

Networking and Social Events

Continue the conversation! The 2017 ISPE Annual Meeting & Expo provides attendees with maximum opportunities to network with industry professionals and regulators.

ISPE San Diego Chapter Golf Tournament

Saturday, 28 October **12.00**
Champions Course at Omni La Costa Resort & Spa *Shotgun Start*

Welcome Reception in the Exhibit Hall

Sunday, 29 October **17.00 - 18.30**
US\$85 (included with Full Education Registration)
Enjoy food and beverages while networking with your peers and representatives from 200+ exhibiting companies.

5K Charity Run/Walk along the San Diego Bay

Monday, 30 October **06.45**
US\$30
Sign up and start your day exercising with others in beautiful San Diego.

Sponsored by:



Proceeds benefit the World Federation of Hemophilia USA.



Young Professionals Networking Event

Monday, 30 October **19.00 - 21.30**
US\$55
The Topsy Crow
(includes food and entertainment; cash bar)

Enjoy entertainment and networking with other Young Professionals. The Topsy Crow occupies one of Downtown's most historic buildings, the Spencer-Ogden building, dating back to 1874. The event will be in the upstairs Nest. Must be over 21.

Membership and Awards Breakfast

Tuesday, 31 October **08.00 - 10.00**
US\$50 (included in Full and Tuesday-Only Education Registrations)
Join ISPE leadership and colleagues for breakfast as we review and recognize the industry's significant achievements of 2017. Celebrate with your peers as the **2017 Facility of the Year (FOYA) Overall Winner** and ISPE International Honor Awards are presented.



Annual Meeting Party Aboard the USS Midway Aircraft Carrier

Tuesday, 31 October **19.00 - 22.00**
US\$225 (included with Full Education Registration)



Join us for a night to remember on one of the longest-serving aircraft carrier designs in history. The Midway is the most-visited floating naval ship museum in the world. Enjoy this living piece of history while networking and having dinner and drinks.

During the party you'll have the chance to explore the entire ship including docent-led tours below decks, simulator rides, 32 restored aircraft, and a unique gift shop.

Facility Tours

Wednesday, 1 November **11.00 - 18.00**
US\$55

Take advantage of behind-the-scenes access to world renowned facilities. All facility tours will include transportation, tour, and lunch. There is limited seating, so reserve your space early!

Genentech Inc. and Gilead Combined Tour

Genentech is a leading biotechnology company that discovers, develops, manufactures, and commercializes medicines to treat patients with serious or life-threatening medical conditions.

Gilead Sciences, Inc. commissioned DGA Architects to design a new development laboratory and cGMP warehouse facility. The B800 project consisted of approximately 263,000 square feet of interior improvements.

illumina Tour

illumina is a leading developer, manufacturer, and marketer of life science tools and integrated systems for large-scale analysis of genetic variation and function. These systems are moving us closer to the realization of personalized medicine.

Brewery Tour

The first stop will be Ballast Point Brewing Company for a behind-the-scenes tour and lunch. This is one of the most advanced brewery labs in the U.S. You will learn about some of the state-of-the-art analytical equipment and processes they use in their lab including HPLC, PCR, and sequencing. Additionally, there will be one to two other breweries on the tour.

Exhibits and Sponsorships

The ISPE Annual Meeting attracts hundreds of decision makers and industry leaders. Don't miss out! Exhibit space is selling fast. Sponsorships and customized packages are still available.

Please contact **Alisa Pachella, Account Manager** at +1-813-739-2274 or apachella@ispe.org for more information and to discuss your marketing needs.

▶▶▶ **Find more details at**
www.ISPE.org/2017-Annual-Meeting



Join ISPE in
Sunny San Diego!

Why Attend?

- Discover new ideas and solutions to complex pharma and bio pharma manufacturing challenges
- Gain industry support for individual professional and company initiatives
- Hear regulatory perspectives and engage in open discussions with regulators and industry
- Network with all levels of the industry – from the C-suite to engineers to regulators
- Access unique opportunities tailored specifically for early career engineering professionals
- Benefit from professional development sessions



600 N. Westshore Blvd., Suite 900
Tampa, FL 33609 USA

2017 ANNUAL MEETING & EXPO

DRIVING INNOVATION TO ADVANCE PATIENT THERAPIES

29 Oct. - 1 Nov. | San Diego, CA

Register Now!
www.ISPE.org/2017-Annual-Meeting



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Keynote Speakers

Sunday, 29 October



Pam Cheng
Executive Vice President of Global Operations and IT
AstraZeneca

Ensuring a Seat at the Table for Manufacturing Operations

Pam Cheng has a wealth of experience in manufacturing and supply chain and commercial operations. She is responsible for all of manufacturing and supply, procurement, and IT, globally for the company. In addition, Pam serves on the Board of Directors for Codexis, an industrial biotechnology company based in California, USA.



Enno de Boer, PhD
Partner and Leader of Digital Manufacturing North America
McKinsey & Company

Digital Manufacturing: The Next Frontier of Innovation

In addition to being a Partner and Leader of Digital Manufacturing North America, Dr. de Boer is a global leader for McKinsey's Digital Capability Center (DCC) and model factory network. He has 20 years of experience serving clients in leading operations topics across industries.

Monday, 30 October



Roger Connor
President, Global Manufacturing and Supply, GlaxoSmithKline

Bringing the Outside In: How Inspiration from outside Pharma Can Transform Our Approach to Manufacturing

Roger Connor is a Mechanical and Manufacturing Engineering graduate who then trained as a Chartered Accountant. He has been working in the pharmaceutical industry for 21 years having spent two years with AstraZeneca and the last 19 years working in various parts of the manufacturing organization within GSK. He has worked at sites in the UK and Ireland and has held a number of central strategic roles.



Glenn Pierce, MD, PhD
World Federation of Hemophilia Board of Directors and Former Senior Vice President Hematology, Cell and Gene Therapy, Biogen

Innovation in Hemophilia: From Blood to Genes and the Unintended Consequences along the Way

Dr. Glenn Pierce is currently an independent consultant, entrepreneur-in-residence at Third Rock Ventures, and serves on the World Federation of Hemophilia (WFH) and WFHUSA Board of Directors and the National Hemophilia Foundation (NHF) (US) Medical and Scientific Advisory Council. He is also a director of Voyager Therapeutics and Global Blood Therapeutics, two publicly held biotechnology companies.

Register Now!
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Education Designed to Fit Your Needs

New Sessions and Formats to Enhance Your Experience

8 Fast-Paced Sessions

- **Asset Information Lifecycle Modelling**
- **Leverage Expiry Date Planning to Reduce Waste – Manufacturing Enterprise Facility Design**
- **Oligonucleotide Synthesis Manufacturing Facility Solutions**
- **Paperless Manufacturing**
- **Surplus Equipment Disposition: Managing Surplus Assets**
- **The Manufacturability Concept of a Commercial Product**
- **Using Statistical Process Control to Meet Product Quality Requirements**

7 In-Depth Workshops

- **Asset Management Triggers to Promote Design for Reliability**
- **Creating a Strong Quality Culture: A Stepwise Interactive Process**
- **Emerging Therapeutic Modalities and Novel Medical Devices**
- **Maximizing Manufacturing Utilization through Facility Design**
- **Production Control Strategy: Enabling Right First Time and Data Integrity**
- **Risk, Reliability, Performance, Compliance, and ASTM E2500**
- **Aligning System Validation and Data Lifecycles**

4 Featured Sessions

- **3D Printing Technology in Dosage Form Design and Drug Delivery**
- **ICH Q12: Fostering Change and Innovation**
- **From College to the Real World: Biotech Facility Design**
- **Career Strategies for Early Career Professionals – Sponsored by**



Track Highlights

End-to-End Supply Chain Management

From Clinical Trials to Commercialization – Managing Supply Chains through Innovative Solutions and Technology

Topic Preview:

- Connecting the Supply Chain Dots: Sales, Inventory, Order, Make, and Deliver
- Exploring Overage from All Directions
- Future Utilization of MedLabel for Clinical Trials
- Shipping Temperature Controlled Products
- Renovating Flexible Laboratories for Changing Research
- Serialization: Holistic Approaches, Current and Predicted Trends
- Techniques to Improve Supply Chain Flexibility and Responsiveness
- The PRA-Takeda Strategic Partnership: Is It the Wave of the Future?
- Using Artificial Intelligence to Take the Mystery out of Supply Chain Planning

Facilities and Equipment

Meeting Unique Requirements for Facility Design and Production

Topic Preview:

- A New Biomanufacturing Paradigm: Off-The-Shelf Facility
- Adaptive Mobile BioPharma Production Suite
- Amgen Singapore Next Generation Manufacturing
- Compliant and Sustainable Facilities: The Future of Pharma
- Improving Efficiencies in Animal Research Labs
- Genentech Oceanside: A Flexible CHO Manufacturing Facility
- Integrated Project Delivery – Best Methods and Practices
- Managing Risk in a Live Facility Renovation
- Pharmaceutical Water Sampling Strategies and Techniques
- Product, Process, and Protection for Solid Dose Therapies
- Sterile Manufacturing: New and Legacy Facility Design and Operation
- Structuring the Execution of the World's Largest Biotech Project
- Water Savings: Green for Your Wallet and the Environment

Information Systems

Driving Innovation with Integrity in Life Science Information/GAMP®

Topic Preview:

- Validation of Computerized eClinical Systems and Data: Supplier and Regulatory Perspectives
- Current Perspectives on Data Integrity: Linking Regulatory Guidance and Observations
- Data Integrity in Clinical Studies: Sponsor Perspective
- Data Integrity, the Cloud, and Compliance with CGMP
- Information Governance for Data Integrity
- The ART of Efficient and Effective Computer Systems Validation

Innovation Forum

Navigating the Current Landscape of Pharmaceutical Research, Development, and Manufacturing for Successful Innovation

Topic Preview:

- 3D Printing Technology in Dosage Form Design and Drug Delivery
- Emerging Methods, Equipment, and Technologies
- Emerging Therapeutic Modalities and Novel Medical Devices
- Global Regulatory and Industry Environments
- Innovative Trends and Applications in PAT
- Innovative, Value-Added, Cross-Industry Strategic Partnerships
- Sustainability: Eco-Friendly Trends and Practices

Product Development and Production Systems

Developing Agile and Flexible Production Systems for the Next Decade

Topic Preview:

- Agility in Biotechnology Process Development
- All-in-One Map: Selection of Prefilled Syringes for mAbs
- Continuous Bioprocessing: Current and Future State
- Engineering and Design for Continuous Manufacturing
- Facility Design Using Standardized Single-Use Assemblies
- Lessons from Implementing BPOG's Risk-Based Deviation Management
- Manufacturing Control Strategy – Real-Time Release
- Process Capabilities for Pharmaceutical and Biotech Industry
- Transformative Thinking for Cellular-Based Therapeutics

Quality Systems and Regulatory

Balancing Regulatory Opportunities and Quality Challenges

Topic Preview:

- Clinically Relevant Specifications for Impurities
- Drug Shortages: A Focused Review
- Enabling Knowledge Excellence: Delivering Quality Innovation
- ICH Q12: Fostering Change and Innovation
- Measuring and Managing Quality
- Globally Harmonized Process Validation
- Quality Systems Considerations for Continuous Manufacturing
- Quality Systems Integration
- Changes in Regulatory Landscape: Updates from Regulators

Register early and save!
www.ISPE.org/2017-Annual-Meeting

Registration

Full Education Prices

CATEGORY	ON OR BEFORE 30 JUNE	1 JULY – 15 SEPTEMBER	AFTER 15 SEPTEMBER
Member	US\$2,050	US\$2,250	US\$2,450
Nonmember**	US\$2,430	US\$2,630	US\$2,830
Committee	US\$1,540	US\$1,690	US\$1,840
Government	US\$700	US\$700	US\$700
Young Professional Member	US\$1,025	US\$1,125	US\$1,225
Student Member – Education Only	US\$100	US\$100	US\$100
Student Member – Full Package	US\$225	US\$225	US\$225
Academic Member	US\$1,540	US\$1,690	US\$1,840

One-Day Expo Hall Prices (Available Sunday, Monday, or Tuesday)

One-Day Price	US\$80
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How to Register

Online:	www.ISPE.org/2017-Annual-Meeting/Register
Via Fax or Email:	Complete the registration form online and fax it to: +1-813-264-2816 or email ask@ispe.org .
Questions?	Call ISPE at +1-813-960-2105, or email ask@ispe.org . Please see the conference website for information about cancellations and substitutions.

Group Discount Rate

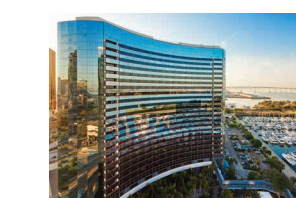
3 – 5 participants – Save 10%

6 – 10 participants – Save 15%

11 or more participants – Save 20%

Group discount applies to full conference registrations only. To qualify, all registrant information must be submitted at the same time; only ONE payment to cover all registrations will be accepted. Registrations that arrive later will NOT be eligible for the group discount. To register as a group, please contact ISPE (tel: +1-813-960-2105).

Hotel Information



Marriott Marquis San Diego Marina

333 West Harbor Drive
San Diego, CA 92101
+1-619-234-1500

Room rate of US\$239 (city view) or US\$269 (bay view) is good until 6 October 2017 or until room

block is full. Make reservations by calling +1-800-228-9290 or +1-619-234-1500 or online at <https://aws.passkey.com/e/16037925>.