

# 2017ANNUAL MEETING & EXPO

# DRIVING INNOVATION TO ADVANCE PATIENT THERAPIES

29 Oct. - 1 Nov. San Diego, CA





## **Table of Contents**

- 4 ANNUAL MEETING HIGHLIGHTS
- **SCHEDULE AT A GLANCE**
- 8 EDUCATIONAL TOPICS
- 13 EXPO HALL
- 14 NETWORKING OPPORTUNITIES
- 18 MEMBERSHIP
- 20 REGISTRATION
- 22 SPONSORS



# Take advantage of this year's multi-faceted program!

- thought provoking keynote presentations
- dynamic education tracks
- exciting social events
- global regulators
- comprehensive education sessions
- exhibitors
- 1700+ attendees
- countless networking opportunities

## **New This Year!**



#### In-Depth Workshops

Take a deep dive into technical topics focused on complex processes in these interactive workshops

- Aligning System Validation and Data Lifecycles
- 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
- Pharmaceutical Water Sampling
- Risk, Reliability, Performance, Compliance, and ASTM E2500

#### Featured Hot-Topic Sessions

Explore hot topics impacting your company strategies and challenges and emerge with a solution

- 3D Printing Technology in Dosage Form Design and Drug Delivery
- Adaptive Mobile BioPharma Production Suite
- Artificial Intelligence: Taking the Mystery Out of Supply Chain Planning
- Cloud Concepts: Cyber Security and Block Chain
- ICH Q12: Fostering Change and Innovation
- Transformative Thinking for Cellular-Based Therapies

#### **Professional Development Sessions**

- From College to the Real World: Biotech Facility Design
- The Most Important Role of a Project Sponsor is...



#### **Sponsored Sessions**

- Career Strategies for Early Career Professionals
- Own Who You Are: Women in Pharma
- "Don't Let It Out!" A Practical Approach to Containment in Sterile Manufacturing Facilities



## **Annual Meeting Highlights**



## **Keynote Sessions**



Pam P. Cheng **Executive Vice President of Global Operations and IT** AstraZeneca

#### Ensuring a Seat at the Table for Manufacturing Operations

Biopharmaceutical companies today are faced with significant challenges on driving R&D productivity, managing patent cliffs, and increasingly more complex

operating environments. At a time of such challenges, how do we in manufacturing operations ensure that we have a core seat at the table? Today, with robust pipelines, complex processes, and device technologies, along with accelerated drug development and approval timelines, it is vital that manufacturing operations is present at the decision table. More than ever, manufacturing operations is a core component to success (or failure). The question is, are we there and are we ready?



**Roger Connor** President Global Manufacturing and Supply (GMS) GlaxoSmithKline

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

Technology limitations and supply chain complexity top the list of challenges facing the pharmaceutical manufacturing industry, but the list is extensive. Where can we find inspiration outside our industry to open new possibilities for sustainable manufacturing that benefits business and our patients? When a factory is needed in the future, what could that factory look like, how do we need to think, and work differently to build it? A range of illustrative examples will be shared during the presentation, including small molecule, biopharmaceuticals, and cell and gene therapy.



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

#### Digital Manufacturing: The next Frontier of Innovation

Four major innovations are hitting the shop floor and will transform the way we manufacture. Today, already half of all activities that people perform can be

automated. The technology innovations are ready. Are you ready? Do you know where and how to start? We will discuss what innovations need to be adopted and what impact is expected for pharmaceutical manufacturers.



Glenn F. Pierce World Federation of Hemophilia Board of Directors and Former Senior Vice President Cell and Gene Therapy Biogen, Inc.

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

The last 50 years have seen unprecedented advances in hemophilia treatment compared to most other diseases. We have witnessed the initial development of the first effective treatment, cryoprecipitate, derived from fresh frozen plasma in 1964, to fully curative therapies utilizing gene transfer in 2016.

These innovations, widely available in resource-rich countries, however, have left much of the developing world behind. As the next wave of innovation is initiated to further improve care and offer a cure, solutions for resource poor countries must be considered. Having lived during the era of no treatment to curative therapy offers a unique perspective on what went right, what went wrong, and what we should do better as the next wave of exciting innovation is mainstreamed into the community.

#### Global Regulatory Town Hall: International Convergence



The Global Regulatory Town Hall provides attendees and regulators a forum for open discussion on topics relevant to the pharmaceutical industry and regulatory agencies, both domestic and international. This year's theme of "International Convergence" will bring regulator perspectives and updates on key international convergence issues including ICH Q12 and mutual reliance and recognition of inspections. Regulators have been invited from FDA/CDER, FDA/ORA, ANVISA, and the South Korean Ministry of Food and Drug Safety (MFDS).

# **Schedule at a Glance**



Saturday, 28 October 2017				
0800 - 1700	Committee Meetings			
1730 - 1900	Leadership Reception (Invitation Only)			
Sunday, 29 October 2017				
0800 - 1530	Committee Meetings			
1100 - 1245	Young Professionals/Students Brunch and Orientation			
1300 - 1515	Education Sessions			
1515 - 1530	Networking Break in Expo Hall			
1530 - 1700	Opening Keynote Session			
1700 - 1830	Expo Hall Opens			
1700 - 1830	Welcome Reception in Expo Hall			
Monday, 30 October 2017				
0645 -0800	9th Annual 5K Charity Run/Walk			
0715 - 0815	New Member/First-Time Attendee Orientation			
0830 - 1000	Keynote Session			
1000 - 1700	Committee Meetings			
1000 - 1615	Expo Hall Open			
1000 - 1100	Networking Break in Expo Hall			
1100 - 1230	Education Sessions			
1230 - 1345	Lunch and Networking Break in Expo Hall			

1345 - 1515	Education Sessions		
1515 - 1615	Networking Break in Expo Hall		
1615 - 1745	Education Sessions		
1800	Open Night for Sponsored Events and Exploring the City		
1900 - 2130	Young Professionals Event at The Tipsy Crow		
Tuesday, 31	October 2017		
0800 - 1000	Membership and Awards Breakfast		
1000 - 1545	Committee Meetings		
1000 - 1600	Expo Hall Opens		
1000 - 1045	Networking Break in Expo Hall		
1045 - 1215	Education Sessions		
1215 - 1330	Lunch and Networking Break in Expo Hall		
1330 - 1515	Global Regulatory Town Hall		
1515 - 1600	Networking Break in Expo Hall		
1600 - 1715	Education Sessions		
1900 - 2200	Tuesday Night Party Aboard the USS Midway Aircraft Carrier		
Wednesday, 1 November 2017			
0800 - 1600	Committee Meetings		
0830 - 1045	Education Sessions		
1100 - 1800	Facility Tours		

#### **End-to-End Supply Chain Management**

From clinical trials to commercialization - managing supply chains through innovative solutions and technology

Track Director: Niranjan Kulkarni, PhD, Operations Specialist, CRB

Co-Director: Neal Gordon, Director MRL Logistics, Global Clinical Supplies, Merck & Co., Inc.

#### **Sessions:**

8

- Advances in Deterministic Parenteral Container Closure Integrity
- Artificial Intelligence: Taking the Mystery out of Supply Chain Planning
- Connecting the Supply Chain Dots: Sales, Inventory, Order, Make, and Deliver
- Direct to Patient: Strategies, Processes, and Lessons Learned
- Future Utilization of MedLabel for Clinical Trials
- Innovation and Technology in the Clinical Supply Chain
- Innovative Techniques to Improve Supply Chain Flexibility and Responsiveness
- Leverage Expiry Date Material Planning to Reduce Waste
- Quality and Compliance Considerations for Shipping Temperature Controlled **Investigational Products**
- Serialization: Holistic Approaches, Current and Predicted Trends
- The PRA-Takeda Strategic Partnership: Is It the Wave of the Future?



#### **Facilities and Equipment**

Meeting unique requirements for the facility design and production

Track Director: Michelle M. Gonzalez, Engineering Director (Retired) AMGEN, Inc., BioPharm Engineering Consultant

Co-Director: Steven Wisniewski, Principal Compliance Consultant, Commissioning Agents, Inc.

- A New Biomanufacturing Paradigm: Off-The-Shelf Facility
- Adaptive Mobile BioPharma Production Suite: Case Study
- Advanced Modeling and Simulation to Improve Efficiencies in Animal Research Lab and Facilities
- Amgen Singapore Next Generation Manufacturing
- Asset Management Triggers to Promote Design for Reliability (DfR)
- Compliant and Sustainable Facilities The Future of Pharma
- "Don't Let It Out!" A Practical Approach to Containment in Sterile Manufacturing Facilities
- FOYA 2017 Winning Project Presentations
- Genentech Oceanside: A Flexible CHO Manufacturing Facility
- How to Execute the World's Largest Biotech Project
- Increasing Operational Efficiency in Existing Facilities
- Integrated Project Delivery
- Lab/Office/WH Project Delivery Methods and Practices
- Managing Risk in a Live Facility Renovation
- Oligonucleotide Synthesis Manufacturing Facility Solution
- Pharmaceutical Water and Energy Savings: Green for Your Wallet and the Environment
- Pharmaceutical Water Sampling
- Project Delivery Impact of Project Driver and Regional Conditions
- Risk, Reliability, Performance, Compliance, and ASTM E2500
- Sterile Manufacturing Facilities: Regulatory and Manufacturing Philosophy, Process Equipment Considerations, HVAC, and Barrier and Isolator Technology
- Surplus Equipment Disposition: Managing Surplus Assets
- The First 100 Days of a Capital Expansion Project
- Understanding the Architectural, HVAC, and Risk Management Considerations for OSD Facilities of the Future

## **Educational Topics**



#### **Information Systems**

Driving innovation with integrity in lifescience information/GAMP®

Track Director: Eric Staib, Executive Director, Quality Assurance, PRA Health Sciences

Co-Director: Sam Brooks, Principal Consultant, Brooks Information Integrity Innovations

#### **Sessions:**

- Aligning System Validation and Data Lifecycles
- Asset Information Lifecycle Modelling
- Cloud Concepts Cyber Security and Block Chain
- Current Perspectives on Data Integrity and cGMP Compliance
- Data Integrity Concepts A Broader Approach
- Paperless Manufacturing
- Practical Approaches to Data Integrity
- Requirements for Demonstrating Compliance with the GDPR
- The Art of Efficient and Effective Computer Systems Validation
- Validation of Computerized eClinical Systems and Data

#### Innovation Forum

Navigating the current landscape of pharmaceutical research, development. and manufacturing for successful innovation

Track Director: Michael K. O'Brien, PhD, Technology and Innovation Consultant

Regulatory Track Director: Sau (Larry) Lee, PhD, Associate Director for Science, FDA/CDER/OPQ

Co-Director: Anne Kantardjieff, PhD, Director, Early Stage Process Development, Biologics Process Development, Alexion

#### **Sessions:**

**Thank You to Our Program Committee** 

Working with them, ISPE has developed this dynamic event with

you in mind! Learn more about this group by visiting

www.ISPE.org/2017-Annual-Meeting

- Accelerating Innovation for Traditional and **Novel Therapeutics Manufacturing**
- Application of 3D Printing Technology in Dosage Form Design and Drug Delivery
- · Emerging Methods, Equipment, and Technologies
- Emerging Therapeutic Modalities and **Medical Devices**
- Innovative Trends and Applications in PAT
- Innovative Cross-Industry Strategic Partnerships
- The Combination Development Process

#### **Product Development and Production Systems**

Developing agile and flexible production systems for the next decade

Track Director: Steven R. Miller, Director, AstraZeneca

Co-Director: Robert Perks, Vice President, Operations, Werum IT Solutions

#### **Sessions:**

- Agility in Biotechnology Process Development
- Challenges of Combination Products
- Continuous Bioprocessing: Current and **Future State**
- Enabling Manufacturing Control Strategy
- Engineering and Design for Continuous Manufacturing: Lessons Learned from the Users
- Facility Design Using Standardized Single Use Assemblies
- Implementing Pharma 4.0 The Holistic Manufacturing Control Strategy
- Lessons Learned from Implementing BPOG's Risk-Based Deviation Management
- Manufacturing Enterprise Facility Design
- Maximizing Manufacturing Utilization through Facility Design
- Process Capabilities for the Pharmaceutical and Biotech Industry
- The Manufacturability Concept of a Commercial Product

### **Quality Systems and Regulatory**

Balancing regulatory opportunities and quality challenges

Track Director: Christine Moore, PhD, Global Head and Executive Director, GRACS CMC-Regulatory Policy and Compendial Affairs, Merck Sharp & Dohme Corporation

Regulatory Track Director: Robert Iser, Director (Acting), Office of Process and Facilities, FDA/CDER/OPQ/OPF

Co-Director: Frank Montgomery, PhD, Global Head, Regulatory CMC, AstraZeneca

#### Sessions:

- Changes in Regulatory Landscape: Regulator Updates
- Clinically Relevant Specifications for Drug Substance and Drug Product Impurities: The Why and How
- Creating a Strong Quality Culture: A **Stepwise Interactive Process**
- Drug Shortages: A Focused Review
- Enabling Knowledge Excellence: Delivering Quality Innovation
- Future State: Globally Harmonized Process Validation
- ICH Q12: Fostering Change and Innovation
- Measuring and Managing Quality from an **Overall System Perspective**
- Quality Management System Considerations for Innovative Technologies and Product Life Cycle Management
- Quality Systems Integration for Acquisitions/Mergers and Suppliers











The overall FOYA Winner will be announced during the Membership and Awards Breakfast. Learn more about the innovative projects from the 2017 Facility of the Year Awards Category Winners at the FOYA Education Sessions. The FOYA Program recognizes state-of-the-art pharmaceutical manufacturing projects utilizing new and innovative technologies to improve product quality, reduce cost, and demonstrate advances in project delivery.





Gain insight and knowledge from the ISPE Women in Pharma community at this year's Annual Meeting & Expo. On Sunday, attend featured sessions focused on issues critical to female executives at various career stages, and visit the ISPE Booth in the Expo Hall to find out how you can get involved. This group will once again be raising money to support the Women in Pharma scholarship fund.

### Expo Hall

Give your company a leading edge! With more than 1,700 pharmaceutical professionals in attendance each year, the ISPE Annual Meeting & Expo brings together industry leaders and decision makers eager to see the latest technology and innovative solutions for their businesses.

By sponsoring or exhibiting at this event, you will gain recognition and the opportunity to develop relationships with leading industry professionals.

Don't miss the chance to reserve your space and take advantage of the many sponsorship opportunities before they sell out.

#### **Expo Hall Hours**

Sunday, 29 October 2017				
0700 - 1500	Exhibitor Move-In			
1700 - 1830	Expo Hall Open			
1700 - 1830	Welcome Reception			
Monday, 30 October 2017				
1000 - 1615	Expo Hall Open			
1000 - 1100	Networking Break			
1230 - 1345	Lunch			
1515 - 1615	Networking Break			
Tuesday, 31 October 2017				
1000 -1600	Expo Hall Open			
1000 - 1045	Networking Break			
1215 - 1330	Lunch			
1515 - 1600	Networking Break			
1600 - 1800	Exhibitor Move-Out			

**DON'T FORGET EXHIBITORS RECEIVE** 15% OFF **FULL EDUCATION REGISTRATION!** 

A limited number of exhibit spaces and sponsorships are still available. For more information, contact Alisa Pachella, Account Manager at apachella@ispe.org or call +1-813-739-2274.

## **Networking Opportunities**



#### ISPE San Diego Chapter Golf Tournament

Saturday, 28 October.....1200 start

Champions Course at Omni La Costa Resort and Spa

#### Welcome Reception

Sunday, 29 October.....1700 - 1830

US\$85 (included with Full Registration)

**Sponsored by** 



# Networking Reception and Lunches in the Expo Hall

Enjoy food and beverages while networking with your peers and representatives from 225+ exhibiting companies.

Sponsored by





#### 9th Annual 5K Charity Run/Walk

Monday, 30 October ......0645 0700 - Race begins

#### US\$30

Sign up to start your day exercising with others in beautiful San Diego. Proceeds benefit the World Federation of Hemophilia USA.

Sponsored by



Proceeds benefit the World Federation of Hemophilia USA.



#### New Member/First-time Attendee Orientation

Monday, 30 October ...... 0715 - 0815

New to ISPE? Is this your first ISPE Annual Meeting? Learn more about the benefits of membership and also how to make the most of your Annual Meeting experience. Bring your business cards for speed networking!

### Young Professionals Networking Event at The Tipsy Crow

Monday, 30 October .....1900 - 2130

US\$55 (includes food and games; cash bar)

Enjoy entertainment and networking with other Young Professionals. The Tipsy 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......0800 - 1000

US\$50(included in Full and Tuesday-Only Education Registrations)

Join ISPE leadership and colleagues for breakfast as we recognize the

Join ISPE leadership and colleagues for breakfast as we 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.



# Sponsored by Flad Architects

#### Tuesday Night Party Aboard the USS Midway Aircraft Carrier



# US\$225 (included only 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.



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## **Facility Tours**

#### **Facility Tours**

#### **US\$55**

Take advantage of behind-the-scenes access to world renowned manufacturing 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, Inc.** 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**

Take a behind the scenes tour and enjoy lunch at Ballast Point Brewing Company. This is one of the most advanced brewery labs in the US. 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. Plus, you will be touring additional breweries and learning about their different processes.





#### **JOB SEEKERS**

Tuesday, 31 October 2017 10.00-16.00

You have the skills and knowledge that employers are searching for - they just need to find you.

**Join** us at the ISPE Career Fair held during the 2017 ISPE Annual Meeting & Expo in San Diego. Dates and times are listed above.

**Meet** directly with employers who have open positions and are searching for professionals in the pharmaceutical manufacturing field.

**Network**, make contacts, and find the job that's right for you. You must be a registered attendee of the ISPE Annual Meeting & Expo to attend the Career Fair.

**Learn** about job opportunities or interview with companies participating in the Career Fair. Attendees can register in advance or on-site. If you are unable to attend the Career Fair but are interested in finding out more about what positions are available, you may upload your resume online to be viewed by participating companies.

**Upload** your resume at ispe-jobs.careerwebsite.com

Register today at: ispe-jobs.careerwebsite.com





## **General Information**



#### **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.

#### **Hotel Cancellation Policy**

Guests cancelling their stay less than 72 hours prior to the day of check-in will be charged for their full stay. Please note that if you do not arrive on the first day of your room reservation, the hotel 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.

# Save up to 20% off Guidance Documents

Members receive up to 20% OFF all Guidance Documents purchased on site at the Annual Meeting. Stock up and take advantage of the savings!

## ISPE Membership Has Its Benefits

ISPE offers unparalleled value for Members, companies, and stakeholders globally and across all constituent parts of the industry. Join today at www.ISPE.org/Join

#### ISPE Booth

Stop by the ISPE booth to enjoy conversation with staff, get questions answered, browse through our array of Guidance Documents, and show your pride in your local Affiliate or Chapter by picking up your ribbon to wear during the conference.



# **NEW!** ISPE Career Solutions Job Fair

Back by popular demand, ISPE's Career Solutions will host an onsite job fair for all attendees. Meet with representative companies to learn more about current openings and future opportunities.

Register today at ispe-jobs.careerwebsite.com.

If your company would like to participate, please contact Jim Cook at jcook@yourmembership.com



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# PURE WATER AND STEAM. ANY SOLUTION, ANYWHERE.

MECO designs and constructs engineered products and systems for water purification and pure steam generation. A broad product line of technology and extensive experience enables MECO to put forward valuable and sustainable solutions for our clients. Located in the USA, Singapore, Europe and the UAE, MECO can service your company's needs anytime and anywhere.

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Stop by the MECO Booth #1515 at the ISPE Annual Meeting 29 October – 1 November 2017 and discover why the world has trusted MECO for water purification for nearly 90 years!

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### How to Register

Online	ISPE.org/2017-Annual-Meeting/Register
	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.	

#### **Full Education Rates**

Category	1 July - 15 September	After 15 September
Member	US\$2,250	US\$2,450
Nonmember**	US\$2,630	US\$2,830
Committee	US\$1,690	US\$1,840
Government	US\$700	US\$700
Young Professional Member	US\$1,125	US\$1,225
Student Member - Education Only	US\$100	US\$100
Student Member - Full Package	US\$225	US\$225
Academic Member	US\$1,690	US\$1,840
One-Day Expo Hall Rate (Available Sunday, Monday, or Tuesday)		
One-Day Rate	US\$80	

<sup>\*\*</sup> SAVE hundreds of dollars by joining and registering as an ISPE Member. To activate your membership visit www.ISPE.org/Join

#### **BRING YOUR ENTIRE TEAM!**

#### **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).

#### **Exhibitor Rate**

#### **SAVE 15% On Full Education Registration**

#### Conference Cancellations and Substitutions

Cancellations must be made in writing. If cancellations are received by 9 October, a full refund, minus a \$100 handling fee, will be issued. After that time, no refunds will be granted. If you are unable to attend, substitutions will be accepted. However, nonmembers substituting for a Member must pay difference in fees prior to the start of the event. ISPE is not responsible for lost airfare due to cancellations.

### **Exhibitor Badge Cancellations/Substitutions**

Cancellations must be made in writing. If cancellations are received by 27 September 2017 a full refund minus a 10% handling fee (maximum of \$100) will be issued. After that time, no refunds will be granted.





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# BRING YOUR ENTIRE TEAM!

# **Group Discount Rate**

- 3 5 participants

  SAVE 10%
- 6 10 participants

  SAVE 15%

11 or more participants

SAVE 20%

Please contact ISPE for group discount details.

Discounts on full registration only.

