2021 ISPE Annual Meeting & Expo
1 – 3 November
Boston MA USA
Call for Proposals

Conference Overview

From introducing new medication, producing millions of vaccine doses, or providing very focused personalized medicines for patients, our Life Science industry has demonstrated creativity and nimbleness, all while focusing on patient safety and product quality. We welcome you to participate at The 2021 ISPE Annual Meeting & Expo to learn and share progress, success stories, best practices and lessons learned, and yes, also have some fun!

The 2021 ISPE Annual Meeting & Expo will focus on aligning the future of pharmaceutical sciences 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 emerging leaders to the most senior executives in drug manufacturing, supply chain, devices and equipment and services, and global regulatory agencies.

Call for Proposals Timeline

Opens: 10 February 2021
Submission Deadline: 14 March 2021
Committee Review Begins: 15 March 2021
Notifications: 23 April 2021

Abstract submissions may be proposed for either of the following:

- Individual Oral Presentation
- Poster Presentation
- ***PLEASE NOTE:*** *Proposals for a full session are not being considered this year.*

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, **the speaker will attend/present in-person at the event and the speaker's attendance at the event will be supported by their organization.**
- Accepted Annual Meeting speakers are **responsible for their own travel and accommodations.**
- **Speakers giving at least a 20-minute presentation (not including Q&A) receive complimentary conference registration for the day on which they speak.**
- **Co-Speakers, Panelists, and Poster Presenters receive a 20% discount on conference registration.**
- **NOTE: Exhibitors** who are accepted to present a poster are required to register as a paid conference attendee (with 20% discount off prevailing registration rate). Complimentary booth staffing registrations cannot be utilized for the poster presentations as these are part of the education sessions and not the exhibition.
- **Interested speakers** may purchase full registration at a discounted rate.
- **Consulting firms or vendor/suppliers** are expected to include a speaker from an owner company to present.
- **Regulators interested in submitting a proposal:** Please contact Marianne Bock to submit your abstract.

Speaker *Full Conference Package* Rates	Early: Before 8/23/2021	Standard: 8/23-9/22/2021	Late: After 9/22/2021
Speaker: Full presentation (25 minutes)	$1,794		
Member Co-Speakers, Panelists, Poster Presenters	$1,516	$1,760	$1,920
Non-Member Co-Speakers, Panelists, Poster Presenters	$2,056	$2,208	$2,400
Speaker *Presentation Day* Rates			

Speaker: Full presentation (25 minutes)	Complimentary		
Co-Speakers, Panelists, Poster Presenters	$530	$616	$672

TRACK DESCRIPTIONS & REQUESTED TOPICS

Facilities and Equipment

Lead: Paul Obringer, President, GxP Impact Consulting LLC
Description: These sessions are 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 (Project Warp Speed) and breakthrough therapies continue to reshape the landscape and resource utilization, 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, utilization, flexibility, 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 and ensure 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.

Requested topics:

- Project Warp Speed
- Cell and Gene Therapy Facilities
- Approaches for design and project delivery for breakthrough therapies
- Consideration of flexibility and ease of change over
- 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

Lead: Rob Dillman, Informatics Specialist, Eli Lilly and Company
Description: The digitalization and the management of big data plus its analytics enables the control, 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 along 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/ML 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.

Requested topics:

- Digitalization Strategies, Concepts and Case Studies
- Practical Experiences in implementing and validating AI/ML
- Practical Experiences in Data Integrity 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

Agile Innovation in Lifesciences Development and Manufacturing

Lead: Eamon Judge, EMEA Global Projects Planning Leader, Eli Lilly and Company
Jim Grunwald, SVP, US Business Development, DPS Group
Description: These sessions 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 is to highlight the global Pharmaceutical industry's challenges, recent innovations including those driven by COVID-19, 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), ATMPs and combination therapies. The focus is on the full lifecycle of therapeutic production: early drug substance production to final drug product and the patient experience. Innovations in development, manufacturing and supply chain driven by the COVID-19 response is of particular interest. 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.

Requested topics:

- Biomanufacturing: Process improvements and advances including single-use systems, aseptic high potency and closed processing.
- Next Generation approaches to Continuous Processing across multiple manufacturing platforms
- Advanced Therapy Medicinal Products (ATMPs), Cell and Gene Therapies, Tissue Engineering
- New Developments in Antibiotics and Vaccines including their commercialization for emerging markets
- Improvement agility and speed in the development to manufacturing handoff - Scale Out vs Scale Up?
- Adoption of Pharma 4.0 including Artificial Intelligence (AI) by Pharma and Biotech
- Advances in robotics and convergent technologies
- Novel trends in drug and smart delivery devices
- Innovative approaches to the sustainable supply of medicines
- Vertical integration and supply chain agility

Communities of Practice/Special Interest Groups: All

Process Development & Manufacturing

Lead: Charlotte Enghave Fruergaard, CEO & Co-founder, PRO Devices A/S

Description: Novel therapies are leading us to reassess the way we develop and manufacture drug substances and drug products. These sessions 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.

Requested topics:

- 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

Lead: Betsy Fritschel, Director, Enterprise Regulatory Compliance, Johnson & Johnson

Description: This year's focus will be on innovation and collaboration as we have all worked to maintain global supply chains during the pandemic. These sessions will explore regulatory and quality challenges and learnings from 2020 and 2021, and potential opportunities to take forward into the post-pandemic new normal. Areas of specific focus may include accelerated development, virtual inspections/PAI, advancing pharmaceutical quality, continuous manufacturing, combination products, and initiatives that may support submission and review efficiency throughout the product lifecycle.

Requested topics:

- Learnings from Virtual Inspections

    - Overcoming challenges
    - Technology solutions
    - Cybersecurity
- Accelerated Development
- Innovative Transformational New Technologies
- Global Harmonization Update ICH
    - How ICH is currently working and next steps
    - QbD, QRM, PQS, more data (in-line, on-line, at-line) what next…..
    - Q9(R1)
    - Q13 Continuous Manufacturing
    - Q12 Implementation
    - Q2(R2)/Q14 Analytical Method Development
- Submission Review and Efficiency – Opportunities and Necessities
    - Managing multiple simultaneous marketing applications globally for EUAs, BLAs, MAAs, etc
    - Future of cloud-based data in submissions – Accumulus (potential link to KASA)
    - Real Time Data Analysis
- Patient Centricity – What's the Real Risk?
- Post-pandemic Managing Access to Medicines
    - Global Supply Chain challenges during global health emergency
    - Multiple countries mandating "local" manufacture
- Advancing Pharmaceutical Quality
- Annex 1
- Pharma 4.0
- What is the future of QA – machine learning, modelling, Real Time Release
        - Testing > compliance to GMP (QA) > QbD & Risk Management
        - Where's the relief? Still big emphasis on the lab and the sample
        - Is there a way to have a higher level of assurance
        - How does Quality Maturity fit

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, North America Focus Group (NAFG)

Supply Chain, Operations, & Packaging Excellence (SCOPE)

Lead: Aaron Weinstein, Senior Director, Validation Services, IPS

Description: The Supply Chain, Operations, and Packaging Excellence (SCOPE) sessions will focus on the operational, supply chain and packaging challenges in a turbulent year for the health care industry. The COVID-19 pandemic did not just affect vaccine production, but also supply chain logistics and operations across all types of therapies. Our intent is to have the track sessions take a deeper dive into how this environment has impacted supply chains and operations by looking at how these areas have changed, whether the change is temporary or permanent and how technology is being used (or is planned oi be used), to address these changes. Additionally, we would like to invite proposals for forward-thinking sessions that look to the future with regard to new therapeutics and how the SCOPE areas may be impacted. We intend to take a "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.

Requested topics:

- Supply Chain Challenges Related to COVID-19
- Vaccine Production & Supply Chain
- Cold Chain
- Next Generation Packaging Solutions
- ATMPs
    - Cell Therapies
    - Gene Therapies
- Unique Drug Delivery Systems
- 3D Printing

- Nanotechnology

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