



ISPE Pharma Best Practices Webinar Series

Be the Next Winner of the Facility of the Year Awards (FOYA)

Tuesday, 1 June 2021, 1100 – 1200 ET

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FOYA

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Welcome

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FOYA

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Introduction/Overview and FOYA Background

Dave DiProspero

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Session Agenda

- Introductions and Overview
- FOYA Background/History and 2021 Winners
- The FOYA Submission Process
- A Judges Perspective
 - What Makes a Great Submission
 - What are the judges Looking for
- Panel Discussion/Q&A
- Wrap Up

Speaker Introductions



Antonio C. Crincoli

Vice President of Global Engineering
Charles River Laboratories Inc



Paula P. Casalino

VP, Operations, Canada Operations
IPS



Avril J. Vermunt

Senior Director, Head of MSAT
Adverum Biotechnology



Dave Di Prospero

Director of Pharmaceutical Process Technology
CRB



Parag Sane

Director Engineering Projects
Amgen, Inc

2021 Category Winners



Johannes Van Der Loo, PhD

Director, Clinical Vector Core
Children's Hospital of Philadelphia



John M. Wichelt

Vice President Client Pharmaceutical Services
Grand River Aseptic Manufacturing



Maneesh Ghildyal

Vice President & Global Head Projects & Engineering
Biocon Ltd



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ISPE Facility of the Year Awards (FOYA)



ISPE's Facility of the Year Awards (FOYA) program is the premier global awards program recognizing innovation and creativity in the pharmaceutical and biotechnology manufacturing industries.

FOYA showcases accomplishments in facility design, construction, and operation. It celebrates the shared commitment and dedication of individuals working for different companies worldwide to enhance patient health and safety through innovation and advancements in pharmaceutical manufacturing technology.

FOYA Winners Span the Globe



Since 2005, FOYA has recognized 115 winners from 20 countries across the globe.

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2021 ISPE FOYA Winners



Takeda Pharmaceuticals International AG

Facility Integration
Grange Castle, Ireland

ElevateBio

Operational Excellence
Waltham, MA USA

Janssen Sciences Ireland

Project Execution
Ringaskiddy, Ireland

Takeda Pharmaceuticals International AG

Process Intelligence and Innovation
Hikari, Japan

Government Pharmaceutical Organization (GPO)

Social Impact
Saraburi Province, Thailand

Gilead Sciences, Inc.

Operational Agility: COVID-19 Impact
Foster City, CA USA

Grand River Aseptic Manufacturing

Operational Agility: COVID-19 Impact
Grand Rapids, MI USA

Biocon Biologics Limited

Honorable Mention
Bangalore, India

Locus Biosciences

Honorable Mention
Morrisville, NC USA

Raymond G. Perelman Center for Cellular and Molecular Therapeutics

Honorable Mention
Philadelphia, PA

2020 – 2005 ISPE FOYA Winners



2020
Sanofi
Facility of the Future
Framingham, MA USA

2019
Kantonsapotheke Zürich
Operational Excellence
Schlieren, Switzerland

2018
Shire
Facility Integration
Los Angeles, California USA

2017
Eli Lilly and Company
Process Innovation and
Facility of the Future
Indianapolis, IN USA

2016
Genentech, a Member of the Roche Group
Process Innovation
Vacaville, California, USA

2015
AstraZeneca China
Project Execution
Taizhou, China

2014
Pfizer Ireland Pharmaceuticals
Operational Excellence
Grange Castle, Dublin, Ireland

2013
Novartis Vaccines and Diagnostics
Process Innovation
Holly Springs, North Carolina, USA

2012
Merck & Co., Inc.
Facility Integration
Durham, North Carolina, USA

2011
MedImmune, LLC
Project Execution
Frederick, Maryland, USA

2010
Genentech
Project Execution
Tuas, Singapore

2009
Roche Pharma Biotech
Production Basel
Project Execution
Basel, Switzerland

2008
Pfizer Manufacturing Deutschland GmbH
Process Innovation
Wertissen, Germany

2007
Genentech
Project Execution
Oceanside, California, USA

2006
Baxter BioPharma Solutions
Bloomington, Indiana, USA

2005
Novo Nordisk A/S
Hillerød, Denmark

The FOYA Submission Process

Avril Vermunt

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Program Overview Highlights/Key Activities

- Submission Submittal
- Judges Review
- Category Award Winner Announcement
- Winners Video - Media and Publicity
- FOYA Education Session Annual Meeting
- FOYA Banquet
- Overall Winner Announcement
- Overall Winner Media and Publicity

Submission Timeline

2022 FOYA Program Schedule

May 2021 – 19 November 2021	Submission packages accepted
19 November 2021	Submission Deadline
January 2022	Judging panel meets to select winners
Q2 2022	Winners are announced
April – October 2022	Winners are recognized by ISPE virtually and opportunistically while developing collateral materials at ISPE Events
Q3/Q4 2022	Winners are recognized at the FOYA Education Session and FOYA Banquet during the ISPE Annual Meeting and Expo
Q3/Q4 2022	Category Winners attend ISPE Annual Meeting & Expo where winning facilities are recognized, and the 2022 Facility of the Year Awards Overall Winner is announced



Submission Requirements

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 2019 and 31 December 2021.

Submission Requirements

- Previous FOYA Winning Projects are not eligible.
- Entries may be submitted by the owner/manufacture or by another company on behalf of the owner/manufacture;
 - Entry must be approved and signed by the owner/manufacture
- All elements of the application must be completed, or the application will be disqualified.

Instructions for Submission

Part 1: Project Submission Format

1. Cover Page
2. Table of Contents
3. Executive Summary
4. Significant Contributions
5. Safety Considerations
6. Sustainability Efforts
7. Reasons for Winning
8. Photographs

Part 2: Required Program Forms

1. General Project Information
2. Program Entry Forms

FOYA Categories

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

Innovation

Operations

Supply
Chain

Pharma 4.0

Social
Impact

FOYA 4.0* | Aligning FOYA Categories to ISPE's Strategic Pillars

5 Main Categories

Sub- Categories

Innovation	Operations	Supply Chain	Pharma 4.0	Social Impact
<ul style="list-style-type: none"> Facility of the Future Process Intelligence & Innovation Novel Technology 	<ul style="list-style-type: none"> Facility Fit & Modernization (formerly Facility Integration) Operational Excellence Project Execution 	<ul style="list-style-type: none"> Service to the Patient for Speed to Market Robustness & Security Disruption response (Pandemic, natural disaster, etc) Drug Shortage Mitigation 	<ul style="list-style-type: none"> Digital Maturity Data Integrity by Design Advancing: <ul style="list-style-type: none"> Quality Organization & Processes Culture Information Systems Resources Impact and Maturity Model 	<ul style="list-style-type: none"> Sustainability Efforts Service to the Patient for Unmet Medical Needs Service to the Patient for Alliances and Collaborations

Examples: Pharma 4.0 Category Winner for Digital Maturity
Supply Chain Category Winner for Disruption Response

A Judges Perspective

Antonio Crincoli
Parag Sane

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What Makes a Winning Entry?

- Improvements to Manufacturing Supply Chain Reliability and Product Quality
- Novel Execution Methods, Process or Tools
- Use of New Technologies, or Clever Integration with Existing Assets
- Overcoming Major Project Risks and Challenges
- Strong Program Performance for Opex and Lean Execution Methods
- Sustainability...Step Changes, next level Social Impact
- Exceptional Safety Execution Performance
- Strong Cost & Schedule Performance
- Great Team Performance & Collaboration

What Are Judges Looking For?

Was it innovative or a clever solution?

- We've seen it all before.....
- Small process improvements make a big impact!
- Was it a step change in the way things are done?

Was it effective in terms of time, cost, quality, safety?

- Large and expensive does not equal "winner"!

Will the industry learn & benefit?

Trends

- Continued trend of innovative automation solutions leveraging machine vision, data mining etc
- Increased use of BIM and deeper penetration of this tool throughout project lifecycles and beyond Use of New Technologies, or Clever Integration with Existing Assets
- Focus on modularization
- Increased focus on sustainability efforts from submissions from all parts of world

Panel Discussion/Q&A

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Panelists



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Biocon Ltd



Wrap Up

Dave DiProspero
Jessica Hardy

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Learn How You Can Be FOYA Winner



2022 Submissions Now Open



Visit ispe.org/FOYA for information on applying



Deadline to submit is **Friday, 19 November 2021**



Winners will be announced in Spring 2022

Upcoming Webinars

- [ISPE Expert Xchange: Enabling Pharma 4.0 through Plug & Produce](#)
Thursday, 10 June
Expert Xchange
- [Getting the Most Out of TOC: How to Improve Data Quality and Increase Productivity](#)
Tuesday, 15 June
Complimentary – Sponsored by Suez
- [Women in Pharma®: Boosting Self Confidence. The Moments That Matter](#)
Wednesday, 23 June
Complimentary
- On Demand Webinars Now Available visit [ISPE.org/webinars](https://www.ispe.org/webinars) for the full calendar