

**2025 ISPE Annual Meeting & Expo --
Sunday 26 Oct – Wednesday 29 Oct
Charlotte Convention Center, NC USA
Call for Proposals**

Conference Overview

The 2025 ISPE Annual Meeting & Expo is poised to herald a transformative era in pharmaceutical science and manufacturing. This year’s theme centers on Pharma 4.0, focusing on the end-to-end implementation of digitalization across all stages of project execution, manufacturing, and regulatory processes. The increasing impact of new technologies, such as artificial intelligence (AI), machine learning (ML), and automation, is sparking interest in many areas of development and CMC, fundamentally reshaping the pharmaceutical industry’s future.

More than ever, an emphasis on cross-discipline collaboration is needed to implement and integrate these groundbreaking technologies, while ensuring organizational readiness and preparing the workforce of the future. This year’s event seeks to illuminate their profound impact on efficiency, innovation, and operational excellence.

Our comprehensive education program offers cutting-edge technical sessions shedding light on the latest advancements in areas like supply chain operations, facilities, and regulatory affairs, with a focus on how Pharma 4.0 is driving the next generation of product development, production systems, and quality assurance.

This signature gathering is not just an opportunity to learn but also to connect. From emerging talents to seasoned executives in drug manufacturing, supply chain, devices, equipment, and services, and global regulatory agencies, attendees will get the chance to network, exchange insights, and preview the latest technologies and services at our expansive Expo Hall.

Call for Proposals Timeline

Opens: 10 January 2025

Submission Deadline: 3 March 2025

Committee Review Begins: 5 March 2025

Notifications: 18 April 2025

Abstract submissions may be proposed for any of the following:

1. Workshop
 - Proposals should outline a plan to develop and lead a 3-hour active and engaging workshop.
 - Include introduction, group activities, demonstrations, proto-typing and/or other creative learning elements
 - Include proposed facilitators (other than submitter), credentials, and contact information
 - Include actionable learning objectives for participants
2. Oral Presentation
 - Each individual presentations includes 20 minutes for content delivery with 7 minutes for Q&A, and 3 minutes for transition time.
 - Presentation should focus on new and innovative trends, a specific real-world strategy or campaign, or a “how-to” demonstration intended to help attendees gain a better understanding of the initiative and best practices that they can apply to their day-to-day objectives or overall missions

Content Areas

The importance of a resilient, agile supply chain, as well as strong collaboration between industry and regulators is well recognized. An aging population and an unprecedented rise in chronic diseases mean that the need for a constant focus on collaborative innovation and agility are needed to shape Pharma’s priorities in the foreseeable future. ISPE will be the leader to set the pace for knowledge sharing that speaks to both current and future needs of the industry.

The 2025 ISPE Annual Meeting & Expo Planning Committee is requesting proposals, with preference given to those aligning with the following themes. Submitters are encouraged to also consider identifying related skills and experience for the workforce of the future and strategies for ensuring organizational readiness.

❖ **Digital Transformation**

Digital transformation is a mainstay of Pharma 4.0 and the advancement of the Life Sciences industry, and this track focuses on advances, achievements, and applications in this area. Organizations undergoing transformation can build digital maturity through a well-defined strategy, clear and consistent processes, provision of sufficient resources and competent personnel operating within a culture of operational excellence. For the safety of our patients, there can be no innovation without validation, and increasingly there are inventive and novel applications of GAMP approaches to managing and maintaining computerized systems including artificial intelligence and machine learning subsystems. The careful application of data integrity by design within any process is needed to ensure available, abundant, and trustworthy data to support informed decision making. Together, these elements facilitate breakthroughs and innovation within our industry.

❖ **Manufacturing, Quality Control & Operational Excellence**

Applying innovative approaches to manufacturing and design solutions to ensure quality therapeutic products are brought to market in an efficient and cost-effective manner to improve patient health and access to new therapies. This includes streamlining operations and support functions, process improvements, incorporating quality by design, efficient project and change management, and ensuring relevant technologies are implemented, while focusing on upskilling and reskilling the workforce to support the future state of our industry.

❖ **Regulatory, Compliance & Quality**

Technological advancements and innovations, including the concept of Pharma 4.0, are redefining the landscape of Regulatory, Compliance, and Quality. The integration of AI/ML with advanced modeling techniques is accelerating drug development for both new and existing modalities. Participants in this track will hear from regulators pioneering innovative collaboration methods and exploring reliance initiatives with a global perspective. Industry leaders will discuss how Pharma 4.0 principles can help introduce complex technologies and innovative medicines to patients worldwide more rapidly. Engage with peers and regulators in discussions to explore solutions to these challenges!

❖ **Sustainability & Supply Chain Resiliency**

This content area combines Supply Chain Resiliency with Sustainability to create an opportunity for these closely related topics. Submissions can address one topic or both.

Supply Chain Resiliency addresses the robustness and adaptive capability of the pharmaceutical industry's supply chain to prepare for unexpected events, respond to disruptions, and recover from them by maintaining continuity of operations at the desired levels of control over structure and function. For 2025, topics on how Generative AI, supply chain risk management and cost-to-serve models are used to increase the robustness of the pharmaceutical clinical and/or commercial supply chain are encouraged.

Sustainability is a central focus for many companies and a key goal for numerous projects. Whether building at a new site or implementing a global sustainability policy, there are approaches and lessons learned that can benefit the industry. This track focuses on the challenges and successes of projects and corporate actions that address sustainability. Submissions that cover the following areas are recommended:

- Trends in ESG/Scope 3
- Use of AI in creating innovative sustainability approaches and data analysis
- How Pharma is working with government initiatives
- Green building practices and retrofitting
- Use of technology to implement sustainability initiatives

❖ **Advanced Therapy Medicinal Products (ATMPs)**

Advanced therapy medicinal products (ATMPs) are medicines for human use that are based on genes, tissues or cells. They offer groundbreaking new opportunities for the treatment of disease and injury. Technical challenges in the manufacture of these products are at the forefront of this complex environment, compounded by different health authority expectations from around the world. Opportunity for international harmonization, alignment, and best practice application exists as this novel area continues to grow within the industry to ultimately help serve patients in need.

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

- **Each proposal must address one conference theme.** As an example, when submitting a proposal, you would choose one from the list such as “Manufacturing, Quality Control & Operational Excellence,” or “Sustainability & Supply Chain Resiliency.”
- 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 will receive** a full registration at a discounted rate.
- **NOTE: Exhibitors** who are accepted to present 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 presentations as these are part of the education sessions and not the exhibition.
- **Consulting firms or vendor/suppliers** are encouraged to include a speaker from an owner company to present.
- **Regulators interested in submitting a proposal:** Please contact Saana Tykka (stykka@ispe.org) to submit your abstract.