



**EMBRACING
THE CHALLENGE**
ISPE Strategic Plan
Summary
2016 – 2019





Purpose Statement

ISPE delivers technical and operational solutions to support our Members across the global pharmaceutical and biopharmaceutical industry in the manufacture of quality medicines for patients

Strategic Themes

Rapid Information Delivery



Ensure rapid access to relevant technical resources anytime, anywhere

Driving Efficient Manufacturing Operations



Develop and share holistic industry business solutions to critical issues

Local and Regional Relevance



Understand and shape strategy to the business, culture, and regulatory issues of local and regional markets

Compelling Member and Industry Value



Engage more individuals globally to join, learn, and contribute

Operational Strength



Execute with excellence and a sustainable business approach

Who We Are, Our Purpose

As the industry has expanded from traditional “home country” manufacturing bases in Western locations to countries around the world, ISPE has been intimately involved. Today, we span the globe as do our Members and their companies.

Our Baseline® Guides are relied on globally by industry and regulators to define the industry standards for design, construction and operation of pharmaceutical manufacturing facilities. ISPE’s training, conferences and Knowledge Networks give professionals solutions for their needs and connect them with other professionals to share best practices. We know how to design, build, qualify, license, operate and maintain these complex facilities, including those that manufacture active pharmaceutical ingredients, finished dosage forms, delivery systems and packaging. Through ISPE’s branded expertise in these areas we have deep technical knowledge that is applied in a practical manner.

We lead and facilitate the development of next generation process technologies and innovative technical solutions. On matters of regulation, our focus is on those requirements that impact—or will impact—the licensing of facilities, manufacturing processes and operations and the sustainability of the supply chain over the product lifecycle. We have developed relationships with and continue to provide key access to major regulatory agencies at the most senior levels.

In this next Plan period 2016 – 2019

To meet evolving industry needs and the changing regulatory environment, we will:

- Deliver on-demand access to ISPE knowledge and training to support execution and learning anywhere around the globe
- Implement a “solutions” approach to critical industry challenges
- Create strong Biotechnology competencies and industry guidance
- Establish a strong and sustainable presence in targeted Emerging Markets and add to our existing geographies

ISPE aims to offer increasing and unparalleled value for Members, companies and stakeholders globally and across all constituent parts of the industry. The end result will be the continued improvement and transformation of the pharmaceutical manufacturing industry to better ensure the availability of quality medicines to patients around the world.



Biotechnology



Supply Chain



Quality and Performance



Regulatory



Facilities of the Future

Strategic Areas of Focus



Operational Excellence



Emerging Markets

Strategic Themes

RAPID INFORMATION DELIVERY

Ensure rapid and timely access to relevant technical resources anytime, anywhere

- Digital strategy and solutions for flows of information/content through multiple channels
- Rapid and lean process for content development and approval
- On-demand access to ISPE knowledge assets

DRIVING EFFICIENT MANUFACTURING OPERATIONS

Develop and share holistic industry business solutions to critical issues

- Emphasis on Biotechnology
- Business results-themed forums, guidance and training sharing deep insights derived from exchange with Members, companies, regulators, suppliers and other organizations
- Leadership in regulation associated to ISPE core concerns and priorities
- Foundational training and related knowledge exchange

LOCAL AND REGIONAL RELEVANCE

Understand and shape strategy to the business, culture and regulatory issues of local and regional markets

- Focus on a targeted emerging market initially; then work to develop next priority countries and/or regions
- Continue to deliver programs in Europe, US/North America and other regions relevant to the needs in the local markets

Strategic Themes

COMPELLING MEMBER AND INDUSTRY VALUE

Engage more individuals globally to join, learn and contribute

- Flexible regionally-pertinent ways for more individuals in the industry to engage with the organization
- Assets that are accessible, easy to understand, fit for purpose and capture user-generated feedback and knowledge
- Strong Membership brand equity
- Value perceived by companies and health authorities

OPERATIONAL STRENGTH

Execute with excellence and a sustainable business approach

- Staff team with the needed skillsets to drive change
- Engaged volunteers in a range of roles that develop their contributions and strengthen ISPE
- Appropriate Information Technology infrastructure to support the strategic themes and operational needs
- Clear purposeful ISPE structure and lean business processes
- Assess opportunities and develop partnerships with external organizations to further advance ISPE initiatives

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