ANNUAL MEETING EDUCATION COMPONENTS

A Continuing Education Session...

- is a discrete and titled grouping of two to five presentations on one topic;
- varies in length depending on the type of session: general education sessions are 3.5 hours in length including a 45 minute break; executive series sessions are 1.75 hours in length with no break.
- may be part of a combination of multiple segments on successive days (proposals can include content for up to six blocks);
- is offered simultaneously with 8 other sessions;
- is given a discrete session number, assigned to a track, and must have a session leader;
- is expected to be composed of varied content delivery methods, including presentations, workshop activities, discussion, and question/answer sessions.

A Continuing Education Track...

- is a set of 5-10 Education Sessions designed to offer programs supporting the 7 ISPE Knowledge Elements along with other selected themes significant to the pharmaceutical industry;
- is expected to address one or more components of the Knowledge Element associated with their track;
- is offered each day of the conference to allow delegates to attend sequential track sessions;
- is guided by a Track Director who serves a member of the Annual Meeting Event Planning Team.

An Executive Series Session...

- is aligned with one of the Global Positional Strategies outlined by the International Leadership Forum;
- is divided into six simultaneous sessions covering the following topics:
    - Next Generation Processes, Equipment, and Facilities
    - Biotechnology
    - Supply Chain Management
    - Enterprise Risk Management
    - Sustainability
    - Organizational Development;
- provides insight into the importance of these areas to the development of a business strategy;
- creates a platform for discussion as an on-going interest and focus;
- details the current and trending industry and regulatory landscape for these issues;
- is led by recognized industry leaders.

The Plenary Session...

- provides the audience with a comprehensive view of industry challenges through the lens of the conference theme;
- includes ISPE Executive and Board speakers;
- marks the transition of Board leadership to a new Chair;
- includes recognition of the FOYA Category winners and the Facility of the Year award announcement.
- offers keynote presentations by global experts in regulatory affairs, global health initiatives, the pharmaceutical and non-pharmaceutical industries, and academic leadership.

EDUCATION TRACK DESCRIPTIONS

(Based on the ISPE Knowledge Elements)

Track 1 - Facilities and Equipment

Includes knowledge required to ensure: (a) that the critical physical and chemical requirements of drug products are properly understood and managed; and (b) that the selection of process equipment and the design of facilities and support utility systems will consistently deliver those requirements and all other aspects of the product specification (including quantity and timely delivery)

Design and Construction/Installation

1. Knowledge of requirements for product protection and containment
2. Knowledge of requirements for personnel and environmental safety and protection
3. Knowledge of the importance of personnel flow and materials flow and their implications for layout
4. Knowledge of the materials and methods of construction of equipment and facilities, particularly from the perspective of cleanliness, functionality, and maintainability
5. Knowledge of critical process equipment and utility systems' attributes (performance, functionality, construction, instrumentation) and their impact on personnel and product
6. Knowledge of cleaning systems including CIP/SIP
7. Knowledge of the fundamentals of good engineering practice

Commissioning and Qualification as a Risk Management Strategy

8. Knowledge of factors that can impact the commissioning and qualification process
9. Knowledge of requirements for executing and documenting the commissioning and qualification
10. Knowledge of concepts, sequencing, and documentation of commissioning and qualification activities required by design intent
11. Knowledge of critical systems impact assessment and implications for the product

Operation and Maintenance

12. Knowledge of equipment and facility reliability and predictability models to establish a maintenance and calibration program
13. Knowledge of equipment operability and maintenance (location and access, type, and frequency of maintenance)
14. Knowledge of linkage of product and process development to operation and maintenance of process equipment and facilities
15. Knowledge of continuous operations improvement

Controls and Automation

16. Knowledge of building management systems
17. Knowledge of types of process automation and associated controls

Track 2 - Information Systems

Knowledge of (a) the types of information and data management systems integral to successful drug development, manufacturing, and distribution; and (b) the controls and methods necessary to maintain data integrity and security.

1. Knowledge of data management systems with product and financial impact (for example, manufacturing execution systems [MES], laboratory information management systems [LIMS], electronic document management systems [EDMS], and enterprise resource planning
2. Knowledge of the basic computer system life cycle model and the activities and software quality assurance practices in each phase
3. Knowledge of data integrity and security measures, such as back-up, archiving, and retention requirements

Track 3 - Supply Chain Management

Knowledge of (a) the key components of the supply and distribution chains and their financial impact; (b) the systems required for dynamically controlling and automating receipt, storage and dispensing of raw materials and packaging materials; and (c) storage and distribution of finished products, so that the integrity of the product is not impaired by any of these processes.

Materials Management

1. Knowledge of the key components of the supply chain
2. Knowledge of supply chain and inventory models (for example, Kanban, JIT, APICS)
3. Knowledge of supply chain constraints that impact material and product throughput and their mitigation strategies
4. Knowledge of contributors to market projections and supply chain strategy for product

Operational Economics

5. Knowledge of the controls required for purchasing, receipt, storage, and dispensing of raw materials, and packaging materials and their related impacts on costs
6. Knowledge of industrial engineering standards and application to capital investments, facility and equipment utilization, and operational efficiencies

Warehouse and Distribution Management

7. Knowledge of warehouse and distribution management systems
8. Knowledge of transportation and logistics systems
9. Knowledge of environmental storage and transportation controls for hazardous and non-hazardous materials
10. Knowledge of distribution chain security and product disposition controls

Track 4 - Production Systems

Knowledge of (a) the full range and scope of unit operations and production steps for manufacturing APIs and both small molecule and biologic pharmaceuticals; (b) the building and critical process utility systems that support the manufacturing process; and (c) the means of managing and dynamically controlling and automating manufacturing and warehousing operations.

Production Unit Operations - Drug (small molecule) and Biologics

1. Knowledge of manufacture of active pharmaceutical ingredients, components, and excipients
2. Knowledge of unit operations
3. Knowledge of labeling and packaging operations
4. Knowledge of critical process equipment and utility systems' attributes (performance, functionality, construction, instrumentation) and their impact on personnel and product
5. Knowledge of the controls required for receipt, storage, and dispensing of raw materials, and packaging materials
6. Knowledge of industrial engineering standards, facility and equipment utilization, and operational efficiencies

Production Management

7. Knowledge of production management
8. Knowledge of storage requirements, production logistics, and RFID
9. Knowledge of environmental conditions, security, and status requirements

Production Control

10. Knowledge of batch records
11. Knowledge of contamination controls (for example, cleaning, segregation, HVAC) and changeover
12. Knowledge of critical factors that impact quality and how to control
13. Knowledge of methods and tools for data manipulation and analysis
14. Knowledge of critical quality attributes and process controls

Track 5 - Regulatory Compliance

(Includes drugs, environmental, health and safety)

A fundamental understanding of (a) international regulations and guidance issued by regulatory bodies and coalitions which shape the world's current pharmaceutical-related requirements and future directions, and (b) the application of regulations and industry-generated guidance for global harmonization of compliance and product registration.

Government Regulations

1. Knowledge of the role of regulatory bodies worldwide and their structure and operations
2. Knowledge of the role of legislation, regulations, guidance, and MRAs worldwide (for example, types of regulatory filings, GMPs)
3. Knowledge of the use of global compendia
4. Knowledge of the common base in requirements of regulating bodies around the world and awareness that differences exist

Standards, Practices, and Guides

5. Knowledge of the role of industry-generated guidance relating to international harmonization (ICH guidance documents; ISPE Baseline® Guides, GAMP®, and Good Practice Guides; and the PDA technical reports)
6. Knowledge of the role of common environment, health, and safety standards
7. Knowledge of the role of consensus standards (ISO, ANSI, ASTM)

Track 6 - Quality Systems

Knowledge of the role and elements of a quality management system and its impact within the overall risk management approach, as well as its implementation in a scientific and pragmatic manner.

Risk Management and Quality Management System (QMS)

1. Knowledge of purpose, elements and implementation of a QMS
2. Knowledge of risk management strategies
3. Knowledge of purpose, elements and implementation of change control programs
4. Knowledge of purpose, elements and implementation of CAPA programs
5. Knowledge of the elements of an internal assessment program

Systems Validation (changed from Validated Controls)

6. Knowledge of purpose, elements and implementation of product, process, facility, equipment, computer system, analytical method, and contamination control programs
7. Knowledge of impact of emerging process development and control strategies on traditional validation practices

Track 7 - Product Development/Investigational Products

Through the interactions of multi-disciplinary functions and the scientific application of experimental design methodologies, implement a process to reproducibly and economically manufacture a product of (a) the desired formulation, dosage form, and specifications that meets predicted quality; (b) is optimized for purity, potency, and efficacy; and (c) facilitates continuous improvement.

Formulation, Clinical Phases, and Manufacture

1. Knowledge of functions and pathways involved in product development
2. Knowledge of the purpose and conduct of clinical trials Phases I, II, and III
3. Knowledge of the impact of decisions (for example, dosage forms, batch size, production method, outsourcing) during drug development on product lifecycle viability and success
4. Knowledge of the production process and the role of interactions of ingredients/materials employed in pharmaceutical development and manufacturing
5. Knowledge of the impact of the processing, storage, and transport environments on ingredients/materials and semi- and finished goods
6. Knowledge of the impact of methods of measurement and control on product and process quality and stability
7. Knowledge that the physical and chemical attributes of the product have implications in production

Technology Transfer

8. Knowledge of the critical activities and success factors required for an effective and efficient technology transfer
9. Knowledge of requirements for planning, execution, and assimilation of technology and knowledge transfer

Production Scale-Up and Optimization

10. Knowledge of the options to increase and/or optimize production
11. Knowledge of the critical factors (for example, rate change, mechanistic properties, equipment design) of scale-up and their impact on manufacturability
12. Knowledge of the impact of factors that can positively or negatively affect scale-up
13. Knowledge of modeling techniques for optimization of product cycle time

Track 8 - Project Management

Project Managers assesses risk, mitigates against change and crisis, controls project knowledge and promotes project culture, establishes communication methods and defines reporting channels, and works to assure a collaborative partnership approach to project execution. Stages of Project Management require:

1. Knowledge of project initiation and business case development
2. Knowledge of early phase project development for process development
3. Knowledge of design management in the capital project lifecycle
4. Knowledge of project implementation of IP infrastructure
5. Knowledge of project closeout, product approval, product launch

Track 9 - Emerging Markets

Includes knowledge needed to understand critical challenges and solutions to those challenges in the delivery of projects in the emerging markets of India, Asia Pacific, Latin American, and BRIC countries. Knowledge explores considerations and solutions for designing, operating and qualifying a manufacturing facility in emerging countries and leads to an understanding of the current regulatory climate and common industry issues that have caused difficulties for companies in any given region.

Facilities

1. Knowledge of critical challenges in the delivery of projects in emerging markets
2. Knowledge of considerations and solutions for designing, operating and qualifying a manufacturing facility in an emerging market
3. Knowledge of regional challenges that must be incorporated into facility design
4. Knowledge of compliance and regulatory latitude available by health authorities in accommodating facility design

Outsourcing

5. Knowledge of the process for selecting CROs/CMOs
6. Knowledge of the importance and benefits of off-shoring for clinical R&D
7. Knowledge of intellectual property risks
8. Knowledge of benefits and constraints of organizational models
9. Knowledge of cross-cultural considerations

Regulatory

10. Knowledge of conducting clinical trials and registering products globally
11. Knowledge of local regulatory requirements and differing harmonized requirements
12. Knowledge of the current regulatory climate in emerging markets
13. Knowledge of how health authorities in emerging markets utilize existing standards