FOYA 2024

ISPE Facility of the Year Awards

2024 CATEGORY WINNERS

SPOTLIGHT ON EXCELLENCE

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2024 FACILITY OF THE YEAR AWARDS (FOYA)

Category Winners Spotlight on Excellence

FOYA 2024
ISPE Facility of the Year Awards

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ABOUT FOYA

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WELCOME & THANK YOU

On behalf of ISPE, I am excited to recognize this year's winners of the 2024 ISPE FOYA Awards. Since 2005, these awards have been showcasing continuous improvement mindset and technology evolutions. This platform continues to provide project execution teams a global forum to demonstrate their exceptional projects and offer industry peers valuable benchmarks.

For us in the FOYA Judging Committee, each year brings new and unique solutions to challenges in project delivery. We continue to see lasting impacts of supply chain constraints, strained resource supply, and inflationary trends reflected in these projects even four years after the COVID-19 pandemic. Despite these challenges, FOYA projects consistently showcase the 'best of the best' in pharmaceutical manufacturing.

The FOYA Judging Committee, is proud to recognize transformational projects that have made a profound impact on humanity, as seen during the pandemic response. We have also celebrated distinguished accomplishments in driving paradigm shifts in Pharma 4.0 technology, sustainability, and supplying to underprivileged populations, all while continuing to innovate and deliver novel treatments for patients.

How do I know if my project can be submitted for FOYA and who judges these ?

FOYA is a globally recognized award program that routinely receives project submissions from multiple international locations. These submissions come from a range of organizations, including large global corporations in pharma, biopharma, and medical devices, regional companies, government-backed organizations, and innovative cell and gene therapy enterprises. FOYA recognizes these projects across multiple categories including an overall FOYA winner.

The submissions are reviewed by the FOYA Judging Committee, composed of a diverse mix of recognized industry leaders from various geographies and organization sizes within the life sciences sector. These judges have demonstrated extensive experience in fields such as engineering, supply chain, manufacturing operations, and quality. These committee members have firsthand experience leading and delivering complex, successful projects, many of which have been recognized with FOYA awards in the past.

What is the submission review process?

The FOYA Judging Committee meets each January to review, discuss and debate each submission on its merits compared to all other submissions. During the pandemic in 2021 and 2022, the panel met virtually, but since 2023, in-person judging sessions have resumed. Each judge reviews all submissions and volunteers to present a summary of one project to the judging panel.

Judging typically lasts multiple rounds through a process of elimination. In the first round, each project is discussed for the quality of the submission, its merits against various FOYA categories, innovative approaches, and social impact. Projects that meet various criteria and compare strongly with other projects advance to the second round. In the second round, projects are compared within the various FOYA categories, with obvious winners and shortlisted submissions advance to third round.

In the third round, each category winner is reviewed and assessed. If no submissions meet the criteria, that category award is not given. At the end of third round then judges assess all finalist projects for holistic execution approach, innovation, social impact, digital innovation and other factors to determine if a project stands out as the overall FOYA winner. All voting for every round is anonymous.

All FOYA judges must sign a confidentiality agreement. If a FOYA judge's organization has submitted a project, that judge abstains from any discussions around that submission.

What does a winning submission look like?

Key differentiators like patient impact, execution, safety, innovation, and unique approaches are essential to FOYA awards, which aren't limited to large and complex projects. Judges understand that smaller projects often enhance production capacities, expedite product transfers, improve supply chain robustness, and deploy new transformational digital technologies, all crucial for resilient supply chains and efficient operations. Therefore, the overall impact of a project is more significant than its size in determining award winners.

Every year we receive numerous submissions, and our judges work diligently to identify the distinguishing factors that set projects apart. Keeping with that goal, ISPE announces the FOYA Submission Finalists to showcase the projects that met all qualification requirements for their respective FOYA Category awards. I would like to thank Antonio Crincoli, PE, VP of Global Engineering at Catalent for his over 10 years of dedicated service as the FOYA Judging Committee Chairman. The diversity represented in today's judging panel is a testament to his industry leadership and outreach in assembling this distinguished panel. I also am grateful for all the judges for their dedication to support these key industry awards. The thoughtfulness and diligence of every single judge have strengthened the ISPE FOYA Awards over the years. The quality of submissions, level of innovation, and execution excellence make the judging process increasingly challenging. Thanks to all the organizations and their service provider partners who put tremendous effort into preparing these high-quality submissions.

__FOYA__ has been recognizing innovations in the pharmaceutical industry since 2005.

Parag Sane
Chair of the FOYA Judging Committee
Executive Director Engineering Projects
Amgen Inc.

ISPE THANKS THE 2024 FOYA JUDGES COMMITTEE

For their continued support of the FOYA program.

Parag Sane
Chair,
FOYA Judging Committee
Amgen Inc.

Antonio C. Crincoli
Past Chair,
FOYA Judging Committee
Catalent Pharma Solutions

Gunter Baumgartner
Takeda Pharmaceuticals International AG

Scott W. Billman
Solventum

James A. Breen, Jr.
Johnson & Johnson Innovative Medicines

Victor M. Cruz
Eli Lilly and Company

Jian Dong
Wuxi Biologics

Edward F. Fitzgerald
Merck

Joydeep Ganguly
Gilead Sciences, Inc.

Michele Ghinizzini
Sanofi

Francesco Intoccia
CSL Behring

Lou W. Kennedy
Nephron Pharmaceuticals

Georg Singewald, PhD
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Boyun Son
Samsung Biologics Co, Ltd.

Felix A. Velez
Johnson & Johnson

Rong Zhang
Bristol Myers Squibb

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2024 FOYA AWARDS PLANNING COMMITTEE

It's time to celebrate the 2024 **ISPE** Facility of the Year Awards! (FOYA)

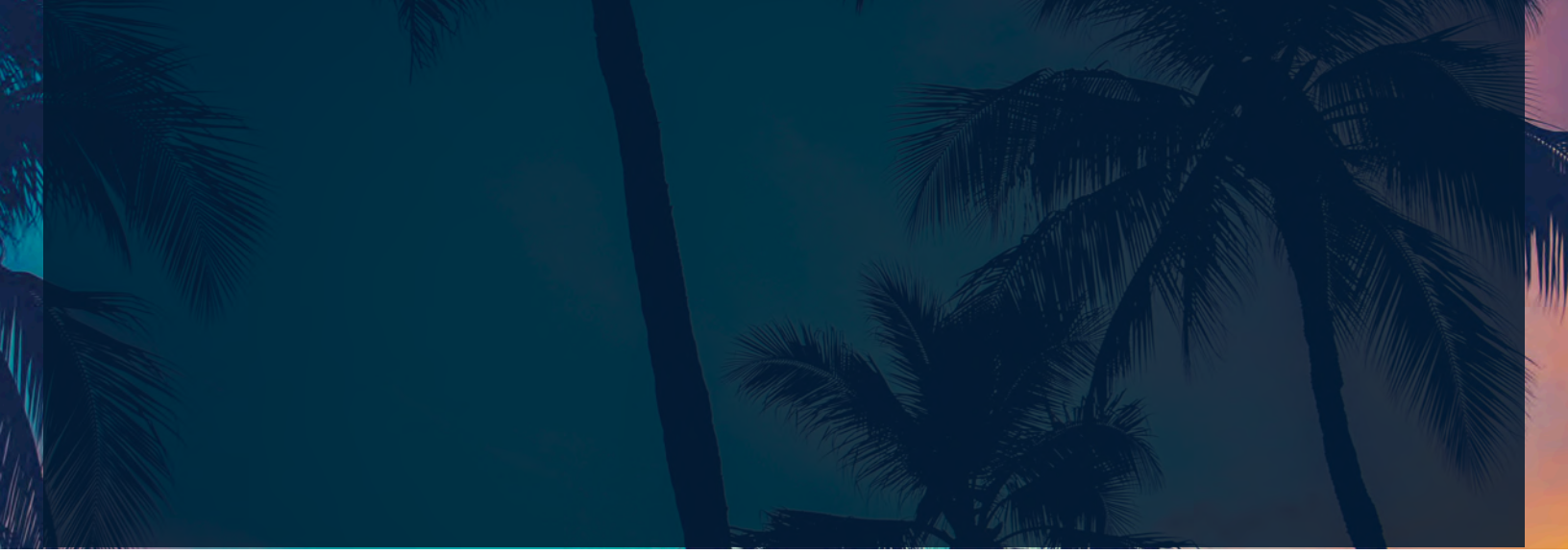
FOYA 2024
ISPE Facility of the Year Awards

It is my distinct pleasure and honor as the Chair of the Facility of the Year Awards (FOYA) Planning Committee to congratulate and celebrate the remarkable achievements in our industry. I am filled with immense pride and admiration for this year's award winners and all who share in the commitment and dedication to innovate and advance pharmaceutical manufacturing technology for the benefit of patients across the globe.

I would like to take a moment to reflect on the journey that has brought us here. My career has afforded me the unique opportunity to experience our industry from multiple perspectives. Having worked directly for a global life sciences company for many years, and now serving as a Vice President for an A/EPCMV firm specializing in the life sciences industry, I have had the privilege of sitting on both sides of the table. This dual perspective has given me a profound appreciation for the collaborative efforts that drive our industry forward.

19 years ago, in 2005, I stood where many of you are today, as a finalist at that time in the Large Project Category during the inaugural year of FOYA. It was a momentous occasion, not just for me, but for our entire team. We had poured our hearts and souls into that project, and being recognized as a finalist was a testament to our hard work, dedication, and unwavering commitment to excellence. I vividly remember the excitement and anticipation that filled the air that evening.

Fast forward, as the Chair of the FOYA Planning Committee, I am reminded of those early days and the incredible journey that has brought us here. I know first-hand the challenges and triumphs that come with building a winning project. It requires not only technical expertise and innovation but also a deep sense of collaboration, trust, and mutual respect among team members.



Today, we celebrate not just the pharmaceutical companies that have achieved excellence, but also the architects, engineers, constructors, equipment partners, and countless others who have contributed to these successes. It is a testament to the power of collaboration and the shared commitment to sustainability, innovation, and quality.

The Importance of Collaboration
In our industry, collaboration is not just a buzzword; it is the cornerstone of our success. The projects we undertake are complex and multifaceted, requiring the expertise and dedication of a diverse group of professionals. From the initial concept and design to the construction and commissioning of a facility, every step of the process demands meticulous planning, coordination, and execution.

As someone who has been deeply involved in both the operational and design aspects of our industry, I can attest to the challenges and rewards that come with this collaborative effort. When a pharmaceutical company receives a FOYA award, it is not just a recognition of their achievement, but a celebration of the collective efforts of everyone involved. It is a moment of pride for the entire team, from the visionary leaders who set the goals to the skilled workers who bring those visions to life.

Innovation and Excellence
The projects we honor today are shining examples of innovation and excellence. They represent the cutting edge of technology, design, and sustainability in the life sciences industry. These facilities are not just buildings; they are state-of-the-art environments that enable groundbreaking research, development, and production of life-saving therapies.

Innovation is at the heart of what we do. It drives us to push the boundaries of what is possible and to continuously improve our processes and outcomes. The facilities we recognize today have set new standards for efficiency, safety, and environmental responsibility. They are a testament to the ingenuity and dedication of the teams that created them.

"It is a profound responsibility and a tremendous privilege to be part of an industry that has the power to change lives. The projects we honor today reflect that commitment to making a difference."

The Human Element

While we celebrate these projects' technical achievements, it is important to remember the human element that underpins everything we do. At the end of the day, our work is about improving the lives of patients around the world. The facilities we build and operate are the places where new treatments are developed, tested, manufactured, and validated to improve patient outcomes.

It is a profound responsibility and a tremendous privilege to be part of an industry that has the power to change lives. The projects we honor today reflect that commitment to making a difference.

Recognizing Excellence

In closing, I would like to extend my heartfelt congratulations to all the FOYA recipients. Your dedication, innovation, and excellence inspire us all. I would also like to thank the members of the FOYA Committee for their hard work and commitment to recognizing the best in our industry.

As we celebrate these achievements, let us also look to the future with optimism and determination. The challenges we face are great, but so are the opportunities. By continuing to work together, we can achieve even greater heights and make a lasting impact on the world.

Paula Casalino, P.Eng.
Chair of the FOYA Planning Committee
Vice President Operations Canada IPS

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2024 CATEGORY AWARD
INNOVATION

ELI LILLY KINSALE LIMITED

Quick Facts

Project: IE2b
Location: Kinsale, Ireland
Total Facility Size: 65,400
Project Mission: To marry innovative technologies into a first-of-its-kind hybrid manufacturing platform for synthetic peptide production

About the Category

Winners in the ISPE Facility of the Year Awards (FOYA) Innovation category exemplify the novel application of process manufacturing techniques, innovative design concepts, innovative technologies, and unique solutions. This includes the implementation of top-of-the-line and custom-developed equipment that yields superior results, improves competitive position, and/or demonstrates imaginative collaboration with vendors, suppliers, and manufacturers. Innovation winners represent the next generation of agile, flexible, efficient, and effective pharmaceutical and biotechnology facilities.

Why Eli Lilly and Company Kinsale Won

The new IE2b facility uses a combination of innovative and novel technologies, including a novel hybrid manufacturing platform that significantly increases annual throughput and substantially reduces risks during the peptide manufacturing process. This, combined with the development and integration of an original digital solution for material tracking, innovative continuous flow chemistry and technology, process analytical technology (PAT) control, and nanofiltration technology, allows the facility to support high-volume throughput life-saving peptide medicines at a commercial manufacturing scale.

Based on these innovative designs and the safe and sustainable implementation of this project, the Eli Lilly Kinsale IE2b project is recognized as the 2024 ISPE FOYA Category Winner for Innovation.

Conceptualizing the Next Generation

Nestled on the Eli Lilly and Company manufacturing campus in Kinsale, Ireland, is the new IE2b Peptide Manufacturing Facility—a state-of-the-art facility that represents years of focus, innovation, attention to detail, and, above all, teamwork. The IE2b project began with a need for a new facility to manufacture crude drug substance synthetic peptides that can be shipped

onwards to other manufacturing sites for final product purification, isolation, and packaging. In the conception of the new synthetic peptide manufacturing facility, the Lilly IE2b team began to ask one critical question: how can we do it better than it's ever been done before?

> **"We stopped and asked: if we were going to build a peptide synthesis platform from the ground up, what would we do differently?"**
>
> – Kevin Seibert, PhD, Vice President, Engineering, Synthetic Molecule Design and Development

The traditional synthetic peptide manufacturing process, which uses solid-phase peptide synthesis, is well-proven but time-consuming and inefficient. While other companies have proposed a hybrid synthesis approach, they didn't take advantage of many of the new technologies that exist today. With this in mind, the Lilly team took a step back to evaluate best practices from the world of peptides and beyond, including small-molecule drugs. The result was a vision for a first-of-its-kind hybrid API synthetic peptide manufacturing platform — a digital-first process that seamlessly integrates continuous manufacturing technology, nanofiltration systems, and process analytical technology (PAT) to create a totally new system for creating complex peptides.

Innovation Driven by Seamless Teamwork

Developing the IE2b facility was a complex and dynamic process with a bold mandate. The team wasn't just tasked with developing a new synthetic peptide manufacturing platform. They were also asked to build the new facility on an operational manufacturing campus.

To make it work, the team leaned into the 'Team Lilly' mindset to ensure cooperation and innovation as they worked from varying points across the globe, along with the "safety first, speak up" culture.

At the very earliest stages of the project, IEb2 staff from Ireland were sent to the company's headquarters in Indianapolis, Indiana, USA, to collaborate on conceptualization and development of various phases of the process. This early partnership ensured the team was cross-functional from the beginning. Because the site required entirely new equipment, staff in Indiana trialed miniaturized prototypes to gain insight into how the equipment and process would work before the designs were sent to workshops in Ireland, where full-size versions were manufactured. Meanwhile, the team in Ireland worked on building the facility structure, leaving room for flexibility as the process unit operations & associated equipment needs were finalized. Once the process and equipment design was completed and the IE2b facility was constructed, all the equipment sets and associated infrastructure were pieced together like Lego® blocks.

Accomplishing this kind of novel accelerated engineering design required teamwork at the highest level. The team approached the process with a high degree of cross-functional collaboration and risk mitigation in mind, investing in proven technology and consulting with regulators along the way regarding robust control strategy approaches to the new manufacturing platform. While the team had to trust their intuition and analysis when making decisions, they also had to keep their minds open to new possibilities for the design and operation of this new facility. The new facility's digitization infrastructure required significant cross functional creativity and solution-oriented thinking. This cross-functional teamwork

performed very effectively as the new technology was prototyped and tested until it met all design requirements. The close teamwork and planning were also critical to keeping team members safe as the COVID-19 pandemic hit shortly after project commencement. The teamwork paid off, and the facility was finished on schedule, with a Right-First-Time startup, with no workplace-related COVID cases or significant safety disruptions after over 1.6 million construction hours.

Making the Dream Technology Real

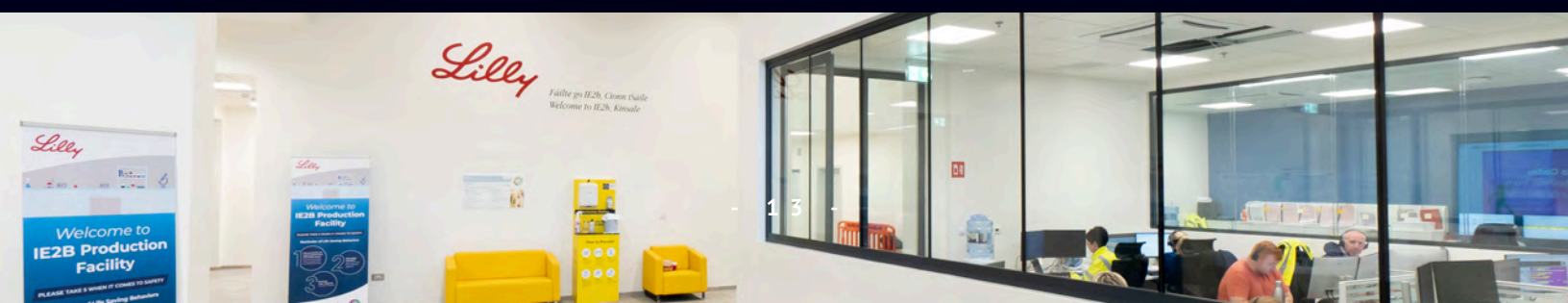
With the goal of facilitating a more reliable supply of new peptide-based medicines, the IE2B team incorporated many new technologies to increase purity and yield while reducing turnaround times, raw material consumption, and environmental impact.

The final process employed in the facility has a high yield and conversion compared to the traditional batch process. It takes advantage of continuous flow processing and a first-of-its-kind nanofiltration system to remove the need for downtime between steps while ensuring more precise control of reagents and materials. Meanwhile, PAT allows the team to control stoichiometry, seamlessly adjusting in real time to ensure high efficiency reaction step conversions and yields. This ensures efficient use of valuable raw materials and highly efficient unit operations.

Integral to the new manufacturing platform and facility is a novel digital mandate. The facility makes use of a digital material tracking model that helps marry the flow process with digitization. With this model, facility personnel can determine what raw materials inputs are in any process step or any item of equipment at any point in time. Adoption of this model and technology not only enables a robust, data rich, process control strategy it also significantly reduces the traditional time-consuming workload, complexity and risk of completing these calculations manually. Integrating the digital solutions into the overall platform design has proved very successful and has been a real enabler for the team to achieve an on time Right-First-Time start up and successful first year of manufacturing operations.

> **"We've proven to ourselves time and time again that this was effort well spent."**
>
> – Kevin Seibert, PhD, Vice President, Engineering, Synthetic Molecule Design and Development

The Lilly IE2b facility puts its team at the forefront of innovation. A year of operation has revealed the value of high-frequency monitoring, high-quality data, and the ability to control and release batches at a phenomenal rate. To date, the team estimates IE2b has an annual throughput multiple times higher than traditional peptide manufacturing processes. The innovative hybrid manufacturing process can produce more products with less waste, higher quality, and lower environmental impact, ultimately bringing a more reliable supply of medicines to patients. While the facility may be an industry trailblazer, the IE2b team hopes it is the catalyst for the next generation of manufacturing innovations guided by the same principles of teamwork, creativity, attention to detail, and problem-solving.



About Eli Lilly Kinsale Limited

Eli Lilly and Company has been operating in Ireland since 1978 and currently has over 1,000 employees and 600 contract partners at a manufacturing campus at Kinsale. Lilly Kinsale uses complex chemical and peptide synthesis and biotechnology manufacturing processes to make active ingredients for Lilly medicines.

About Eli Lilly and Company

Lilly unites caring with discovery to create medicines that make life better for people around the world. We've been pioneering life-changing discoveries for nearly 150 years, and today our medicines help more than 51 million people across the globe. Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing new discoveries to solve some of the world's most significant health challenges, redefining diabetes care, treating obesity and curtailing its most devastating long-term effects, advancing the fight against Alzheimer's disease, providing solutions to some of the most debilitating immune system disorders, and transforming the most difficult-to-treat cancers into manageable diseases. With each step toward a healthier world, we're motivated by one thing: making life better for millions more people. That includes delivering innovative clinical trials that reflect the diversity of our world and working to ensure our medicines are accessible and affordable. To learn more, visit Lilly.com and Lilly.com/newsroom or follow us on Facebook, Instagram, Twitter and LinkedIn.

Supply Partners and Key Participants

Manufacturer/Owner Name:
Eli Lilly Kinsale Limited
Engineer/Architect (A&E): Jacobs, Cork Office
Construction Manager: PM Group, Cork Office
Piping Subcontractor: Radley Engineering Limited
HVAC Subcontractor: Rockwell Engineering
Automation and Control Supplier:
Cognizant, Cork Office

Major Equipment Suppliers:
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Bronkhorst High-Tech BV
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DDPS – Vessels
D&M Continuous Solutions
Envair Technology
MMS Membrane Systems
Radley Engineering Limited
Zeton

"There were more barriers to doing this than anyone could imagine, but we put a group of people together who were thinking big with a bold, can-do attitude. It's amazing to see what can be achieved and has been achieved here."

- Darragh Mcdonagh, Senior Director of Engineering

2024 CATEGORY AWARD
OPERATIONS
PROJECT EXECUTION

PFIZER ASIA PACIFIC MANUFACTURING LTD

Quick Facts

Project: Pfizer API Facility Extension (Tuas 2)
Location: Tuas, Singapore
Total Facility Size: 429,000 square feet
Project Mission: To accelerate the supply of active pharmaceutical ingredients (APIs) through an innovative, new facility

About the Category

Winners in the ISPE Facility of the Year Awards (FOYA) Operations category exemplify the application of novel tools and approaches to delivering projects that improve productivity, overcome unusual challenges, promote effectiveness, and organize collaborators in effective ways. These initiatives often entail engaging stakeholders and project team participants in ways that lead to successful outcomes, such as efficiency, delivery, quality, product yield, consistency, and cost of goods. These principles, systems, and tools also ensure business continuity through a stable supply environment, health and safety, and customer satisfaction.

Why Pfizer Asia Pacific Manufacturing Ltd Won

The Pfizer API Facility Extension (Tuas 2) project was a master class in execution under unprecedented and challenging circumstances. Carried out entirely during the COVID-19 pandemic, the project team faced challenges including higher restrictions on travel and on-site personnel allowances, global construction material supply shortages, transportation disruptions, and remote collaboration with significant time zone differences. Despite this, the project was completed ahead of schedule and under budget with no lost time incidents. For these reasons, Pfizer Asia Pacific Manufacturing Ltd is recognized as the 2024 ISPE FOYA Category Winner for Operations, Project Execution.

Building a Pandemic Era Facility

Even as many industries ground to a halt during the COVID-19 pandemic, organizations and consumers around the globe continued to depend on pharmaceutical manufacturing. As a designated manufacturer of active pharmaceutical ingredients (APIs), the Tuas 2 site had a vital role to play in the launch and production of medicines across a range of therapeutic areas, such as oncology, autoimmune disease, cardiology, and antibiotics. The team thus knew the project couldn't afford to be delayed. In the face of pandemic-related disruptions, the project moved forward with its original deadlines in pursuit of a singular mission: to deliver the facility on time and enhance production of key APIs.

The basis of design (BOD) for the facility began in Q2 2020 with project teams already working from home due to work and travel restrictions. Even as the project progressed toward construction, which started in Q1 2021, restrictions on travel meant many of the stakeholders involved in the project couldn't get to the facility site. To overcome this, the team members who were able to make it to the site used cameras, microphones, and ear sets fixed to their construction helmets to provide virtual tours. Using this technology, remote contributors were able to weigh in safely to support continuous improvements.

Once the construction phase began, keeping on-site workers safe became a focus. At peak construction, there were over 4,500 people working on-site each day. The Pfizer Asia Pacific Manufacturing team credits the calm, focused approach of their project leadership and the implementation of an incident-free workplace (IFW) behavioral-based safety program for their success in ensuring that everyone got home safe at the end of every day. Ultimately, dedication to workplace safety helped the team

surpass 14 million safe work hours with zero lost time accidents over the life of the project.

Of course, the pandemic didn't only present challenges to workplace safety. The facility was dependent on materials shipped from across the world, including the United States, European Union (EU), and China, and supply chain disruptions caused by the limited movement of goods required careful and consistent attention. To add to the team's challenges, the obstruction of the Suez Canal in March 2021 delayed the delivery of materials from Europe by up to six weeks. Overcoming these combined supply chain holdups required ingenuity and flexible planning to avoid delaying the project. In some cases, the team was able to pivot and rearrange scheduling to work around the delays, and in others, they found solutions by increasing the sourcing of local, sustainable supplies and vendors.

Innovative and Efficient Design Features

The Pfizer Asia Pacific Manufacturing Ltd team refused to let the COVID-19 pandemic hold back their drive to create a facility that exceeded the status quo for API manufacturing. Key requirements for the facility, including the lean movement of material, the reduction of lead times and process turnarounds, and the continuation of the best good manufacturing processes (GMP), were the catalysts for important design choices that would ultimately set the facility apart.

Beginning with their goal to improve process changeovers and efficiency, the team leveraged a design with a central pool concept and central spine corridor that connects all of the main facilities. This design separates process equipment groups into discrete processing suites. To further enhance the benefits of the central pool and spine corridor design, the team leaned into automation to improve the lean movement of material.

Combined with the implementation of wash/wet in place (WIP) technology, automated cleaning recipes, and process analytical technology (PAT) to detect cleaning endpoints, the facility accomplished a 70 percent reduction in current process turnaround times.

Completed after just 33 months (a full year ahead of schedule), Tuas 2 features an organic synthesis plant (OSP) building spanning five floors with five equipment pools for batch sizes between 50 and 1000 kilograms, a dry milling building with a jet mill, hammer mill, and a pack-off suite, and a wastewater treatment plant complete with solvent storage and tanker loading/unloading bays, to name just a few of the 429,000 square foot facility's features. In addition to the existing buildings, the site has scope for extension of all the main buildings to add additional processing suites, dry-end suites, dispensaries, warehouses, and ancillary equipment as required in the future.

Caring for Workers and Patients Alike

While data, deadlines, and goals provided the framework for the Pfizer Asia Pacific Manufacturing Ltd team, the project's success was driven by the actions and attitude of every individual working on the project. To project leadership, executing this project during such challenging circumstances speaks to the can-do mentality, perseverance, and flexibility of their team. Ultimately, the culture created during the pandemic was one in which members were supported and had the freedom to express themselves, something that speaks to the capabilities of leadership and the willingness of team members to work together for a common goal.

Tuas 2 was launched on an ambitious timeline before the COVID-19 pandemic even began, and despite countless unexpected hurdles, the facility was built on time and under budget.

This wasn't just a major accomplishment for team members — it was a win for the most important stakeholders, the patients. By fortifying the supply chain with an additional state-of-the-art facility capable of improved changeover times, the Tuas 2 team is proud to have played a part in ensuring patients will continue to have access to critical medications without interruption.

"This project represents the best in people. A team whose dedication, talent, and resilience motivated them to challenge convention and embrace uncertainty to deliver on Pfizer's purpose of breakthroughs that change patients' lives."

- Carmel Keane, Vice President,
Global Engineering, Pfizer Global Supply

About Pfizer Asia Pacific Manufacturing Ltd

At Pfizer, we apply science and our global resources to deliver medical breakthroughs to prevent, treat, and cure multiple conditions and diseases. We strive to set the standard for quality, safety and value in the discovery, development, and manufacture of health care products, including innovative medicines and vaccines.

2024 CATEGORY AWARD
OPERATIONS
FACILITY FIT

TAKEDA AUSTRIA GMBH

Quick Facts

Project: beePFS – Prefilled Syringe Filling
Location: Linz, Austria
Total Facility Size: 12,378.5 square feet
Project Mission: To optimize a pre-existing facility and strengthen the security of supply for syringes through the accelerated implementation of a prefilled syringe filling line

About the Category

Winners in the ISPE Facility of the Year Awards (FOYA) Operations category exemplify the 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 principles, systems, and tools also ensure business continuity through a stable supply environment, health and safety, and customer satisfaction.

Why Takeda Austria GmbH Won

Takeda's beePFS project is a testament to the company's commitment to innovation, adaptability, and excellence in project execution. By achieving remarkable success within an accelerated timeline, Takeda has demonstrated its capacity to overcome challenges and deliver outstanding results. Their efforts resulted in the optimization and modernization of a preexisting pharmaceutical manufacturing facility through the addition of a prefilled syringe line. The project team managed to reduce the process performance qualification (PPQ) time for the new line by 50% and set a new standard for production line PPQ, ultimately helping to shorten the time to market. The beePFS project enhances supply chain resilience and showcases Takeda's dedication to pushing boundaries and achieving excellence.

Empowering Patients Through Injectables

When creating therapies, drug developers have an opportunity to empower patients by putting treatment into their hands and reducing barriers to access, such as long hours spent in a treatment facility. Prefilled syringes and the injectable medications they house are an essential part of making this possible. The Takeda team behind the beePFS project was driven by this goal as they undertook a project to add a prefilled syringe line to the biologics manufacturing facilities on the Takeda site in Linz, Austria. The hope for the project was to further improve the facility's output and potentially reduce manufacturing time for injectable products by bringing the manufacturing of prefilled syringes in-house, opening the door for further process optimization.

Underlying the work to optimize and modernize the facility was the establishment of a unique culture that blends the local Austrian heritage with the Takeda ethos: a focus on patients, people, and the planet. In fact, the project gets part of its name from the workings of a beehive, an ecological symbol that also served as a metaphor for the essence of the beePFS project. In a beehive, every bee has a mission and ultimately works to support a queen. In the case of beePFS, team members across diverse focus areas worked closely to reach the end goal of fortifying the supply of potentially lifesaving injectables.

Building a Hive of Excellence

The beePFS project represented an incredible opportunity to develop a more efficient prefilled syringe line. Modernization efforts, including the use of 3D planning, increased automation capabilities across the facility, and implementation of a manufacturing execution system (MES) and historian system, helped make the facility more efficient and allowed the Takeda team to establish a central platform for improved data accessibility. The beePFS project was also built with an integrated, first-of-its-kind pre-use, post-sterilization integrity testing (PUPSIT) system, using a fully assembled single-use system to bring additional agility and swift reaction times during sterile filter integrity tests.

> **"In a beehive, every bee counts and is important. This is the same for our team – it didn't matter if one team was highly efficient if the process got held up somewhere else."**
>
> – Roland Fabris, Managing Director and Site Head Linz, Takeda.

Manufacturing a prefilled syringe requires specialized, complex equipment that must be isolated to guarantee product integrity. In addition to the equipment's complexity, the beePFS team had the added challenge of making the equipment work in a preexisting facility with limited space. In some cases, the team installed equipment in incredibly tight spaces, leaving mere inches of extra space. Successfully implementing this technology required additional work, such as adding a vertical conveyor and using auto cranes, to bring the new heavy-load equipment into the fourth and sixth floor of the preexisting facility.

With so many advanced technologies and the delicate nature of the resulting products, the team also worked to optimize training processes. To help the facility workers successfully assemble syringe components within a clean room environment, the beePFS team developed specialized augmented reality (AR) training. This training model includes a wooden model of the machinery paired with 3D-printed components equipped with sensors. Wearing an AR headset, the staff can train on the tactile aspect of their jobs outside of the clean room while getting live feedback. With this system in place, the beePFS team

hopes to provide a pressure-free training environment that could empower staff to feel confident when working with the real thing.

Innovation at Warp Speed

The standard project timeframe for a project like beePFS is 50 months. Instead, beePFS was a pioneer project in Takeda's Super-Fast Track WARP Speed program, an initiative that ultimately drove the project to complete all process performance qualification runs within a 24-month timeline—50 percent faster than standard projects. Adherence to regulatory guidelines was another critical proof point for the project, with the team noting the importance of protecting patients by adhering to good manufacturing practices while also maintaining speed and efficiency. These efforts produced robust results, and in August 2023, the Austrian Agency for Health and Food Safety (AGES) approved the new line, providing regulatory validation to beePFS and its innovative technologies.

The team had to simplify, plan, and work smart to accomplish operational and regulatory success, leveraging individuals' strengths and capabilities. Project leadership believes that this focus on people was the most critical aspect of the team's success. Instead of a large internal project management team, for example, the project was fueled by close collaboration and cross-departmental partnerships. Collaborative efforts also extended into supplier relationships, enabling the implementation of tailored equipment that enhanced the project's overall success.

"This project was based on setting the example of letting people grow and shine. This project is all about people... the team understood that they could really make a difference."

– Roland Fabris, Managing Director and Site Head Linz, Takeda.

By working together, the team completed a challenging but rewarding project. With the new beePFS line now active, the Takeda team has additional flexibility and capabilities to supply larger quantities of therapies. Perhaps most importantly, they have navigated the barriers that make projects like these so challenging and paved the way for other facilities to optimize and further support patients.

"This project is proof if you put the right people in the right place, 'mission impossible' becomes possible."

– Roland Fabris, Managing Director and Site Head Linz, Takeda.

About Takeda in Austria/Linz

Takeda's mission is to develop and produce life-transforming medicines for the treatment of rare and complex diseases. At Takeda in Austria, every step of the process for innovative therapies takes place: research and development, manufacturing, quality assurance and patient supply. More than 4,500 employees help to ensure that medicines from Austria reach over 100 countries worldwide and that patients in Austria have access to Takeda's innovative medicines. In Linz, the focus is on the production of innovative biologics for the treatment of inflammatory bowel diseases. This long-term focus of the site in Linz is strengthened by investments in new production lines.

Supply Partners and Key Participants:

Manufacturer/Owner Name: Takeda
Engineer/Architect (A&E):
PROject Puhringer + Bisteghi GmbH
VTU Engineering GmbH
IHM – Ingenieurburo Hartmut Meier
Construction Manager:
Trimont Consulting & Project Management
Main/General Contractor:
OPTIMA pharma GmbH
Piping Subcontractor:
SMB Pure Systems GmbH
HVAC Subcontractor:
Molin Gesellschaft mbH. & Co KG
Major Equipment Suppliers/Contractors:
OPTIMA pharma GmbH
Korber Pharma Inspection GmbH
Mostl Anlagenbau GmbH

2024 CATEGORY AWARD
SOCIAL IMPACT
SUSTAINABILITY

CHUGAI PHARMA MANUFACTURING CO., LTD.

Quick Facts

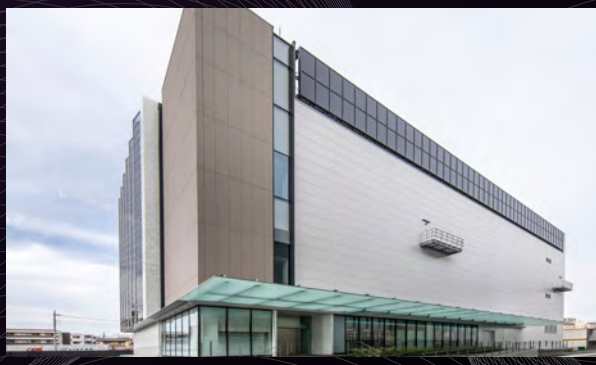
Project: UK4
Location: Tokyo, Japan
Total Facility Size: 40,000 square feet
Project Mission: To deliver a greenhouse-gas-free manufacturing facility ready to fulfill the company's mission of manufacturing the potential medicines of the future

About the Category

The ISPE Facility of the Year Awards (FOYA) Social Impact – Sustainability category honors projects that exemplify the application of novel approaches, standards, and practices that accelerate the shift to sustainable facility design. These facilities enact efficient processing, resourceful utilities, and business advantages by ensuring the effective use of energy, minimizing waste, reducing carbon footprint, incorporating green manufacturing techniques, and reducing environmental impact.

Why Chugai Pharma Manufacturing Co., Ltd. Won

In building the UK4 facility, Chugai Pharma Manufacturing Co., Ltd. employed innovative solutions to achieve "Three Zeros for Sustainable Development": zero halogenated hydrocarbons, zero natural gas use, and zero carbon dioxide (CO_2). This project is, without a doubt, a model for sustainable design. By leveraging innovative and interconnected solutions, Chugai has been able to deliver a greenhouse-gas-free manufacturing facility that will further its mission. For these reasons, Chugai Pharma Manufacturing Co., Ltd. is recognized as the 2024 ISPE FOYA Category Winner for Social Impact – Sustainability.



R&D for Patients and Planet

The Chugai Pharmaceutical Manufacturing Ukima site in Northern Tokyo, Japan is the first in the next generation of sustainable manufacturing facilities. Known as UK4, the facility was built to produce early-stage investigational biologics and act as an essential component of Chugai Pharmaceutical's biopharmaceutical research and early development efforts.

Building this kind of facility — where process development and manufacturing teams can work together to manufacture the first batches of investigational products — represents an important part of the drug discovery cycle. In the wake of a strong desire and passion for developing novel medicines, the Chugai Pharma Manufacturing team was keenly aware of UK4's vital role in maintaining the pharmaceutical supply chain by helping new therapies get to market. The more efficient facilities can be at establishing manufacturing methods for drug-candidate substances, the faster potential treatments can undergo testing and reach patients waiting for innovative therapeutic options.

To the UK4 team, the facility's efficiency wasn't the only critical aspect of the project. The team was also passionate about sustainability. Namely, the team wanted to create a facility that targeted three of the most critical sustainability metrics, dubbed the "Three Zeros for Sustainable Development": zero halogenated hydrocarbons, zero natural gas use, and zero CO_2 emissions.

Sustainably manufacturing pharmaceuticals is inherently challenging, but biologics are particularly energy and resource-intensive to produce. Massive heating and cooling systems are required to ensure the integrity of clean rooms for the sake of product quality and safety. Large amounts of water and energy are also required to clean and sterilize equipment between batches. The additional challenges associated with producing early-stage investigational medicinal products, such as the speed and flexibility needed to manufacture in parallel with evolving manufacturing and analytical techniques, made the team's sustainability goals even more ambitious.

Tackling Challenges with Sustainable Innovation

From the onset of the UK4 project, the Three-Zeros stood over most decisions. The team began by identifying key measures that could contribute to sustainability and evaluating each option's cost, practicality, and effectiveness in reducing environmental impact. In fact, the facility was shifted from a renovation project to a new build when the team determined renovating the pre-existing facility to meet new sustainability standards would have a larger environmental footprint than building a new facility with the latest sustainable features.

Achieving each of the "zeros" in their goal required unique innovation, beginning with solutions to eliminate halogenated hydrocarbons. Halogenated hydrocarbons are synthetic compounds that can have a bigger greenhouse effect than CO_2 and contribute to global warming when introduced to the environment. Because of their efficiency as a refrigerant, however, halogenated hydrocarbons are often used as a coolant in traditional manufacturing facility HVAC systems. To achieve zero halogenated hydrocarbons, UK4 was built to utilize a natural-coolant-based heat source system, with ammonia (NH_3) chillers providing cooling while CO_2 heat pumps provide a heating source, removing halogenated hydrocarbons from the facility.

To avoid using natural gas, the UK4 team moved away from gas boilers and instead installed electric boilers to supply the steam needed to maintain the process water system and other utilities. In tandem with this shift, the team made several design decisions that reduced the demand for steam, including the use of CO_2 heat-pumps as heat sources, the high utilization of single-use equipment, and the adoption of a membrane-based process water system (cold WFI system) instead of distillation-based equipment.

The final of the "Three-Zeros" was no CO_2 in non-GMP areas. To accomplish this, several design solutions were combined with design plans that would reduce energy consumption. Solar panels were integrated as part of the façade of the building. Moveable louvers are installed in front of the first-floor rooms on the south side of the building to minimize the amount of energy used in general office areas, and additional energy management solutions were implemented across the site, including automatic adjustments to lightning based on a room's occupancy load. Ultimately, non-GMP areas of the facility can be run entirely with natural energy generated on-site. As a result, the facility has a projected energy reduction of approximately 44% compared to actual energy use by existing structures with similar floor space, manufacturing equipment configurations, and manufacturing capacity.

A Blueprint for an Eco-Friendly Future

UK4 accomplishes a unique level of sustainability that signifies the future within Chugai Pharma Manufacturing and the industry. As technologies improve, sustainability remains an ongoing effort after a facility's completion, something the UK4 team takes seriously. With UK4 complete and operational, the team is using data on the facility's performance to reveal key opportunities to improve sustainability efforts. One example has been apparent to the team from the beginning — the utilization of single-use equipment. While the single-use equipment used in the facility reduces the need for steam and water, it can have its own environmental impact in the form of plastic waste. To manage this, the UK4 team is actively working in collaboration with suppliers, industry groups, and other companies to explore new methods for chemical recycling, with the hope of reducing UK4's environmental impact even further.

The team behind the UK4 facility can attest that building a sustainable facility isn't just an exercise in innovation. It's also an exercise in teamwork and collaboration, with a dedicated focus on the future in support of patients, the industry, and the planet. With UK4, Chugai Pharma Manufacturing brought together specialized teams to build a facility that can serve as an example of the future of more sustainable pharmaceutical manufacturing.

"We're thrilled to have constructed critical — and sustainable — infrastructure in an exciting new era of medicine. Chugai's founding spirit of 'creating drugs that benefit the world' remains our mission statement that's felt in everything we do."

– Yo Aiba, UK4 Project Owner

About Chugai Pharma Manufacturing Co., Ltd.

Chugai Pharma Manufacturing Co., Ltd. is a pharmaceutical company that nurtures innovative drug discovery ideas researched and developed by Chugai Pharmaceutical Co., Ltd. into real medicines, mass-produces them stably, and supplies them to patients around the world.

Supply Partners and Key Participants

Manufacturer/Owner Name:
Chugai Pharma Manufacturing Co., Ltd.
Engineer/Architect (A&E):
Taisei Corporation
Construction Manager:
Taisei Corporation
Main/General Contractor:
Taisei Corporation
HVAC Subcontractor:
Fuji Furukawa Engineering & Construction Co., Ltd.
Automation and Control Supplier:
Nihon Dengi Co., Ltd.

Major Equipment Suppliers/Contractors:
TEC Project Services Corporation
IWAI Pharma Tech Co., Ltd.

2024 CATEGORY AWARD
HONORABLE MENTION

UNITED THERAPEUTICS

Quick Facts

Project: Project Lightyear
Location: Research Triangle Park, North Carolina, USA
Total Facility Size: 54,955 square feet
Project Mission: To expand United Therapeutics' warehousing and supply chain capabilities and ensure facility resiliency while minimizing the environmental impact

About the Category

The ISPE Facilities of the Year Awards (FOYA) Honorable Mention category recognizes projects that did not win a specific category but were successful in overcoming significant challenges in planning, execution, and delivery.

Why United Therapeutics Won

FOYA winning Facility are traditionally focused on the manufacturing of clinical or commercial products and research lab facilities enabling the discovery of medicine. However, United Therapeutics' dedication to environmental sustainability and innovative technologies in their new warehouse and logistics center, Project Lightyear, set it apart, making it the first FOYA-recognized net-zero facility and recipient of an honorable mention.

A Rare Approach to Rare Disease

United Therapeutics' Project Lightyear began where many of the company's projects do — with the needs of their patients. United Therapeutics' mission is centered on saving lives through the provision of treatments to patients with rare diseases, including two medications (Tyvaso and Tyvaso DPI) approved by the US Food and Drug Administration (US FDA) for patients with pulmonary arterial hypertension (PAH) and pulmonary hypertension with interstitial lung disease (PH-ILD). For patients with these rare, untreatable conditions, these treatments can be life-altering, increasing blood flow for vessels in the lungs and improving stamina for exercise and everyday activities. To maintain the supply chain for these critical drugs, the company identified an urgent need for expanded warehouse facilities.

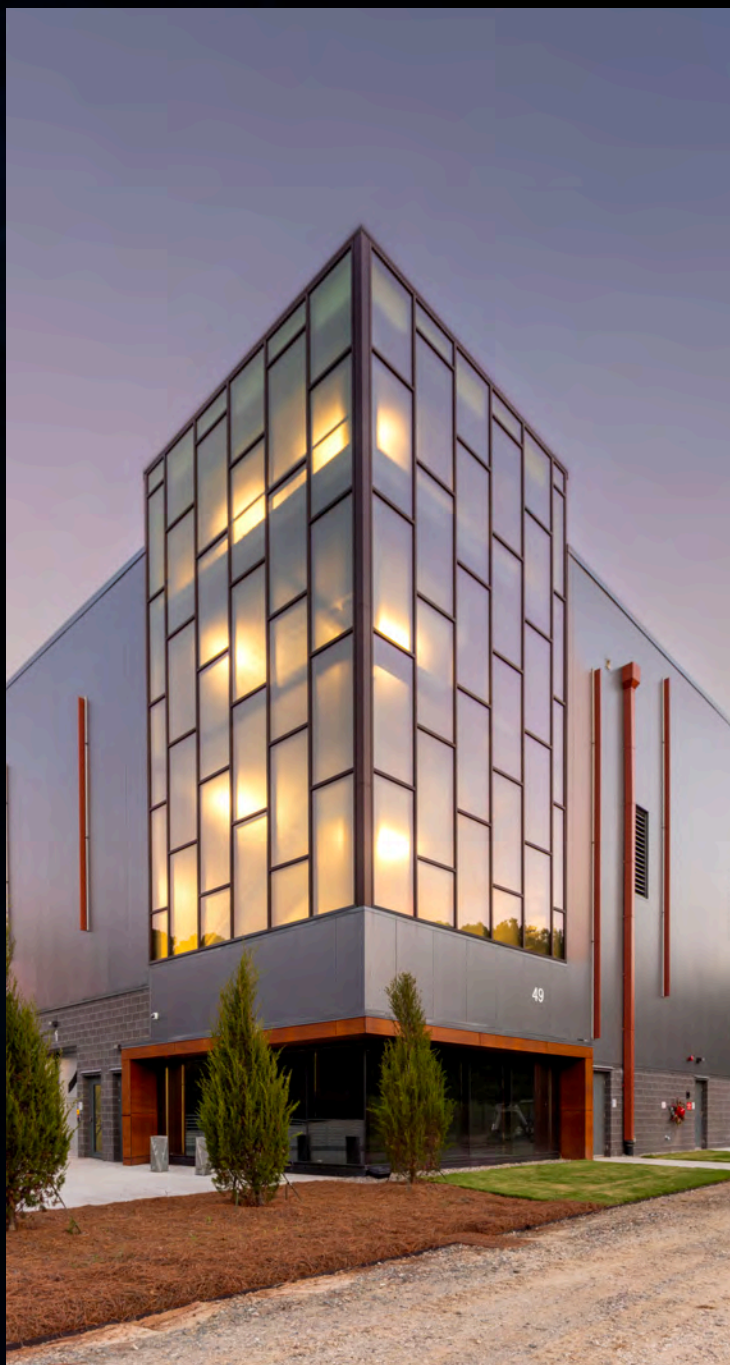
Warehouses represent a crucial lynchpin in the drug manufacturing process, housing large quantities of medication before they are shipped to distributors and the patients who need them. To the Project Lightyear team at United Therapeutics, a new warehouse served as an opportunity to push the envelope and meet sustainability goals unrivaled in cGMP logistics and warehouse facilities: a net-zero energy and zero carbon emissions facility.

Meticulous Detail for Infinite Payoff

United Therapeutics is no stranger to creating facilities with a strong sustainability ethos. The company has a 210,000 square foot, site net-zero office building in Silver Spring, Maryland, USA. However, creating a robust warehouse and logistics facility that could generate its own power and exist independently of the power grid presented a daunting challenge. As a crucial cog in the United Therapeutics machine, all operations within the facility — including the maintenance of controlled cold and ambient storage — had to be considered to ensure the products in the warehouse were adequately protected.

To minimize ecological impact, United Therapeutics selected an existing but underutilized soccer field

> **"At United Therapeutics, we adopted the mindset that we could develop life-saving medicines for patients without harming the planet."**
>
> – Martine Rothblatt, PhD, CEO
> United Therapeutics



and associated field house on their campus for the project site. By choosing this location, the team was able to avoid clear-cutting the remaining wooded area on campus, protecting adjacent wetlands, the existing tree canopy, and other natural habitats.

At the onset of the project, the Project Lightyear team defined "site net-zero energy" as a facility for which every watt of energy needed to operate and run the facility over a 12-month period would be offset by onsite renewable generation, without relying on off-site production or carbon credits to close the gap. Beginning in the design stage, the team generated an energy usage intensity (EUI) estimate that could be used as a baseline for efforts to reduce the energy demands of the facility. This required extensive analysis where no detail, such as how often the overhead door into the cold storage room would be opened on a typical day and for how long, was too small to be considered. From there, passive and active energy reduction strategies, such as the type and amount of insulation in the building, rooftop photovoltaic array, and a geothermal exchange system, combined to reduce the facility's energy usage as much as possible.

Taken together, the site is designed to produce more energy from renewables than it consumes and offsets all carbon emissions associated with energy for building operations with on-site renewables. In the event of power loss, the facility is supported by two Tesla megapacks of battery energy storage systems (BESS) with a total of 6.2 MWH of backup power. Ultimately, the design team anticipates the site could run for three days in a worst-case scenario in which there is little to no solar recharge. Under normal conditions with a fully operational microgrid, the entire facility should stay online for weeks, if not months, while disconnected from the electrical grid or during an extended outage.

"It's fun and motivating for the staff to participate in things that are this groundbreaking."

– Patrick Poisson, Executive Vice President Technical Operations, United Therapeutics

For the Good of Patients and the Planet

Project Lightyear was fueled by a strategic push to be ready for tomorrow, for the sake of patients and the planet alike. Completed in 2023, the facility housed its first cGMP products in October 2023 after achieving US FDA approval and is meeting the team's goal of operating as the first Site NetZero Zero Carbon emissions cGMP warehouse facility. Since its finalization, the project has been monitored closely and is expected to receive LEED Gold, LEED Zero Energy, LEED Zero Carbon, and Energy Star certifications.

Environmental sustainability was just one measure of success for the Project Lightyear team. With over 2,600 ambient pallet positions and over 500 cold storage pallet positions, the facility accomplishes its critical goal of greatly expanding the company's capability to support patients with PAH and PH-ILD, ultimately providing a stable supply of medication to its current and future patient population.

With the facility now active, the team at United Therapeutics has turned their eyes to the future. The facility is uniquely primed to incorporate new technologies that could streamline operations and further reduce environmental impact, such as the charging of autonomous, electric vehicles used to move products within the facility. In the short term, the facility team is hoping that Project Lightyear can serve as proof that state-of-the-art facilities can be built in a way that protect patients and the planet.

> **"It's our hope that we're leading by example here...that other companies will see this and say that we've shown this can be done."**
>
> – Patrick Poisson, Executive Vice President
> Technical Operations, United Therapeutics

About United Therapeutics

At United Therapeutics, our vision and mission are one. We use our enthusiasm, creativity, and persistence to innovate for the unmet medical needs of our patients and to benefit our other stakeholders. We are bold and unconventional. We have fun; we do good. We are the first publicly traded biotech or pharmaceutical company to take the form of a public benefit corporation. Our public benefit purpose is to provide a brighter future for patients through the development of novel pharmaceutical therapies and technologies that expand the availability of transplantable organs.

Supply Partners and Key Participants

Manufacturer/Owner Name:
United Therapeutics Corporation
Engineer/Architect (A&E):
Hanbury – Architecture, Planning, and Project Management
AEI – MEP/FP Engineering
NV5 – Civil/Structural
Commissioning Qualifications & Validation Services:
Cornerstone Commissioning, Inc.
Construction Manager:
Stranix Associates LLC
Main/General Contractor:
DPR Construction
Piping Subcontractor:
SPC Mechanical
HVAC Subcontractor:
SPC Mechanical
Automation and Control Suppliers:
Schneider Electric
Major Equipment Suppliers/Contractors:
Environmental Specialites (Formerly Bahnson)
PV Integrator – Green State Power

2024 CATEGORY AWARD

HONORABLE MENTION

ZYDUS PHARMACEUTICALS

Quick Facts

Project: Oral Solid Dosage (OSD)
Location: Ahmedabad, Gujarat, India
Total Facility Size: 279,129 square feet
Project Mission: To implement advanced technologies and sustained quality culture to provide affordable and quality medicines globally.

About the Category

The ISPE Facility of the Year Awards (FOYA) Honorable Mention category recognizes projects that did not win a specific category but were successful in overcoming significant challenges in planning, execution, and delivery.

Why Zydus Pharmaceuticals Won

The new cutting-edge OSD manufacturing facility is 100 percent dedicated to exporting OSD products to the United States and is built on the concepts of agility and economies of scale. This facility is versatile and robust, with two production blocks: one for agile, small-volume manufacturing and another for large-volume manufacturing at scale. The Zydus OSD project focused on process innovation and automation to scale up, reducing costs and turnaround times. For those reasons, it has been recognized with a 2024 ISPE FOYA Honorable Mention.

A Dose of Opportunity

The production of oral solid dose (OSD) forms of medication is a critical part of the pharmaceutical ecosystem. Medications delivered in OSD are often more cost-effective, shelf-stable, and simple to administer compared to other delivery methods, making them popular with physicians and patients. In the production of OSD medications, the team at Zydus Pharmaceuticals saw an opportunity for improvement — to go beyond the conventional manufacturing process to produce medications for a range of medicinal uses, including anti-depressants, anti-hypertensives, and anti-diabetics, in a manner that makes them more cost-effective and accessible.

Traditional OSD manufacturing has two major pain points that can drive up production time and, by extension, cost: long cycle time caused by multi-stage, human-driven processes and the inability of infrastructure to support scaling to high volumes. To overcome these pain points, the Zydus team evaluated manufacturing standards, facility design, manufacturing processes, and even their team.

The resulting facility has two distinct manufacturing zones, enabling adaptable production of OSD medications: a small volume block that facilitates the manufacturing of intricate and specialized medicines and a large volume block that can produce essential medicines at large scales.

"The mission of this project was to unlock new possibilities by offering patients affordable and high-quality products."

– Prashant Sharma, Chief Technical Officer, Zydus Pharmaceuticals

The Cheetah and Elephant: Pairing Agility with Volume

The small volume block of the Zydus OSD manufacturing facility, which has been given the moniker "Cheetah," is focused on the production of intricate and specialized medicines. Much like the animal that lends it its name, the small volume block is built for agility, with a conventional horizontal design and a range of capabilities that produce the necessary flexibility to accommodate a range of products and therapeutic categories with different manufacturing processes.

In contrast, the large volume block, called "Elephant," is tailored for high-volume products. Advanced technologies, including a custom, unidirectional vertical material flow design, fully automated integrated closed system train, and AI-enabled robots used for material transfer and floor cleaning, minimize human intervention and improve the efficiency of production. Everything in the large volume block is built for size, as the name elephant would suggest, including one of the largest blenders available (an 18-kiloliter Glatt bin blender), two Fette compression machines with segmented turret technology that allow for 110 stations, an O'Hara continuous coater with 1,200 kilograms per hour of throughput, and a fully automated 360-degree Sensum tablet inspection machine. This emphasis on volume also extends to the central packaging area, which consists of three, 200 bottle-per-minute high-speed CVC Technologies bottle packaging lines. Together, this combination of machinery can dramatically increase output.

Production at Elephant's scale can have a unique set of challenges. Because of the large volume block's atypical design, processes had to be redesigned to produce the desired results. Ensuring smooth material transfer was another hurdle. To accomplish this, the Zydus team looked to other industries and ultimately incorporated a "dense phase transfer system" used in the dairy, nutraceutical, and cement industries. Its incorporation into the OSD manufacturing facility was a first for the pharmaceutical industry.

Blenders were equipped with process analytical technology (PAT) for online blend homogeneity, and a seamless material handling system was developed to reduce material loss. Automated wash-in-place (WIP) systems were installed in all equipment to ensure no cross-contamination while also conserving water. All together the system can handle an astounding volume: 600 kilograms of material in 15 minutes and batch sizes of approximately 6 million tons, or 6 million to 50 million tablets.

> **"The facility's commitment to cutting-edge technology demonstrates its dedication to innovation and staying ahead in the pharmaceutical industry"**
>
> – Prashant Sharma, Chief Technical Officer, Zydus Pharmaceuticals

Unlocking New Possibilities for Patients and the Industry

Completed in a record time of 18 months, the OSD manufacturing facility is a feat of engineering and collaboration. The safety and efficiency of the facility were paramount, but the well-being of the project team was also mission critical. From safety measures to mitigate the risk of COVID-19 exposure to safety standards put in place to prevent injury, the project has a 0.25 total recordable incident rate (TRIR) across 3,931,200 total person-hours.

With its two blocks combined, the OSD manufacturing facility has the potential to significantly impact patients' lives. The OSD manufacturing facility, specifically the large volume block, has an installed capacity of six billion units per year and is dedicated to the export of OSD forms of medications such as metformin, trazadone, and carvedilol to the United States. Not only are its volume capabilities extreme, but it can also deliver one of the fastest manufacturing turnaround times: five days from dispensing to packaging, all with a significant reduction in the number of batches. Combining its capabilities into an affordable and still high-quality product was a major success for the Zydus team as they strive to be the lowest-cost producer of these medications globally. Dedication to innovation at scale, in concert with a focus on the delivery of cost-effective treatments, drives home the facility's value and role as a trailblazer in the pharmaceutical industry.

"We're proud of the team, whose out-of-the-box thinking and, most importantly, execution of the concept made this project successful."

– Prashant Sharma, Chief Technical Officer, Zydus Pharmaceuticals

About Zydus Pharmaceuticals

Zydus Pharmaceuticals Ltd. is a subsidiary of Zydus Lifesciences Ltd. (Formerly known as Cadila Healthcare Ltd.), a leading Indian Pharmaceutical company that is a fully integrated, global healthcare provider. With in-depth domain expertise in the field of healthcare, it has strong capabilities across the spectrum of the pharmaceutical value chain. From formulations to active pharmaceutical ingredients and animal healthcare products to wellness products, Zydus has earned a reputation amongst Indian pharmaceutical companies for providing comprehensive and complete healthcare solutions.

Supply Partners and Key Participants:
Manufacturer/Owner Name:
Zydus Pharmaceuticals Limited
Engineer/Architect (A&E):
Knexir Consultants Pvt Ltd
Construction Manager:
Phenix Construction Technologies
Main/General Contractor:
Riviera Infraprojects Pvt. Ltd
Piping Subcontractor: J & H Infra
HVAC Subcontractor:
Shinryo Suvidha Engineers India Private Limited
Automation and Control Suppliers:
Conexao Technology Solutions Private Limited
Major Equipment Suppliers/Contractors:
GEA Process Engineering (India) Pvt Ltd
O'Hara Technologies Inc.
Glatt Systems Pvt Ltd
CVC Technologies Inc.
Sensum D.O.O.
Fette Compacting GmbH
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