



CALL FOR PROPOSALS

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Conference Overview

The 2018 ISPE Annual Meeting & Expo will focus on excellence, modernization, and harmonization in pharmaceutical science and manufacturing across the globe. This signature event draws pharmaceutical and biopharmaceutical professionals at all levels of the industry from young professionals to the most senior executives in drug manufacturing, supply chain, devices and equipment and services, and global regulatory agencies.

Call for Proposals Timeline

- Opens: 15 December 2017
- Deadline: 28 February 2018
- Committee Review: 28 February – 1 April 2018
- Notification: 2 April 2018

By submitting a proposal, you acknowledge that, if your proposal is accepted, your organization will support your attendance at the conference(s). Accepted Annual Meeting Leaders and Speakers are responsible for their own travel and accommodations and receive complimentary registration for the day on which their session is scheduled. Interested Leaders and Speakers may purchase full conference registration at the following discounted rates:

Before 24 August	24 Aug – 25 Sep	After 25 Sep
\$1,365	\$1,495	\$1,625

REQUESTED TRACK TOPICS

End-to-End Supply Chain Management

New Therapies: Impacting and Impacted by Supply Chains

- Capacity Planning – synchronizing the supply chain
- Continuous Manufacturing – integration with traditional batch processes
- Biologics Growth – adaptability in supply chain for new processes, products, and technologies
- Lean Improvements in Pharma – demand pull
- Technology – applications of technology in the supply chain and operations research
- Packaging – cold chain, temp monitoring, innovative packaging techniques
- Supply Chain Industry Model Changes – how patients affect supply chains
- Business Continuity models for acquisitions and mergers
- Process Excellence - Lean Training and Organizational Culture
- Serialization – Understanding the complexities and roll-out of Serialization
- Package Inspection – Physical and visual Inspection for final fill-finish quality

Facilities and Equipment

Fitness-for-Use - Sustainability - Cost Effectiveness: The Critical Industry Facility Challenges!

- Innovative approaches to facility function and design. (i.e., modular design, continuous manufacturing operations, flexibility, disposables)
- Integrating ASTM principles into the project delivery process; optimizing the Regulatory approval process.
- Latest trends in Sustainability (i.e., water, waste, energy, equipment reliability). Industry best practices and savings that have been achieved.
- Latest trends in F&E maintenance. Moving past PM and PM shutdown periods.
- Challenges in designing and delivering same product/ process facilities in multiple countries
- Repurposing legacy facilities for new products

**4-7 NOVEMBER PHILADELPHIA, PA**

Facilities and Equipment, Continued

- Applying QRM to Critical Utilities. How applying QRM to design and qualification of CUs can simplify the design process and expedite the qualification and validation.
- Moving “out of the box”, shifting from traditional manufacturing strategies to innovative means

Information Systems

Trends in Digital Health

- Data Integrity
- Clinical/R&D Systems
- Mobile Apps in Biotech and Therapeutic Applications
- Digital Health
- Working with our Cloud Providers
- IT and Cyber Security Case Studies
- IS Industry Career Path - Diversity and Inclusion
- Blockchain Applications in Pharma

Innovation Forum

New Frontiers in Medicine – Innovative Technologies and Applications

- The genomic revolution: Cell and gene therapy, including cell engineering, such as CAR-T cells, gene editing technologies, such as CRISPR/Cas9 and TALENs and next generation gene therapy technologies
 - Enabling technologies in the cell and gene therapy field
 - How manufacturing facilities will need to adapt to enable cost-effective regulatory compliant production of these new modalities
 - Considerations for the cost vs value of these new therapies
 - How the field of quality assurance and sciences has to adapt to personalized medicine
- Advances in the field of 3D printing
 - Recent advances in 3D printing of biomaterials including implants, diagnostic platforms, scaffolds for tissue engineering and biomedical devices. Personalized regenerative medicine is of high interest
 - Drug delivery applications
 - Utility in pharmaceutical manufacturing facilities
- Applications of multivariate data analysis in the context of continuous manufacturing
- Digital innovation in an evolving manufacturing paradigm
 - Applications of machine learning
- Advancements in predictive process and plant modeling tools...data acquisition, storage and analysis

Product Development & Production Systems

Exploring the Future State of Development and Manufacturing Technology

- Pharma 4.0 and the Production Control Strategy
- Continuous Processing
- Operational Excellence
- Flexible Manufacturing
- Knowledge Management and Data Analysis, including Data Integrity

Quality Systems & Regulatory

Global Trends in Quality, Technical, and Regulatory Harmonization

- Clinical Relevance
- Drug device combinations
- Facility and utility impact on quality



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Quality Systems & Regulatory Continued

- Global Regulatory Harmonization – accelerated development programs
- GMP, CMC aspects of Continuous Improvement
- Impact of natural disasters on drug supply/shortages
- Inspection challenges with novel and breakthrough therapies
- Process Validation
- Continuous Manufacturing and other emerging technologies
- Quality and regulatory implications for continuous manufacturing
- Regulatory aspects of analytical methods development
- Technology Transfer

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