FOYA 2024

ISPE Facility of the Year Awards

Program Guide and Submission Instructions

ISPE

FOYA 2024
ISPE Facility of the Year Awards

ISPE.org/FOYA

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Entries are due no later than Monday, 4 December 2023

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

I. 2024 FOYA Program Information

About the Facility of the Year Awards 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 2024 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.

FOYA 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 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, or
- Substantial improvement to production efficiency.

Facilities must have completed construction and major systems validation between **1 November 2021** and **31 December 2023**. 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 2023.**

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I. 2024 FOYA Program Information (cont'd)

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 7–9 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$750 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 2024 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 2024 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

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I. 2024 FOYA Program Information (cont'd)

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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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 to be the ability to change their culture, processes, and people orienting them toward a 4.0 future. Significant contributions in the lude 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 and strategically implemented across the organization.

Subcategory Examples

- Digital Maturity
- Data Integrity by Design
- Advancing: Quality, Organization and 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 and preventing drug shortages through in-country-for-country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment and 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

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I. 2024 FOYA Program Information (cont'd)

2024 FOYA Program Schedule

May – December 2023	Submission packages accepted
4 December 2023	**Submission Deadline**
January 2024	The judging panel meets to select notable submissions and winners
2024 Quarter One	FOYA Submission Finalists are announced
2024 Quarter Two	FOYA Category Winners are announced
April – November 2024	FOYA Category Winners are recognized by ISPE virtually and opportunistically while developing collateral materials at ISPE events
2024 ISPE Annual Meeting & Expo	Category Winners attend the 2024 ISPE Annual Meeting & Expo where they will be recognized during education sessions, the Facility of the Year Awards Celebratory Reception & Banquet, and the ISPE Membership Meeting and Awards Lunch. The 2023 FOYA Overall Winner will be announced during the Celebratory Reception & Banquet

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I. 2024 FOYA Program Information (cont'd)

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 Project Cost (TPC)	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)*

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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 to an email or submit via a file-sharing service and send the link and access information via email.

Part 2: The Required Program Entry Forms
Complete and sign the required entry forms and send them as a PDF email attachment. Failure to complete all required fields on the entry documents will disqualify your submission.

The submission packet and project information should be provided as a PDF or Word document. All required entry materials must be submitted by email or through a file-sharing service. In the event of a discrepancy between multiple versions of the submission, the last version received before the deadline will be used for judging purposes. All submissions must be properly completed and received by the deadline of Monday, 4 December 2023.

***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. When sending multiple emails, please send at the same time and number the emails (i.e.., 1 of 3, 2 of 3, 3 of 3).

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:

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II. Instructions for Submission (cont'd)

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 and 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 and organizational change

Significant contributions to the manufacturing and **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

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II. Instructions for Submission (cont'd)

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 2024 Facility of the Year Award.

8. **Photographs** *(minimum of nine photos requested)* — Please include at least nine high-resolution images (300 dpi or more is required) within the submission 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.

   Additionally, please send all nine of the images as separate high-resolution .jpeg files to **foya@ispe.org**.

Part 2: Required Submission Forms

9. **General Project Information** — Please provide general project information using the General Project Information Forms as the last section of your submission package. The glossary page is for informational purposes and should not be included in your submission.

10. **Program Entry Forms** — All required entry forms must be signed and be provided separately from the submission by email. Please do not include the required entry forms as part of the actual submission package.

    A. Program Entry Form

    B. Submission Information Form: This must be sent as an excel file and will not be accepted in any other format. *(see linked spreadsheet):*

    C. Applicant Release Form

    D. Photography Release Form

    E. Payment Form

How to Submit Project Submission:

Email your submission to the FOYA Team at foya@ISPE.org

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.

The deadline to submit your application is Monday, 4 December 2023.

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III: Required Submission Forms

General Project Information Sheets

Please only provide required information and do not include glossary page.

Project name

Location

Project mission

Site information *(e.g., square footage of site and facility, construction type, and materials used)*

Project category or categories most applicable:
Please choose at least one category. See Award Category Definitions in Program Guide page 5 for more information about each category.

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

Do you meet the eligibility requirements for the 2024 FOYA program?

- ☐ YES
- ☐ NO

Submission finalist recognition
By selecting YES, you understand that your submission may be considered a "FOYA Submission Finalist" and will be featured at various ISPE events and digitally through ISPE. This does not guarantee that your project will be selected as a 2024 Category Winner.

By selecting NO, you prefer NOT to be recognized as a "FOYA Submission Finalist," and only wish to be featured at various ISPE events and digitally through ISPE if selected as a Category Winner.

- ☐ YES
- ☐ NO

III: Required Submission Forms (cont'd)

Applicable regulatory authority *(e.g., FDA, EMEA, MHLW, etc.)*

Status of regulatory approval—please specify date applied and date of approval

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III: Required Submission Forms (cont'd)

Please download the **General Project Information spreadsheet.** The submission will include the form below and the the excel spreadsheet.

Key Project Participants

Provide the names of those companies/organizations that participated on the project.

Manufacturer/Owner	
Name	
Mailing Address	
Telephone Number	
Email Address	
Engineer/Architect (A&E) *(Please list each company, if there was more than one.)*	
Name	
Mailing Address	
Telephone Number	
Email Address	
Engineer/Architect (A&E) *(Please list each company, if there was more than one.)*	
Name	
Mailing Address	
Telephone Number	
Email Address	
Engineer/Architect (A&E) *(Please list each company, if there was more than one.)*	
Name	
Mailing Address	
Telephone Number	
Email Address	
Commissioning qualifications & validation services *(Please list each company, if there was more than one.)*	
Name	
Mailing Address	
Telephone Number	
Email Address	

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Construction manager	
Name	
Mailing Address	
Telephone Number	
Email Address	
Main/General contractor	
Name	
Mailing Address	
Telephone Number	
Email Address	
Piping subcontractor	
Name	
Mailing Address	
Telephone Number	
Email Address	
HVAC subcontractor	
Name	
Mailing Address	
Telephone Number	
Email Address	
Automation and control supplier	
Name	
Mailing Address	
Telephone Number	
Email Address	
Major equipment supplier or contractor	
Name	
Mailing Address	
Telephone Number	
Email Address	
Major equipment supplier or contractor	
Name	
Mailing Address	
Telephone Number	
Email Address	

* Please list any additional suppliers, along with their contact information, on a separate sheet and attach it to the back of this form.

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III: Required Submission Forms (cont'd)

Project Size and Type – Provide the following information about the size and type of the project scope only (in square feet)

Production area	sf
Production support areas only including storage/staging *(if applicable)*	sf
Laboratory area *(if applicable)*	sf
Laboratory support areas only *(if applicable)*	sf
Total *(gross)* project floor area	sf
Production Area Classifications (identify all that apply) *Grade A/Class 5/ISO 100, Class 1000, Grade C/Class 7/ISO 10000, Grade D/Class 8/ISO 100000, Controlled/Unclassified*	
Delivery type: *Design/Bid/Build, Design Build, Guaranteed Maximum Price, EPCM, Other*	

Production Size

Provide the following information about the production size of the project:

Production capacity per year *(e.g. capsules/yr, dosage form/yr, units/yr) (if applicable)*	
Reactor/bioreactor total volume *(m3) (if applicable)*	
Other particular equipment sizing of interest	

Project Costs

Provide the following information about the cost of the project in US Dollars *(costs must be included for submission to be complete):*

Budgeted total project cost *(TPC)*	US$
Total direct cost *(TDC)*	US$
Total installed cost *(TIC)*	US$
Total project cost *(TPC)*	US$

Engineering Costs

Provide the following information about the engineering cost of the project in US Dollars *(costs must be included for submission to be complete):*

In-house design/engineering services costs	US$
Consultant design/engineering services costs	US$
Construction management costs	US$
Commissioning costs	US$
Qualification/validation costs *(including IQ/OQ, but not PQ/PV)*	US$

Project Timing

Provide the following information about the timing of the project:

Start date of feasibility/concept study	
Total feasibility/concept study duration *(in months)*	
Start date of casis of design concept design	
Total basis of design concept design duration *(in months)*	
Start date of detailed design	
Total detailed design duration *(in months)*	
Start date of construction	
Total construction duration *(in months)*	
Major systems validation completion date	
Start date of commissioning and IQ/OQ	
Total commissioning and IQ/OQ duration *(in months)*	
Start date of PQ/PV *(performance lots)*	
Total PQ/PV *(performance lots)* duration *(in months)*	
Date product first produced *(if applicable)*	
Date license granted to allow manufacture *(if applicable)*	

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III: Required Submission Forms (cont'd)

Project Provisions

Provide the following information about the special provisions made for the project: *(Use an additional sheet if necessary and submit with this form. However, please limit each response to a 250-word maximum.)*

Please complete ALL sections.

Personnel safety
This is of particular importance to the judges in evaluating submissions and data provided, and must take into account all contractors and support people. All injuries or loss of life must be disclosed. If there is loss of life, the entry will be rendered ineligible.

Construction safety statistics, for example LTIR, RIR, DARTIR, TRIR
(See the Glossary on page 8 for more information.)

Total direct construction hours

Hazard control

Environmental impact

Sustainability

Access for people with disabilities, if appropriate

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A. Program Entry Form

I, _____ as a representative of *(company name)* _____ affirm acceptance of all policies and guidelines for the 2024 Facility of the Year Awards Program and officially submit the enclosed materials to be considered a candidate submission for the Awards. In addition, I verify the following to be true of the facility and companies specified in the submission as of the date of signature:

- The facility submitted has completed construction between 1 November 2021 and 31 December 2023. Major systems have been validated and the facility is in operation. Specifically, this means that the facility should be in operation or is capable of producing product in accordance with an approved product license, if applicable. The facility has been granted an operating license, if applicable, by an appropriate health authority, or is awaiting such approval based on an application that has already been made.
- There is no information I am aware of that could potentially prevent the facility from being licensed or used for the purposes stipulated in the submission.
- I agree to notify ISPE immediately of any changes in the submission status including, but not limited to:
  - Feedback from regulatory authorities that suggest the ability to obtain a license to operate the facility is in question or subject to substantial delay
  - Unexpected problems in startup or actual manufacturing that suggest the plant will not begin operation as scheduled or will not operate within the cost parameters originally anticipated when the project was initiated and/or submitted for the 2024 Facility of the Year Awards program review process
  - A change in business plans that would prevent this facility from proceeding into commercial manufacturing as planned for whatever reason
  - Failure to perform, or significant under-performance, of any new technology, or new approaches to regulatory considerations, of any significant elements of the project submitted. Of particular importance would be notification of the failure of any elements of the submission that were highlighted for consideration by the judges for the various category awards.
- The facility has not received a regulatory review or citation indicating that it may not be approved.
- The facility is in full compliance with appropriate local, national, and international laws required for operation and production.
- There is no additional information known about the organizations involved, or the facility submitted, that by not being disclosed could disparage or damage the integrity of the 2024 Facility of the Year Awards Program and/or ISPE.
- ISPE reserves the right, in its sole discretion, to rescind an award, at any time, should a winning company or facility be the subject of any legal or regulatory non-compliance action, or any other action that could disparage or damage the integrity of the 2024 Facility of the Year Awards Program.
- Upon notification of the rescission of an award, the company and facility shall immediately cease using the FOYA winner logo and cease any representation it is a FOYA award winner, for all purposes, including but not limited to, any marketing, advertising, or other publicity purposes.

Signature	Date

This form must be completed and signed by an authorized representative of the owner/manufacturer.

ISPE's regional Affiliates are important to the successful promotion of the Facility of the Year Awards Program. Regional offices assist in promoting Facility of the Year Award winners and their projects around the world, as well as help disseminate important lessons-learned from each of the winning projects to benefit the pharmaceutical industry. Although not a requirement of the program, ISPE hopes that award winners will consider allowing site visits by industry professionals involved with ISPE regional Affiliates.

The information submitted for consideration in the FOYA program is kept strictly confidential and is only shared with the Judging Committee for review of the project's merit. This submission will not be shared outside of ISPE staff/contracted partners or the judging team.

Entries are due no later than Monday, 4 December 2023

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

FOYA 2024
ISPE Facility of the Year Awards

ISPE.org/FOYA

Entries are due no later than Monday, 4 December 2023

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B. Submission Information Form

Official company name (Make sure to include the EXACT company name which will be used for all publicity and publication purposes.)	
Owner's name/organization	
Authorized representative's name	**Title**
Street address	**City**
State/Province	**Postal code**
Country	
Telephone	**Fax**
Email	**Website URL**
Primary point of contact	
Company name/organization	
Telephone	**Email**
Submitting firm name (if different from owner)	
Contact name	**Title**
Telephone	**Fax**
Email	**Website URL**
Public relations representative	**Title**
Company name/organization	
Telephone	**Email**

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C. Applicant Release Form

I, _____, with _____ *(company name)*, affirm acknowledgement and acceptance that ISPE may use any and all non-confidential information contained in the submission for publicity purposes, only if the submission is selected as a Category Winner or Facility of the Year Awards Overall Winner. Individual financial information will not be publicly disclosed. I thereby grant ISPE authorization to publicize, publish, and exhibit the enclosed Facility of the Year Awards Program submission information as noted above free of charge and without restrictions.

It is understood written authorization must be provided by each photographer or photography studio authorizing use of all photography for promotional purposes before an entry will be considered complete. In the event the submitting company owns the photography, the submitting company will provide said authorization at no charge to the FOYA Program and ISPE.

Subject to my review, I agree to allow ISPE authorization to publicize and publish quotes from me and my company representatives free of charge and without restrictions.

☐ Yes ☐ No

Signature	Date

This form must be completed and signed by an authorized representative of the owner/manufacturer.

Entries are due no later than Monday, 4 December 2023

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D. Photography Release Form

This photography release form must be completed by each photographer or photography studio for all photography included in your submission.

I, _____, am the original owner of all photography and retain appropriate copyrights. I grant authorization for all materials (i.e., slides or prints) submitted for the 2024 Facility of the Year Awards Program application to be used on the Facility of the Year Awards Program website, in the magazine *Pharmaceutical Engineering*®, in press releases, or any other legitimate industry periodical free-of-charge for any or all of the following:

- Editorial coverage
- Advertising
- Promotional material
- Any other purpose deemed necessary by ISPE.

Signature	Date

Entries are due no later than Monday, 4 December 2023

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E. Payment Form

Payment by check or credit card billing information, and authorization in the amount of **US$750** must accompany submission. Please contact **the FOYA team at foya@ispe.org** for additional information and check payments.

☐ Check #_____ enclosed
(payable to ISPE in the amount of **US$750** *and drawn on a US bank)*

Credit Card Payment

☐ Visa ☐ MasterCard ☐ Eurocard ☐ American Express

Card number	**Expiration date**	**CCV#**

Cardholder name *(as it appears on card)*

Cardholder email address	**Company name**

Cardholder signature	**Date**

Entries are due no later than Monday, 4 December 2023

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