



2021 ISPE Facility of the Year Awards

The International Society for Pharmaceutical Engineering (ISPE) have announced the 2021 Facility of the Year Awards (FOYA) Category Winners—including two winners of Special Recognition Awards for Operational Agility: Covid-19 Impact.

FOYA is the premier global awards program recognizing innovation and creativity in manufacturing facilities serving the pharmaceutical industry. The award-winning projects selected by the FOYA program set the standard for pharmaceutical facilities of the future by demonstrating excellence in facility design, construction, and operations.

“Now more than ever, it is important to spotlight the dedication of companies like the 2021 FOYA Category Winners who are at the forefront of setting the leadership example for the design, construction, and project execution of pharmaceutical facilities incorporating unique approaches to innovation, operability, flexibility, and key principles regarding social impact. These factors accelerate the industry’s interests to bring the next generation of transformational medicines to patients worldwide,” said Thomas

Hartman, President & CEO, ISPE. “Covid-19 has certainly presented significant challenges to the pharmaceutical industry, and the innovations of these dedicated companies has a direct impact in shaping global expectations for the manufacture of effective and safe medicines.”

2021 Facility of the Year Category Awards Winners

Facility Integration

The Facility Integration Category was awarded to **Takeda Pharmaceuticals International** for its Ninlaro The Grange Castle Factory P2 Facility in Grange Castle, Ireland. The P2 facility includes drug substance manufacture (DS), drug product (DP) blistering and secondary packaging, quality control (QC) testing, and quality assurance

(QA) operations in one dedicated building. The vision for the facility was to keep it small, simple, safe, and integrated. The most novel concept of the four was the integration of the three facilities. The project exemplifies how application of good design practices and superior conceptual planning leads to excellent integration of facility and process, yielding efficient, safe, and excellent processing outcomes.

Operational Excellence

ElevateBio was awarded the Operational Excellence Category Award for its Elevate Bio Base Camp in Waltham, Massachusetts, USA. The project’s goal was to tackle some of the obstacles that prevent cell and gene therapies from rapidly being available to patients. The 140,000-square-foot Base Camp facility integrates various strate-

gic utilization improvements to the cell and gene therapy development process. By embracing a business model that provides flexible capacity, high throughput, and process expertise while optimizing efficacy and safety, BaseCamp establishes itself as a Next Generation model for rapid therapy development and launch. ElevateBio is proving that it is possible to bring successful therapies to market faster and more efficiently than ever before.

Process Intelligence and Innovation

Takeda Pharmaceuticals International won the Process Intelligence and Innovation Category Award for its F36 New Solid Pharmaceutical Production Building in Hikari, Japan. The strategic use of digital and automated systems in the design solution has produced a state-of-the-art packaging facility with increased safety, quality, and overall efficiency. The outcome provides a "first time right" packaging operation, significantly reducing potential human errors and the likelihood of product mix-ups between batches. This achievement was made possible through strict adherence to Quality by Design (QbD) principles embedded in the project design and execution, leading to a highly compliant facility that is certain to impress regulatory authorities and inspectors.

Project Execution

The Project Execution Category was awarded to **Janssen Sciences Ireland** for its BioCork2 — Large Scale Fed Batch Facility in Ringaskiddy, Ireland. Janssen embarked on expanding its biologics manufacturing facility to ensure a sustainable supply of lifesaving medicines for patients. The BioCork2 Project was initiated to add new drug substance fed batch capacity at 15,000 L scale. With the assistance of Project Management Group (PMG) as designer and John Sisk & Sons as builder, the team constructed a 200,000 square foot facility on time and within budget with a strong safety performance record. Construction of the facility started in October 2017, with PPQ batches commencing in September 2020.

Social Impact

Government Pharmaceutical Organization (GPO) was awarded the Social Impact Category Award for its Thailand Self Sufficient for Pandemic Vaccines; Influenza and Covid-19 project in Saraburi Province, Thailand. Attempting to adopt a zero-waste concept, solid waste from eggs used in production is recycled — decontaminated, dehydrated, and grounded — and used as fertilizer or in cement blocks. The GPO plant also uses roof-top solar panels that provide 800 kilowatts of power. The team hopes to ramp up use of solar panels to produce 1,200 kilowatts of power, which would make the plant self-sufficient when it comes to the use of electricity.

Special Recognition Awards

The first of two companies to be awarded a Special Recognition Award for Operational Agility:



Covid-19 Impact was Gilead Sciences, Center for Innovative Drug Research (CIDR) in Foster City, California, USA. Gilead's application of its research facilities within the CIDR was key in bringing forward Remdesivir — the first therapy that was approved to counter the debilitating impact of the Covid-19 virus. The facility design was dominated by the overarching principles of interconnectivity between laboratories, allowing Gilead to expedite promising treatments to be developed without compromising other pipeline projects. In response to the Covid-19 pandemic, Gilead researchers leveraged this flexibility within the facility to further a promising molecule for clinical trials, which required quickly completing complicated development work.

The second of two companies to be awarded a Special Recognition Award for Operational Agility: Covid-19 Impact was **Grand River Aseptic Manufacturing (GRAM)** for its Large-Scale Fill-Finish Facility in Grand Rapids, Michigan, USA. This facility stood out for the agility and responsiveness demonstrated in becoming available to support supply needs. GRAM created a project execution framework that allowed safe operations while the schedule was being accelerated. This included PPE provisions and facility inspections before and after the construction day to limit exposure and keep the inspection process moving forward. In addition, GRAM started the qualification process in parallel with the final construction to get a jump on the schedule.

Honorable Mentions

Biocon Biologics Limited was awarded an Honorable Mention for its Biocon Biologics Manufacturing (B3) Project in Bangalore, India. The goal was to build a state-of-the-art facility that includes consideration for future commercial products. This involved expanding the site to construct new manufacturing, laboratory, office, cafeteria, utility, and warehouse buildings. Several design elements and execution strategies implemented in this facility showed teams focus on robust supply chain while focusing on the cost of goods manufactured reduction, which could potentially lead to a beneficial cost structure on products for patients, increasing affordability. They demonstrated their concentrated efforts to minimize the impact through multiple sustainability elements. In addition, this project team displayed a superior execution approach in managing construction safety.

Locus Biosciences received an Honorable Mention for its Commercial Phage Production Facility Upfit in Morrisville, North Carolina, USA. Locus uses bacterial phages and DNA editing technology, CRISPR Cas3, to produce Cas3-enhanced bacteriophage (crPhageTM). Once Locus started the first recombinant phage phase 1b clinical trial, they needed a larger cGMP facility to continue this and future clinical trials. Locus built a 12,000 square foot facility in a 30-year-old building with three equally capable suites with the ability to provide for simultaneous and interchangeable production space and the capability to produce three different products simultaneously. Design attributes and operational procedures go beyond the regulatory requirements, delivering safe and effective products.

Raymond G. Perelman Center for Cellular and Molecular Therapeutics was awarded an Honorable Mention for its Raymond G. Perelman Center for Cellular and Molecular Therapeutics in Philadelphia, Pennsylvania, USA. The facility is dedicated to the manufacture of adenoassociated and lentiviral vectors supporting clinical trials and is located in the nation's first hospital dedicated to the care of children, the Children's Hospital of Philadelphia (CHOP). The 13,000 square foot GMP facility offers the capability for a wide range of vectors and genes of interest. The benefit of the cell and gene therapy scale is that significant capability arises within a small footprint. The CCMT facility offers cell expansion, 4 cleanroom suites, fill finish, and support space. It has already completed multiple clinical trials, demonstrating a successful outcome of the project.

2021 ISPE Annual Meeting & Expo

The 2021 FOYA Category Winners will be formally recognized at the ISPE Facility of the Year Awards Banquet, held in conjunction with the 2021 ISPE Annual Meeting & Expo taking place 1-3 November 2021. The banquet will feature acceptance speeches from the FOYA recipients and presentations from noted industry leaders. The 2021 FOYA Overall Winner will be announced at the conference during the Membership and Awards Breakfast.

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