FOYA 2025

ISPE Facility of the Year Awards

Program Guide and Submission Instructions

ISPE

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

Table of Contents

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

Entries are due no later than Friday, 6 December 2024

For more information, contact the FOYA Team at FOYA@ISPE.org

I. 2025 FOYA Program Information

About the Program

Has your company recently designed, built, or renovated a state-of-the-art pharmaceutical or biotechnology (including ATMP) facility that is the best in its class? Submit an entry into the 2025 ISPE Facility of the Year Awards (FOYA) Program, and your facility may win the coveted Facility of the Year Award.

ISPE's Facility of the Year Awards Program is the premier global awards program recognizing innovation and creativity in the pharmaceutical and biotechnology manufacturing industries. The FOYA program showcases accomplishments in facility design, construction, and operations.

FOYA celebrates the shared commitment and dedication of teams working for various companies worldwide to enhance patient health and safety through innovation and advancements in pharmaceutical and biotechnology manufacturing.

Projects selected for these prestigious awards set the standard for pharmaceutical facilities by demonstrating excellence in the five main categories:

- Innovation
- Operations
- Supply Chain
- Pharma 4.0™
- Social Impact

The judges will further designate awards in subcategories for each award such as:

- Ex: Operations Category Winner for Project Execution (where Project Execution is the subcategory)

Subcategories allow judges more flexibility in awarding excellent and noteworthy projects throughout the industry. Judges may select multiple projects in each main category but not all subcategories need to be pre-defined before the submission window opens. While subcategories may not be predefined, they can initially be based on precedent awards and suggestions for which examples are provided in the Award Category Descriptions section.

Eligibility Building Types

Manufacturing Projects

- GMP manufacturing-based projects consisting of buildings, equipment, systems, and manufacturing methodologies deployed to manufacture regulated pharmaceutical drug substances, drug products, medical devices, combination products, and other commercial entities under the purview of the US Food and Drug Administration (US FDA), and other global regulatory bodies.
- Non-regulated facilities that meet the criteria listed above may also be eligible if the demonstration is provided to indicate they are operated within similar GMP guidelines.

Process Development Projects

Projects examples may include laboratories, pilot plants, medical devices, fill/finish, packaging facilities, and other similar process development facilities that may or may not be regulated. Submittals will be primarily judged on the merits of the applied innovation as it pertains to the development of pharmaceutical and biotechnology products.

Facility Requirements

The following types of projects may be submitted:

- Interior renovation of an existing facility
- Facility addition
- Newly constructed free-standing facility
- Substantial improvement to production efficiency

Facilities must have completed construction and major systems validation between **1 November 2022** and **31 December 2024**. As an example, the facility should be occupied and in full operation, or capable of producing products by an approved product license or under similar operational guidelines.

For GMP-regulated facilities, the facility should have been granted an operating license by an appropriate health authority or be awaiting such approval based on an application that has already been made by **31 December 2024.**

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

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I. 2025 FOYA Program Information (continued)

Submission Requirements

- Previous FOYA Winning Projects are not eligible.
- Entries may be submitted by the owner/manufacturer or by another company on behalf of the owner/manufacturer; however, the entry must be approved and signed by the owner/manufacturer and the owner must sign the Program Entry and Applicant Release Forms from the Submission Forms packet.
- All elements of the application must be completed, or the application will be disqualified.

All required entry forms are to be downloaded, completed, and emailed to ISPE. The full submission should be prepared by the guidelines provided in these instructions and submitted electronically. **See pages 9-11 for detailed submission instructions and recommendations for electronic submission.** Submissions must be received by the stated deadline and each submission must include all required information, signatures, and payment to be complete.

Payment for the US $800 entry fee must accompany each submission.

Judging

- Judges are interested in learning the reasons why a project is exceptional. They are looking for concise submissions that highlight relevant information and distinguish the innovative features of a project.
- Judging of submissions is based solely on the relevance and quality of the content provided and not the quantity or length of the submission.
- An independent panel of judges will be convened to evaluate all submissions, and select Submission Finalists, Category Winners, and the Overall Winner of the 2025 Facility of the Year Awards Program.
- FOYA Submission Finalists are selected which signifies that the project met all of the criteria to be considered for the Category Award. This does not guarantee that your project will be selected as a 2025 Category Winner.
- Judging will be undertaken by the schedule provided within this document.
- ISPE does not endorse any participating companies or submissions and reserves the right to make the final determination as to which entries meet eligibility requirements.
- Judges will be selected by ISPE and may include experts and industry leaders from manufacturers, equipment suppliers, regulators, design consultants, construction managers, commissioning and validation consultants, universities, and others as ISPE may deem appropriate.

Characteristics of Winning Projects

Winning projects are inspiring landmarks or lighthouses for future pharmaceutical and biotechnology facilities. Winning projects must relate to sites where the occupants work in a safe and productive manufacturing environment, where the facility applies new or innovative technological solutions, and where the facility enhances the client's ability to recruit top talent.

Examples of exemplary features of the previous Facility of the Year Awards Category Winners include:

- Fast-track project delivery through the innovative use of modular design
- Effective use of innovative process technology combined with practical functionality including but not limited to continuous manufacturing, real-time release testing, continuous quality verification (PAT), automation, robotics, or emerging designs/technologies
- Extraordinary planning, flexibility, and adaptability to ensure existing features meet the future needs of the facility
- Novel project delivery methods
- Use of key innovations throughout the project to meet and exceed business needs
- Effective integration of multiple technologies into a single unit
- Innovative approach to industrial facility design where core functions drive manufacturing and material handling
- Unique combination of established industry best practices that optimize manufacturing, ensure team-oriented project delivery, drive collaboration and increase overall speed to market
- Championing Pharma 4.0™ principles and applications

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

I. 2025 FOYA Program Information (continued)

Award Category Descriptions

Innovation

Novel application of process manufacturing techniques, innovative design concepts, new technologies, and unique solutions that exemplify the next generation of agile, flexible, efficient, and effective new and existing pharmaceutical and biotechnology facilities. This includes implementation of commercially available and custom-developed equipment that yielded superior results, improved competitive position, and/or demonstrated imaginative collaboration with vendors/suppliers/manufacturers. (Examples: continuous manufacturing, real-time release testing, continuous quality verification (PAT), automation, robotics, and other elements that set the direction for new and emerging designs/ technologies for a facility of the future.)

Subcategory Examples

- Facility of the Future
- Process Innovation
- Novel Technology
- Process Intelligence
- Equipment Innovation

Operations

Application of novel tools and approaches to delivering projects that improved efficiencies, overcame unusual challenges, promoted effectiveness, and organized stakeholders and project team participants in ways that led to successful outcomes such as efficiency, delivery, quality, product yield, consistency, and cost of goods. These projects should demonstrate a culture of continuous improvement behaviors which yielded superior results. Additionally, these principles, systems, and tools ensure business continuity through a stable supply environment, health and safety, and customer satisfaction from existing or new facilities, processes, and manufacturing operations use of a scorecard or other reports is encouraged to identify key performance metrics of operational excellence and demonstrate improvement. Application of good design practices and superior conceptual planning, which led to excellent integration of facility and process, yielding efficient, clean, pleasant environments promoting business advantages for staff and enterprise, encouraging excellent processing outcomes, and enhanced capabilities. Synergistic merging of process and building to create an environment of form and functional excellence.

Subcategory Examples

- Facility Fit
- Facility Modernization
- Operational Excellence
- Project Execution

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FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

Entries are due no later than Friday, 6 December 2024

For more information, contact the FOYA Team at FOYA@ISPE.org

I. 2025 FOYA Program Information (continued)

Supply Chain

Novel application of principles, systems, and management tools aimed at improving operational speed, robustness, and response. These could be applied to areas in which delivery to market impacts patients, technology amplifies supply chain robustness or security, or candidates exemplify modern approaches to disruption.

Subcategory Examples

- Service to the Patient with Speed to Market
- Robustness & Security
- Disruption Response
- Drug Shortage Mitigation

Pharma 4.0™

Assigned to projects that embody the Pharma 4.0 concept. Applicants to the award should not only have implemented one or more technological innovations but also demonstrated the ability to change their culture, processes, and people orienting them toward a 4.0 future. Significant contributions include application of one or more applied science-based solutions or digital innovations like automation, robotics, digital twin, or advanced processing understanding; substantial improvement to operational practices; or technologies widely & strategically implemented across the organization.

Subcategory Examples

- Digital Maturity
- Data Integrity by Design
- Advancing: Quality, Organization & Processes, Culture, Information Systems, OR Resources
- Impact and Maturity Model
- Process Intelligence

Social Impact

Application of novel approaches, standards, and practices that result in efficient processing, resourceful utilities, and business advantage by:

- Accelerating a shift to sustainable facility design, intended to ensure the effective use of energy, minimize waste, reduce carbon footprint, incorporate green manufacturing techniques, and reduce environmental impact.
- Increasing patient access & preventing drug shortages through in-country-for-country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment & fast- track drug production; and designs that overcome specific geographical challenges.

Subcategory Examples

- Sustainability Excellence
- Unmet Medical Needs
- Service to the Patient with Alliances and Collaborations

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

I. 2025 FOYA Program Information (continued)

2025 FOYA Program Schedule

August-December 2024	Submission packages accepted
6 December 2024	**Submission Deadline**
January 2025	The judging panel meets to select notable submissions and winners
January 2025	FOYA Submission Finalists are announced
May 2025	FOYA Category Winners are announced
May-November 2025	FOYA Category Winners are recognized by ISPE virtually and opportunistically while developing collateral materials at ISPE events
2025 ISPE Annual Meeting & Expo	Category Winners attend the 2025 ISPE Annual Meeting & Expo where they will be recognized during education sessions, the 2025 FOYA Banquet and Awards Celebration, and the ISPE Membership Meeting and Awards Lunch. The 2025 FOYA Overall Winner will be announced during the Banquet and Awards Celebration

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FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

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I. 2025 FOYA Program Information (continued)

Glossary

This page is for reference only. Do not include in submission.

DART	Ref. Construction Industry Institute—Days away, restricted or transferred
Delivery Type	Design/Bid/Build, Design/Build, Guaranteed Maximum Price, EPCM, and Other
Hazard Control	Any novel measures included in the project for containment purposes to protect the safety of the employees and/or product being manufactured. Typical containment measures include airlocks for personnel and/ or equipment, material pass-throughs, RABs system, glove boxes, air pressurization, HEPA filtration, dedicated HVAC zones, etc.
L2A	UK Building Regulations Approved Document L2A: Conservation of fuel and power *(new buildings other than dwellings)*
LEED*	U.S. Green Building Council— Leadership in Energy and Environmental Design, a green building rating system
Major System Validation	Defined as the confirmation, through the provision of objective evidence, that the requirements for the specific intended use or application have been fulfilled for all systems critical to supporting the intended process. *(Mechanical, WFI, Compressed Air, etc.).* Validation of the manufacturing process is not included in this requirement.
Production Area Classifications	Grade A/Class 5/ISO 100, Class 1000, Grade C/Class 7/ISO 10,000, Grade D/ Class 8/ISO 100,000, and Controlled/Unclassified
Production Facility Floor Area	The total floor area of a production facility *(not footprint)* including all production associated storage, in-process laboratories, and distribution areas but excluding general warehousing, laboratories, and administration areas
Site Safety: LTIR (During Construction)	Lost Time Incident Record *(OSHA definition)* Lost Time Incident (ECIA definition) Rate = No. of incidents x 200,000/ number of hours worked
Site Safety: RIR (During Construction	Reportable Incident Record
Sustainability	The Brundtland Commission defined sustainable development as development that "meets the needs of the present without compromising the ability of future generations to meet their own needs." This includes for example, energy efficiency, and environmental impact.
Total Direct Cost (TDC)	Direct cost *(i.e., as TIC but excluding project services costs, and owners' costs)*
Total Installed (TIC)	Cost of all buildings, equipment, utilities, and services, including engineering project services and an estimate of manufacturer's services but excluding land cost, off-site infrastructure, taxes, chemicals, and start-up costs.
Total Installed Cost (TIC)	As TIC but also including land cost, off-site infrastructure, taxes, chemicals, start-up, soft costs, and owners' costs
TRIR	Total recordable injury rate *(ref. Construction Industry Institute)*

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

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II. Instructions for Submission

Prepare all required project submission documents and entry forms in English and submit all materials as indicated below.

How to Prepare and Submit a Project Submission

A complete FOYA project submission has two parts, which should be submitted separately as indicated:

Part 1: The Project Submission Document

The Project Submission Document shall be limited in length to the number of pages and the items described in the Project Submission Document Format section below. Prepare as a Microsoft Word or Adobe PDF attachment and then upload into the online FOYA Submission Form.

Part 2: FOYA Submission Form

Complete the FOYA Submission form where you will be required to read and acknowledge various entry forms. Failure to complete all required fields on the entry documents will disqualify your submission.

You will be able to work on your submission form periodically by saving throughout the journey. Note, drafts will only be saved for up to 14 days. All submissions must be received by the deadline of Friday, 6 December 2024.

***Do not submit video or other content not specifically requested in these instructions.** Mailed copies of submissions will not be accepted.

Part 1: Project Submission Document Format

Project submissions are limited to the number of pages specified and should include all required information contained below. All required information should be provided in the same order. All Submission Documents will be uploaded into the online FOYA Submission form.

1. **Cover Page** *(one page)* — The cover page of the submission should include the company name, project name, project completion date, and categories for consideration.
2. **Table of Contents** *(one page)*
3. **Executive Summary** *(two pages)* — Narrative executive summary that includes:
   - General information about the company
   - Key technological engineering and innovative features of the facility
   - What products are manufactured in the facility?
   - What makes the facility unique or makes your project stand out?
   - Where were the anticipated results achieved or exceeded? If so, how what this accomplished?
   - Site selection, including the number of buildings and the opportunities for expansion
   - Societal impact on patient population (if applicable)
4. **Significant Contributions** *(this section should be the bulk of your submission and is limited to a maximum of 10 pages total)* — Provide the following information about the significant contributions your facility has made to the industry. Remember, judges, are looking for relevant information that distinguishes or differentiates the outstanding features of your project. Please tell us what you accomplished and how you accomplished it using any of the following areas as a guide:

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

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II. Instructions for Submission (continued)

For this section of the submission, it is not necessary to include information on all the sections listed below. **You only need to describe contributions in the areas relevant to your submission.**

Significant contributions to the pharmaceutical manufacturing & development **Innovation** in any of the following areas:

- Originality
- Innovative approaches/developments
- Systems/facility/process innovations
- Applications of new technology or new applications of existing technology
- Advances in manufacturing technology such as Continuous manufacturing
- Advances in facility design technology
- Advances in equipment design technology
- Advances in commissioning/validation technology

Significant contributions to **Pharma 4.0™**

- Real-time release testing
- Continuous quality verification (PAT)
- Automation
- Robotics
- Emerging design
- Emerging technologies
- Culture & organizational change

Significant contributions to the manufacturing & **Operations** in any of the following areas:

- Systems integration
- Flexibility/adaptability
- Facility/process integration
- Facility Fit
- Project Execution
- Project management
- Budget control
- Organization
- Innovative project delivery
- Response to business plan
- Change control
- Resource management
- Schedule control/expediting
- Novel strategy

Significant contributions to the **Supply Chain** resilience in any of the following areas:

- Ensuring business continuity through the reliability of supply
- Reduced downtime
- Faster product change over
- Increased efficiency
- Reduced cost of goods
- Reduced labor
- Reduced working capital
- Reduced cycle time
- Quality standards
- Response to environmental challenges
- Response to safety challenges
- Innovative approaches to cGMPs
- Lean/Six Sigma
- Proactive or predictive quality systems

Significant contributions to **Social Impact** in any of the following areas:

- Applications of green chemistry
- Reductions in carbon and/or total greenhouse gas emissions; solvent usage, VOC emission; wastewater COD, and energy reduction with downward trends in annual figures
- Responsiveness to environmental challenges
- Process intensification, reduced product waste, and improved yield that is translated to patient accessibility or affordability.
- Certification of general-purpose areas (e.g., USA LEED® level, UK L2A)
- Implemented policies and standards which aim to reduce the cost of drugs to consumers
- Advances in the prevention of drug shortages
- Designed to supply the capacity requirements for in-county-for-country manufacturing
- Rapid deployment and fast-track drug deployment to quickly respond to a health crisis
- Overcame barriers to address geographic challenges

FOYA 2025
ISPE Facility of the Year Awards

ISPE.org/FOYA

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II. Instructions for Submission (continued)

5. **Safety Considerations** *(one page)* — The health and safety of personnel are of utmost importance to ISPE and the FOYA Judges when evaluating projects. Please explain what measures were taken to ensure that this project met all safety requirements.

6. **Sustainability Efforts** *(one page)* — Sustainability is a global imperative that involves efficient design and operations of facilities and processes. Please explain what measures were taken to ensure that this project incorporated sustainability best practices.

7. **Reasons for Winning** *(one page)* — Please state the top five reasons why this facility should win the 2025 Facility of the Year Award.

8. **Photographs** *(minimum of nine photos requested)* — Please include at least nine high-resolution images within the submission (300 dpi or more is required) document or as an Appendix within the submission document. Each photograph must be numbered and clearly labeled with a short description of what the image depicts, and the photographer's name and year the photos were taken.

   - Two exterior images of your facility
   - Four interior images of your facility
   - At least three high-resolution images related to the category to which you are applying, as well as the innovative technological or other pertinent features of the project.

   Please include all (9) images in the Project Submission document. Additionally, you will upload your Project Submission document, along with the (9) images in the FOYA Submission Form.

Part 2: FOYA Submission Form

1. **Contact Information**
2. **General Project Information**
3. **Key Project Participants** — Provide the names of those companies/organizations that participated on the project.
4. **Project Size & Type** — Provide the following information about the size and type of the project scope only (in square feet)
5. **Project Provisions** - Provide the following information about the special provisions made for the project.
6. **Uploads & Acknowledgements**
   - **a.** Program Entry Form
   - **b.** Applicant Release Form
   - **c.** Photography Release Form
   - **d.** Photography Upload
   - **e.** Project Submission Document Upload
7. **Review Submittal**
8. **Submission Complete**

Part 3: FOYA Submission Payment

The FOYA submission fee is $800 USD. This must be received for your submission to qualify. Note, you will recieve a receipt of payment upon completion.

None of the materials received as part of a submission will be returned. All materials submitted will become the property of the ISPE Facility of the Year Awards Program and will be used to evaluate the submission. All materials submitted, including photographs, may be used at the discretion of ISPE, Pharmaceutical Engineering® magazine, other industry periodicals and publications free of charge.

2025 FOYA winners will be notified prior to the official announcement and before publicity is sent to the media.

The deadline to submit your application is Friday, 6 December 2024.