CALL FOR PROPOSALS

Submit Proposal

Conference Theme: *Driving the Future of Pharma*

Conference Overview

The 2020 ISPE Annual Meeting & Expo will focus on aligning the future of pharmaceutical science and manufacturing as the industry becomes more global, synchronized, digitalized, and quality driven. This signature event draws pharmaceutical and biopharmaceutical professionals at all levels of the industry from students and 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: 20 December 2019
Submission Deadline: 15 March 2020
Committee Review Begins: 16 March 2020
Notifications: 20 April 2020

Abstract submissions may be proposed for any of the following:

- 90-Minute Session
- 2-Hour Workshop
- Individual Oral Presentation
- Poster Presentation

All presentations must be free of commercial intent. Incomplete proposals will not be considered.

- By submitting a proposal, you acknowledge that, if your proposal is accepted, your organization will **support** your attendance at the conference.
- Accepted Annual Meeting session leaders and speakers are responsible for their own **travel and accommodations**.
- Session leaders and speakers giving a full (25-minute or longer) presentation receive complimentary **conference registration** for the day on which their session is scheduled.
- Co-Session Leaders, Co-Speakers, Panelists or Poster Presenter who are not giving a full presentation receive a 20% discount on conference registration. **NOTE:** Exhibitors who are accepted to present a poster will be required to register as a paid conference attendee (with 20% discount off prevailing registration rate). Complimentary booth staffing registrations cannot be utilized for poster presentations as these are part of the education sessions and not the exhibition.
- Interested leaders and speakers may purchase full conference registration at a discounted rate.

Speaker Package Rates

Before 3 July	3 July – 20 Sep	After 20 Sep
$1,328	$1,528	$1,728

REQUESTED TOPICS

Facilities and Equipment

Track Directors:
Brian Pochini, Principal Engineer, Facilities and Utilities, Sanofi
Paul Obringer, Director of Operations, CAI

The Future of Facilities and Equipment – Innovative Designs and Cutting-Edge Solutions
This track is designed to inform attendees on options to design, build and qualify modern and efficient facilities and equipment used to

support the development, manufacturing, testing, storage and distribution of therapeutic products today and into the future. As speed to market and breakthrough therapies continue to reshape the landscape, there is even more need to apply a harmonized approach to innovative design solutions and project delivery strategies. Each product component and the product itself create unique challenges for facility design, equipment selection and overall project execution. How these challenges are addressed will ensure that quality therapeutic products are brought to market in an efficient manner in order to improve patient health. The emphasis of the topics presented by the F&E Track has been arranged to provide Owners/ Users/ Designers – whose experiences, wants and needs are invaluable – with modern-day examples of how to modernize, harmonize, and transform the facilities and products of the future.

- Cell and Gene Therapy Facilities
- Approaches for design and project delivery for breakthrough therapies
- Consideration of reliability and sustainability impacts
- Application of QRM to the C&Q process to ensure facilities and equipment fit for their intended purpose
- Managing regulatory assessments of new facilities

Communities of Practice/Special Interest Groups:
API, Biotechnology, Commissioning & Qualification, Critical Utilities, GAMP®, HVAC/Sustainable Facilities, Oral Solid Dosage, Project Management, Sterile Products Processing

Information Systems

Track Directors:
Christian Woelbeling, Senior Director Global Accounts, Werum IT Solutions
Rob Dillman, Informatics Specialist, Eli Lilly and Company

Holistic Digitalization of the Artificial Intelligent Smart Factory – Pharma 4.0
The digitalization and the management of big data and its analytics enables not only the control, but also the prediction and optimization of all related business processes. This disruptive change from retrospective control to predictive control is enabled by big data management and the data integrity by design approach. The Digitalization of the pharmaceutical industry coming with the ISPE Pharma 4.0 Operating Model and the Smart Manufacturing approach results in disruptive changes in Information Systems (IS) design and lifecycle management. The new digital ICH Q10 Pharmaceutical Quality Systems / PQS enablers Digital Maturity and Data Integrity by Design need new design concepts, enabling inspection readiness. The PQS Digitalization Element Information Systems has a key role in the Digitalization of the AI Smart Factory. This includes the end-to-end ICH based pharmaceutical lifecycle management from Development, Clinical, Tech Transfer, Scale Up to Commercial Manufacturing streamlining the manufacturing supply chain.

- Digitalization Strategies, Concepts and Case Studies
- Practical Experiences in Data Integrity by Design and DI Inspection Readiness
- Practical Experiences in achieving Digital Maturity
- Clinical/R&D Systems digitalization
- Technologies & Devices in Biotech, Cell & Gene, ATMPs
- Smart Digital Health Devices

Communities of Practice/Special Interest Groups: GAMP®, Pharma 4.0, Oral Solid Dosage, Supply Chain, Operations, & Packaging, Data Integrity, Blockchain, AI, MES, PAT & Lifecycle Control Strategy

Innovation in Pharmaceutical Manufacturing

Track Director:
Steven Miller, CPIP, Director of Engineering and Facilities, Emergent BioSolutions
Eamon Judge, EMEA Global Projects Planning Leader, Eli Lilly and Company

New Frontiers in Medicine – Innovative Technologies and Applications
The innovation forum will focus on emerging and evolving technologies that are helping drive a revolution in medicinal therapies, analytical techniques, manufacturing paradigms, medical devices including novel methods to deliver the next generation of drugs to patients. The intent of this track is to highlight the global Pharmaceutical industry's challenges, recent innovations, opportunities and success stories relative to the discovery and adoption of emerging technologies for pharmaceutical applications. This forum seeks to highlight innovations in small molecule, biopharmaceutical (large molecule) as well as whole cell and tissue engineering. The focus is on the full lifecycle of therapeutic production : early drug substance production to final drug product and the patient experience. Regulatory perspectives on the key challenges and opportunities for the adoption of these technologies will also be in scope for the innovation forum sessions. Novel approaches that will improve the sustainability / global social responsibility of the sector are welcome as are operational excellence examples that improve efficiency. Bioprinting

- Adoption of Pharma 4.0 including Artificial Intelligence (AI) by Pharma and Biotech
- New Developments in Antibiotics and Vaccines including their commercialization for emerging markets
- Advanced Therapy Medicinal Products (ATMPs) and Cell and Gene Therapies
- Biomanufacturing: Process improvements and advances including single-use systems and closed processing
- Advances in robotics and convergent technologies such as 3D printing in the Pharmaceutical industry

- Novel trends in drug and smart delivery devices
- Innovative approaches to the sustainable supply of medicines
- Next Generation approaches to Continuous Processing

Communities of Practice/Special Interest Groups: All

Process Development & Manufacturing

Track Directors:
Sarah Mancini, Director, Global API Technology, Zoetis
Charlotte Enghave Fruergaard, Managing Consultant , Compliance Consulting, NNE

Innovations in Process Development and Manufacturing - Driving the Future State
Novel therapies are leading us to reassess the way we develop and manufacture drug substances and drug products. The track will explore the business strategies and technology aspects associated with the future state of manufacturing. This includes transition to continuous processing to streamline process development, minimize manufacturing footprint and provide supply flexibility. Utilizing plug and play equipment for an agile approach to process development and manufacturing. Integration of data analytics and process control to define process capability and robustness. If you are involved in any aspect of drug substance and drug product development and manufacturing (Quality, Regulatory, Technical, Project Management, Equipment, EHS or Supply Chain) you should plan to attend this session to share best practices and benchmark solutions which will enable the future state of process development and manufacturing.

- Continuous Manufacturing for API and Drug Product
- Flexible/Agile Laboratory and Manufacturing Environments
- Manufacturing Technologies for Personalized Medicines
- API/Drug Product Interface
- Ensuring Process Capability/Product Robustness
- Process Control and Integrated Data Analytics in Manufacturing
- Technology Transfer
- Knowledge Management

Communities of Practice/Special Interest Groups: Regulatory, Information Systems, Knowledge Management, Sterile Products Processing, Containment, Biotechnology, Oral Solid Dosage, PAT and Lifecycle Control Strategy, Process/Product Development

Quality Systems & Regulatory

Track Directors:
Sarah Pope Miksinski, PhD, Senior Director, Global Regulatory Affairs, AstraZeneca
Betsy Fritschel, Director, Enterprise Regulatory Compliance, Johnson & Johnson

Patient Centricity Amidst Global Complexity
This year's focus will be on global harmonization as an enabler for patient centricity in the regulatory and quality landscape. Track sessions will explore current challenges in both patient centricity and global convergence, while identifying opportunities and ideas that support both concepts. Areas of specific focus include accelerated development, benefit/risk in the quality space, continuous manufacturing, combination products, and initiatives that may support submission and review efficiency.

- Patient Centricity – What's the Real Risk?
- Accelerated Development
- Opportunities in Global Harmonization
- Submission Review and Efficiency – Opportunities and Necessities
- Continuous Manufacturing
- Advancing Pharmaceutical Quality
- Combination Products

Communities of Practice/Special Interest Groups: Advancing Pharmaceutical Quality Team (APQ), Product Quality Lifecycle Implementation (PQLI), Regulatory Quality Harmonization Committee (RQHC), Quality Metrics, Continuous Manufacturing

Supply Chain, Operations, & Packaging Excellence (SCOPE)

Track Directors:
Oliver Stauffer, CEO, PTI Inspection Systems
Aaron Weinstein, Senior Director, Validation Services, IPS

Anticipating Supply Chain, Operations, and Packaging Challenges of the Future
The Supply Chain, Operations, and Packaging Excellence (SCOPE) track will focus on the operational, supply chain and packaging challenges that have arisen during a period of intense technological advances. Rising technologies and process innovations hold promise for companies faced with meeting new supply chain, operations, and packaging demands. We intend to take a unique "campfire"

approach to knowledge sharing during our sessions. Attendees will have the opportunity to interact with subject matter experts and each other to shed light on paths forward to address unexpected and newly emerging challenges with next generation therapies.

- Cell Therapies
- Gene Therapies
- CAR-T
- mAbs
- ATMPs
- Unique Drug Delivery Systems
- 3D Printing
- Nanotechnology
- Cold Chain
- Next Generation Packaging Solutions

Communities of Practice/Special Interest Groups: Supply Chain, Operations, Packaging, Sterile Products Processing, GAMP®

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