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FOYA 2021

Facility of the Year Awards

#FOYA #ISPEFOYA

2021 Category Winners

Spotlight on Excellence

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FOYA 2021
Facility of the Year Awards
CATEGORY WINNER
Project Execution Supply Partner

Janssen Sciences Ireland
'BioCork 2' Project

FOYA 2021
Facility of the Year Awards
CATEGORY WINNER
Facility Integration Supply Partner

Takeda Pharmaceuticals International
'Ninlaro' Project

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FOYA 2021
Facility of the Year Awards

CATEGORY WINNERS

ADVERTISER INDEX

2021 FOYA Awards Welcome and Thank You

Antonio Crincoli
Chair, FOYA Judges Commitee
Vice President of Global Engineering
Charles River Laboratories Inc.

For the past eight years, I have been honored to collaborate with ISPE to recognize the Facility of the Year Awards (FOYA) Winners. Although this year has continued to present new and unique challenges for us all, the FOYA program continues to represent the best of the best, informs our industry about truly exceptional projects, and provides the winners a forum to present them. We are particularly proud to have recognized facilities that are currently supporting the international industry response to COVID-19.

FOYA has been recognizing innovations in the biopharmaceutical industry since 2004. Submissions are reviewed by recognized industry leaders – from all regions of the world and both small and large pharmaceutical and medical device companies. These leaders have extensive experience in their fields – engineering, manufacturing, supply chain, and quality, most with international responsibilities. They are experienced, knowledgeable, and understand the global landscape. They have had the privilege of working on and delivering many innovative projects.

This year, submissions came from all corners of the world and represented projects that included breakthroughs in automation & integration, cell & gene therapy development, rapid pandemic response, and dedication to developing medicines for unserved communities.

How are the submissions reviewed?

The judging panel meets each year in January to review and discuss merits of submissions. Due to pandemic travel restrictions, this year was the first fully virtual FOYA judging. Judges start by assessing the novel character of each project and discuss industry trends and how they are reflected in the submissions. While a template is used to help catalog analyses, judges have the freedom to use their expert judgement in reviewing each project. If a project does not demonstrate excellence in any one category, that category will not be awarded.

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2021 Facility of the Year Awards Category Winners Spotlight on Excellence

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Once judges have screened each submission for compliance with program requirements, they use their broad experience to understand the project. Do proposed costs and schedule seem reasonable? Did the project team clearly articulate accomplishments and business value for the overall outcome outlined? Judges also use their networks to benchmark project information and ensure outcomes as stated were achieved.

Judges then select an overall winner from among the category winners. The process involves several rounds of discussions, often very passionately, followed by a series of secret ballots. Once winners have been selected, judges are sworn to secrecy until ISPE announces the category winners.

A myth to dispel is that only large complex projects win awards. Most are actually smaller projects that improve quality and efficiency, reduce costs, improve transfer of new products, or implement new information technology solutions. Judges understand that these projects are critical to the success at each facility, so we focus on and award projects that demonstrate these innovations.

I would like to thank my fellow FOYA judges for volunteering their time as well as the companies that submitted projects. Selecting the final awards gets more difficult each year as the quality of submissions continues to increase. We are privileged to work in an industry that improves the lives of patients. We strive to continue this mission, and improve our performance in every way, and FOYA allows us to recognize the efforts of those that have.

ISPE thanks the **2021 FOYA Judging Committee** for their continued support of the FOYA program.

FOYA Judges Chair
Antonio Crincoli
Vice President, Global Engineering
Charles River Laboratories, Inc.

Michael Alltoft
Director, Global Engineering & Facilities
Novartis Gene Therapies

Gunter Baumgartner
Senior Vice President, Head of Global Engineering
Takeda Pharmaceuticals International AG

Carla Boragno
SVP Head Global Engineering & Facilities
Genentech

James Breen
Vice President, Lead Biologics Expansion
Janssen Pharmaceuticals

James Dickow
Principal Engineer
BioMarin Pharmaceutical

Jian Dong
Vice President & Site Head, Biomanufacturing
Wuxi Biologics

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Senior Vice President Global Engineering
CSL Behring

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Gary Schoenhouse
Vice President, Global Engineering and Facilities
Orchard Therapeutics

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Samsung Biologics

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J&J

Rong Zhang
Director Process Engineering Design
Bristol Myers Squibb

FOYA Planning Committee

Avril Vermunt
Chair, FOYA Planning Committee
Adverum Biotechnology
Senior Director, Head of MSAT

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, whose honorees represent the future of pharma. We are a community of dedicated experts whose cumulative thousands of projects and millions of lessons learned brought solutions, calm, and confidence to the industry during the COVID-19 pandemic.

Years before the pandemic, FOYA was asked to consider the overall program to ensure it remained relevant and was flexible enough to embody today's excellence. Over the past years, the program committee has created the Social Impact category and modernized category descriptions to better recognize our best projects. This preparation culminated in 2021's roster of winners and special recognition for the COVID-19 response.

Starting with the 2022 submissions, we have also aligned categories with ISPE's strategic pillars, provided new flexibility for the judges to award multiple category winners with the creation of subcategories, eliminated honorable mentions, and elevated sustainability as a minimum requirement for all submissions. The new FOYA award categories include Innovation, Operations, Social Impact, Pharma 4.0™, and Supply Chain. More details on these categories can be found on the "Submit Your Facility" page at ISPE.org/facility-year-awards/submit.

Past FOYA award winners include expected manufacturing facilities, as well as laboratories, pilot plants, medical device production, fill/finish and packaging facilities, and process development facilities. If your company has, or will have, completed construction and major systems validation on a new project between 1 November 2019 and 31 December 2021, please consider applying for a FOYA. FOYA gives you a platform to share your knowledge and expertise and showcase major technological advances and pioneering design as well as the opportunity to improve and shape the future of pharmaceutical engineering.

I'd like to congratulate the companies that won a 2021 Facility of the Year Award – several of which were able to use their new processes and innovative design to quickly continue to operate and produce medicine during the COVID-19 pandemic.

For information on submitting your project for consideration in 2022, visit ispe.org/FOYA for submission requirements.

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FOYA 2021
Facility of the Year Awards

Facility Integration

Takeda Pharmaceuticals International AG

Facility Integration honors projects that exemplify the application of good design practices and superior conceptual planning, leading to excellent integration of facility and process, efficient, clean, pleasant environments, and merging of process and building to create an environment of form and functional excellence.

Quick Facts

Project
Grange Castle P2 Facility

Location
Dublin, Ireland

Total Facility Size
31,840 square feet

Project Mission
To build a facility capable of manufacturing and packing an oncology drug including producing highly potent APIs and drug product.

WHY THEY WON

The facility includes drug substance manufacture (DS), drug product (DP) blistering and secondary packaging, QC testing, and QA operations in one dedicated building. The vision for the facility was small, simple, safe, and integrated. 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.

Helping Patients Heal at Home

The oncology drug manufactured in Grange Castle is used to treat multiple myeloma in combination with other medicines. It is different from other medicines because it can be taken orally so patients do not have to go to a medical facility for injections, taking time away from their family or work.

"Before the Grange Castle P2 Facility went live, the production of Ninlaro was spread across different facilities in multiple countries. Now all manufacturing steps from the production of the API to packaging is handled end-to-end in one facility, allowing Takeda to simplify and strengthen our supply chain for this life-changing medicine," said Gunter Baumgartner, Head of Global Engineering at Takeda.

All in One Facility

Located at the high technology Pharmaceutical and Biotechnology Business Park in Dublin, Ireland, the Grange Castle P2 was designed as an 'all-in-one' facility. The entire production process from active pharmaceutical ingredients to drug product and packaging is completed under one roof. This increases the agility, flexibility, and robustness of the supply chain to ensure unconstrained availability of crucial medicines to patients worldwide.

Takeda kept the design of the new plant simple, designed everything as one unit, implemented flat management structures, and integrated teams to reduce the risk of communication issues.

"We do not have to transport ingredients or medicine from one facility to another and we are able to keep our inventories small," said Dennis Kim, Head of Oncology & External Supply Small Molecules Operating Unit at Takeda. "Compared with the need for three separate contract manufacturers, it is easy to see how this facility has truly delivered on Takeda's agile vision."

Containment Strategies

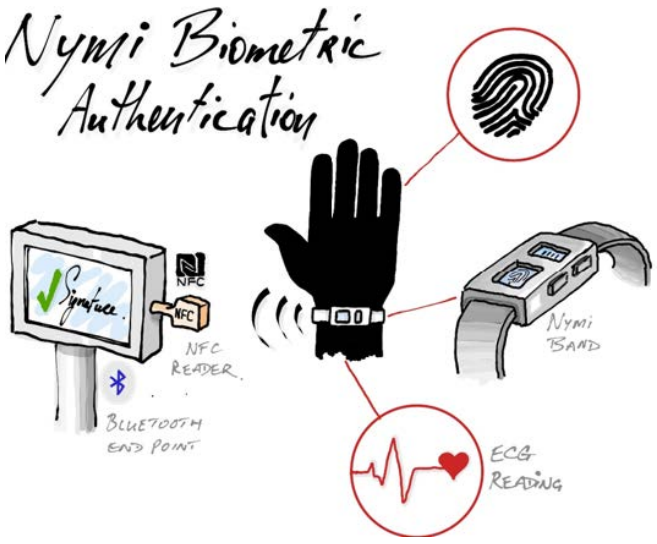
The Active Pharmaceutical Ingredients (API) used to make this oncology drug were defined to be as within occupational exposure band 5 (OEB), the second most severe rating in a 6-band occupational exposure banding system. Due to the highly potent nature of the API used to make the drug, Takeda took significant measures using the best available technology to prevent operator exposure. The design includes a permanent barrier between the operator and the material. Closed material handling and transfer is undertaken inside isolators and Restricted-Access Barrier Systems (RABS) via glove-ports. Even inside the isolator, material is not openly handled, instead RTPs and split valves are used.

Takeda choose an encapsulator because of its capacity to complete the full capsule process including capsule filling, metal detection, and weight checking. Traditionally, these processes are all done using separate machines which would require a need for separate isolators, increasing space requirements, complexity, and cost.

Digital Innovations

Innovative technology was used throughout the P2 facility. The plant will be operated completely wirelessly using a Manufacturing Execution System (MES) with equipment-integrated Electronic Batch Recording (EBR). The MES system provides data for the real time digital performance management boards which track the overall performance of the plant. Takeda is also piloting the use of wearable wrist technology for electronic signature requirements.

When operating teams have questions or need outside help, they put on a pair of augmented reality glasses for a remote expert collaboration overview. The head-mounted display uses a video camera to transmit a live image of what the user is looking at from their perspective. Unlike a simple video call, the remote participant can create spatial annotations in the view of the front-end user. This makes it easier for operators to describe their support needs and comprehend guidance. By implementing this approach, the operating team has improved their efficiency and reduced downtime.



Takeda offers virtual reality tours lead by a virtual assistant, which proved to be especially useful during the COVID-19 pandemic. Takeda is also using virtual reality training for aseptic practices. These experienced based trainings immerse trainees into simulated environments based off those in P2 and allow the trainees to receive real-time feedback about the tasks they are performing.

Simple, Safe, Integrated

Takeda's efforts have resulted in a plant that has increased efficiency, reduced labor needs, and increased the reliability of supply.

"From the beginning the vision for the facility was clear: simple, safe, and integrated," said Baumgartner. "The project delivered on all three, each adding value to the final result. However, we believe the most novel aspect was the integration of the three facilities. While this has been seen in other areas of the pharmaceutical industry, it is new to API manufacturing. The benefits have been apparent from the beginning – a single batch record system, reduced logistics and inventory, and a small environmental footprint, The project was the first of its kind, but it is unlikely that it will be the last."

Supply Partners and Key Participants

Manufacturer/Owner Name
Takeda Ireland Ltd

Engineer/Architect (A&E)
PM Group

Construction Manager
PM Group

Main/General Contractor
PM Group

Piping Subcontractor
Jones Engineering

HVAC Subcontractor
Dornan Engineering

Automation and Control Suppliers
Control & Information Management

Major Equipment Suppliers/Contractors
Isolators; Howorth Air Technology; Reactors; 3V Tech S.p.A.; Isolator / Mill / Blender; Powcon; Filter Dryer; Powder Systems Ltd; Capsule Filling ; IMA Group; Blister line; Marchesini Group S.p.A

ABOUT THE COMPANY

Takeda is a patient-focused, values-based, R&D-driven global biopharmaceutical company committed to bringing better health for people and a brighter future for the world. Their passion and pursuit of potentially life-changing treatments for patients are deeply rooted in over 240 years of distinguished history in Japan.

FOYA 2021
Facility of the Year Awards

Operational Excellence

ElevateBio

Winners in this category exemplify the application of modern management techniques aimed to improve operating efficiencies, promote excellent quality and consistency, and yield competitive cost of goods from existing and new facilities, processes, and manufacturing operations.

Quick Facts

Project
BaseCamp

Location
Waltham, Massachusetts, USA

Total Facility Size
140,000 square feet

Project Mission
To accelerate the rate of innovation in cell and gene therapy with a disruptive capital-efficient model and to quickly and safely deliver effective, life-saving novel therapeutics to patients globally at as low of a cost as possible.

WHY THEY WON

ElevateBio's BaseCamp facility is a gamechanger for cell and gene therapy. 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. It proves to the industry that it is possible to bring successful therapies to market faster and more efficiently than ever before.

Changing the World of Cell and Gene Therapies

ElevateBio was founded in 2017 by David Hallal, Vikas Sinha, and Mitchell Finer, PhD, who wanted to change the way cell and gene therapies (CGTs) are researched, developed, and delivered. "While there are many brilliant scientists driving research and innovation behind cell and gene therapy products on the market and in the pipeline, few know how to scale them up and deliver them at affordable costs," said Finer CSO, ElevateBio and President of ElevateBio, BaseCamp. "This knowledge gap leaves CGTs well beyond the reach of most patients and, indeed, most of the world. Unless we make major strides in our ability to scale them, we will not be able to democratize these medicines and make them accessible to as many patients as possible."

ElevateBio's BaseCamp is home to leading scientists and academic researchers who are working with medical centers and corporate partners to advance CGTs. It is a cGMP facility where those, and other, therapies can be made safely and cost-effectively.

BaseCamp is a dedicated cell and gene therapy technology, research and development, process development, and manufacturing facility. BaseCamp consists of 140,000 square feet of manufacturing, lab, and support space including:

- Research and development for immunotherapy, regenerative medicine, and cell therapies
- Process development and scaled manufacturing capabilities for rapid translation of processes
- Laboratories that include manufacturing labs, protein engineering, virology, and immunology capabilities
- CGMP manufacturing with industry-leading product development know-how for the manufacturing of viral vectors and cell therapies
- Quality assurance through systems, analytics, and Quality Control laboratories with state-of-the-art levels of automation

Built for Future Discoveries and Flexibility

BaseCamp is a Center of Innovation for ElevateBio. ElevateBio provides the tools, time, and environment where researchers can innovate, develop, and accelerate life-transformative therapies. The team at BaseCamp has years of experience in cell and gene therapy process development and manufacturing. They have developed a toolbox of unit operations that can be used to rapidly translate cell and gene therapy and regenerative medicine products allowing them to enter the clinic quickly and at a lower cost than traditional cell and gene-based therapies.

"We have a toolbox for cell therapy processing that allows us to have innovative unit operations and analytics rather than force fitting a process into a specific device," said Michael Paglia, COO of BaseCamp. "This allows us to make the right process decision for the product and clinical design intent, but also keeps us at the forefront

of the industry when new technology becomes available as we can easily adapt and implement new technologies into our library of capabilities."

Opening the Doors to New Therapies

Traditionally, biotechnology companies have invested in and built manufacturing facilities after clinical trials proved the therapy would work. This can lead to delays in getting life-saving medicines to patients. ElevateBio's founders wanted to build the team, technology, and infrastructure to support a portfolio of cell and gene therapy and regenerative medicine programs, and what started as a modest investment and small footprint quickly grew as other interested parties learned what they were working on.

The laboratories and clean rooms at BaseCamp were designed to accommodate current state-of-the-art process equipment, while still allowing flexibility for innovation and automation. Utility panels and room utilities are robust to allow for a broad range of process equipment and expandability. Ancillary support rooms, such as buffer preparation, were designed to be mirror images of the production rooms allowing for expandability of processing if needed. Plant utilities, including bio-waste management, were designed to handle early phase small volume requirements and large volume commercial-scale production.

ElevateBio built BaseCamp with the idea to open it up to like-minded partners in the industry allowing them to use the manufacturing space and providing high-quality process development, manufacturing, analytics, technology, and teams to help advance their own therapies.

Saving Time and Money

By implementing a highly automated and integrated facility, ElevateBio has been able to effectively reduce the time from development to GMP manufacturing. They establish robust systems and user requirements at the beginning of every project so that once procurement begins, everything goes smoothly during the translational stage of the program. BaseCamp is designed so that multiple patient therapies can be manufactured in the same suite.

Companies working with ElevateBio have access to the talent and facility at a cost structure that covers staff and overhead, without charging large markups, saving them money they can use to continue innovative research.

"Our capital-efficient business model and cell and gene therapy manufacturing knowledge helps us to reduce the cost of goods and increase the probability of success for products that we manufacture at BaseCamp," said Finer. "Developing commercially viable processes from the beginning eliminates the risk of costly and risky clinical comparability studies. The goal of our model is to develop high-quality transformative therapies in a cost-effective way so that accessibility and affordability can be realized in a commercial setting."

Supply Partners and Key Participants

Manufacturer/Owner Name
ElevateBio

Engineer/Architects (A&E)
DPS Group, Inc. (Architect of Record, Process Eng. Process Arch, MEP/FP)
TRIA Architects, Inc. (Interior Design & Lab)
McNamara/Salvia
Thompson Consulting, Inc. (Engineer for Warehouse Space)

Construction Manager
The Richmond Group (TRG)

Main/General Contractor
42 North Solutions, LLC

Piping Subcontractor
DECCO

HVAC Subcontractor
Environmental Systems

Automation and Control Supplier
NECI

Major Equipment Suppliers/Contractors
ThermoFisher Scientific; BWT Pharma & Biotech Inc; Holloway America; Belimed AG; SKAN; Cytiva

ABOUT THE COMPANY

ElevateBio is a cell and gene therapy technology company built to power the development of transformative cell and gene therapies. The company has built an initial technology stack, including gene editing, induced pluripotent stem cells, and protein, viral, and cellular engineering, that can be leveraged across the entire portfolio and by strategic partners. The company is focused on increasing long-term collaborations with industry partners while also continuing to develop its own highly innovative cell and gene therapies. ElevateBio's team of scientists, drug developers, and company builders are redefining what it means to be a technology company in the world of drug development, blurring the line between technology and healthcare.

FOYA 2021
Facility of the Year Awards

Project Execution

Janssen Sciences Ireland

Winners in this 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.

Quick Facts

Project
BioCork2

Location
Ringaskiddy, County Cork, Ireland

Total Facility Size
200,000 square feet

Project Mission
To expand the existing biologics manufacturing facility to ensure a sustainable supply of lifesaving medicines for patients.

WHY THEY WON

Janssen and their partners worked as an integrated team throughout the project to ensure the workers were focused on safety, compliance, and schedule always. The team overcame many issues during the more than three years of execution, including proceeding forward during the COVID-19 pandemic, which happened as they completed construction and started in full commissioning.

Expanding Facility to Meet Expanding Needs

Janssen Sciences Ireland, part of the Johnson & Johnson Family of Companies, develops innovative and integrated products and medicines to restore and extend the quality of life for patients globally. The expansion of their existing facility in County Cork, Ireland, included adding large-scale fed batch technology, the first of its kind in Ireland and for Johnson & Johnson globally. The expansion and new technologies will guarantee efficient and sustainable delivery of biologic medicines in the areas of immunology and oncology.

The project nearly doubled the facility's manufacturing space, adding more than 200,000 square feet to the existing 280,000-square-foot campus. The expansion provides full time employment for an additional 200 people and is designed to produce 72 batches of monoclonal antibody product a year.

"This manufacturing facility delivers cutting-edge healthcare that advances how medicines are manufactured so Janssen can stay at the forefront of treating and preventing some of the world's most devastating and complex diseases," said Gary Hartnett, Site Lead at Janssen Sciences Ireland.

Excellent Execution

Janssen's integrated project schedule was developed with more than 15,000 line items incorporating design, construction, commissioning, and regulatory approval.

Throughout the planning and execution no detail was left to chance. Janssen's stringent weekly progress tracking included recovery strategies and biweekly lookaheads to ensure that critical milestones were met along the way. The project was completed on time and budget, without construction disrupting or impacting existing live operations.

The BioCork2 project also made use of some of the latest interactive technologies to help the team plan and manage the project. All teams involved with the design of the project were able to use virtual reality for an initial collaborative review process which enabled them to make decisions in a timely matter, avoid costly re-work, and ultimately resulted in a schedule that was never delayed. Design and construction teams used 3D BIM Modelling to understand the installation sequence and coordination steps in detail throughout the project. Drone footage was used in weekly interactive planning sessions to highlight work areas, interactive white boards allowed sessions leaders to email all attendees directly from the screen during meetings, and 360° internal cameras allowed for visual oversight of the project progression and helped to identify inefficiencies.

Working Together from the Start

Janssen's BioCork2 project was led by an internationally diverse group. The project team was comprised of people from 40 different countries, and Janssen engaged vendors from all over the world. Janssen relied on interactive workshops and visits with global partners, and integrated the teams, management techniques, and values throughout project execution to ensure that the transition from concept to fully operation plant was smooth and seamless. To ensure that the facility could be operational as quickly as possible, Janssen leveraged talent from their existing plant for key roles

and reached out to local universities to hire graduates in the early phases of construction. As a result of this approach and other ongoing training efforts throughout the development stage, Janssen had a skilled and knowledgeable team ready to move the plant into production as soon as construction was complete.

Stellar Safety Performance

Almost 6,000 people went through Janssen's on-site Safety Culture and Safety Performance induction training resulting in a Total Recordable Incident Rate (TRIR) and Days Away Restricted Transferable (DART) of 0.056 and almost four million hours accident-free. As an additional safety step, personnel on site wore high visibility pants and long sleeve high visibility vests as well as the standard personal protective equipment (PPE).

Bees and Bunnies

From the very start of the project, Janssen engaged in corporate responsibility. They invited local residents to "Open Days" for tours and implemented a successful carpool plan to reduce traffic during the construction phase. The Laboratory Administration and Production buildings achieved LEED Silver Certification and the facility includes 22 electric car charging stations, covered bicycle parking, open space, adjustable sunshades on each building, and a wind turbine that provides renewable energy.

Janssen also made every effort to mitigate any negative impact on the environment surrounding the plant. The site includes nature walks that are home to bird boxes, bug hotels, and beehives. The area surrounding the plant is home to the Irish Arctic Hare, a protected species in Ireland. Janssen planted the hare's favorite food, wild meadow grass, and planned for protection of its habitat during and after construction.

Meeting Unforeseen Challenges

Like most of the world, Janssen had to adapt due to the COVID-19 pandemic but they were able to quickly adjust to keep everyone safe and healthy while maintaining the project's production schedule.

"The strength and character of our project teams were even more evident as they addressed head on the additional challenges and restrictions around the COVID-19 pandemic," said Jim Breen, BioCork2 Project Director and Vice President of Janssen Pharmaceuticals. "Protective measures were continually audited to allow operations to continue working as seamlessly as possible while maintaining all the milestone dates on our project."

Reflecting on the challenges posed by COVID-19, Hartnett paid tribute to the commitment of the project team in keeping on schedule. "Our business continuity planning kicked in, and our onsite teams worked around the clock to ensure we could deliver this project as planned. As a result of their efforts, we have been able to expand our ability to meet the medical needs of our patients all over the world."

Supply Partners and Key Participants

Manufacturer/Owner Name
Janssen Sciences Ireland (JSI)

Engineer/Architect (A&E)
PM Group

Construction Manager
John Sisk & Sons

Main/General Contractor
John Sisk & Sons

Automation and Control Supplier
Zenith Technologies, a Cognizant Company

ABOUT THE COMPANY

Janssen Pharmaceuticals is a global biopharmaceutical company that is creating a future where disease is a thing of the past. Part of the Pharmaceutical Companies of Johnson & Johnson, they focus on areas of medicine where the need is high, the science is compelling, and the opportunity to make a difference is great.

FOYA 2021
Facility of the Year Awards

Process Intelligence & Innovation

Takeda Ltd.

Winners in this category are recognized for their novel application of process manufacturing techniques, applied science-based solutions, and/or commercially available and custom developed equipment which yielded superior results, improved competitive position, and/or demonstrated imaginative collaboration with vendors/suppliers/manufacturers. This category also recognizes application of one or more digital innovations like automation, robotics, digital twin, or advanced processing understanding.

Quick Facts

Project
F36 New Solid Pharmaceutical Building and Automatic Line Clearance

Location
Hikari, Japan

Total Facility Size
122,294 square feet

Project Mission
To build fully automatic end-to-end packaging lines in a four-story production building with a high level of equipment automation, AGVs, and an innovative fully automated best-in-class line clearance check system.

WHY THEY WON

As the first pharmaceutical company in a commercial packaging facility, Takeda developed and implemented an automatic line clearance system (ALC) with 360° cameras, laser sensors, dry run mode utilizing artificial intelligence (AI). From development to a GMP compliant system is already a remarkable success story, but to standardize the technology and issue it as "off the shelf" technology positions the ALC as one of the most important improvements in the pharmaceutical packaging industry today and elevates Takeda`s packaging operation significantly higher than comparable technologies currently used in the industry. The project exemplifies how novel application of commercially available and custom developed process manufacturing tools yields superior results, advances process understanding, and improves the competitive position.

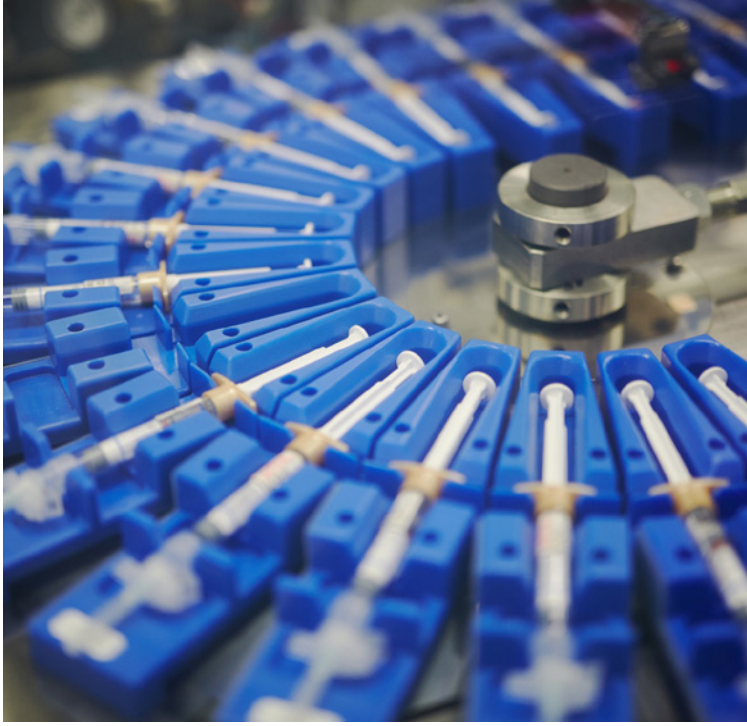
Elevating Automation to the Next Level

Takeda's F36 Solid Pharmaceutical Production Building in Hikari, Japan, is a four-story building designed to elevate pharmaceutical packaging operations to a new industrial standard. Active pharmaceutical ingredients, drug products, injectable liquids, pre-filled syringes, lyophilizates, injection infusions, and high-potency drugs are produced and packaged at the site. Nine of Takeda's brands are produced at Building F36 for distribution across Japan with anticipated worldwide distribution soon. Cutting-edge technologies were used throughout the building design and operations that help Takeda make and package medicines more efficiently and safer than ever before.

"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, greatly reducing the possibility of potential human errors or product mix ups between batches," said Hideki Fujiwara, Hikari Site head. "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 positively impress regulatory authorities and inspectors."

First-of-its-Kind Innovative Technology

Line clearance is a requirement for GMP as it is essential that equipment and work areas are free from previous products, documents, or raw materials. Traditionally the line clearance is performed by fully manual interactions, which can lead to mistakes since operators cannot



get under the machine to fully inspect it. To solve this problem, Takeda developed an automatic line clearance with 360° cameras, laser sensors, dry run mode, and artificial intelligence (AI) software.

A typical line clearance that took 30 minutes before can now be done in 10 minutes. Additionally, the AI software can teach itself to differentiate between good and bad conditions to help it avoid false good or bad results.

"As this state-of-the-art system has transformed Takeda's packaging operation in Hikari, attaining a new standard of innovation through digitalization in AI software, a global rollout across Takeda's manufacturing network is now in development," said Gunter Baumgartner, head of Global Engineering at Takeda.

Digitally Optimized Packaging

Cutting edge Pharma 4.0 technology was used throughout the facility including a paperless Manufacturing Executing System (MES), Overall Asset Effectiveness (OAE) line visualization system, Supervisory Control and Data Acquisition (SCADA) system for full data acquisition, and "ready to go" digital operator voice instruction systems that raised the project to a new standard of packaging operations. F3 also has highly automated end-to-end packaging equipment including "end of line" case packers, Automated Guided Vehicles (AGVs), and robots to feed the Automated Storage and Retrieval System (ASRS). It is also home to a cutting-edge Virtual Reality (VR) training room.

"The reduction of potential human error to a minimum using automatic packaging equipment, MES and SCADA systems, AGVs, Smart Operations, and the outstanding technology of the Automated Line Clearance system is best-in-class," said Masahiro Kondo, Senior Director Inspection & Packaging, Hikari Plant. "These systems also reduce the amount of necessary operator manual interaction with the packaging line to a minimum, thus greatly improving operator safety. Altogether, this is an incredible translation of quality, GMP, and safety requirement into futuristic technologies that has been realized today."

Digitally Optimized for the Future

"In the years to come, technology will continue to advance toward development of line clearance robots that combine cleaning robots, cameras, and artificial intelligence based on Takeda's developments," said Kondo. "This allows operators to focus on other critical work in delivering high quality pharmaceuticals to our patients. Takeda expects to share these digital innovations with related companies and to elevate the industry again to a new level of innovation. The target of 'one-click' line clearance is there, including the possibility for a one-second line clearance."

Supply Partners and Key Participants

Manufacturer/Owner Name
Takeda

Engineer/Architect (A&E)
Obayashi Corporation

Construction Manager
Obayashi Corporation

Piping Subcontractor
Sanki Engineering Co., LTD.

HVAC Subcontractor
Sanki Engineering Co., LTD.

Automation and Control Supplier
Kurihara Kogyo Co., LTD.

Major Equipment Suppliers/Contractors:
Blister Machine Supplier; CKD Corporation; Cartoner & Caser Supplier; Kyoto Seisakusho Co., Ltd.; Form-Fill-Seal Machine; Omori Machinery Co., Ltd.; Line Clearance System Developer; MicroTechnica Co., Ltd.; Logistic System Suppler; Murata Machinery, Ltd.; SCADA & MES Solution Supplier; Hitachi Kansai Area Operation

ABOUT THE COMPANY

Takeda is a patient-focused, values-based, R&D-driven global biopharmaceutical company committed to bringing better health for people and a brighter future for the world. Their passion and pursuit of potentially life-changing treatments for patients are deeply rooted in over 240 years of distinguished history in Japan.

FOYA 2021
Facility of the Year Awards

Social Impact

The Government Pharmaceutical Organization

Winners in this category exemplify application of novel approaches, standards, and practices which results in efficient processing, resourceful utilities, and business advantage by accelerating a shift to sustainable facility design to reduce environmental impact, and/or increasing patient access and preventing drug shortages through in-country-for-country manufacturing.

Quick Facts

Project
Biological Product (Vaccine) Production Plant

Location
Saraburi Province, Thailand

Total Facility Size
119,469 square feet

Project Mission
Providing equal access to vaccines for all Thai citizens in a zero-waste facility.

WHY THEY WON

A part of the government of Thailand, Government Pharmaceutical Organization (GPO) produces vaccines in a government-owned facility, where a key focus is providing free inoculations to high-risk groups. Increased patient access, such as the kind GPO offers, prevents drug shortages by manufacturing critical medications for patients at home. GPO helps mitigate the consequences of rapidly developing public health crises through rapidly deployed vaccines. Another part of the GPO success story, qualifying it for social impact recognition, is sustainability in its facility design. This has reduced the environmental impact of GPO on Thailand and, ultimately, the world.

A Focus on Vaccines

Even before the COVID-19 pandemic spread across the world, the Government Pharmaceutical Organization (GPO) was focused on the health benefits of vaccines. During the avian flu outbreak of 2004, the Thai government realized the importance of seeking new ways to more effectively get vaccines to people in need. As part of the effort, they asked the GPO to build a new vaccine plant to meet the needs of Thailand and the surrounding countries.

"Vaccines are the most successful and cost-effective medical solution to combat diseases that affect the whole population," said Dr. Withoon Danwiboon, GPO's Managing Director. "Even before the COVID-19 pandemic, Thailand recognized that there was a threat of a possible pandemic and invested in a new vaccine manufacturing facility to make vaccines of high quality and affordable cost for the people of Thailand and the region."

Located in Saraburi province in Thailand, the Biological Product (Vaccine) Production Plant consists of five buildings and has the capability to produce seasonal (trivalent) inactivated influenza vaccines, pandemic (monovalent) influenza vaccines, and COVID-19 vaccines using egg-based technology. The primary goal is to produce enough vaccine to cover national seasonal demand. Building capacity is driven by public health and not commercial concerns. The production plant is designed for 10 million doses of seasonal flu vaccine, 30 million doses of monovalent vaccine, and 300 million doses of pandemic influenza vaccine which would enable GPO to supply vaccines to other ASEAN countries.

A Global Effort

Thailand began an immunization program in 1977 that has grown to provide countrywide vaccinations for children for diseases such as tuberculosis, polio, meningitis, diphtheria, tetanus, and pertussis. However, an avian flu outbreak in 2005 had a high fatality rate, leading to the Ministry of Public Health to include the establishment of a domestic vaccine production as a key element of the country's five-year health plan.

The World Health Organization (WHO) provided GPO a 10-year support under a Global Action Plan (GAP) for influenza vaccine, which gave both financial and expert support. Thailand was one of the first countries to get support to develop egg-based live attenuated influenza vaccine (LAIV). The U.S. Department of Health and Human Services (HHS) also provided financial support for human resource development in the field of vaccine production.

While GPO staff have managed their own R&D over the last 15 years, as well as all parts of the supply chain, they have had additional help developing their COVID-19 vaccine from the global organization called "PATH." Under license agreements with Mount Sinai and the University of Texas at Austin, PATH is helping to provide GPO access to the vaccine seed virus.

Zero Waste Goal

GPO is also striving to adopt a zero-waste concept. As part of this policy, biological solid waste from the eggs used in vaccine production is decontaminated, dehydrated, and grounded to be recycled and used as fertilizer or combined in cement block. The plant is fitted with solar panels on the roof which currently provide 800 kilowatts of power. GPO plans to increase the number of panels by 2023 to make the plant as energy self-sufficient as possible.

National and International Awards

GPO's egg-based vaccine production technology has been recognized on both national and international levels with awards from the National Innovation Award, the National Research Council of Thailand, and several ASIA-Pacific Bioprocessing Excellence Awards.

Unexpected Delays

Two main delays had to be overcome during the project. First, a flood in 2011 affected a huge area to the north of Bangkok, blocking access to the site resulting in work coming to a stand-still for 6 months. WHO requested modification to the plant's bio-safety specifications from level 2 to level 2+ and while the required modifications were being planned, the Thai government underwent a period of turmoil with changes in leadership and an Army coup.

Life-Saving Outcomes

Despite these setbacks, GPO was able to construct the Biological Product (Vaccine) Plant designed to provide 10 million vials of multiple dose vaccine and 4.8 million prefilled syringes. The conventional design includes office area, lab areas, CNC areas, and sections for sterile preparation. After successfully developing vaccines to protect the population from flu outbreaks, GPO is now setting its sights to stopping the spread of COVID-19.

"GPO's vaccine against coronavirus was developed under the support from PATH, which allowed GPO to acquire access to the seed virus for vaccine production using egg-based technology. The vaccine's innovative design works by using another virus, inactivated Newcastle Disease virus (NDV), to induce the body to build protective defenses against COVID-19. After receiving the GMP seed virus (NDV-HXP-S virus) in September 2020, GPO successfully developed the NDV-HXP-S COVID-19 vaccine by applying the GPO's existing egg-based technology used for influenza vaccine production. The vaccine has been successfully produced at industrial scale under GMP," said Kittisak Poopipatpol, the Senior Expert of GPO.

"In November 2020, we obtained the prototype vaccine to be tested for proof-of-concept and the results showed that the vaccine is safe, immunogenic, and protective against coronavirus. The vaccine is ready for testing at clinical level and entered the clinical study phase 1 in March 2021. We expect to start the clinical efficacy trial phase 3 in November 2021, and aim to submit for Emergency Use Authorization to the Thai FDA in June 2022."

ABOUT THE ORGANIZATION

The Government Pharmaceutical Organization (GPO) was established in 1966 and now is the largest pharmaceutical producer and distributor in Thailand. GPO has three major sites; headquarters in Bangkok, Rangsit Pharmaceutical Production Plant 1 and the Biological Product (Vaccine) Production Plant located in Saraburi province. GPO provides over 300 medicines of all types. The company manages the complete supply chain, from R&D to process development, clinical trials, regulatory submissions, purchase raw materials, manufacturing operations, and distribution to government hospitals and pharmacies.

Supply Partners and Key Participants

Manufacturer/Owner Name
The Government Pharmaceutical Organization (GPO)

Engineer/Architects (A&E):
M+W (Thailand) Ltd
STEPWISE.CO,LTD.
Miti Civil Engineer Co., Ltd

Construction Manager
M+W (Thailand) Ltd

Main/General Contractor
M+W (Thailand) Ltd

Piping Subcontractor
AES Engineering Co., Ltd.

HVAC Subcontractor
AES Engineering Co., Ltd.

Automation and Control Supplier
The Auto-info Co. Ltd.

Major Equipment Suppliers/Contractors:
Filling & Capping & Inspection & Incubator Machines; Entech Associate Co., Ltd.; Formulate Mixer & Oven & Decontamination Machines; Oskon Co., Ltd.; Water for injection & Clean Steam Generator; Unique Industrial Products Co. Ltd.; Autoclave & Washing & Isolator Machines; N.Y.R. Limited partnership; Inoculator & Harvester Machines; SCIENTIFIC PROMOTION Co. Ltd.; Hatching & Candling Machines; Prima Scientific Co., Ltd.; Continuous Ultracentrifuge (CC40) Machine; Bio-Active Co., Ltd.; Solar Roof Top; Provincal Electricity Authority (PEA); Softener & Purify Water system; Liquid Purification Engineering International Co., Ltd.; Dehydrator; Disposal Matters Inc.; Generator 2000KV; Tharikan Company Limited; Transformer 2500 KV; Transformer 2500 KV

FOYA 2021
Facility of the Year Awards

Operational Agility: COVID-19 Impact

Gilead

This is a very special category that the FOYA Judges deemed important during such an unprecedented year, not only because of the impact the COVID-19 pandemic had on the pharmaceutical industry but because of the impact it had on the entire world. These winners are receiving special recognition for their operational agility to make progress and/or impact the efforts for therapies and vaccines to combat the pandemic.

Quick Facts

Project
The Center for Innovative Drug Research

Location
Foster City, California, USA

Total Facility Size
365,200 square feet

Project Mission
To create a collaborative research incubator for tomorrow's discoveries.

WHY THEY WON

During the brief period it has been in operation, the facility has already demonstrated its ability to support researchers by stimulating new discoveries and moving vital therapies forward. Researchers were highly involved in all aspects of the Center's design and construction, integrating directly into the design team, leading to the deployment of an "agile" laboratory that allowed the teams to pivot between different modalities and platforms effortlessly. Integrated flexibility aimed to maximize collaboration and speed was built into every aspect of the design and engineering of the facility.

The Future of Discovery

For more than 35 years Gilead has pursued bold and transformative science, creating therapies that have the potential to become the next generation of life-changing medicines. Before the Center for Innovative Drug Research (CIDR) was built, Gilead's researchers and their laboratories were spread across six different facilities on the company's 101-acre campus in Foster City, California.

However, Gilead's leadership thought their researchers would be more creative in a more collaborative environment where discoveries could be shared, and spontaneous conversation was encouraged. "Researchers can be very productive working on their own or in controlled meeting environments, but I think spontaneity is what generates thoughts and ideas that result in creative leaps," said Dr. William Lee, Gilead's Executive Vice President of Research.

The CDIR is home to 12 different research teams including virology, pathobiology, biomarker sciences, oncology inflammation, fibrosis, and immunology. The facility was consciously designed to be agile and collaborative. "Collaboration relies on random interactions – seeing someone in the hallway, chatting while making coffee, running into someone on the stairs," said Flad Architects' Marc Walker, the CIDR's lead designer. "We carefully placed intersections and paths of movement with break rooms and amenities where staff could interact. It may seem random, but it is actually by design."

These random encounters have already sparked discoveries that have improved lives. In the CIDR, the Inflammation Group is next to the Fibrosis Group. "Suddenly our groups are talking all the time and meeting regularly," said Julie DiPaul, PhD, Executive Director, External Innovation – Inflammation Lead. "We discovered we had a great deal of common ground. We can clearly see some of the targets they are working on, and some of their profiles are actually related to what we're working on. Now we have more pathways to explore because we never would have explored them before. Now, a brief conversation can spur new ideas and concepts."

One of these hallway conversations led to improvements to Richard Mackman, Gilead's Vice President of Medical Chemistry, team's research into an effective therapy for COVID-19. "It was an impromptu interaction that started us looking into an inhaled version."

Designed for Agility and Flexibility

CIDR's agile laboratories are designed to accommodate rapid changes to research models. The laboratories are designed on a common module with a standard relationship between the lab and its support spaces, providing the most agility for interconversion of laboratory functions and types. Standardizing the location of lab support spaces enables easy repurposing to support changes in lab functions. Maintaining a repeated layout on each biology floor allowed standard

locations for pipe racks and electrical conduit, allowing for a "plug and play" approach to lab reconfiguration.

Gilead recently expanded their immune-oncology research capabilities and though the laboratory space was not originally designed for that type of research, thanks to the agility and flexibility of the space, they were able to adapt easily and quickly without costly and complicated renovations.

Meeting COVID Challenges Head-On

The CIDR gives researchers the ability to scale up production of drug candidates to 1000 liters, giving them the ability to design and start clinical trials in rapid response to an emerging threat. The interconnectivity of the laboratories and size of the facility allows Gilead to expedite promising treatments to be developed without compromising other pipeline projects. Because of the systems Gilead has put in place at the CIDR, Gilead's Vice President of Biology Tomáš Cihlár's work to prepare a molecule to be used for COVID-19 treatment was able to be scaled to clinical trials in less than three months.

If the pandemic shutdown had happened before CIDR, Gilead, in all likelihood, would have had to shut down most of their labs due to space constraints. But thanks to the large, open laboratory design, researchers had sufficient space to spread out, and have enough distance between each other to continue their work safely.

The Icing on the Cake

Not only did Gilead bring scientists and researchers together into a new facility that has already had many success stories, but they also managed to do so under budget and ahead of schedule with 1.2 million hours worked during construction with no lost time, and earn an LEED Gold certificate.

"The next generation workspace recognized the way we create, absorb, assimilate, and disseminate knowledge," said Andrew Dickinson, Chief Financial Officer, "This Center represents the future of technology workspace, inspiring our scientists to create our next generation of therapies."

Supply Partners and Key Participants

Manufacturer/Owner Name
Gilead Sciences, Inc.

Engineer/Architects (A&E)
Flad Architects
EXP
Rutherford + Chekene

Construction Manager
Gilead Sciences, Inc.

Main/General Contractor
McCarthy Building Companies, Inc.

Piping Subcontractor
Southland Industries

HVAC Subcontractor
Southland Industries

Automation and Control Supplier
Banks Integration Group

ABOUT THE COMPANY

Gilead Sciences, Inc. is a biopharmaceutical company that has pursued and achieved breakthroughs in medicine for more than three decades, with the goal of creating a healthier world for all people. The company is committed to advancing innovative medicines to prevent and treat life-threatening diseases, including HIV, viral hepatitis, and cancer. Gilead operates in more than 35 countries worldwide, with headquarters in Foster City, California.

FOYA 2021
Facility of the Year Awards

Operational Agility: COVID-19 Impact

Grand River Aseptic Manufacturing

This is a very special category that the FOYA Judges deemed important during such an unprecedented year, not only because of the impact the COVID-19 pandemic had on the pharmaceutical industry, but because of the impact it had on the entire world. These winners are receiving special recognition for their operational agility to make progress and/or impact the efforts for therapies and vaccines to combat the pandemic.

Quick Facts

Project
Large-Scale-Fill-Finish Facility

Location
Grand Rapids, Michigan, USA

Total Facility Size
61,500 square feet

Project Mission
To develop a state-of-the-art, customer-centric facility with plenty of manufacturing flexibility.

WHY THEY WON

This project was selected for creating a facility that was able to support a pressing need of the day, response to the COVID-19 pandemic. The judging committee recognized that agility as an engineering value driver is getting increasingly important, and in a year where the promise of therapies and vaccines provided much-needed hope for the broader community, GRAM's sense of urgency, commitment to creative project execution and collaboration are commendable. The facility design reflects the flexibility, the speed, and the operational agility that ISPE believes are critical to continue driving our collective value.

A Perfect Time for Expansion

As demand for their services grew, Grand River Aseptic Manufacturing (GRAM) knew they needed a large-scale fill-finish facility. As part of the new facility, GRAM planned to offer general pharmaceutical liquid-filling, lyophilization, and straight liquid filling/terminal sterilization on a larger scale than previously available. They also wanted to offer contained formulation suites to support their multi-product facility design.

When GRAM begin planning the project in 2016, no one had ever heard of the COVID-19 virus, but GRAM's timing and the choices they made throughout the project meant that they were in the perfect position to help during a pandemic.

"Our new facility gives GRAM the capacity, technology, and equipment to support urgent response efforts – starting with U.S. based manufacturing in the fight against COVID-19," said John Wichelt, Vice President, Client Pharmaceutical Services, GRAM. "We were faced with delays and geographic challenges but with excellent planning and the right equipment choices, an emphasis on pre-fabrication, accelerated qualifications and validations, and meticulous resource management we were able to complete GRAM's facility ahead of time and under budget."

The new facility was built with future expansion in mind and includes:

- State-of-the-art isolator technology
- Two Grade C formulation suites
- Filling suites
- Cold and frozen storage
- QA Laboratory
- Customer viewing rooms
- Future capacity for new technologies

Making the Right Choices

GRAM wanted to handpick the best equipment from various vendors which would play nicely together. They started researching equipment years before they were ready to purchase including visiting overseas Original Equipment Manufacturers to examine their processes, assembly floors, and equipment. Once equipment was selected, GRAM worked with a design and construction firm to create their space around the central core of aseptic manufacturing equipment.

Digging In the Dirt

GRAM chose the site of their new facility because of its proximity to their existing facilities and a major university and for its ease of accessibility in the downtown area, but the location ended up being the biggest challenge to the project. Since the site had previously been used as a laundry chemical producer, there were toxic chemicals in the ground, and it had to undergo intense soil remediation. The ground was also filled with gypsum and

had to be stabilized before construction could begin. The soil stabilization process required huge equipment which took up most of the construction site but in order to stay on-time the foundation footings were prefabricated off site. Once the ground was ready, a crane brought them in and they were set in a matter of hours, eliminating weeks off the schedule.

Ramping Up for Vaccine Delivery

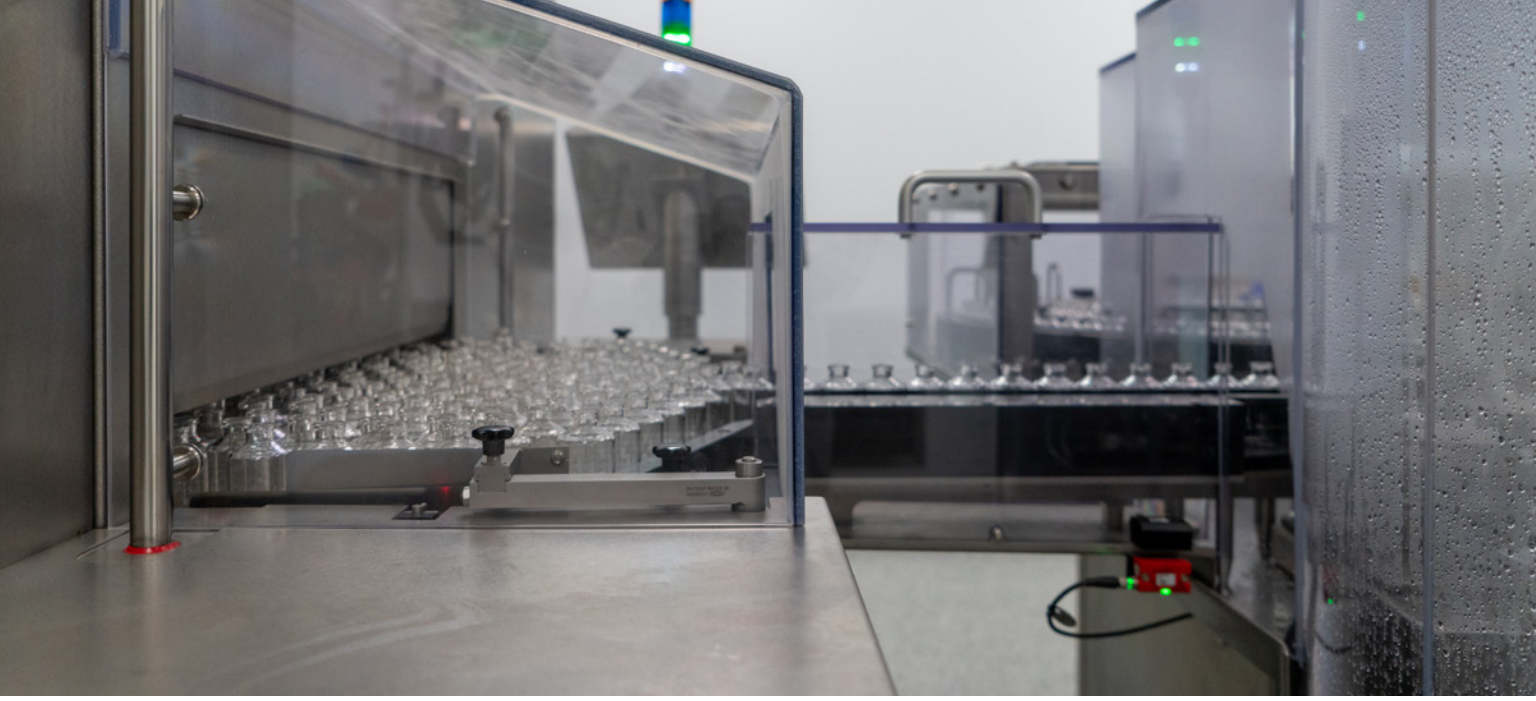
On-site, there was constant collaboration between management, design teams, construction crews, and outside contractors. Off-site contractors collaborated with design and construction teams using 3-D modeling which meant that almost 90% of the mechanical systems were able to be prefabricated. These time-saving solutions paid off. As news of the COVID-19 pandemic began to spread in early 2020, GRAM went into overdrive and speed up work to get operations fully functional as soon as possible.

"In May 2020, we received a BARDA questionnaire asking if we could be part of the response to the pandemic," said Wichelt. "The one problem was we weren't scheduled to be operational until October. But the entire team leapt into action so that we could meet BARDA's schedule."

GRAM conducted a new security audit for vaccine-related activities and began onboarding new hires. They started the qualification process in parallel with final construction and worked to successfully bring the facility up to sterility standards. They hired additional validation consultants and re-deployed several of their own employees to speed up validation efforts. Team members worked 60 to 90 hours a week to get ahead of the original schedule.

Because of the smart choices GRAM had made throughout the planning and construction phases and thanks to the team working tireless together to meet the new goals, GRAM was able to run its first batch of a COVID-19 vaccine candidate six weeks ahead of their original operational schedule.

"Bringing a new facility online is stressful under normal circumstances," said Wichelt. "But doing it during a pandemic with less staff and higher stakes required almost superhuman effort and laser focus on the enormous social impact the facility would offer. GRAM's capacity not only supports the U.S. government's Operation Warp Speed efforts and the COVID-19 pandemic response, but also increases U.S. preparedness for future public health emergencies."



Supply Partners and Key Participants

Manufacturer/Owner Name
Grand River Aseptic Manufacturing

Engineer/Architects (A&E) and Construction Manager
CRB

Piping Subcontractor
Andy J Egan

HVAC Subcontractor
Andy J Egan

Automation and Control Supplier
Rockwell Automation

Electrical Subcontractor
Buist Electrical

Architectural
D&D Building

Clean Room
Midwest Clean Rooms

ABOUT THE COMPANY

Grand River Aseptic Manufacturing, Inc., a leading injectable contract development and manufacturing organization, delivers customized solutions to meet clients' fill and finish needs from development through commercialization. With capabilities for biologics, small molecules, and vaccines, GRAM's advanced technology and nimble staff supports pharmaceutical development and cGMP manufacturing, analytical testing, and regulatory filing.

FOYA 2021
Facility of the Year Awards

Honorable Mention

Biocon Biologics Limited

Honorable Mention recognizes projects that did not win a specific category but were clearly successful projects that overcame significant challenges in planning, execution, and delivery.

Quick Facts

Project
Biocon Biologics Manufacturing (B3) Project

Location
Bangalore, India

Total Facility Size
341,797 square feet

Project Mission
To build a state-of-the-art facility that included consideration for future commercial projects.

WHY THEY WON

This project team demonstrated focused efforts to minimize the environmental impact of a large facility and demonstrated superior execution in managing construction safety. Additionally, several of the design elements and execution strategies they implemented showed a focus on ensuring a robust supply chain while focusing on COGM (Cost of Goods Manufactured) reduction.

A Leader in Global Biologics

Biocon Biologics Limited is a fully integrated global biosimilars organization and a subsidiary of Biocon Ltd, an innovation led global biopharmaceuticals company. In 2019 Biocon Biologics decided they wanted to consolidate the development, manufacturing, and commercialization operations for biosimilars into one facility, the Biocon Biologics Manufacturing Plant (B3).

"This project is in line with our mission to become the most admired global leader in biologics by delivering affordable access to innovative and inclusive healthcare solutions that transform patients' lives," said Maneesh Ghildyal, Vice President and Global Head, Projects and Engineering. "We optimally designed the facility with a focus on cost and future processes, thereby expecting a significant impact from a drug affordability standpoint."

The facility is located at Biocon Park in Bangalore, India, a 100-acre integrated complex. B3 is a mAbs manufacturing facility with 6000 L production bio reactor scale. The facility includes both production and laboratory space and is intended to be used for commercial and clinical manufacturing for global markets. B3 is designed for multiproduct operations with upstream and downstream processing and an in-process quality control testing lab. The adjacent warehouse is fully equipped to complete all the operations associated with biologics manufacturing from the receipt of raw materials to the shipment of bulk mAb/protein.

Built with the Environment in Mind

While Biocon Biologics pursues its purpose of using biotechnology to develop therapies that heal the world, it is equally concerned about the health of the planet and the depleting ecological balance. The Company incorporated environmentally friendly elements into the construction and ongoing operation of B3. The excavated

soil of the building was reused for back-filling, reducing solid waste generation.

Ongoing daily efforts are made to reduce water use – liquid waste is piped to one of three tanks (two underground and one above), pumped to a centralized ETP for treatment, and used for irrigation. All roof surfaces are connected to a rainwater harvesting tank and used for irrigation, cooling towers, and flushing. Recovered condensation is sent back to the boiler and effluent from the clean utility systems is reused for the cooling tower.

Energy efficiency was also considered when designing the layout of the building. All offices and conference rooms are located at the northeast and east sides of the building because those sides receive less intense sunlight. Noncritical areas such as staircases, service shafts, and loading bays are located on the south and west sides of the building where the sunlight is the most intense. Services which can be housed in ventilated areas like chillers, AHU plants, and cooling towers are located on the top floor with a covered roof. All clean utilities

are planned within the building, minimizing required pumping and other energy loads due to reduced pipe connection lengths.

Stellar Safety Record

All contractors and vendors were provided with safety induction training and the project safety plan and asked to provide a Hazard Identification and Risk Assessment for activities performed onsite. The collaborative approach and rigorous planning resulted in a project with close to three million labor hours with zero lost time incidents.

Saving Patients Money

Biocon Biologics operates on the belief that everyone has a right to affordable, high quality medicines. From design and construction through product delivery, they remained focused on this belief incorporating cost savings throughout resulting in a project that was completed under budget by 35 million dollars. B3 also has ongoing policies and procedures in place

that could result in a reduction in the cost to produce medicines. For example, Biocon Biologics' drug substance manufacturing unit capacity increased by 6-fold after construction of the B3 facility impacting cost optimization and reducing the production cost per unit.

"This facility was delivered within the key deliverables of safety, cost, and timeline which has helped Biocon Biologics Limited mission to provide affordable healthcare and reach more patients worldwide," said S.P. Vivek, Senior Director, Projects, and Engineering.

Supply Partners and Key Participants

Manufacturer/Owner Name
Biocon Biologics India Limited

Engineer/Architects (A&E)
Jacobs Engineering India Private Limited; NNE Private Limited; IPS

Construction Manager
Tata Consulting Engineers Limited

Main/General Contractor
Sobha Limited

Piping Subcontractor
Fluid – Fluid Line Engineers and Fabricators (P) Ltd.

HVAC Subcontractor
Sterling and Wilson Private Limited

Automation and Control Supplier
Siemens Limited

Major Equipment Suppliers/Contractors

Bioreactor
Bioengineering AG

Upstream Equipment (Centrifuge)
Alfalaval – Alfalaval Tumba AB

Downstream Equipment (Chrom Systems)
GE Health Care PTE Limited

Upstream and Downstream Equipment
Millipore SAS

Autoclaves
Fedegari – Fedegari Asia PTE Ltd.

Clean Utility Systems
Pharmatec GMBH (A Syntegon company)

Filling Equipment – Equipments
Sartorius Stedium Systems GMBH

Washers
STEELCO S.P.A

Downstream Equipment (Mixers)
Life Technologies Corporation

Clean Room Equipment
M/S. Integrated Cleanroom Technologies Private Limited

Downstream Equipment (Tanks)
D.D Enterprises; Shanghai Morimatsu Pharmaceutical Equipment Engineering Co., Ltd.

ABOUT THE COMPANY

A subsidiary of Biocon, Biocon Biologics' cutting-edge R&D and global scale manufacturing have provided an innovative portfolio of in-market and in-development life-changing biosimilars. Three of these biosimilars have received global acclaim with commercialization in the EU, U.S., Japan, and Australia. It has provided over 2.75 billion doses of human insulin worldwide, making it a leading global insulins provider.

FOYA 2021
Facility of the Year Awards

Honorable Mention

Locus Biosciences

Honorable Mention recognizes projects that did not win a specific category but were clearly successful projects that overcame significant challenges in planning, execution, and delivery.

Quick Facts

Project
Commercial Phage Production Facility Upfit

Location
Morrisville, North Carolina, USA

Total Facility Size
12,000 square feet

Project Mission
To provide a cGMP commercial phage production environment with maximum flexibility to generate, purify, and aseptically fill therapeutic doses of antibacterial phage to fight critical unmet medical needs and diseases.

WHY THEY WON

The design attributes and operational procedures Locus Biosciences incorporated into their new facility go beyond the Regulatory requirements. ISPE would like to recognize Locus Biosciences for building a facility that will produce safe and effective products.

Fighting Back Against Bacteria

Founded in 2015, Locus Biosciences is a clinical stage biotechnology start-up that develops Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR) Cas3-enhananced bacteriophage (crPhage™) precision antibacterial products to address critical unmet needs in bacterial infections and microbiome indications in oncology, immunology, and central nervous system therapeutic areas. Based in Morrisville, North Carolina, the company has become a world-leading developer of products based on today's most advanced CRISPR technology. As demand for their product has grown so did the need for more space.

"Our product is a bacteriophage that is very effective at attacking E. coli," said Joseph Nixon, Senior Vice President. "Unfortunately, many contract manufacturers use E. coli cells to manufacture other products. Therefore, producing the bacteriophage in those facilities was impossible."

Faced with extremely limited options, Locus leadership decided they needed build their own dedicated space to ensure their research and clinical trials would be able to advance unimpeded.

Retrofitting for the Future

Locus' entire process is a comprehensive raw material to finished dosage form, produced in one facility. In the new space, bacteriophage are produced in an aqueous buffered solution. The process steps include:

1. Upstream processing of high concentrations of potentially virulent and non-virulent bacteria, including introduction of bacteriophage into bioreactors for amplification of phage
2. Downstream processing including clarification filtration, tangential flow filtration (TFF), chromatography, and bioburden reduction filtration
3. Sterile filtration and vial/syringe filling

The process requires a high-quality clean space environment that minimizes contamination and provides a safe and secure barrier for potentially virulent and non-virulent bacteria and bacteriophage.

Locus was able to renovate a 30-year-old, one story shell space into a leading-edge BSL-2 laboratory and cGMP biomanufacturing space. The new facility provides for revolutionary advancements in biocontainment through its leading-edge design and efficiencies. Several innovative facility advancements include:

- The first commercial BSL-2 multi-bacteriophage facility in the U.S. that can work with 5-litre and up to 200-litre bioreactor capacity
- Process areas designed to provide unidirectional traffic flow
- HVAC system with higher-than-average air change rates
- Aseptic filling using a VanRx Microcell, a closed gloveless isolator
- All liquid waste is collected through the SUSs and disposed via the Actini sterilization system

The space includes three equally capable suites with the ability to provide for the simultaneous and interchangeable production space. Each of the three suites is fully interchangeable with the capacity to execute any part of the process.

Safety Matters

Due to the ubiquitous nature of the product (i.e., the ability for bacteriophage to get anywhere), containment and safety were essential when designing the new facility. In addition to the required HEPA filtration in and out of each suite, Locus provided the additional safeguard of an independent bubble for each suite through secondary airlocks. The additional airlocks and resulting innovative pressure cascade resulted in two levels of bacterial containment.

To further enhance facility safety, the HVAC system is designed with a purge system function. In the event of an emergency, the system is designed to transition to 100% fresh air in with 100% exhaust. The facility's process area was designed to provide unidirectional traffic flow for both personnel and materials, four separate airlocks were constructed for each of the three separate suites and each suite was designed with a Personnel Airlock (PAL) and Material Airlock (MAL) for both entry and exit.

Locus' dedication to safety was stellar throughout construction as well. Through extensive planning and skilled execution, the project was completed with 67,070 work hours, no COVID-19 cases or impacts on any workers (despite ongoing construction during the pandemic), and 0 recordables or lost time.

Changing the World of Medicine

"According to the World Health Organization, 'Antibiotic resistance is one of the biggest threats to global health, food security, and development today,'" said Paul Garofolo, CEO. "Locus' project represents a seismic shift in science to combat bacteria in the human body at a time when it is most needed. These products represent a much-needed precision tool in physician's armamentarium in the fight against drug-resistant bacterial infections and may eventually displace the use of broad-spectrum antibiotic therapies. The ripple effects of the science that will be conducted in this facility are endless. In addition, this new facility may now be the safest BSL-2 facility in the U.S. where the operators and scientists have the ability to develop life-saving products with the greatest confidence and personnel protection."

Supply Partners and Key Participants

Manufacturer/Owner Name
Locus Biosciences

Engineer/Architects (A&E)
Bozenhardt Consulting Services; IPS (CQV Contractor)
Jacobs Engineering

Construction Manager
BE&K Building Group

Piping Subcontractor
Gamewell Mechanical

HVAC Subcontractor
Gamewell Mechanical

Automation and Control Supplier
Vantage Consulting Group

Major Equipment Suppliers/Contractors
AES Clean Technology; Code Electric

ABOUT THE COMPANY

Locus is a clinical-stage biotechnology company developing CRISPR-enhanced precision antibacterial products (crPhage™) to address critical unmet medical needs in bacterial infections and high-value microbiome indications. The Locus platform combines CRISPR-Cas3, which degrades targeted DNA within a bacterial cell, with bacteriophage to kill target pathogens while leaving non-target bacteria unharmed.

FOYA 2021
Facility of the Year Awards

Honorable Mention

Raymond G. Perelman Center for Cellular and Molecular Therapeutics

Honorable Mention recognizes projects that did not win a specific category but were clearly successful projects that overcame significant challenges in planning, execution, and delivery.

Quick Facts

Project
Raymond G. Perelman Center for Cellular and Molecular Therapeutics at Children's Hospital of Philadelphia

Location
Philadelphia, Pennsylvania, USA

Total Facility Size
13,000 square feet

Project Mission
To create a facility with the capacity to produce personalized gene therapies, manufacture adeno-associated virus vectors and lentivirus vectors, and support multiple trials simultaneously.

WHY THEY WON

The Raymond G. Perelman Center for Cellular and Molecular Therapies (CCMT) located at the Children's Hospital of Philadelphia (CHOP) particularly appealed to the judges because of its impact on the future of cell and gene therapy facilities. In addition to being a thought-provoking example of integrating R&D, manufacturing, and treatment in one environment, the facility delivered a high-quality design with strong infrastructure capabilities and redundancy. A bonus was the ability to leverage the existing city and campus infrastructure, thus improving resiliency and cost while also putting shelled but exiting space to use.

Saving Young Lives

Children's Hospital of Philadelphia (CHOP) is the nation's first hospital devoted exclusively to the care of children. CHOP's Research Institute's advanced breakthrough treatments and innovations have changed lives and pushed pediatric scientific knowledge forward. Families from all over the world bring their children to CHOP when they are facing complex medical conditions.

"CHOP has a long and successful track record of research innovation and has been researching cell and gene therapy for more than twenty years," said Beverley Davidson, Chief Scientific Strategy Officer, Director, Center Cellular and Molecular Therapeutics at CHOP. "Given the success we've had with our research and the successful treatment of previously uncurable diseases, we wanted to expand our capability in ground-breaking research and manufacturing and bring life-saving therapies to our patients."

The CCMT is dedicated to the manufacturing of viral vectors in support of Phase I and Phase II clinical trials in compliance with current Good Manufacturing Practice (cGMP). The CCMT aims to be in the forefront of pediatric medicine by fostering a multidisciplinary approach to leading edge research endeavors that will lead to a variety of applications in the treatment of inherited and acquired disorders.

Creating a Safe, Sterile Environment

Fitting new manufacturing and research space into an already existing space is always a challenge and fitting manufacturing suites, designed to produce personalized gene therapies, into an existing building was no exception. But architects, engineers, and scientists involved with the project worked together to ensure the quality of the design and the safety of the drugs manufactured in it. The project team developed a rigorous risk assessment program where risks were categorized by numerical values based on risk to a product and severity of the effect. The analysis provided them with a document they were able to reference throughout the design process and use to demonstrate the reliability of the project to the FDA. This analysis and assessment was crucial to the success and design of a facility that maximizes reliability for generating human drug products.

The facility's systems are capable of maintaining 100 percent uptime and designers did not leave anything to chance – the team included extra redundancy for power supply to the facility. If the building's existing humidification systems fail, a redundant chilled water system is ready. The team was also able to use existing infrastructure and add additional layers of back-up systems throughout.

Bench to Bedside

The Raymond G. Perelman Center for Cellular and Molecular Therapeutics has manufactured viral vectors in support of over 30 clinical trials in 10 countries with more than 550 patients treated. These ground-breaking scientific clinical trials include treatments for hemophilia, chronic lymphoid leukemia, retinal degenerative diseases, and pancreatic cancer.

Over the past 10 years, CHOP researchers have seen the demand for viral vectors for human use increase. Proximity to the basic research being done at the hospital has given the CCMT an advantage in being able to develop personalized gene therapies and get them to patients immediately. To support this rapid translation from laboratory bench to hospital bedside, the CCMT has the resources to manufacture a wide range of viral and non-viral vectors to transfer genes of interest and the capacity to separate and manipulate human cells to make gene therapy trials possible.

The facility was designed to support multiple trials simultaneously. The HVAC system was designed to handle multiple campaigns in the facility and separated room supply and exhaust streams can be sealed so individual suites can be decontaminated as needed. CCMT does not have to shut down the whole facility during decontamination but can seal off specific rooms.

Designed for Staff Welfare

As with any successful institution, staff recruitment and retention are critical components to the success of CCMT. To that end, the project team designed the space to be appealing to today's workforce while still meeting rigorous manufacturing and safety requirements. High ceilings and hundreds of windows give the facility a light and airy feeling while helping staff navigate from area to area. Designers also added elements of wellness and humanity throughout the sterile facility, including lines of sight that allow workers inside and outside of the sterile and laboratory areas to stay connected and splashes of color to personalize the otherwise sterile looking manufacturing suites.

"In this facility, we make the tools – the vectors – that scientists use to deliver cell and gene therapies, bringing dramatic precision medicine treatments to patients," said Madeline Bell, President and CEO, Children's Hospital of Philadelphia. "The new facility is allowing us to continue our mission in the growing field of gene therapy and supporting the new generation of gene therapy clinical trials."

Supply Partners and Key Participants

Manufacturer/Owner Name
Raymond G. Perelman Center for Cellular and Molecular Therapeutics

Engineer/Architects (A&E)
Ballinger, IPS (CQV Contractor)

Construction Manager
Turner Construction Company

Main/General Contractor
Turner Construction Company

Piping Subcontractor
Limbach

HVAC Subcontractor
WM.J Donovan

Automation and Control Supplier
Johnson Controls, Inc.

Major Equipment Suppliers/Contractors
Turner Logistics; AES Clean Technology

ABOUT THE COMPANY

Children's Hospital of Philadelphia (CHOP) is the nation's first hospital devoted exclusively to the care of children. Since 1855, CHOP has been the birthplace for countless breakthroughs and dramatic firsts in pediatric medicine. Built on a foundation of delivering safe, high-quality, family-centered care, the Hospital has fostered medical discoveries and innovations that have improved pediatric healthcare and saved countless children's lives. Today, families facing complex conditions come to CHOP from all over the world, and their compassionate care and innovation has repeatedly earned them a spot on the U.S. News & World Report's Honor Roll of the nation's best children's hospitals.

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