emerging Markets

schedule
by day

205: GAMP® Part 1 - Information Security in the Global Market
206: Innovation in Laboratory Operations
208: Early Phase Project Planning for Process Development
209: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 1)
7002: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 2)

08.30 – 12.30 Optional Tour: Alcatraz

08.30 – 17.00 Training Courses Begin

09.30 – 10.15 Networking Break in Exhibit Hall

11.45 – 13.15 Membership Luncheon and Award Ceremony

13.30 – 17.00

301: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 2)
302: FOYA 2012 Category Winners (Part 2)
303: Regulatory and Industry Perspectives of QbD
304: Biotechnology Manufacturing
305: GAMP® Part 2 – The Regulatory Focus on Data Integrity
306: Strategies for Raw Material Variability
308: Design Management in the Capital Project Lifecycle
309: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 2)
7003: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 3)

15.00 – 15.45 Networking Break in Exhibit Hall

19.00 – 22.00 Tuesday Night Party – Streets of San Francisco

Wednesday, 14 November

07.30 – 08.30 ISPilates

08.00 – 09.00 Continental Breakfast

08.00 – 09.00 Certified Pharmaceutical Industry Professional™ (CPIP™) Information Workshop

08.00 – 09.00 Young Professionals Meet and Greet

08.30 – 17.00 Training Courses Begin

09.00 – 12.30

401: Practical Application of C&Q Applied Risk Management
402: Ultraviolet Applications and Dose Calculation for Pharma Water Treatment
403: Process Validation: A Lifecycle Approach with Biotech Applications
404: Latin America Regulatory Compliance Forum
405: Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships
406: Sterile Products Processing Update
408: Project Implementation of IT Infrastructure Projects
409: Bridging the Compliance and Operational Excellence Gap
7004: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 4)

10.30 – 11.15 Networking Break

11.00 – 12.00 Cycling for a Cure Organizing Meeting

12.30 – 13.30 Lunch

13.00 – 16.00 Optional Tour: Chinatown Discovery

13.00 – 17.00 Facility Visits
Boehringer Ingelheim
Genentech
UCSF

schedule
by day

13.30 – 16.30
- 501: Facility of the Future, Impact of Innovative Technology and Continuous Manufacturing
- 502: Design and Operation of Water and Steam Systems
- 503: Implementing PQS Elements
- 504: Compliance and Technology in Emerging Markets
- 505: Improving Manufacturing Through Innovation: Continuous Processing and Process Control
- 506: A Strategic Approach to Containment Systems: An Integrated Process from Concept to Use
- 508: Managing Project Closeout, Product Approval, Product Launch
- 509: Advanced Aseptic Processing
- 7005: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 5)

15.00 – 15.15 Networking Break

Young Professionals

Sunday, 11 November

12.30 – 15.00 Young Professionals Luncheon and Orientation
15.00 – 16.00 Student Poster Set-up
17.00 – 19.00 Welcome Reception in the Exhibit Hall

Monday, 12 November

08.30 – 12.00 Plenary Presentations
13.30 – 17.00 International Student Poster Competition
19.30 – 22.00 Young Professionals Networking Dinner
Jillian's at Metreon

Tuesday, 13 November

07.00 – 08.00 Young Professionals Meet and Greet
11.45 – 13.45 Membership Luncheon and Awards Ceremony (ticket required)

International Student Poster Competition Winners and Student Chapter of the Year Announced!

14.00 – 17.30 Affiliate/Chapter Young Professionals and Students Workshop

Wednesday, 14 November

08.00 – 09.00 Young Professionals Meet and Greet

Affiliate/Chapter Council

Saturday, 10 November

16.30 – 17.30 ISPE Volunteer Leaders

Sunday, 11 November

08.30 – 12.30 Joint Affiliate Councils Meeting
13.30 – 17.00 North America/South America Affiliate Council Meeting
17.00 – 19.00 Welcome Reception in Exhibit Hall

Tuesday, 13 November

08.30 – 11.30 Asia-Pacific Affiliate Council
11.45 – 13.15 Membership Luncheon and Awards Ceremony
14.00 – 17.30 Affiliate/Chapter Hot Topics Workshop
14.00 – 17.30 Affiliate/Chapter Young Professionals and Students Workshop
19.00 – 22.00 Tuesday Night Party - Streets of San Francisco

Wednesday, 14 November

08.30 – 12.00 Affiliate/Chapter Managers' Meeting

Sunday PM 11 November 13.30 - 17.00 BREAK: 15.00 - 15.45	Monday AM 12 November 08.30 -12.00 BREAK: 10.00 -11.00	Monday PM 12 November 13.15 - 17.15 BREAK: 14.45 - 15.30	Tuesday AM 13 November 08.00 - 11.30 BREAK: 09.30 - 10.15
101: Case Studies of a Greenfield Site's Positive FDA-PAI Experience with Maintenance and Reliability	Plenary Session: Nancy Berg, CEO, ISPE, USA Charlotte Engave Fruergaard, PhD, Director of Technology, NNE Pharmaplan, Denmark Facility of the Year Awards (FOYA) Murray Aitken, Executive Director, IMS Institute for Healthcare Informatics, USA Stephen Spielberg, MD, PhD, Deputy Commissioner for Medical Products and Tobacco, FDA, USA	INTERNATIONAL REGULATORY SUMMIT 13.15-14.45	201: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 1)
102: The Challenges of Bringing New Products into Existing Facilities		EX1: Next Generation Processes, Equipment and Facilities	202: FOYA 2012 Category Winners (Part 1)
103: C&Q Risk Task Team Forum IV		EX2: Biotechnology	203: New GMP Regulations and Inspection Programs in Asia Pacific Countries
104: Manufacturing Facility Design for Global Organizations		EX3: Supply Chain Management	204: Practical Experiences of Manufacturing Projects in Emerging Markets
105: The Challenges Facing Disposable Technology and Their Solutions		EX4: Enterprise Risk Management	205: GAMP® Part 1 – Information Security in a Global Market
106: Nanotechnology in the Pharmaceutical Industry		EX5: Sustainability	206: Innovation in Laboratory Operations
		EX6: Organizational Development	
107: Back to Basics: Good Documentation to Facilitate Compliance and Electronic Batch Record Implementation		7001: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 1)	7002: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 2)
108: Project Initiation and Business Case Development			208: Early Phase Project Planning for Process Development
109: Process Analytical Technology: NIRS Implementation			209: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 1)

Emerging Markets	Facilities & Equipment	Investigational Products	International Regulatory

Topic By Color Key

education

Tuesday PM 13 November 13.30 - 17.00 BREAK: 15.00 - 15.45	Wednesday AM 14 November 09.00 - 12.30 BREAK: 10.30 - 11.15	Wednesday PM 14 November 13.30 - 16.30 BREAK: 15.00 - 15.15	Wednesday PM 14 November 13.00 - 17.00
301: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 2)	401: Practical Application of C&Q Applied Risk Management	501: Facility of the Future, Impact of Innovative Technology and Continuous Manufacturing	Facility Visits • Boehringer Ingelheim • Genentech • UCSF
302: FOYA 2012 Category Winners (Part 2)	402: Ultraviolet Applications and Dose Calculation for Pharma Water Treatment	502: Design and Operation of Water and Steam Systems	
303: Regulatory and Industry Perspectives of QbD	403: Process Validation: A Lifecycle Approach with Biotech Applications	503: Implementing PQS Elements	
304: Biotechnology Manufacturing	404: Latin America Regulatory Compliance Forum	504: Compliance and Technology in Emerging Markets	
305: GAMP® Part 2 – The Regulatory Focus on Data Integrity	405: Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships	505: Improving Manufacturing Through Innovation: Continuous Processing and Process Control	
306: Strategies for Raw Material Variability	406: Sterile Products Processing Update	506: A Strategic Approach to Containment Systems: An Integrated Process from Concept to Use	
7003: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 3)	7004: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 4)	7005: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 5)	
308: Design Management in the Capital Project Lifecycle	408: Project Implementation of IT Infrastructure Projects	508: Managing Project Closeout, Product Approval, Product Launch	
309: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 2)	409: Bridging the Compliance and Operational Excellence Gap	509: Advanced Aseptic Processing	
Manufacturing Operations	Project Management	Technology	Executive Series

sunday 11.11

09.00 – 18.00
International Leadership Forum (by invitation)

12.30 – 15.00
Young Professionals/Student Luncheon and Orientation

13.00 – 17.00
Optional Tour: San Francisco Highlights

13.00 – 19.00
Exhibit Hall Open

13.30 – 17.00
Education Sessions

16.00 – 17.00
New Member/First-Time Attendee Orientation

17.00 – 19.00
Welcome Reception in Exhibit Hall

education sessions 11.11.12

13.30 – 17.00

101: Case Studies of a Greenfield Site's Positive FDA – PAI Experience with Maintenance and Reliability

Learn about what the FDA is looking at with respect to maintenance and reliability. Several examples highlighting the triggers for FDA 483s and Warning Letters due to poor maintenance practices will be shared. The maintenance and reliability thought processes required to ensure compliance while leading good and best practices will be explored and encouraged. Understanding the challenge maintenance and reliability faces to meet regulatory requirements while leading innovative, efficient, effective, on-condition monitoring and world-class maintenance and reliability practices is the highlight of this session. Come prepared to revolutionize your thought processes around maintenance and reliability. The workshop will provide you with personalized guidance on how to accomplish this challenge.

Leader: **Marie Getsug**, Commissioning Agents, Inc., USA

Speakers: **Mary Kay Garcia**, *Recent 483s Issued for M&R Violations, Ensuring a Strong Foundation in M&R and Workshop-Bringing the Message Back to your Site*, Eli Lilly & Co., USA; **Marie Getsug**, *FDA Inspections for the Unprepared – The Feared 483s, Ensuring a Strong Foundation in M&R to Avoid 483s, A Great Experience with the M&R Portion of a PAI, Workshop – Bringing the Message Back to Your Site, Working Session to ID Area(s) to Focus in M&R, Audience Participation – Shared Learnings and Approach*, Commissioning Agents, Inc., USA; **Mark Kehrer**, *FDA Inspections for the Unprepared – The Feared 483s, Ensuring a Strong Foundation in M&R to Avoid 483s, A Great Experience with the M&R Portion of a PAI, Workshop – Bringing the Message Back to Your Site, Working Session to ID Area(s) to Focus in M&R, Audience Participation – Shared Learnings and Approach*, Commissioning Agents, Inc., USA

102: The Challenges of Bringing New Products into Existing Facilities

Learn how to address the business level and the economics that must be taken into consideration, risks that must be weighed and contingency plans that must be evaluated before a final decision is made. Avoid potential pitfalls with specific guidance and awareness. Important consideration will be given to the facility and how it interfaces with the used equipment to mitigate equipment installation and operational problems.

Leader: **Steve Sirabian**, Glatt Air Techniques, Inc., USA

Speakers: **Jeff Biskup**, *Facilities Implications: The Practical Realities*, CRB Consulting Engineers, Inc., USA; **Eric Bohn**, *The Legacy Pharmaceutical Facility*, Jacobs/Wyper Architects, LLP, USA; **Witold Lehmann**, *Facilities Implications: The Practical Realities*, CRB Consulting Engineers, Inc., USA; **Robert Matje**, *Drivers for Pharmaceutical Manufacturers: The Business Case*, Qualitest Pharmaceuticals, USA; **Steve Sirabian**, *Equipment Issues: A Template for Smart Decision-Making*, Glatt Air Techniques, Inc., USA

103: C&Q Risk Task Team Forum IV

This session will identify the best practices and associated tools to drive an efficient and effective science- and risk-based approach to C&Q. The C&Q Task Team will present tools and templates representing best practices from companies implementing the science- and risk-based approach concepts. Examples will be presented.

Leader: **Steve Wisniewski**, Commissioning Agents, Inc., USA

Speakers: **Ronald Brunelle**, *Risk Assessments*, Amgen, Inc., USA; **David Dolgin**, *User Requirements*, Abbott Laboratories, USA; **Rose Mary Dollard**, *Subject Matter Experts*, Johnson & Johnson, USA; **Matthew McMenamin**, *Summary Reports*, GlaxoSmithKline, USA; **Armen Nahabedian**, *Verification Plan,* Pfizer, Inc., USA; **Brian Pochini**, *Trace Matrices*, Genzyme, USA; **Mark Rezac**, *Design Reviews/Qualification, Questions and Answers*, Merck & Co., Inc., USA; **Steve Wisniewski**, *Change Management,* Commissioning Agents, Inc., USA

104: Manufacturing Facility Design for Global Organizations

Discuss the considerations in trying to design and construct FDA/EU/WHO compliant manufacturing facilities for the biotech and pharmaceutical industries that also satisfy the regional regulatory requirements for the building. There will be a focus on anticipating both the unique operating considerations and subsequent design solutions to effectively operate in the Chinese market.

Leader: **Bob Chew**, Commissioning Agents, Inc., USA

Speakers: **Andreas Bahne**, *Lean Manufacturing in China*, Boehringer Ingelheim Pharma Co. Ltd., China; **Simon Chalk**, *Assessing the Opportunities and Potential Pitfalls of Setting Up and Operating Bioprocess Manufacturing Activities in China*, BioPhorum, UK; **Bikash Chatterjee**, *Manufacturing Facility Design for Global Organizations*, Pharmatech Associates, USA; **Dennis Stamm**, *Lean Manufacturing in China*, CH2M Hill, USA

105: The Challenges Facing Disposable Technology and Their Solutions

Discuss the new challenges and requirements of the biotech industry to improve quality, product integrity, assurance of supply and validation for extractable and toxicity assessment in single-use systems.

Leader: **Adam Goldstein**, Genentech, USA

Speakers: **Jean-Mark Cappia**, *Technology Advances and Integration for Implementing Single-Use BioProcessing, Single-Use Mixing Solutions for Large-Scale Media and Buffer Preparations and Downstream and Implementing Single-Use Technologies in a GMP Facility: A Case Study*, Sartorious Stedim Biotech, France; **Kevin Lear**, *Secure Supply Chain Management for Single-Use Components, Single-Use Mixing Solutions for Large-Scale Media and Buffer Preparations and Downstream and Implementing Single-Use Technologies in a GMP Facility: A Case Study*, Hyde Engineering, USA; **Peter Watler**, *Secure Supply Chain Management for Single-Use Components*, Hyde Engineering, USA (Invited)

education sessions 11.11.12

106: Nanotechnology in the Pharmaceutical Industry

Participants will discuss nanotechnology approaches developed for pharmaceutical applications and technologies. Learn the strengths and weaknesses of these different approaches to leverage the full potential of these emerging technology platforms.

Leader: **Gregg Ekberg**, PharmaTech Associates, USA

Speakers: **John Ervin**, *Advanced Biomolecular Interaction Analysis Using NPOI (Nano-Pore Optical Interferometry)*, SiliconKinetics, USA; **Nicholas Kerkhof**, *Increasing Drug Bioavailability Through Nanotechnology,* Co Censys, Inc., USA; **Xiaoling Li**, *Application of a Novel Nanotechnology to Drug Formulation*, Thomas J. Long School of Pharmacy and Health Sciences - University of the Pacific, USA

107: Back to Basics: Good Documentation to Facilitate Compliance and Electronic Batch Record Implementation

During this session, you will discuss the GMP Preamble to provide the quality compliance requirement for controlled documentation. An analysis of documentation observations cited during FDA inspections will be presented and a top ten list of actions to take to prevent documentation observations by regulatory authorities will be provided. Learn how to utilize good documentation to effectively implement Electronic Batch Records (EBR).

Leader: **Felicia Ford-Rice**, PAREXEL Consulting, USA

Speakers: **Chuck Krumwiede**, *Leaning Batch Record Documentation Before Implementing EBR (Electronic Batch Records)*, Malcom Associates, USA; **Felicia Ford-Rice**, *To Document or Not to Document…Should NOT BE the Question!*, PAREXEL Consulting, USA; **Pat Sullivan**, *Getting Value Out of an EBR System*, Avid Solutions, USA

108: Project Initiation and Business Case Development

Discover the first step in project management. Case study examples will take delegates through the lifecycle on how to create and present a business case. Using the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* as a knowledge platform, delegates will be shown how to justify the reasons for proposing the project in terms of the measurable benefits to the organization versus the costs incurred, the return on investment and how the project will further strategic business objectives and align with other projects.

Leaders: **Keith Gibbs**, Innovative Process Solutions, USA and **Trish Melton**, Mime Solutions, UK

Speakers: **Japan Affiliate**, *An Introduction to the Japan Affiliate* (Invited); **Trish Melton**, *Defining Project Initiation, Developing Your Business Case-Guided Exercise, Project Management-10 Minute Toolbox Topic*, Mime Solutions, UK; **Operations Management COP**, *Developing Your Business Case-An Operations Management COP Case Study* (Invited); **David Vaughn**, *Business Continuity and Disaster Management*, Fluor, USA

109: Process Analytical Technology: NIRS Implementation

NIRS emerges as one of the analytical methods that is most widely used in PAT applications. In this workshop, case studies of NIR implementation will be presented and issues related to model development, maintenance and submission will be discussed. Experiences from implementation will be presented along with thoughts on the future of real-time release. Both technical and regulatory perspectives will be covered.

Leader: **Dora Kourti**, GlaxoSmithKline, USA

Speakers: **Theodora Kourti**, *NIRs as a PAT Tool in Pharmaceutical Industry, Discussion on Industrial Experiences/Perspectives, Discussion on Regulatory Experiences/Perspective*, GlaxoSmithKline, USA; **Bogdan Kurtyka**, *FDA Perspective*, *Discussion on Industrial Experiences/ Perspectives, Discussion on Regulatory Experiences/Perspectives*, FDA, USA (Invited); **Victor Saucedo**, *NIR Implementation in Genentech, Discussion on Industrial Experiences/Perspectives, Discussion on Regulatory Experiences/Perspectives*, Genentech, USA; **Bruce Thompson**, *NIR implementation in Merck, Discussion on Industrial Experiences/ Perspectives, Discussion on Regulatory Experiences/Perspective*, Merck & Co., Inc., USA; **Tony Wang**, *NIR Implementation in Amgen, Discussion on Industrial Experiences/Perspectives, Discussion on Regulatory Experiences/ Perspectives*, Amgen, USA

monday 11.12

06.00 – 07.00
Charity 5K Run/Walk

07.00 – 17.00
Exhibit Hall Open

07.00 – 08.15
Contintental Breakfast in Exhibit Hall

07.15 – 08.15
New Member/First-Time Attendee Networking Breakfast

08.30 – 12.00
Plenary Session

10.00 – 14.30
Optional Tour: Magical Marin

13.15 – 14.45
International Regulatory Summit

13.30 – 17.00
Education Session

15.30 – 17.15
Executive Series

17.30 – 19.00
Communities of Practice (COPs) Night General Reception

19.30 – 22.00
Young Professionals Dinner

education sessions 11.12.12

Plenary Session

08.30 – 12.00

Industry leaders present on global issues, opportunities and challenges facing the industry.

Nancy S. Berg, CEO, ISPE, USA – Strategic Direction for ISPE

Charlotte Enghave Fruergaard, PhD, Director of Technology, NNE Pharmaplan, Denmark – The Role of ISPE as a Global Organization

Facility of the Year Award (FOYA) – 2012 Category Winners

Murray Aitken, Executive Director, IMS, USA – Top Priorities and Trends for the Pharmaceutical Industry

Stephen P. Spielberg, MD, PhD, Deputy Commissioner for Medical Products and Tobacco, FDA, USA – How the FDA is Advancing Regulatory Science Through High Quality Collaboration

International Regulatory Summit

13.15 – 14.45

In our global economy, the interaction between industry and regulators is crucial. This summit will bring together high-level regulators from North America, Europe, Asia, and Latin America to discuss regional regulatory challenges and examine those challenges within the context of a global regulatory environment.

13.30 – 17.00

7001: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 1)

Gain insight into the regulatory requirements for the key clinical development countries (Brazil, Russia, India and China) and how to manage these requirements. The program will also provide "real-life" solutions for the proper planning of clinical supplies for these key countries and managing the global supply chain.

Leaders: **Neal Gordon**, Merck & Co., Inc., USA and **Steve Yoder**, Fisher Clinical Services, USA

Speakers: **Tom Haverty**, *Biosimiliars Keynote*, Merck & Co., Inc., USA; **Rob Pizzie**, *How Does Your Clinical Supply Chain Survive in These Days of Mergers*, Merck & Co., Inc., USA

15.30 – 17.15

Executive Series - The International Leadership Forum (ILF), recognized thought leaders of our industry, created a blueprint of the areas deemed critical to the future of our industry titled *Global Positioning Strategy* (GPS). Their goals are to enhance innovation, facilitate global operations, enable continuous improvement, provide for sustainability and address a product throughout its lifecycle, while being ever vigilant of quality. The Executive Series, led by distinguished industry leaders, is designed to create an opportunity for all members of the ISPE community to engage in this challenging dialogue.

education sessions 11.12.12

EX1: Next-Generation Processes, Equipment and Facilities

Industry is actively applying advanced technologies, new systems and equipment, driving facility innovation and utilizing new regulatory approaches that enable cost-effective manufacturing with enhanced flexibility without sacrificing product quality. Presentations in this session will focus on "Use of Single Use Systems for Large Scale Manufacturing" and "Use of Mobile Devices and Apps in Biopharmaceutical Manufacturing." The presented case studies will highlight current experiences, benefits realized, lessons learned and their organizations' vision for the future facilities for biopharmaceutical manufacturing.

Speakers: **Alan Pruitt**, Genentech, Inc., USA; **Karl Curtis**, Enhanced Information Systems (EIS), USA; **Stacey Kaneshiro**, Eli Lilly & Co., USA

EX2: Biotechnology

Each year, biotech makes up a larger percentage of the total number of pharmaceutical products. As a result, there continues to be significant innovation and technological advancement which is changing the development and manufacturing landscape. This program will address several key technological areas that are a priority to realize the potential of biotechnology.

Leader: **Andrew Scherer**, Scherer & Associates Inc., USA

Speakers: **Parrish Galliher**, *Development of Flexible/Disposable Manufacturing Equipment in Non-Cho Production*, Xcellerex LLC; **Robert Preti**, *Immunotherapies and Tissue Culture Manufacturing Technologies*, Progenitor Cell Therapy, USA; **Melinda Richter**, Prescience International, USA

EX3: Supply Chain Management

Today's extended supply networks potentially present some of industry's greatest complexities, efficiencies and risks, spanning countries and continents and including companies of all sizes and capabilities. This session will focus on the global issues as well as specific technical situations that have been effectively addressed through customer and supplier collaboration and integrated quality systems. Attendees will hear about mitigating risks, quality and management challenges, signal and detection processes, tracking and coding, packaging and more.

Leader: **Larry Kranking**, Coldstream Laboratories, Inc., USA

Speakers: **Ron Guido**, Johnson & Johnson, USA; **Zhong Li**, High Throughout Biology, Inc. USA; **Michael Mesa**, Net-Inspection, USA

EX4: Enterprise Risk Management

Learn how some companies use Enterprise Risk Management approaches to insure optimal quality and to mitigate risks throughout the product lifecycle.

Leader: **Georges Frances**, Novartis Consumer Health, Switzerland

EX5: Sustainability

Pharmaceutical and biotechnology companies are keen to incorporate best practices in the design, delivery and operation of efficient and sustainable facilities and infrastructures. This session will present real-world industry and non-industry case studies demonstrating how to develop innovative short- and long-term sustainability strategies that are both viable and cost-effective.

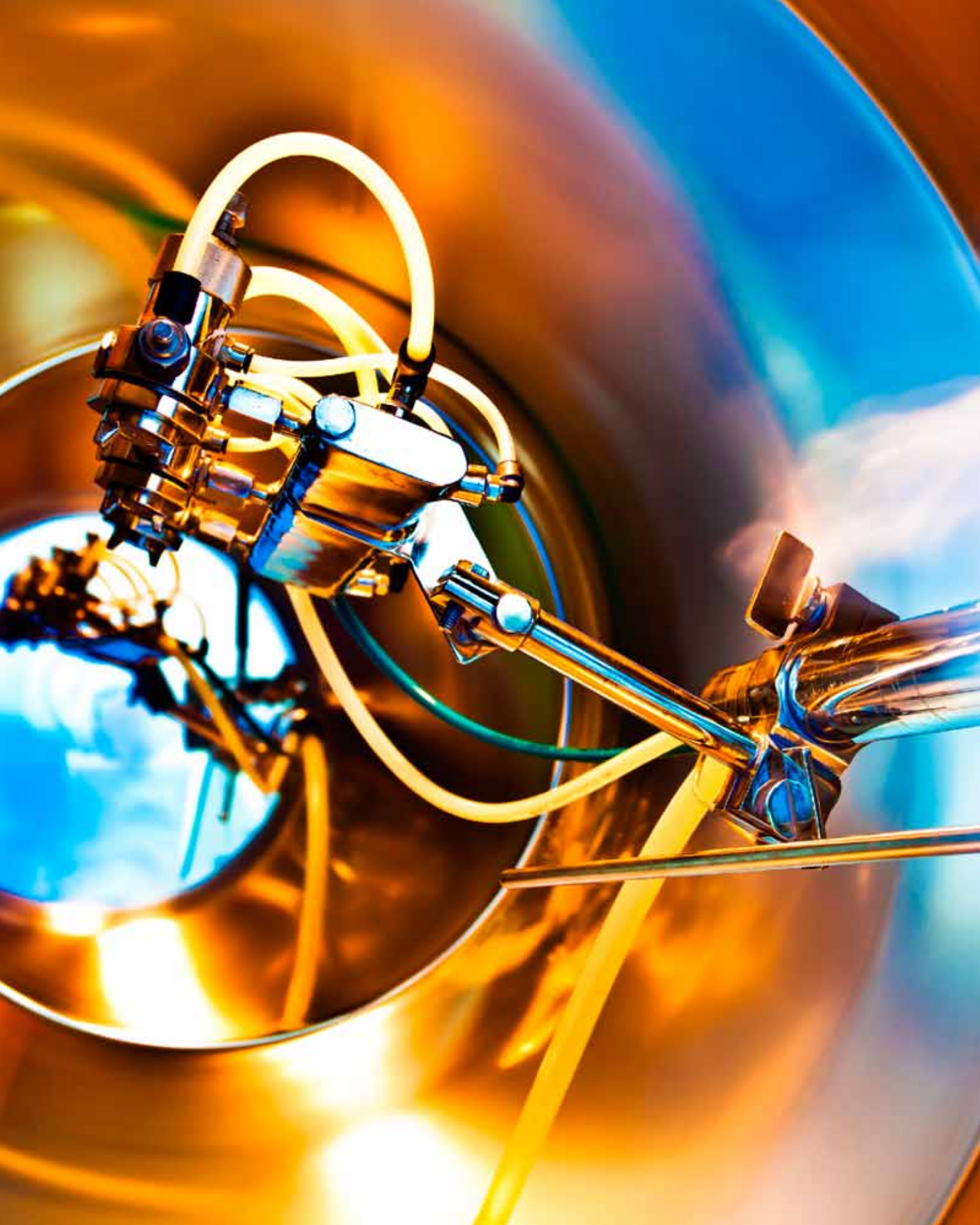
Leaders: **James M. Brinkman**, Pfizer, Inc., USA and **Margaret O'Toole**, Pfizer, Inc., USA

EX6: Organizational Development

Learn how operational excellence is driven by robust knowledge management and developing effective learning organization. Speakers in this session will share comprehensive knowledge management initiatives, personnel qualification programs and professional certification programs.

Leader: **Timothy Howard**, Pfizer, Inc., USA

Speakers: **Dennis Murphy**, *Be an Effective Learning Organization, Using HRP, Defense in Depth*, Amgen, USA; **Timothy Howard**, *Qualification of Resources*, Pfizer, Inc., USA; **Bob Lechich**, *Certification and Training*, Pfizer, Inc., USA (Invited)



tuesday 11.13

06.00 – 07.00
ISPilates

07.00 – 08.00
Continental Breakfast in Exhibit Hall

07.00 – 08.00
Certified Pharmaceutical Industry Professional™ (CPIP™) Information Workshop

07.00 – 08.00
Young Professionals Meet and Greet

07.00 – 16.00
Exhibit Hall Open

08.00 – 17.00
Education Sessions

08.30 – 12.30
Optional Tour: Alcatraz

08.30 – 17.00
Training Courses

11.45 – 13.15
Membership Luncheon and Award Ceremony

19.00 – 22.00
Tuesday Night Party – Streets of San Francisco

education sessions 11.13.12

08.00 – 11.30

201: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 1)

These highly interactive sessions will focus on planning, designing and constructing a biopharmaceutical facility and applying rigorous Value Management (VM) tools to reflect the realities of today's cost-conscious capital environment. The group will participate in a detailed VM of their project design and lessons learned using best practices from actual projects in the region which will be brought into the VM component.

Leader: **Donna DeFreitas**, Vanderweil Engineers, USA

Speakers: **Peter Cramer**, *Process Architecture*, M + W Group, USA; **Donna DeFreitas**, *Infrastructure and Support Systems*, Vanderweil Engineers, USA; **Jerry Guillorn**, *Process Architecture*, M + W Shanghai Co., Ltd., USA; **Bill Jacobsen**, *Process Definition*, Gallus BioPharmaceuticals, USA; **Jon Tomson**, *Corporate Trends and Business Drivers*, JT Collaborative LLC, USA; **Speaker Invited**, *Value Management from Day One*, **Speaker Invited**, *QbD/ Sustainability*

202: Facility of the Year Awards (FOYA) 2012 Category Winners (Part 1)

Learn about the latest, state-of-the-art developments being implemented, the winning projects and see how excellence was delivered via innovative thinking. Featured presentations include the 2012 Facility of the Year Awards Program Category Winners.

Leader: **Jim Kimmel**, MJK Solutions, USA

Companies Represented: **Chiesi Farmaceutici**, *Category Winner for Sustainability,* Italy; **Eisai Pharmatechnology & Manufacturing Pvt. Ltd.**, *Category Winner for Project Execution*, India; **Merck & Co., Inc.**, *Category Winner for Facility Integration,* USA

203: New GMP Regulations and Inspection Programs in Asia Pacific Countries

Most pharmaceutical companies have an emerging market component as part of their strategic plan. This presentation will talk about the considerations and solutions for designing, operating and qualifying a manufacturing facility in China that will be used to manufacture products for sale to the US and Europe.

Leader: **Chi-wan Chen**, Pfizer, Inc., USA

Companies Represented: **DCGI** (Invited); **HPRG** (Invited); **SFDA** (Invited)

204: Practical Experiences of Manufacturing Projects in Emerging Markets

Short presentations related to project delivery in emerging markets, followed by an extensive panel discussion from representatives of EPCM firms will be featured. An open forum panel discussion will allow participants the opportunity to question and hear about issues critical to project success.

Leader: **Jim Breen**, Johnson & Johnson, USA

Speakers: **Sue Joiner**, *The Application of China Sourcing for the Pharmaceutical Industry*, Fluor, China; **Cecile Jolibois**, *Capital Project Delivery in Emerging Markets and Vaccine Project in Chengdu: A Case Study*, TECHNIP, France; **Patrick Pouillot**, *Capital Project Delivery in Emerging Markets and Vaccine Project in Chengdu: A Case Study*, TECHNIP, France; **Allan Schouten**, *Successful Biopharma Project Delivery in Emerging Markets within Asia*, PM Group, Singapore

205: GAMP® Part 1 - Information Security in the Global Market

Discuss proven approaches and technologies that can methodically eliminate information breaches without compromising compliance or regulatory commitments while meeting the strategic imperatives of the business. The first part of this session focuses on the evolution of Brazilian regulations on CSV and the current requirements in comparison with USA and EU regulations.

Leaders: **Kevin Martin**, Azzur Group LLC, USA and **Marcelo Decanio de Oliveira**, Boehringer Ingelheim de Brasil, Brazil

Speakers: **Mario Brenga Giampietro**, *Current Brazilian Regulation on Computerized Systems Validation Comparing to USA and EU*, Telstar, Brazil (Invited); **Bikash Chatterjee**, *Securing Information as Part of the Global Supply Chain*, Pharmatech Associates, USA; **Marcelo Decanio de Oliveira**, *Current Brazilian Regulation on Computerized Systems Validation Comparing to USA and EU*, Boehringer Ingelheim de Brasil, Brazil

education sessions 11.13.12

206: Innovation in Laboratory and Production Operations

Recent advances in laboratory and production operations have been developed to improve both quality and efficiency. This session will cover a wide range of topics from new state-of-the-art weighing technologies, the evaluation of the performance of liquid metrology concentration monitors, and methods to reduce energy usage within the laboratory HVAC system without adversely affecting air quality.

Leader: **Brad Cochran**, CPP, Inc., USA

Speakers: **Ronald Chiarello**, *A Comparison of Liquid Metrology Concentration Monitor Technologies for Use in Buffer Preparation Process*, Jetalon, USA; **Brad Cochran**, *Minimizing Laboratory Exhaust Energy Consumption While Maintaining a Safe Laboratory Environment: Case Study of the Genentech Site Lab Exhaust Optimization Project (SLEO)*, CPP, Inc., USA; **Klaus Fritsch**, *Good Weighing Practices – An Innovative Risk-Based Approach to Calibration and Testing of Weighing Systems to Ensure GxP Compliance and Enhance Process Quality and Efficiency*, Mettler Toledo AG, Switzerland

208: Early Phase Project Planning for Process Development

The second phase of Project Management is the planning for process development. You will learn the key project controls needed to understand the business environment and insure that all necessary controls are incorporated into the project. Explore the unique role a Project Manager plays in Process/Product Development by referencing the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry.*

Leaders: **Keith Gibbs**, Innovative Process Solutions, USA and **Jeff Odum**, Integrated Project Services, USA

Speakers: **David Bendet**, *Early Phase Project Definition-Part 1, Early Phase Project Definition-Part 2*, Perkins and Will, USA; **Jeff Odum**, *Defining the Early Phase of a Project, Early Phase Project Definition-Guided Exercise*, Integrated Project Services, USA; **Process/Product Development COP**, *Process Development Projects-A Process/Product Development COP Case Study* (Invited); **Emily Stump**, *An Introduction to the Pacific Northwest Chapter*, Commissioning Agents, Inc., USA

209: HVAC and Sustainability COPs Present: Quality Doesn't Have to Cost the Earth (Part 1)

Discuss some of the regulatory requirements for classified areas – current expectations and the history behind those expectations. The session will continue with presentations on recent innovations and experiments that show how current operation costs can be reduced while maintaining a compliant manufacturing area. The use of new technologies will also be explored.

Leaders: **Nick Haycocks**, Amgen, USA and **Paul Malinowski**, Becton Dickinson & Co., USA

Speakers: **David Brande**, *UAF Air Velocities – The Origin of 90 ft/Minute, and Issues Around its Use,* Cleanroom Project Management, Inc., USA; **George Cadwell**, *HEPA Filter Testing – The History and Origin of the 0.01% Acceptance Criteria*; **Norm Goldschmidt**, *UAF Air Velocities – The Origin of 90 ft/Minute, and Issues Around its Use,* Genesis Engineers, Inc., USA; **Terry Jacobs**, *LEED for Pharmaceutical Manufacturing Facilities,* Jacobs/Wyper Architects, LLP, USA; **Dan Milholland**, *UAF Air Velocities – The Origin of 90 ft/Minute, and Issues Around its Use,* Milholland & Associates, USA; **Walt Tunnessen**, *Energy Star and the Pharmaceutical Industry,* US Environmental Protection Agency, USA; **Representative**, *The FOYA Sustainability Category Winner – What Made It a Winner,* Chiesi Farmacetici, Italy

7002: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 2)

Gain insight into the regulatory requirements for the key clinical development countries (Brazil, Russia, India and China) and how to manage these requirements. The program will also provide "real-life" solutions for the proper planning of clinical supplies for these key countries and managing the global supply chain.

Leader: **Neal Gordon**, Merck & Co., Inc., USA

Speakers: **Michelle Foust**, Almac Clinical Services, USA; **Steve Yoder**, *Building a Supply Chain around a Protocol – Part 1 and Part 2*, Fisher Clinical Services, USA

13.30 – 17.00

301: Build a Biotech Facility: Real-Time Value Management Decision-Making Workshop (Part 2)

These highly interactive sessions will focus on planning, designing and constructing a biopharmaceutical facility and applying rigorous Value Management (VM) tools to reflect the realities of today's cost conscious capital environment. The group will participate in a detailed VM of their project design and lessons learned using best practices from actual projects in the region which will be brought into the VM component.

Leader: **Donna DeFreitas**, Vanderweil Engineers, USA

Speakers: **Donna DeFreitas**, *Results,* Vanderweil Engineers, USA; **Jerry Guillorn**, *Results,* M + W Shanghai Co., Ltd., USA; **Dean Poillucci,** *Constructability Concerns,* Skanska USA Building Inc., USA; **Speaker Invited**, *CQV Concerns*; **Panel Members**, MedImmune, Pfizer Inc., USA and Merck & Co., Inc., USA (Invited)

education sessions 11.13.12

302: Facility of the Year Awards (FOYA) Category 2012 Winners (Part 2)

Learn about the latest, state-of-the-art developments being implemented, learn more about the winning projects, and see how excellence was delivered via innovative thinking. Featured presentations include the 2012 Facility of the Year Awards Program Category Winners.

Moderator: **Jim Kimmel**, MJK Solutions, USA

Companies Represented: **Roche Diagnostics GmbH**, *Category Winner for Operational Excellence*, Germany; **National Institute of Bioprocessing Research and Training (NIBRT) New Greenfield Facility**, *Special Recognition for Novel Collaboration*, Ireland; **Rentschler Biotechnologie GmbH**, *Category Winner for Equipment Innovation*, Germany

303: Regulatory and Industry Perspectives of QbD

Regulatory, industry and academia speakers will be invited to give presentations on Quality by Design (QbD) implementation. The main focus of this symposium is to discuss the practical experience and detail expectations and approaches from regulatory agency and industry perspectives. The opportunities, challenges and future direction for QbD implementation will be also discussed.

Leaders: **Daniel Peng, Sr.**, FDA, USA and **Lawrence Yu**, FDA, USA

Speakers: **Bruce Davis**, *ISPE PQLI's Perspective of QbD*, Global Consulting, USA; **Yatindra Joshi**, *Generic Industry Perspective of QbD*, Teva, USA; **Christine Moore**, *QbD: Objectives, Benefits and Challenges, Regulatory Perspective of QbD,* FDA, USA; **Christopher Sinko**, *Innovator Industry Perspective of QbD,* Bristol Myers Squibb, USA; **Lawrence Yu**, *QbD: Objectives, Benefits and Challenges,* FDA, USA

304: Biotechnology Manufacturing

This session will address the dynamic changes that are occurring in process development, facility design and integration which are enabling technologies and manufacturing strategy to meet the needs of the global enterprise. Discuss design methods, risk assessment and identify key factors enabling to design the facility of the future. Discuss current approaches and discover an alternative plan to reduce risk.

Leader: **Victor Warren**, Warren Architects, Inc., USA

Speakers: **David Estape**, *Biotech Facility Design: The Missing Pieces,* M + W Germany, Germany; **John Hyde**, *Single-Use and Disposables Case Study,* Hyde Engineering & Consulting, Inc., USA; **Dr. Niranjan Kulkarni**, *Dealing with Operational Variability and Uncertainties in Evolving Biopharmaceutical Manufacturing,* CRB, USA; **Jeff Odum**, *Biotechnology 2012: Looking Ahead to the 4th Decade,* IPS, USA; **Victor Warren**, *Planning Strategies for New Cell Culture Manufacturing Facilities,* Warren Architects, Inc., USA; **Darren Whitman**, *Human Error Reduction in Biotech Manufacturing,* BioPhorum Operations Group, UK

305: GAMP® Part 2 – The Regulatory Focus on Data Integrity

Pharmaceutical managers will engage in discussions to ensure that their organizations are prepared for increased regulatory focus on laboratory systems. The session will utilize chromatography systems as an example due to their role in business-critical analyses. The second part of this session will explore the breakdown of the clinical development process and how the principles of GAMP® 5 can be applied to associated data (e.g., study data) using a risk-based approach.

Leaders: **Marcelo Decanio de Oliveira**, Boehringer Ingelheim de Brasil, Brazil and **Kevin Martin**, Azzur Group LLC, USA

Speakers: **Monica Cahilly**, *Data Integrity for Senior Managers*, Green Mountain Quality Assurance, LLC, USA (Invited); **Oliver Herrmann**, *Applying GAMP® 5 Principles to Data in R&D: How to Maintain Data Integrity in the Clinical Development Process*, Q-FINITY Quality Management, Germany; **Michael Rutherford**, *Data Integrity for Senior Managers*, Eli Lilly & Co., USA; **Eric Staib**, *Applying GAMP® 5 Principles to Data in R&D: How to Maintain Data Integrity in the Clinical Development Process*, Covance, USA (Invited); **Dana Yurach**, *Data Integrity for Senior Managers*, Waters, France

306: Strategies for Raw Material Variability

ICH Q8 outlines the expectations for a comprehensive pharmaceutical development strategy. One of the goals is to generate product and process understanding to a level where it supports process control to compensate for raw material variability in an adaptable way and assure constant quality drug product. During this session, you will share examples of industry strategies for dealing with such raw material variability.

Leader: **Wim Oostra**, MSD, Merck & Co., Inc., Netherlands

308: Design Management in the Capital Project Lifecycle

Learn how to successfully plan time, costs and resources to estimate the work needed and effectively manage risk during project execution. This session will teach you how to develop and maintain a business environment in which an organization can achieve its strategic and mission goals through design, and by establishing and managing an efficient and effective system.

Leader: **Keith Gibbs**, Innovative Process Solutions, USA
Speakers: **David Bendet**, *More and More with Less and Less: A Project Guide to Delivering High Value Design and Delivery Strategies in Challenging Economic Times*, Perkins and Will, USA; **Allan Chasey**, *Building Information Modeling: A Process to Mitigate Risk*, Arizona State University, USA; **GAMP COP**, *Engineering Standards Benchmarking-Guided Exercise* (Invited); **John Honey**, *Defining Design Management Project Management-10 Minute Toolbox Topic*, Genetech, USA; **Corey Veverka**, *An Introduction to the San Francisco Bay Area Chapter*, Total Validation Services, Inc., USA

education sessions 11.13.12

309: HVAC and Sustainability COP's Present: Quality Doesn't Have to Cost the Earth (Part 2)

Discuss some of the regulatory requirements for classified areas – current expectations and the history behind those expectations. The session will continue with presentations on recent innovations and experiments that show how current operation costs can be reduced while maintaining a compliant manufacturing area. The use of new technologies will also be explored.

Leaders: **Nick Haycocks**, Amgen, USA and **Paul Malinowski**, Becton Dickinson & Co., USA

Speakers: **Thomas Arista**, *Sustainability – The FDA View,* FDA, USA (Invited); **Negat Babur**, *Improving the Efficiency of Pharmacopeial Water Systems,* IPS, USA; **Rob Bowen**, *Facility Design for Continuous Manufacturing,* Facilities Integration Ltd., UK; **David Brande**, *Air Change Rates – Regulatory Expectations, What is Required to Obtain the Required Classifications,* Cleanroom Project Management, Inc., USA; **Norm Goldschmidt**, *Air Change Rates – Regulatory Expectations, What is Required to Obtain the Required Classifications,* Genesis Engineers, Inc., USA; **Pete Meginnis**, *Airflow Pattern Testing/Smoke Studies, What is Required, and When Is It Required,* Eli Lilly & Co., USA; **Dan Milholland**, *Air Change Rates – Regulatory Expectations, What is Required to Obtain the Required Classifications,* Milholland & Associates, USA; **Ulla Thomsen**, *Airflow Pattern Testing/Smoke Studies, What is Required, and When Is It Required,* Novo Nordisk A/S, Denmark

7003: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 3)

Gain insight into the regulatory requirements for the key clinical development countries (Brazil, Russia, India and China) and how to manage these requirements. The program will also provide "real-life" solutions for the proper planning of clinical supplies for these key countries and managing the global supply chain.

Leader: **Neal Gordon**, Merck & Co., Inc., USA

Speakers: **Cat Hall**, *Product Pooling and What It Can Do for Your Studies,* Pfizer, Inc., USA; **Tom O'Connell**, *More Intelligent Uses of IRT,* O'Connell Search International, USA; **Steve Yoder**, *Linking the Supply Chain to IRT,* Fisher Clinical Services, USA

Membership Luncheon and Award Ceremony
11.45-13.15

Enjoy lunch and hear from 2012 Chair Arthur (Randy) Perez, PhD as he reflects on his year as ISPE Chair and his impressions of the important role ISPE plays for Members. Special recognition awards will be presented to Members, Affiliates, Chapters, Committees, companies, authors and Students.

Arthur (Randy) Perez, PhD

In his remarks, Dr. Arthur "Randy" Perez, 2012 Chair of the ISPE International Board of Directors, will discuss a year of transformation for ISPE. Under his leadership, the Society identified strategic priorities and leveraged resources to increase the Society's technical and Member engagement, and leadership in regulatory affairs. His remarks will be reflective of his year as ISPE Chair and will highlight his impressions of the important role ISPE Members have in shaping industry consensus around technical and regulatory issues.

ISPE International Student Poster Competition

Student poster finalists from around the world showcase visual displays of their research or program highlights. A panel of distinguished industry judges will select the international graduate and undergraduate winners, who will be recognized at the Annual Meeting Membership Luncheon and Awards Ceremony. Visit www.ISPE.org/Students for details.

Tuesday Night Party – Streets of San Francisco
19.00 – 22.00

Experience beautiful San Francisco without leaving your hotel on Tuesday night. Hit the streets of San Francisco to taste the exotic and savory flavors of Little Italy, Chinatown, Fisherman's Wharf and Ghirardelli Square. Dance the night away at the San Fran Discotheque or hit AT&T Park and play a variety of games or enjoy highlights from the sidelines. If city life is not for you, then head over to a more quiet corner for networking and catching up with friends. You don't want to miss this City by the Bay evening.

wednesday 11.14

07.30 – 08.30
ISPilates

08.00 – 09.00
Continental Breakfast

08.00 – 09.00
Certified Pharmaceutical Industry Professional™ CPIP™) Information Workshop

08.00 – 09.00
Young Professionals Meet and Greet

08.30 – 17.00
Training Courses

09.00 – 16.30
Education Sessions

11.00 – 12.00
Cycling for a Cure Organizing Meeting

13.00 – 16.00
Optional Tour: Chinatown Discovery

13.00 – 17.00
Facility Visits

education sessions 11.14.12

09.00 – 12.30

401: Practical Application of C&Q Applied Risk Management

Using several Guides, this session will teach delegates how to create or enhance current C&Q programs with solid risk-based principles for every aspect of the pharmaceutical manufacturing environment, as well as develop and present specific risk-based C&Q tools and work instruction for low-impact implementation.

Leader: **Rose Mary Dollard**, Johnson & Johnson, USA

Speakers: **Andrew Collentro**, *Overview of the Proposed Revisions to the Commissioning and Qualification of Pharmaceutical Water and Steam Systems Good Practice Guide,* Water Consulting Specialists, Inc., Belgium; **Machteld Deconinck**, *A Case Study for a Science- and Risk-Based Approach to the Commissioning and Qualification of a Purified Water System*, Janssen Pharmaceutica, Belgium; **Jose Ochoa**, *A Case Study for a Science- and Risk-Based Approach to the Commissioning and Qualification of a Purified Water System*, Vistakon, USA

402: Ultraviolet Applications and Dose Calculation for Pharma Water Treatment

Ozone can be a cost-effective alternative to heat or chemical sanitization and ultraviolet technology is needed to destroy residual ozone in the product water. This course will focus on dose sizing required for proper application of ultraviolet irradiation for various purposes in pharma water systems. Discussion will include review of the current state of ultraviolet technology such as validated ultraviolet as well as ultraviolet application as part of an overall strategy for ozone sanitization of water systems. Highlights from two ongoing independent dose-related studies will be included.

Leader: **Joe Manfredi**, GMP Systems, USA

Speakers: **Ismail Gobulukoglu**, *Ultraviolet Dose Verification for Ozone Removal – An Industry Study*, Aquafine Corporation, USA; **Bill LaVoice**, *Validated Ultraviolet Applications*, Aquafine Corporation, USA; **Joe Manfredi**, *Ultraviolet Dose Verification for Ozone Removal – An Industry Study*, GMP Systems, USA; **Peter Petrillo**, *Ultraviolet for Chlorine and Organics Reduction,* Millennium Facilities Resources Inc., USA; **Phil Sumner**, *Ultraviolet Dose Verification for Ozone Removal – An Academic Study*, Pfizer, Inc., USA

403: Process Validation: A Lifecycle Approach with Biotech Applications

Industry and regulatory representatives will discuss application of the lifecycle approach to process validation for biotech drug substance and drug product manufacturing. Most significant issues, challenges and ideas for practical implementation will be discussed.

Leader: **Joanne Barrick**, Eli Lilly & Co., USA

Speakers: **Jeffrey Baker**, *Practical Impact of Lifecycle Approach to Process Validation on Biotech – From FDA Perspective*, FDA CDER, USA; **Joanne Barrick**, *Electronic Benchmarking About Implementation of Process Validation Lifecycle Approach in Biotech Manufacturing*, Eli Lilly & Co., USA; **Kurtis Epp**, *ISPE Process Validation Implementation Practical Support Update and Biotech Continued Process Verification Example,* BioTechLogic, Inc., USA (Invited); **Beth Junker**, *Integrated Approaches to Developing a Biotech Product-Specific Process Validation Lifecycle Strategy*, Merck & Co., Inc., USA; **Wendy L. Zwolenski-Lambert**, *Practical Impact of the Lifecyle Approach to Process Validation to Biotech Manufacturing*, Abbott Laboratories, USA

404: Latin America Regulatory Compliance Forum

Companies continue to face challenges when conducting clinical trials and registering products globally due to local regulatory requirements and lack of harmonized requirements. Discussion of these topics will help inform industry of potential challenges and will provide opportunities for dialog and collaboration between industry and regulators to discuss science-based and risk-based approaches to stability.

Leaders: **Maria Guazzaroni-Jacobs**, Pfizer, Inc., USA and **Bekki Kamos**, GlaxoSmithKline, USA

Companies Represented: **ANMAT** (Invited); **ANVISA** (Invited); **DIGEMID** (Invited)

405: Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships

Recent years have seen significant rationalization of internal manufacturing and packaging facilities at big pharma in favor of contracting these services with third-party providers worldwide. Learn how to effectively select CMOs and suppliers for strategic partnerships while driving value for both parties.

Leader: **Steve Poehlein**, Merck & Co., Inc., USA

Speakers: **Roger LaForce**, *Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships*, Zambon Group, Italy; **Werner P. Liebig, Jr.**, *Criteria for Success for External Manufacturing: Roles, Relationships and Rewards: One Company's Journey*, Johnson & Johnson, USA; **Bob Piccirillo**, *Better Practices in Developing Effective Contract Manufacturer and Supplier Partnerships*, Jacobs Engineering, USA; **Steve Poehlein**, *Win-Win CMO Relationships: Tools, Tactics, Successes, Challenges*, Merck & Co., Inc., USA

education sessions 11.14.12

406: Sterile Products Processing Update

Aseptic processing technologies and the applicable regulatory requirements are constantly evolving. Learn how different users are handling and managing this change.

Leader: **Manmohan Sihra**, Sihra Consulting, USA

Speakers: **Gordon Farquharson**, *New Technology – Fine Particle Visualization by Laser Sheet*, Critical Systems Ltd., UK; **Rajeev Kabbur**, *Prefilled Syringes – A New Approach*, Brevetti Angela Sri, Italy; **Francesco Nigris**, *Modular Cleanrooms*, Nicos Group, Italy

408: Project Implementation of IT Infrastructure Projects

Explore project implementation using IT infrastructure project case studies, balanced against the processes described in the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* and GAMP®. The session will include hands-on, detail-oriented processes that result in a positive, collaborative leadership style for a wide variety of project types.

Leaders: **Keith Gibbs**, Innovative Process Solutions, USA and **Alf Penfold**, Pfizer, Inc., UK

Speakers: **Mike Barbera**, *IT Project Management – Guided Exercise*, Project Management Advisors, Inc., USA; **GAMP COP**, *Implementation Challenges for IT Projects* (Invited); **Alf Penfold**, *Defining IT Infrastructure Projects/Project Management Case Study/10-Minute Toolbox Topic*, Pfizer, Inc., UK

409: Bridging the Compliance and Operational Excellence Gap

Find the best practices to drive performance of manufacturing operations using methods such as QbD and Operational Excellence. This session will follow a comprehensive, modern approach to managing and assuring quality, including technology, software and information management solutions for continuous process validation that ensures compliance with evolving regulatory expectations.

Leader: **Gilad Langer**, NNE Pharmaplan, USA

Speakers: **Michelle Byas**, BioMerieux, USA (Invited); **Adam Fermier**, Johnson & Johnson, USA (Invited); **Gilad Langer**, *Bridging the Compliance and Operational Excellence Gap by Means of People, Technology and Science*, NNE Pharmaplan, USA; **Representative**, Advanced BioHealing, USA (Invited); **Jeff Schaaf**, Merck & Co., Inc., USA (Invited); **Steve Trank**, Amway, USA (Invited); **Chris Watts**, NNE Pharmaplan, USA; **Clinton Weber**, CMC Icos Biologics, USA

7004: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 4)

Gain insight into the regulatory requirements for the key clinical development countries (Brazil, Russia, India and China) and how to manage these requirements. The program will also provide "real-life" solutions for the proper planning of clinical supplies for these key countries and managing the global supply chain.

Leader: **Neal Gordon**, Merck & Co., Inc., USA

Speakers: **Lorna Briddick**, *Regulatory Requirements for "BRIC" Countries* Schering-Plough, USA; **Hedley Rees**, *Good Distribution Practices – What Do They Mean to You?*, Biotech PharmaFlow Ltd., UK; **Sherri Willson**, *Ensuring Cold Chain Product Integrity for Patient Safety*, Pfizer, Inc., USA; **Steve Yoder**, *IP Update*, Fisher Clinical Services, USA; **Lynn Wang**, *Regulatory Requirements for "BRIC" Countries,* Merck & Co., Inc., USA

13.30 – 16.30

501: Facility of the Future, Impact of Innovative Technology and Continuous Manufacturing

This session will provide you with the current trends in the development, design, construction and operation of drug manufacturing facilities of the future. There will be a 20-minute presentation on specific progress areas.

Leader: **Raj Vora**, Southland Industries, USA

Speakers: **Bikash Chatterjee**, *Tomorrow's Drug Manufacturing Facilities,* Pharmatech Associates, USA; **Hector Davila – Lozada**, *Continuous Oral Solid Dosage Manufacturing – Technology Review,* Professional Sealing Devices Co., USA; **Reinhard Hanselka**, *Provisions and Application of the New "L" Occupancy,* aidi, Inc., USA; **Sarah Mancini**, *Facility of the Future – The Impact of Technology and Continuous Processing,* Pfizer, Inc., USA; **Raj Vora**, *Fast-Track Life Sciences Projects – Why Design-Build MEP Works,* Southland Industries, USA

502: Design and Operation of Water and Steam Systems

Learn practical solutions to problems experienced in every portion of the health science industry. Examples will be provided on how one plant addressed issues via a case study in their bioprocess operations. Water and steam sampling techniques and problem solving will be discussed using the recently published guides *ISPE Baseline® Guide: Water and Steam Systems (Second Edition)* and *ISPE Good Practice Guide: Ozone Sanitization of Pharmaceutical Water Systems*.

Leader: **Joe Manfredi**, GMP Systems, USA

Speakers: **Joe Manfredi**, *Pharmaceutical Water and Steam Sampling Techniques and Problem Solving,* GMP Systems Inc., USA; **Ryan Schad**, *Evolution and Optimization of a High Purity Water System for Bioprocess Operations*, Eli Lilly & Co., USA; **Cameron Sipe**, *Water and Steam Guide Presentation and Roundtable*, Pfizer, Inc., USA; **Phil Sumner**, *Water and Steam Guide Presentation and Roundtable*, Pfizer, Inc.,USA

education sessions 11.14.12

503: Implementing PQS Elements

Engage in interactive discussions with both industry and regulators on how to prevent consequences that lead to unreliable supply and product shortages. A focus will surround biopharmaceuticals and many of the life-saving, medically beneficial yet complex large molecule products that will benefit from these approaches.

Leader: **Joe Famulare**, Genentech, USA

Speakers: **Rick Friedman**, *FDA Overview of PQS – How Do We Implement Modern Quality Systems, Address Legacy Products, Engage Senior Management and Encourage Modern Approaches,* FDA CDER, USA; **Jaspreet Gill**, *Process Performance and Product Quality Monitoring, How Can You Leverage This for New and Legacy Products and in Support of Qbd Approaches,* Baxter Healthcare Corporation, USA; **David Perkins**, *Quality System Management Review QSMR, How Can You Focus on the Heath of Your Products, Keep Senior Management Informed and Prevent Issues Shortages*, Abbott, USA (Invited); **Susan Schleber**, *Change Management PQLI's Latest Guide - Focus on Examples Illustrated in the Guideline and Practical Implementation for Your Products Whether Legacy and/or Include Qbd Elements,* Eli Lilly & Co., USA; **Jeffrey Watson**, *Panel Discussion,* FDA San Francisco District Office, USA (Invited)

504: Compliance and Technology in Emerging Markets

Off-shoring of chemical and pharmaceutical R&D represents a powerful tool to cope with the current productivity challenges in multinational Big Pharma. This session will focus on chemical and pharmaceutical research and development in Asia. In particular, the importance and benefits of off-shoring for clinical R&D, selecting the right partners and the necessity for Big Pharma to go East.

Leader: **Tony Margetts**, Factorytalk Co., Ltd., Thailand

Speakers: **Bikash Chatterjee**, *Technology Transfer in Emerging Markets: A Case Study,* Pharmatech Associates, USA; **Gordon Farquharson**, *Achieving GMP Compliance for Local Operations: Technical – Process and Engineering Systems*, Critical Systems Ltd., UK; **Tony Margetts**, *Achieving GMP Compliance for Local Operations: The Business Environment*, Factorytalk Co., Ltd., Thailand; **David Margetts**, *Achieving GMP Compliance for Local Operations: Computer Systems*, Factorytalk Co., Ltd., Thailand

505: Improving Manufacturing Through Innovation: Continuous Processing and Process Control

Join a forum for best practices and regulatory feedback regarding the application of GMP concepts to continuous processing. Case studies will be based on a continuous process facility consisting of two dosing stations, a continuous mixer, and a tablet press equipped with NIR technology providing 100% inspection for process control.

Leader: **Sunday Kaerner**, Eli Lilly & Co., USA

Speakers: **Jim Cashman**, Eli Lilly & Co., USA; **John Brennan**, Eli Lilly & Co., USA; **Sven Borchert**, *Continuous Processing and 100% Inspection*, Uhlmann Visiotec, Germany; **Sunday Kaerner**, *GMP Aspects of Continuous Processing*, Eli Lilly & Co., USA

506: A Strategic Approach to Containment Systems: An Integrated Process from Concept to Use

This session will provide an overview of containment methodologies by process and include a hierarchy of containment strategy. Challenges will be reviewed for transfers between various pieces of equipment, cleaning, maintenance, industrial hygiene validation and sampling, process sampling and upset conditions. Combining technologies to enhance containment applications will also be discussed.

Leaders: **Alan George**, ILC Dover LP, USA and **Jon Lind**, Corden Pharma Colorado, Inc., USA

Speakers: **Beth Brock**, *Hierarchy of Containment*, Elanco, USA; **Jon Lind**, *Containment Considerations, Options and Applications*, Corden Pharma Colorado Inc., USA; **George Petroka**, *The Updated Good Practice Guide for Assessing Containment Performance (APCCPE)*, IES Engineers, USA; **Bob Sussman**, *Applications of the Updated Good Practice Guide and Making the Case for Testing,* SafeBridge Consultants, Inc., USA

508: Managing Project Closeout, Product Approval, Product Launch

The transition of personnel and project knowledge across the boundary between project closeout and product approval/launch are complex. This session will explore Project Management methodologies using real-worldcase studies and processes described in the *ISPE Good Practice Guide: Project Management for the Pharmaceutical Industry* and *GAMP®*.

Leaders: **Keith Gibbs**, Innovative Process Solutions, USA and **Peter Iles-Smith**, GlaxoSmithKline, UK

Speakers: **Biotechnology COP**, *Project Close-Out – Preparing for Product Approval/Product Launch/Lessons Learned from Closing Out Projects* (Invited); **Peter Iles-Smith**, *Defining Project Close-Out/Project Management Case Study – Project Close-Out*, GlaxoSmithKline, UK; **Los Angeles Chapter**, *An Introduction to the Los Angeles Chapter* (Invited); **Trish Melton**, *Project Close-Out – Guided Exercise/10 Minute Toolbox Topic*, Mime Solutions, UK; **Josef Trapl**, *Major Design Aspects*, M+W Process Industries GmbH, Germany

education sessions 11.14.12

509: Advanced Aseptic Processing

Case studies will be used to learn new innovations and better understand the "c" in cGMP related to the use of RABS or isolators for aseptic processing. Interact with current users of RABS and isolators during the question-and-answer session.

Leader: **Jack Lysfjord**, Lysfjord Consulting LLC, USA and **Ryan Hawkins**, Cook Pharmica, USA

Speakers: **Caroline Eichberger**, *Potent Isolated Syringe Filling Line for Clinical Trial Materials*, Bristol Myers Squibb, USA; **Thomas Huber**, *Update on the Latest Developments in Isolator Technology*, Skan AG, Switzerland; **Manmohan Sihra,** *Optimization of Isolator Glove Maintenance – A Case Study*, Sihra Consulting, USA

7005: Transforming Your Clinical Supply Chain: Finding Your Golden Gate (Part 5)

Gain insight into the regulatory requirements for the key clinical development countries (Brazil, Russia, India and China) and how to manage these requirements. The program will also provide "real-life" solutions for the proper planning of clinical supplies for these key countries and managing the global supply chain.

Leader: **Neal Gordon,** Merck & Co., Inc., USA

Speakers: **Karen Gram**, *Knowledge Sharing: Booklet Label/New Topics*, Novo Nordisk A/S, Denmark; **Christine Milligan**, *Knowledge Sharing: Patient Impact Survey*, Fisher Clinical Services, Inc., UK; **Esther Sadler-Williams**, *Knowledge Sharing: NIMPs*, Catalent Pharma Solutions, UK

Facility Visits

13.00 – 17.00

Take a look at top level facilities and learn the stories of their operations. Limited seating available - **Reserve your spot today!**

Boehringer Ingelheim - Meet with site experts and discuss potential partnerships.

Genentech - The visit will include a traveling tour of FRC (Founder Research Center) and the South Campus.

UCSF Neurosciences Research Building, Block 19A - This facility will house the Institute for Neurodegenerative Diseases, the Department of Neurology and the Keck Foundation Center for Integrative Neuroscience.

Certified Pharmaceutical Industry Professional™ (CPIP™) Information Workshop

Tuesday 07.00 – 08.00
Wednesday 08.00 – 09.00

This complimentary one-hour workshop provides an overview of the CPIP™ Certification Program, a pharmaceutical industry-focused, international competency-based credential made available through the ISPE Professional Certification Commission.

Topics include:

CPIP™ introduction
Eligibility criteria
Overview of the application, examination and recertification processes
Information on CPIP™ study groups

ISPE PCC CPIP Certified Professional Industry Practitioner

ISPE Professional Certification Commission

training Tuesday, 13 November – Wednesday, 14 November

During this conference, ISPE will conduct topic-intensive training courses. These courses are designed to provide delegates with an in-depth learning experience around specific new technology such as Quality by Design (QbD), Quality Risk Management and GAMP. For registration information, see page 47 or visit www.ISPE.org/2012SanFranciscoTraining.

Practical Application of Computerized Systems Compliance: Applying the GAMP® 5 Guide: A Risk-based Approach to Compliant GxP Computerized Systems (T11)

Instructor: Jim John | CEUs: 1.5

This highly interactive workshop gives participants hands-on experience in applying practical techniques and solutions to solve computerized systems compliance challenges. Participants will discuss and analyze case studies, apply newly acquired knowledge to hypothetical case-study systems, and have the opportunity to discuss their own real-life challenges with other participants and an expert trainer.

Take Back to Your Job

- Build upon and expand understanding of the regulatory requirements and expectations for the compliance of computerized systems used in pharmaceutical manufacturing
- Apply this understanding to example systems and case studies
- Analyze case studies and apply the GAMP® 5 process for achieving compliance and fitness for intended use
- Apply quality risk management and risk assessment concepts

Applying Quality Risk Management (T42) – New Course!

Instructor: Steve Wisniewski | CEUs: 1.3

Through interactive workshops, this course will explain and apply the key principles of QRM programs that need to include Quality Systems elements (ICH Q10) within the product/system lifecycle.

Take Back to Your Job

- Understand the philosophy and application of a holistic QRM process through the development of a Quality Risk Management Plan
- Learn how to develop and implement a risk decision tree and the appropriate use of risk assessment tools
- Know the *ISPE Guide: Risk-Based Approach for the Delivery of Facilities, Systems, and Equipment* and the *ISPE Good Practice Guide: Applied Risk Management for Commissioning and Qualification* and how this aligns with the overall implementation of a robust QRM system that is applicable for the product lifecycle
- The ability to apply risk management methodologies throughout design and verification phases
- Explain the link between risk assessments, design review and quality risk management
- Understand the expected format of the risk management plan and file inclusive of risk ranking
- Understand the importance, format and maintenance of a Risk Dashboard
- Summarize US/EU/SFDA/WHO regulatory requirements, citations and expectations that may influence the implementation of a holistic QRM process

Turning QbD into a Practical Reality (T43) – New Course and Guides!

Instructor: John Donaubauer | CEUs: 1.3

Through group exercises and new Guidance Documentes (*Part 1 – Product Realization using Quality by Design (QbD): Concepts and Principles* and *Part 2 – Product Realization using Quality by Design (QbD): Illustrative Example*), the course will delve into implementation and operation of an effective and efficient control strategy in manufacturing which is a key element of process performance and product quality monitoring and continual improvement. The link to control of attributes and parameters to relevant critical quality attributes of the product and application and implementation of enhanced QbD approaches and USFDA Process Validation Guidance will also be explored.

Note: This course will not cover the regulatory submission processes or detailed engineering designs.

Take Back to Your Job

- Understand and apply QbD terminology, including the principles of a science- and risk-based approach, the importance of product and process understanding and patient requirements
- Use tools and techniques provided to understand the application of Quality Risk Management (QRM)
- Understand the implications of relevant ICH, EMA and FDA Guidelines
- Learn about the QbD process
- Review some QRM tools (FMEA, risk ranking) and apply FMEA to Control Strategy selection
- Understand the relationship between PQS and GMP and how they link to Control Strategy
- Understand the considerations when implementing a control strategy derived from enhanced, QbD approaches
- Review the scope of the US FDA Process Validation Guidance, including equipment qualification, ASTM E2500 and the ISPE Commissioning and Qualification Guide and the links to science- and risk-based approaches
- Examine opportunities for continual improvement arising from application of statistical techniques

Did you know that ISPE offers custom training for companies at their facility?

For more information, contact Ali Montes: amontes@ispe.org or +1-813-960-2105.

thank you

Annual Meeting Program Committee Chair:
Robert Chew
President, Commissioning Agents, Inc., USA

ISPE would like to thank the following 2012 ISPE Annual Meeting Committee Members.

Annual Meeting Program Committee Members:

Deepak Agarwal
Director, Pharma Technology
Jacobs Consultancy, USA

Michael Arnold
Senior Director, Strategic Partnerships
Pfizer, Inc., USA

Jane Brown
Director of External Advocacy
GlaxoSmithKline, USA

Jennifer Lauria Clark, CPIP
Southeast Manager of Technical Services
Commissioning Agents, Inc., USA

Charlotte Enghave Fruergaard, PhD
Director of Technology
NNE Pharmaplan, Denmark

Charles Hoiberg
Executive Director
Pfizer, Inc., USA

Tim Howard
Vice President
Commissioning Agents, Inc., USA

Gary Knight
Project Manager
Commissioning Agents, Inc., USA

Gordon Leichter
Regional Sales Manager
Belimed, Inc., USA

Randy Perez
Director IT Risk Managment Compliance
Novartis Pharmaceuticals, USA

Allen Pfitzenmaier
President
Vectech Pharma Consultants, Inc., USA

Emily Stump
Validation Scientist
Commissioning Agents, Inc., USA

Cheryl Tucker
Alliance Management
Eli Lilly & Co., USA

Annual Meeting Local Hosts:

Kelly Keen
Senior Project Manager
Genentech, USA

Ian Larson
Director Business Development and Project Executive
Dome Construction, USA

David Bendet
Architect – Science+Technology Leader
Perkins+Will, USA

Simon Forder
Principal Consultant and CEO
Hyde Engineering + Consulting Inc., USA

Karl Wilks
President and Principal Engineer
WCS, Inc., USA

The San Francisco Bay Area Chapter will have many more volunteers helping at the event.

networking events

ISPE understands that conferences are not only an educational opportunity; they are also a valuable chance to build your professional network and discuss the common challenges faced by the industry.

We are dedicated to bringing together ideas, expertise and industry leaders to provide you with a forum for career growth, education, participation and knowledge. Through our recognition and social events, you can participate in celebrating industry success.

networking events

Young Professionals/ Student Luncheon

Sunday, 11 November
12.30 – 15.00

This Luncheon and Orientation is your chance to meet other ISPE Members and professionals in your peer group, learn about industry trends and make valuable connections to boost your career potential.

New Member/First-Time Attendee Orientation

Sunday, 11 November
16.00 – 17.00

New to ISPE or to Annual Meeting? This Orientation session will help make the most of your time at Annual Meeting. Veteran ISPE Members will share their experience and tips for a successful Annual Meeting experience.

Welcome Reception

Sunday, 11 November
17.00 – 19.00

Network over hors d'oeuvres, catch up with old friends and meet new ones. More than 250 suppliers will be onsite to answer questions and share industry knowledge. Be sure to stop by the Facility of the Year Awards booth to learn about the 2012 Category Winners and their innovative projects

Charity 5K Run/Walk

Monday, 12 November
06.00 – 07.00

Start the day off with a run with fellow Members and guests - everyone is welcome! The Crissy Field route is one of the world's most beautiful running courses, taking you along the San Francisco Bay with views of the Golden Gate Bridge and the San Francisco skyline. Transportation will be provided.

New Member/First-Time Attendee Breakfast

Monday, 12 November
07.15 – 08.15

ISPE has made the most important meal of the day even more important. Take part in this high-impact networking session where you will get to build new relationships with fellow conference attendees. **Don't forget your business cards!**

Register through the 2012 Annual Meeting Delegate Registration Form online by checking "I'm a New Member" or "I'm a First Time Attendee" box.

Communities of Practice (COP) Night General Reception

Monday, 12 November
17.30 – 19.00

Join these groups of like-minded professionals for casual networking activities while enjoying delicious appetizers and cold beverages.

Admittance is complimentary for full education delegates and exhibitors, but you must register for the COP Night General Reception on your event registration in order to join the fun!

Young Professionals Dinner

Monday, 12 November
19.30 – 22.00

Everyone is welcome to enjoy an evening of fun hosted by ISPE's Young Professionals. This year's event will take place at San Francisco's famous Jillian's at Metreon, where you will enjoy great food, networking and the largest billiard lounge in the city. Register online.

ISPilates

Tuesday, 13 November
06.00 – 07.00
Wednesday, 14 November
07.30 – 08.30

Wake up with ISPilates. Led by a fellow Member, the class will incorporate yoga, stretching and breathing in a basic core strength class, perfect for beginners but challenging enough for a seasoned athlete. Register online or email ISPE.

Young Professionals Morning Meet and Greet

Tuesday, 13 November
07.00 – 08.00
Wednesday, 14 November
08.00 – 09.00

Join the Young Professionals Tuesday and Wednesday mornings for an opportunity to meet like-minded professionals and learn about the educational sessions offered for the day. Brief introductions and overviews of the session topics will be provided to help you choose which sessions are right for you and to provide you with some background before attending. Meet some new faces or find a mentor to join you during the educational sessions. All are welcome to attend – Young Professionals and our "Seasoned Veterans" alike!

Membership Luncheon

Tuesday, 13 November
11.45 – 13.15

Join ISPE leadership and colleagues for a banquet lunch as we review Society accomplishments from 2012 and look ahead to 2013 goals. Special recognition awards will be presented to Members, Affiliates, Chapters, Committees, companies, Authors, and Students who have made significant contributions to ISPE this year.

Tuesday Night Party – Streets of San Francisco

Tuesday, 13 November
19.00 – 22.00

ISPE is bringing the city to you! Experience beautiful San Francisco without leaving your hotel on Tuesday night.

Take a stroll through Chinatown or Little Italy to taste the exotic and savory flavors of these prominent districts. Visit Fisherman's Wharf for some seafood and don't forget to save room for dessert at Ghirardelli Square – a must stop for chocolate lovers.

Dance the night away at the San Fran Discotheque. Hit AT&T Park and play a variety of games or simply enjoy sideline highlights. Perhaps city life is not for you – then head to a more quiet corner for networking and catching up with friends. You don't want to miss this City by the Bay evening. It will be a night to remember. **Register online today!**

Cycling for a Cure Organizing Meeting

Wednesday, 14 November
11.00 – 12.00

LEUKEMIA & LYMPHOMA SOCIETY® | TEAM IN TRAINING®

Plan to attend an organizing meeting for "Team ISPE," our own volunteer cycling team that will train to ride in "America's Most Beautiful Bike Ride" (on 3 June 2013). This century ride (100 miles) around Lake Tahoe is in conjunction with the Leukemia & Lymphoma Society's Team in Training Program. Those interested in being a part of our virtual team will train with a national cycling coach and work with fundraising mentors as part of the LLS Team in Training Program.

Facility Visits

Wednesday, 14 November
13.00 – 17.00

Look at top level facilities and learn the stories of their operations. **Limited seating available – Reserve your spot online today!**

Tours Include:

Boehringer Ingelheim
The guided tour of the Boehringer Ingelheim state-of-the-art cell culture facility will demonstrate their core capabilities in process development and manufacturing. Explore and witness biopharmaceutical manufacturing, highest quality standards and overall excellence. Meet with site experts and discuss potential partnerships.

Genentech
The visit will begin with a short presentation of the integration of Roche and Genentech and how they work together, followed by a tour of the campus including Founder's Research Center and South Campus.

UCSF Neurosciences Research Building, Block 19A
This facility will house the Institute for Neurodegenerative Diseases, the Department of Neurology and the Keck Foundation Center for Integrative Neuroscience. Bringing together these three UCSF departments, the building is designed to encourage collaboration among investigators working in clinical, translation and basic research focused on the development of treatments and cures for diseases of the nervous system at functional and molecular levels such as Alzheimer's Disease, Parkinson's Disease, Lou Gehrig's Disease (ALS) and Multiple Sclerosis.

guest options

Explore San Francisco one day at a time!
Choose from any or all of the tours below.
Reserve your spot now!
See page 47 for registration details.

San Francisco Highlights

Sunday, 11 November
13.00 – 17.00

Discover 49 square miles of San Francisco, where you will see legendary landmarks of "Everybody's Favorite City."

Cost includes: roundtrip transportation via deluxe motorcoach and narration by professional uniformed guide.

Magical Marin

Monday, 12 November
10.00 – 14.30

Cross the Golden Gate Bridge into Marin County to visit Muir Woods National Monument, where you can enjoy ancient giant sequoias trees. The next stop, Sausalito, will give you a chance to explore unique boutiques and galleries or just walk around the waterfront and view the San Francisco skyline and Bay.

Cost includes: roundtrip transportation via deluxe mini-coach, narration by professional uniformed guide, admission fee to Muir Woods, time to stroll in Sausalito.

Alcatraz: "The Rock"

Tuesday, 13 November
08.30 – 12.30

Starting at the San Francisco waterfront, you will take a short ferry ride across the Bay to "the Rock," to visit the cells once occupied by the nation's infamous and incorrigible criminals. An audio tour contains interviews with former prisoners and guards from "the Rock," providing you with a fascinating insight into life here in the middle of the San Francisco Bay.

Cost includes: roundtrip transportation via deluxe motorcoach, narration by professional uniformed guide, guaranteed ticket (purchased in advance) to Alcatraz Island, National Park fee at Alcatraz and Alcatraz audio tour.

Chinatown Discovery

Wednesday, 14 November
13.00 – 16.00

A walking excursion - discover exotic Chinatown! From the towering steel and concrete of the Financial District, you will pass the historic Lion Gates and be transported into the "city-within-the-city," which recalls the days of early Chinese immigration. Enjoy a walking tour down the narrow streets and alley of this historic neighborhood with a knowledgeable tour guide.

Cost includes: roundtrip transportation via deluxe motorcoach, narration by professional uniformed guide, walk in groups of 10-12 people, donation and admission to Buddhist Temple and Fortune Cookie Factory.

onsite services

Expand and enhance your Annual Meeting experience!

Career Solutions Onsite

Visit the ISPE 2012 Annual Meeting Career Solutions Job Board to review job postings and potentially meet with prospective employers who are exhibiting at the event.

Employers, gain exposure to a highly targeted and experienced audience – all 2012 Annual Meeting delegates, Students, speakers, Committee Volunteers, and exhibitors. Please visit www.ISPE.org/CareerSolutions to view Featured Employer packages for this event or contact **Valerie Valentin at vvalentin@ispe.org** for more information.

CAREER SOLUTIONS

Internet

Wireless internet will be available throughout the meeting areas. You can also stop by the Cyber Café to check email or charge your wireless devices.

Volunteer Lounge

The Volunteer Lounge is one of the ways ISPE recognizes the hard work of the Volunteers who dedicate their time to work on Society initiatives. Enjoy complimentary wireless internet access, desktop computer, and access to a printer in your temporary onsite office.

ISPE Knowledge Center

Visit the ISPE Knowledge Center for answers to all of your ISPE and Annual Meeting questions. The Knowledge Center is also home to the ISPE Bookstore, where you can browse ISPE's world-renowned Guidance Documents, including these valuable new releases:

- *GAMP® Good Practice Guide: A Risk-Based Approach to GxP Compliant Laboratory Computerized Systems (Second Edition)*
- *GAMP® Good Practice Guide: Testing of GxP Systems (Second Edition)*
- *ISPE Guide: Biopharmaceutical Process Development and Manufacturing*

20% OFF
Guidance Documents

ISPE Members receive 20% off all Guidance Documents purchased onsite.

Stock up and take advantage of the savings!

ISPE – Membership Has its Benefits

Did you know that ISPE Members attend training programs and other events at discounted rates?

New Member registration fees include a one-year ISPE membership, a $239 value. Visit www.ISPE.org/Join for details on Member benefits and special rates for Young Professionals, Students, Regulators and persons from countries with Emerging Economies.

exhibit
hall schedule

Sunday, 11 November
13.00 – 19.00 Exhibit Hall Open
15.00 – 15.45 Networking Break
17.00 – 19.00 Welcome Reception

Monday, 12 November
07.00 – 17.00 Exhibit Hall Open
07.00 – 08.15 Continental Breakfast
10.00 – 11.00 Networking Break
12.00 – 13.00 Lunch
14.45 – 15.30 Networking Break

Tuesday, 13 November
07.00 – 16.00 Exhibit Hall Open
07.00 – 08.00 Continental Breakfast
09.30 – 10.15 Networking Break
15.00 – 15.45 Networking Break

thanks our Sponsors

PINNACLE PROGRAMME
2012 Global Sponsor

CAI
Commissioning Agents, Inc.
An Employee-Owned Company

HOST SPONSOR

PHARMATECH ASSOCIATES

PLATINUM SPONSOR

PROPHARMA GROUP

SILVER SPONSORS

acco engineered systems

bürkert FLUID CONTROL SYSTEMS

SPECIALITY ITEMS

Hotel Key Card
ips

Sunday Welcome Reception
INNOVATION + INTELLIGENCE + PASSION
INTERPHEX

Badge
YONKERS

Bag Stuffer
CH2MHILL
MIT PROFESSIONAL EDUCATION
M+W GROUP
SYNCADE

Lanyard
CAI Commissioning Agents, Inc.

Tuesday Night Party
werum SOFTWARE & SYSTEMS

5K
Belimed Infection Control

Exhibit Hall Give Away

BlueCielo ECM SOLUTIONS
MARCHESINI GROUP U.S.A. Sales organization
NICOS GROUP
PHARMATECH ASSOCIATES
QUMAS
SOUTH CAROLINA POWER TEAM

exhibits and sponsorships

Annual Meeting Exhibits

The 2012 ISPE Annual Meeting provides an excellent opportunity to gain exposure for your company. Exhibiting at Annual Meeting is the perfect occasion to showcase your innovative products and services, reinforce your brand profile and establish new business relationships. **Limited space is still available.** For a full list of current exhibitors, please visit www.ISPE.org/2012-Annual-Meeting/Exhibits.

Support ISPE as an Annual Meeting Sponsor

Choose from a variety of sponsorship packages designed to build brand awareness and increase your exhibit traffic. Many sponsorship opportunities include: exposure via web and electronic communication before, during and after the event; onsite exposure through value-added exhibit opportunities, signage and mentions in print materials. For more information, contact **John Phillips at jphillips@ispe.org** or **Daniel Murphy at dmurphy@ispe.org.**

general info

Dress is Business Casual
Dress for all ISPE Annual Meeting delegate functions is business casual. The evening functions are casual. Typical November weather in San Francisco calls for average high temperatures around 63°F/17°C and lows around 50°F/10°C. Temperatures in meeting rooms tend to be cool, so bring a light jacket or sweater

Notice Regarding Speakers
Speakers selected to present programs are leading professionals in their fields. However, it may be necessary to make substitutions. If so, every possible effort will be made to substitute 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.

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 fields or professions. 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 Website, www.aia.org.

ACPE CEUs
ACPE CEUs are awarded only for educational offerings that relate to Investigational Product topics. Application for these credits is pending.

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 Member fees.

Guests
Guest registration for these events is available. Visit the registration page online for easy steps to register for networking events and optional tours.

Hotel
In order to make the most of your Annual Meeting experience, we strongly advise that you stay at the San Francisco Marriott Marquis, the official headquarters of the 2012 ISPE Annual Meeting. This beautiful property will keep you at the center of the action so you won't miss a single minute of valuable education or networking opportunities. Make your reservations through ISPE immediately and take advantage of the discount room rate of **US$274** per night.

Education Program and Exhibit Badge Cancellations
Education program and exhibit badge cancellations will be accepted only in writing. Cancellations will result in a $100 cancellation fee. **No refunds after 22 October 2012.** Telephone cancellations will not be accepted.

Members-in-Transition
If you are unemployed, but would like to attend the conference to network with other professionals, contact Member Services for details about options available to you. **Email memberservices@ispe.org** or **call +1-813-960-2105.**

hotel information

San Francisco is often called "Everybody's Favorite City," because of its scenic beauty, cultural attractions, diverse communities, and world-class cuisine. Measuring 49 square miles, this city is dotted with landmarks like the Golden Gate Bridge, cable cars, Alcatraz and the largest Chinatown in the USA. A stroll of the City's streets can lead to Union Square, Fisherman's Wharf, the Castro, Japantown and the Mission District.

San Francisco Marriott Marquis

55 Fourth Street
San Francisco, California 94103
+1-415-896-1600
www.sfmarriott.com

The San Francisco Marriott Marquis is the headquarters hotel for the ISPE 2012 Annual Meeting. It is a downtown hotel located just south of Market Street.

Reservations

Reservations need to be made through ISPE. The ISPE room rate is **US$274 single/double**. Thank you for staying at the Marriott Marquis as this enables ISPE to meet contract requirements for the event.

How to Make a Hotel Reservation

1. *Use a credit card and register completely online for the Annual Meeting Conference. Once you have registered for the Conference online, you will see the link on the order detail page to make your hotel reservation.*

2. *Or, fax or mail your reservation request with credit card information to ISPE, or send a check or money order covering the first night's stay (US$316.72 including taxes) drawn on a US bank and payable to the Marriott Marquis.*

Make your hotel reservation immediately in order to ensure a room at the headquarters hotel. Changes may be made by following the directions from your hotel acknowledgement email. When sending changes to ISPE, please send in writing.

ISPE will send the reservations to the hotel on 17 October 2012. The hotel will send out confirmations by email after 18 October 2012. **Please do not contact the hotel directly about your reservation until after 19 October 2012**.

Nonrefundable Deposit

A deposit of one night **(US$316.72 including taxes)** is required to hold your room reservation and is **nonrefundable after 17 October 2012**. Credit cards will be charged for one night as of 18 October 2012. Please complete the credit card information in full in order to have a guaranteed reservation.

Cancellation Policy

Guests cancelling their stay **after 18.00 on the day of check in will be charged for their full stay**. Any cancellations after 17 October 2012 will be charged the deposit stated above. Please note that if you do not arrive on the first day of your room reservation, the Marriott Marquis will charge you a no-show fee equal to one night and may not have a hotel room available when you arrive. *Please remember to contact the hotel if you are delayed.*

Upgrade Requests

Please make your reservation through ISPE first, then you can contact Michael Lopez - michael.j.lopez@marriott.com to ask about room upgrade options.

Airport Transportation

The closest airport to the Marriott Marquis is the San Francisco International Airport or the Oakland International Airport. Both offer shuttle services or Subway/BART access.

registration

Annual Meeting Full Education Delegate Fees	ON or BEFORE 15 October	AFTER 15 October
Current Member Fee	US$1,700	US$1,900
New Members (Fee includes one year ISPE Membership)	US$1,940	US$2,140
Non-Member Fee	US$2,040	US$2,250
Committee Fee	US$950	US$950
Young Professional	US$950	US$950
Government	US$950	US$950
Emerging Economy	US$950	US$950
Academia Member	US$950	US$950
Student Members	US$525	US$525

Single Day Fees		
Member* Sunday 1/2 Day	US$300	US$350
Member* Monday, Tuesday, Wednesday 1-day (does not include night events)	US$600	US$700
*One day choice to Members only - Sun. or Mon. or Tues. or Wed.		

A La Carte Event Fees	
Monday Charity 5K Run/Walk	US$25
Monday Lunch (included in full education and exhibitor badge)	US$65
Monday COP Reception (included in full education and exhibitor badge)	US$45
Monday Young Professionals Networking Event (dinner, cash bar)	US$50
Tuesday Night Party (included in full education)	US$200
Tuesday Lunch/Awards (included in full education)	US$65
Wednesday Lunch (included in full education)	US$55
Facility Visits	US$50
Optional Tour: San Francisco Highlights	US$38
Optional Tour: Magical Marin	US$63
Optional Tour: Alcatraz:"The Rock"	US$74
Optional Tour: Chinatown Discovery	US$43

Training Fees	ON or BEFORE 15 October	AFTER 15 October
Member	US$1,710	US$1,910
New Member	US$1,949	US$2,149
Non-Member	US$2,050	US$2,260
Government	US$855	US$855
Student/Academic/Emerging Economy	US$855	US$955

How to Register

Online: www.ISPE.org/2012AnnualMeeting
Via Fax: Complete the registration forms online and fax them to: +1-813-264-2816
Via Mail: Complete the registration forms online and mail them with payment to: ISPE Headquarters, 600 N. Westshore Ave., Suite 900, Tampa, Florida 33609 USA
Questions? Call ISPE at tel: +1-813-960-2105 or email: ask@ispe.org

Full Access

Full conference registration includes access to all four days of conference educational sessions, continental breakfast, breaks, lunches (Monday – Wednesday), Sunday Welcome Reception, Monday COP Reception and the Tuesday Night Party. Full conference registration does not include training courses.

Alternately, you may also purchase a one-day pass to attend daytime education on Sunday, Monday, Tuesday or Wednesday. The one-day pass does not include evening events or training courses, which may be purchased a la carte.

Optional Tours

To register for Optional Tours, fill out the Optional Tours Form Online and send by mail, or email ispe@mana-allison.com by **Friday, 19 October 2012.** Alcatraz Tours must be submitted by **Friday, 30 August 2012.** Tours cancelled prior to the cancellation date (same as the registration date stated above) will be refunded in full minus a 10% administrative charge. No refunds will be available after the deadline dates. Tour tickets will not be mailed. You may pick up your ticket at the ISPE Registration desk or Tour Desk starting on Sunday, 11 November 2012. Tour registrations will be available onsite, based upon availability.

Payment

Payment must be included with registration. Complete credit card information is required for all registrations. We accept American Express, VISA, or MasterCard. 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. For more information, visit the Conference Hotel Reservations Page.

Confirmation

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 22 October 2012.**

Registration Agreement

By registering for this event, I grant ISPE permission to record and/or copy my image and the right to use these images for education, outreach, promotional or archival activities and other purposes of trade without limitation and/or compensation. I hereby waive any right to inspect or approve the finished photograph or advertising copy or printed matter. By registering for this event, I hereby exempt ISPE, its staff, Board and Advisory Board, or its agents from any and all liability resulting from said use. If you do not want to have your picture taken and be used in future ISPE promotional materials, please inform ask@ispe.org.

ISPE Global Headquarters
600 N. Westshore Blvd., Suite 900
Tampa, Florida 33609 USA

Tel: +1-813-960-2105
Fax: +1-813-264-2816
Email: ask@ispe.org

www.ISPE.org

register today

ISPE.org/2012AnnualMeeting

ISPE European Office
Avenue de Tervueren, 300
B-1150 Brussels, Belgium
Tel: +32-2-743-4422
Fax: +32-2-743-1550
Email: ispe@associationhq.com

ISPE Asia Pacific Office
20 Bendemeer Road
#04-02/06, Cyberhub
Singapore 339914
Tel: +65-6496-5500
Fax: +65-6496-5599
Email: asiapacific@ispe.org

ISPE China Office
Suite 2302, Wise Logic
International Centre
66 North Shan Xi Road
Shanghai, China 200041
Tel: +86-2-151-160265
Fax: +86-2-151-160260
Email: china@ispe.org