FOYA 2022

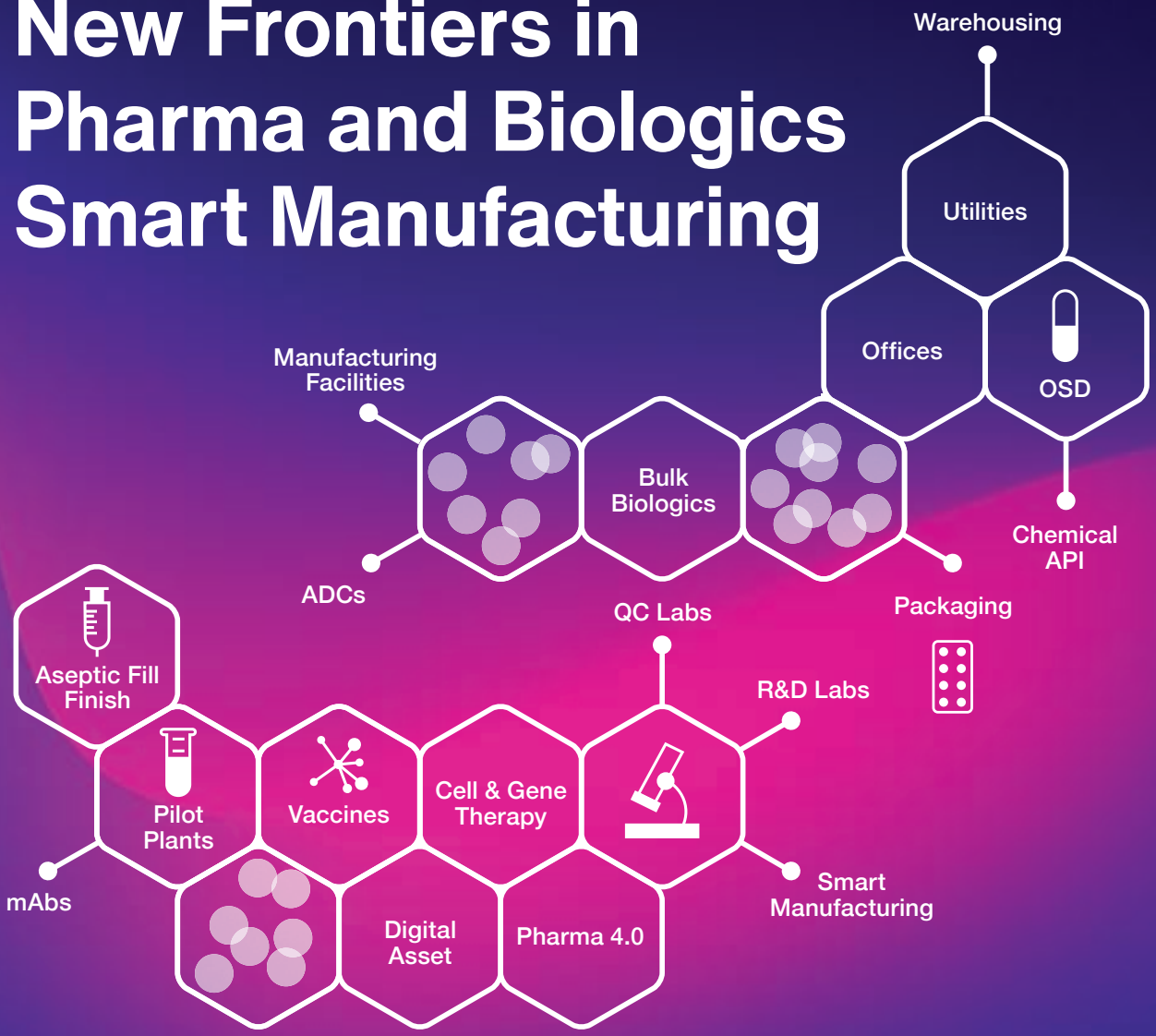
ISPE Facility of the Year Awards

2022 CATEGORY WINNERS

Spotlight on Excellence

Europe | USA | Asia

New Frontiers in Pharma and Biologics Smart Manufacturing



Find out about our flexible, adaptable, future-ready solutions to meet your new challenges.

Engineers
Architects
Project Managers
Constructors

Visit **www.pmgroup-global.com/pharma**

The project delivery specialists

PM GROUP

2022 FACILITY OF THE YEAR AWARDS (FOYA)

Category Winners Spotlight on Excellence

Jessica Hardy
Sr. Director, Membership and Chapter Relations
Carrie McManus
Manager, Member Engagement
Marcy Sanford
Contributing Writer and Editor
Doug Whitmore
Sales Account Manager
Jen McQueen
Creative Services Manager

ISPE Global Headquarters
and Training Center
6110 Executive Blvd., Suite 600
North Bethesda, MD 20852 USA
Tel: +1-301-364-9201
Fax: +1-240-204-6024
ask@ispe.org
www.ISPE.org/FOYA

About FOYA

Category Winner Profiles

Thank You to Our Advertisers

Thank you to our 2022 FOYA Supporting Sponsor

STERIS
Life Sciences

Welcome & Thank You

For the past 10 years, I have been honored to collaborate with ISPE to recognize the Facility of the Year Awards (FOYA) Winners. This year, as always, continues to present new and unique challenges for us all. FOYA 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 proud to have recognized projects supporting the international industry pandemic response and supply chain challenges while continuing to deliver innovation for the patients we serve.

FOYA has been recognizing innovations in the biopharmaceutical industry since 2005. 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 global experience in their fields—engineering, manufacturing, supply chain, and quality. They are experienced, knowledgeable, and understand the global landscape. They have had the privilege of personally working on and delivering many innovative projects.

Submissions come from all corners of the world and represent projects that include breakthroughs in automation and integration, cell and gene therapy development, supply chain delivery, process improvements, project delivery excellence, and dedication to developing medicines for underserved populations.

How are submissions reviewed?

The judging panel meets each year in January to review and discuss merits of submissions. Due to pandemic travel restrictions, judging was conducted virtually. Judges start by assessing the novel character of each project and discuss industry trends and how it is 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.

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? Are they executed safely? 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 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 Co-Chair, Parag Sane, Executive Director Capital Projects at Amgen, and all my fellow FOYA judges for volunteering their time as well as all the companies that submitted projects. Selecting 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.

Antonio Crincoli, PE

Chair
FOYA Judges Committee

Vice President,
Global Engineering
Catalent Pharma Solutions

ISPE thanks the 2022 FOYA Judges Committee for their continued support of the FOYA program.

Antonio Crincoli
Vice President of Global Engineering
Catalent Pharma Solutions

Parag Sane
Executive Director Capital Projects
Amgen Inc.

Michael Alltoft
Vice President, Global Engineering & Facilities
Medicago USA, Inc

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

Carla Boragno
Senior Vice President, Head Global Engineering & Facilities
Genentech (Roche Group)

James Breen
Vice President, Lead Biologics Expansion
Janssen Pharmaceuticals

James Brinkman
Vice President, Global Engineering
Thermo Fisher

Flemming Dahl
Head of AP Expansion, Senior Vice President
Novo Nordisk A/S

James Dickow
Principal Engineer
BioMarin Pharmaceutical

Jian Dong
Vice President & Site Head, Biomanufacturing
Wuxi Biologics

Joydeep Ganguly
Senior Vice President, Corporate Operations
Gilead Sciences Inc

Michele Ghinizzini
Vice President, Head of Engineering & Maintenance
Sanofi

Francesco Intoccia
Senior Vice President, Global Engineering
CSL Behring

Lou Kennedy
CEO & Owner
Nephron Pharmaceuticals

Brian Lange
Associate Vice President, ERMD Lead
Merck

Roland Rocafort
Senior Vice President, Facilities & Engineering Moderna

Gary Schoenhouse
Chief Technical Advisor
GeneSuites

Sangwon Seo
Vice President, Head of Business Strategy
Samsung Biologics Co, Ltd.

David Sternasty
Vice President, Corporate Engineering
Eli Lilly and Company

Frank Vanermen
Senior Vice President Head of Strategic Program Management
Bayer AG Pharmaceuticals

Felix Velez
Vice President, Engineering & Project Delivery
Johnson & Johnson

Rong Zhang
Director, Process Engineering Design
Bristol Myers Squibb

The numbers speak for themselves.

Complicated? Not at all! When it comes to digital solutions, we think progressively – and combine high-performance technologies with maximum user-friendliness. Syntegon's smart solutions support you where it really matters: condition monitoring, overall equipment effectiveness (OEE) and product quality. **Our secret? Comprehensive experience in the development and application of intelligent software solutions.**

www.syntegon.com

SYNTEGON
PROCESSING & PACKAGING

Reliable - Trusted - Sustainable Water Treatment Solutions

WFI - PW - Pure Steam

One Singular Source For Biopharmaceutical Grade Water.

MECO

A GRUNDFOS COMPANY

FOYA 2022
ISPE Facility of the Year Awards

www.MECO.com

2022 FOYA AWARDS

Planning Committee

ISPE's Facility of the Year Awards (FOYA) Program represents the future of pharma. Past and present winners inspire our industry to achieve innovative, modern processes and systems to better supply medicines throughout the world. These winners have led adoption of flexible, digitally enabled, cutting-edge technology delivered through the latest approaches in project execution and operational excellence. They continue to impact society through attention to employees, sustainability, and patients. This years' winners also acknowledged special contributions to the COVID-19 pandemic response.

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, starting with the 2020 submissions, we also aligned categories with ISPE's strategic pillars, provided new scope for the judges to award multiple category winners, added subcategories designations, and elevated sustainability as a minimum requirement for all submissions. This resulted in the first category award for Pharma 4.0™ and two category winners for Social Impact in 2022!

Past FOYA award winners include not only manufacturing facilities, but also laboratories, pilot plants, medical device production, fill/finish & 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 2020 and 31 December 2022, please consider applying for a FOYA award. The FOYA awards give 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. More details on submitting can be found in the "Submit Your Facility" page (ispe.org/facility-year-awards/submit).

In my last year as the FOYA committee chair, I'd like to thank all of the program committee members and judges for their role in supporting & improving the FOYA program. Jim Grunwald, who has been part of the FOYA committee since 2020, will be succeeding me as the chair at Annual Meeting in Orlando. I know he will elevate the program while continuing to focus on innovation, modernization, & excellence! I'm impressed by how this program is evolving and appreciate all the work behind the scenes that has gotten it to where it is today! I'm also looking forward to seeing upcoming winners in years to come! To wrap up, I'd like to applaud the 2022 FOYA Category Award Winners – to all the companies, projects, and teams behind this year's roster, well done & congratulations!

For information on submitting your project for consideration in 2023, visit ispe.org/FOYA for submission requirements.

Avril Vermunt

Chair
FOYA Program Committee

Senior Director, Manufacturing Sciences & Technology
EQRx

CONGRATULATIONS TO OUR PARTNER CRISPR THERAPEUTICS.

FOYA

WE SPECIALIZE IN BUILDING EXCEPTIONAL FACILITIES WHICH ENABLES CRISPR TO TRANSFORM THE LIVES OF PATIENTS.

- cGMP Facilities
- Laboratories
- Vivaria
- cGMP Warehouses

Commodore 20 YEARS

commodorebuilders.com

Congratulations

to our client CRISPR Therapeutics and project partners on winning the ISPE Facility of the Year Innovation Award! DECCO is proud to have supported this award-winning project.

DECCO

We provide specialized construction, maintenance, and fabrication services to leading biopharmaceutical, technology and industrial clients throughout New England.

- DECCOServ
- DECCOFab
- DECCO Construction
- Critical Equipment Handling

Unsurpassed Quality. Unwavering Professionalism.

(603) 673-2200 www.DECCO.com info@decco.com

2022 FOYA Category Award

Social Impact

CATALENT

PROJECT
Mercury

LOCATION
Bloomington, Indiana, USA

TOTAL FACILITY SIZE
130,150 square feet

PROJECT MISSION
To build a state-of-the-art aseptic fill-finish building with vial and syringe filling lines supporting biologic products that could provide maximum flexibility to respond to industry needs.

Social Impact

The FOYA Social Impact category honors projects that exemplify the application of novel approaches, standards, and practices that result in efficient processing, resourceful utilities, and business advantage by increasing patient access and preventing drug shortages through in-country-for-country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment and fast-track drug production; and designs which overcome specific geographical challenges.

Under normal circumstances, projects of this type are challenging. However, the global public health driver to execute these projects in record time, and deliver commercially approved vaccines, in large volumes, was unprecedented and therefore deserves recognition for Social Impact.

Given the unique challenges surrounding the COVID-19 pandemic, there are two projects the FOYA judges are recognizing in the category of Social Impact—Catalent and Janssen Biologics BV.

Why Catalent Won

Catalent's Project Mercury was delivered in the face of the global pandemic. With an unknown manufacturing process for a vaccine candidate under development, the team pivoted on existing projects to ensure success, adding 40% more scope including secondary packaging and inspection. The project added 40,000 square feet to cover the most stringent of the unknown needs of the process, reducing the risk to supply. The project team also cut six months off their schedule. The team beat the clock while managing the complexities of execution within the COVID-19 restricted environment and delivered the needed capacity to meet important pandemic demands.

Changing Course to Help Combat COVID-19

In 2017, after moving into a new one-million-square-foot facility in Bloomington, Indiana, Catalent turned their attention to an existing shell space at their site, known as Building C. Their plan was to tear down half of that unused shell space and rebuild it into a state-of-the-art aseptic fill-finish building with vial and syringe filling lines supporting biologic products. The project, dubbed Project Mercury, started in July 2019 with the goal to provide maximum flexibility to respond to industry needs, but like most plans made and started in 2019, Catalent's pivoted in 2020.

On 11 March 2020, as the Catalent team was installing structural steel at the site, the WHO (World Health Organization) declared a global pandemic. Shortly after, Catalent was approached by a vaccine candidate producer to secure manufacturing capacity, however, it would require Catalent to complete Project Mercury and be ready to produce by January 2021, a year earlier than previously planned. Catalent immediately added more members to the Project Mercury team and began modifying their plans.

Originally, the plan was to integrate Building C into the rest of the Catalent facility with warehousing, packaging, inspection, and other core functions happening at the main

facility next door. But Catalent still faced many unknowns surrounding the kind of vaccine they would be manufacturing, so they made a bold choice to ensure their ability to produce any life-saving therapies or vaccines: they upgraded the building to segregated viral manufacturing.

While this decision would ready Catalent for any type of vaccine and provide future flexibility beyond the pandemic, it meant adding several new and complex requirements:

- Automated visual inspection equipment
- Cartoner
- Palletizer
- QC labs
- Cold chain warehousing
- Dedicated material entrance and exit
- Segregated HVAC
- Modified air pressure cascades
- Additional airlocks

The new equipment alone would normally require a nine-to-twelve-month delivery lead time. With only eight months until opening day, Catalent had to find a supplier with equipment ready so they could have the facility re-designed, built, installed, and qualified by the

end of the year. The team also had to add dock spaces, lab space, two stability chambers, two levels of cold storage, as well as inspection, packaging, shipping—all squeezed into the same footprint as the original design and requiring sensible incorporation into a completed program. The design team dug in immediately and completely overhauled the original plans.

In addition to these challenges, Catalent faced supply chain issues, potential worker fatigue, and fear of an internal COVID-19 transmission; but by planning thoroughly and being flexible, when necessary, Catalent completed a brand-new building that has room for continued expansion and offers future capacity for innovative technologies.

In January 2021, Catalent ran its first batch of a potential COVID-19 vaccine—a full six months ahead of the original operational schedule and within ten days of the accelerated timeline. Using single-use-systems and product dedicated process equipment, the finished facility offers aseptic processing and controlled substance manufacturing of biologics and small molecules.

“Of my 30-year career, this was the most challenging, rewarding, and stressful experience,” said John Machulski, Catalent Vice President of Engineering, Biologics, and Gene Therapy. “It was also the most exciting project of my entire career. I never needed to remind workers why we were there. We all watched it on the news.”

Safety First

From March 2020 onwards, the constant threat of the COVID-19 virus hung over the entire project. Therefore, Catalent knew they needed to go beyond masks, hand sanitizer, and mobile hand washing stations to keep staff safe. As soon as COVID-19 made itself known as a threat, they brought in a consultant to advise them on infection control measures.

Environmental Responsibility

Catalent's goal was to create a highly efficient, cost-saving green building which met their business needs while responsibly using resources and vigorously protecting the health and well-being of the highly skilled workforce. To do so, they carefully assessed everything from material and resources to indoor environmental quality to ventilation systems. Some of their sustainability efforts included installing low flow plumbing fixtures and LED lights with occupancy sensors, selecting environmentally friendly refrigerant, and successfully implementing an iAQ Air Quality Management Plan.

About Catalent

Catalent is a global leader in enabling pharma, biotech, and consumer health partners to optimize product development, launch, and full life-cycle supply for patients around the world. With broad and deep scale and expertise in development sciences, delivery technologies, and multi-modality manufacturing, Catalent is an industry partner for personalized medicines, consumer health brand extensions, and blockbuster drugs. Catalent helps accelerate over 1,000 partner programs and launch over 150 new products every year. Its flexible manufacturing platforms at over 50 global sites supply over 70 billion doses of 7,000 products to over 1,000 customers annually. Catalent's expert workforce exceeds 19,000, including more than 2,500 scientists and technicians.

SUPPLY PARTNERS AND KEY PARTICIPANTS:

Manufacturer/Owner
Catalent, Inc.

Engineer/Architect (A&E)
CRB; Bledsoe Riggert Cooper James; Silver Creek Engineering, Inc.

Construction Manager
CRB Builders, LLC

Structural Steel Subcontractor
Steel Supply & Engineering

Concrete & Site Subcontractor
Weddle Bros. Building Group, LLC

Electrical Subcontractor
Cassady-PayneCrest Joint Venture, LLC; ERMCO, Inc.

Piping Subcontractor
Freitag-Weinhardt, Inc.; Harrell-Fish, Inc.

Interior Fit-Out Subcontractor
Taylor Bros. Construction, Inc.

Resinous Epoxy Flooring Subcontractor
Cornerstone Industries Corp.

HVAC Subcontractor
Poynter Sheet Metal

Automation and Control Suppliers
Thermo Systems, LLC
Rockwell Automation
Water Consulting Specialists, Inc.

Major Equipment Suppliers/Contractors
OPTIMA pharma GmbH
Integrated Process Engineers & Constructors (IPEC)
Rollie Johnson, Inc
Air Enterprises, LLC
Cleaver-Brooks, Inc.
Koch Air
Cummins, Inc.
EMD Millipore
VWR International, LLC

2022 FOYA Category Award

Innovation

CRISPR THERAPEUTICS

PROJECT
CRISPR Therapeutics Framingham Manufacturing Facility

LOCATION
Framingham, Massachusetts, USA

TOTAL FACILITY SIZE
49,301 square feet

PROJECT MISSION
To harness the CRISPR/Cas9 gene-editing platform, to develop and deliver potentially curative therapies to patients to treat hemoglobinopathies, cancer, diabetes, and other diseases.

Innovation

Winners in the Innovation category exemplify the novel application of process manufacturing techniques, innovative design concepts, innovative technologies, and unique solutions that exemplify the next generation of agile, flexible, efficient and effective new and existing pharmaceutical and biotechnology facilities. This includes implementation of commercially available and custom developed equipment which yielded superior results, improved competitive position, and/or demonstrated imaginative collaboration with vendors/ suppliers/manufacturers.

Why CRISPR Therapuetics Won

The CRISPR Therapeutics manufacturing facility was designed thoughtfully and innovatively, and the ability of the facility to catalyze the promise of the technology impressed the judges. The facility is unique in utilizing a compact design with multiple independent production suites, each capable of producing a different product at a different stage of development while maintaining strict product segregation. Digital tools were embedded into the facility design so that multiple production suites and multiple products at various stages of development can be managed simultaneously. While the facility design was grounded in fundamental good engineering practices, there was intentionality in the flexibility of the facility that the committee found very innovative.

Designed to Develop Transformative Gene-Based Therapies

CRISPR Therapeutics was co-founded in 2013 by Dr. Emmanuelle Charpentier, who won a Nobel Prize in Chemistry in 2020. The company is focused on developing gene-based therapies for serious human diseases including sickle cell disease, beta thalassemia, cancer, and diabetes using the CRISPR/Cas9 gene-editing platform.

They opened a GMP (Good Manufacturing Practice) manufacturing facility in Framingham, Massachusetts, USA to focus on the production of CRISPR-based therapeutics. The facility is being used to produce clinical candidates and is designed with the capacity to produce commercial products in the future. It was built purposely to provide an end-to-end solution for production and fill operations and has support space for managing raw materials and waste along with warehouse, quality control (QC), manufacturing, science, and technology (MSAT), and office space.

Aspects of the design and implementation that are innovative include the use of separate and redundant air handling capacity that allows for independent operation and shutdown of each of the manufacturing suites, the ability to treat any of the suites with vaporized hydrogen

peroxide (VHP) and isolation of personnel flows for operators involved in critical starting material and final drug product manufacturing. This flexibility allows the plant to be configured to produce multiple clinical products (when only a small number of lots per year are needed), a single commercial drug product (when many lots per year of only one product would be needed), or any combination in between.

Because CRISPR Therapeutics can have multiple production suites producing several products at various stages of development, there is an immense amount of data that is collected and the ability to access the right data at the right time is critical to managing production, testing, and release of products, calibration and maintenance of equipment, and staff training. To manage this, CRISPR Therapeutics implemented a fully digital control system that monitors and controls shop floor and laboratory equipment, collects and archives process and testing data, feeds batch records, maintenance, and facility status to the operating floor, and integrates personnel training and environmental, health, and safety (EHS) data. The information is available through a secure network and provides traceability to the quality management system (QMS).

The facility and manufacturing systems require minimal time for product changeover and has resulted in reduced cost of goods, labor, and cycle times and limited downtime. In fact, the facility can operate 24/7/365 due to the design of the dedicated utility sets for each clean manufacturing space and the supporting spaces in the facility. This approach provides a consistent and reliable supply chain.

"Driven by our unwavering commitment to address patient needs, we are proud to be recognized by ISPE as 2022 Facility of the Year Award Winner in Innovation for our state-of-the-art manufacturing facility in Framingham, Massachusetts, that has been innovatively designed with flexibility and scale in mind," said Stephen Kennedy, Head of Tech Operations at CRISPR Therapeutics.

Safety First

The project required 113,877 total construction hours to complete. This effort was particularly significant considering the additional challenges of factoring in a remote work environment and the reality of COVID-19 management practices for site-based activities. The Project Execution

Plan provided detailed protocols/SOPs for the EHS program and was updated on a weekly, and often daily basis, to comply with federal, state, and local requirements specific to COVID-19 testing and reporting. Thanks to these efforts the project was completed with 0.0 OSHA recordable incident rate and zero impact to project schedule due to COVID-19.

Environmental Responsibility

CRISPR Therapeutics upgraded a facility built in the 1970s to meet current energy code standards. They installed a fully integrated VHP System for Clean Rooms and the VHP Pass-Through Chamber which significantly cuts down on the amount of cleaning chemicals being used. The VHP Tunnel was designed in lieu of an autoclave which provides a significant energy reduction and simplifies the operation; and cuts down on the amount of cleaning chemicals being used. Additionally, CRISPR Therapeutics installed LED lighting throughout the building, electric shades that adjust according to level of sunlight, drought tolerant landscaping, and electric vehicle charging stations.

About CRISPR Therapeutics

CRISPR Therapeutics is a leading gene editing company focused on developing transformative gene-based medicines for serious diseases using its proprietary CRISPR/Cas9 platform. CRISPR/Cas9 is a revolutionary gene editing technology that allows for precise, directed changes to genomic DNA. CRISPR Therapeutics has established a portfolio of therapeutic programs across a broad range of disease areas including hemoglobinopathies, oncology, regenerative medicine, and rare diseases. To accelerate and expand its efforts, CRISPR Therapeutics has established strategic collaborations with leading companies including Bayer, Vertex Pharmaceuticals and ViaCyte, Inc. CRISPR Therapeutics AG is headquartered in Zug, Switzerland, with its wholly owned U.S. subsidiary, CRISPR Therapeutics, Inc., and R&D operations based in Boston, Massachusetts, USA and business offices in San Francisco, California, USA and London, United Kingdom.

SUPPLY PARTNERS AND KEY PARTICIPANTS:

Engineer/Architect (A&E)
DPS Group Inc.
TRIA Design - Architects

Owners Representative (OPM)
Leggat McCall Properties LLC

Construction Manager
Commodore Builders LLC
Main/General Contractor: Commodore Builders LLC

Piping Contractor
DECCO Inc.

HVAC Subcontractor
Engineering Company

Automation and Control Supplier
New England Controls Inc.
Albireo Energy LLC

Mechanical Equipment – Semi-Custom EAHUs
Skyplume Technologies

Mechanical Equipment – Semi-Custom AHUs
Daikin

Mechanical Equipment – Chillers
Trane US Inc.

Process Equipment – VHP System
Steris Corporation

Mechanical Equipment – Boilers
The Fulton Companies

Electric Equipment – Emergency Generator:
Kohler Power Systems

2022 FOYA Category Award

Project Execution

JANSSEN BIOLOGICS, BV

PROJECT
Vaccines Facility Expansion

LOCATION
Leiden, The Netherlands

TOTAL FACILITY SIZE
25,000 square feet

PROJECT MISSION
To design and build the expansion for Janssen's Vaccines Facility (VF) and secure regulatory approval for commercial production of the Janssen COVID-19 vaccine in record time.

Project Execution

The Project Execution category honors projects that 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.

Janssen also won a FOYA Award in the Social Impact Category for this project.

Why Janssen Biologics, BV Won

A fast-track project was developed to design and build the new facility within nine months and to secure regulatory approval for initial commercial batches produced in the facility within twelve months. The ambitious timeframe required a Herculean effort and flawless collaboration on the part of all involved parties, including best-in-class design and construction partners and an integrated, cross-functional team within J&J (Johnson & Johnson). In addition to an aggressive timeframe, the project faced other challenging circumstances including completing the project and simultaneously setting up the production of small-scale vaccine batches without any operational impact and ensuring the safety and wellness of the entire project team during the height of the pandemic by observing additional safety protocols to prevent COVID exposure.

Life Saving Vaccines During a Time of Crisis

Janssen Biologics provides commercial and clinical manufacturing services in the field of biotherapeutics and vaccines. It is part of the family of companies of Johnson & Johnson (J&J) and is in Leiden, the Netherlands. This Dutch city also houses Janssen Vaccines and Prevention, where research and development activities on infectious diseases and vaccines take place and which developed the Janssen COVID-19 vaccine. As part of the Leiden campus, Janssen Biologics was in a unique position to contribute to the pressing need for vaccines at the height of the pandemic. They produced the drug that helped supply the vaccine to the world from a newly expanded facility.

As COVID-19 spread across the world, Janssen Vaccines and Prevention developed several potential candidate vaccines, which showed potential during clinical trials. With successful candidates in the pipeline, J&J researched the production capacity within their network and determined that Janssen Biologics could meet production needs if their Vaccines Facility were expanded. The plans available at the time aimed for expanding the facility in five to seven years. However, the current health crisis drove Janssen to develop an enhanced, fast track project execution approach to design and build a new facility in nine months and to secure regulatory approval for the initial commercial batches of the vaccine in twelve months.

Expanding Janssen Biologics' Vaccines Facility was a big operational challenge. New tools helped the project team to ensure full alignment with business needs and to drive accountability within the teams. The project required flexibility, resilience, and teamwork from the talented and motivated people of Janssen Biologics. "We worked around the clock to ramp up the production of the COVID-19 vaccines in challenging times, together with many partners," said Henri van Drunen, General Manager of Janssen Biologics. "As a big site, we have shown that we are agile and innovative as well. Thanks to our driven and expert colleagues we are ready to face the health challenges of today and tomorrow."

Good collaboration throughout the project also helped its success. Hans Weverling, Program Lead COVID-19 Vaccine Manufacturing Readiness, emphasized that excellent long-term relations with local partners enabled everybody to move fast. "We worked together with trusted teams, from local construction partners to global

partners within J&J. This helped us in moving forward quickly and realizing our ambitious planning." The early contractor engagement during the design activities significantly reduced the number of handovers and transition of information throughout the construction supply chain and led to the feeling of inclusion and a first time-right approach.

Another strategy that helped J&J to fast-track the project was to work closely with the city of Leiden from the beginning of the project. "Our ties with local authorities contributed to our success," Weverling explained. "We always followed rules and regulations, but efficient collaboration enabled us to complete all steps needed in record time." For instance, city officials agreed to a phased permit authorization approach which allowed J&J to start some of the construction activities in parallel with design development efforts. This strategy allowed for a smooth review and approval process by the municipality of Leiden, leading to a complete building permit without any delays.

On 1 July 2020, the team laid the groundwork for construction when the first construction pile for the expansion facility was driven into Leiden soil. The official approval of the facility by the European Medicines Agency came one year and one day later, on 2 July 2021.

When awarding the Project Execution FOYA, the judges said, “Ultimately, this project is an inspiring landmark that proves that if stakeholders’ goals are aligned, facilities can be developed on a highly accelerated schedule while complying with regulatory requirements, benefitting the community and the planet, and upholding project and product safety.”

Safety First

All design and construction activities for involved stakeholders encompassed 600,000 total person-hours, including 150,000 construction hours without a serious safety incident. There were zero lost-work day cases, no serious injuries, A Days Away Restricted Time (DART) value of 0.0, and a Total Recordable Incident Rate (TRIR) of 0.0.

Environmental Designs

The facility is designed to meet LEED silver requirements. It includes water efficiency, HVAC energy recovery, LED lighting, and low emitting materials in building construction. The project includes a biowaste decontamination system (biokill) with a holding tank of 6,000-liter capacity to thermally inactivate process waste and the decision to expand adjacent to an existing site, reduced the need for additional transport and the total carbon footprint.

About Janssen Biologics, BV

Janssen Pharmaceuticals is a global biopharmaceutical company that aims to create a future where disease is outdated. As part of the Pharmaceutical Companies of Johnson & Johnson, they focus on areas of medicine where the need is high, science is compelling, and the opportunity to make a difference is great.

SUPPLY PARTNERS AND KEY PARTICIPANTS:

Manufacturer/Owner Name

Janssen Biologics B.V. (affiliate of Johnson & Johnson)

Engineer/Architect (A&E)

DPS Engineering (Netherlands) B.V. (affiliate of DPS Group)

Construction Manager

John Sisk & Son (Europe) Ltd. (affiliate of John Sisk & Son)

Main/General Contractor

Van Lith Bouwbedrijf B.V.; Kuijpers PHF Services B.V. (affiliate of Kuijpers)

Project Management Services

Plan B Advies B.V.

Clean Room Contractor

Cleangrad d.o.o.

Piping Subcontractor

Engie

Electrical Subcontractor

Elektravon Elektrotechniek (part of De Groot Installatiegroeop)

Automation and Control Supplier + Process Equipment Commissioning & Qualification

Agidens Life Sciences B.V.

Automation and Control Suppliers

Honeywell B.V. (part of Honeywell Building Solutions)

Major Equipment Suppliers/Contractors

WHP; Cytiva Europe GmbH; Merck Millipore Ltd.; Sartorius Stedim Systems GmbH

2022 FOYA Category Award

Social Impact

JANSSEN BIOLOGICS, BV

PROJECT
Vaccines Facility Expansion

LOCATION
Leiden, The Netherlands

TOTAL FACILITY SIZE
25,000 square feet

PROJECT MISSION
To design and build the expansion for Janssen's Vaccines Facility (VF) for delivering its single-shot COVID-19 vaccine around the world.

Social Impact

Given the unique challenges surrounding the COVID–19 pandemic, there are two projects the FOYA judges recognized in the category of Social Impact. Under normal circumstances, projects of this type are challenging. However, the global public health driver to execute these projects in record time, and deliver commercially approved vaccines, in large volumes, was unprecedented and therefore deserves recognition for Social Impact.

The Social Impact category honors projects that exemplify the application of novel approaches, standards and practices that result in efficient processing, resourceful utilities, and business advantage by increasing patient access and preventing drug shortages through in-country-for country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment and fast-track drug production; and designs which overcome specific geographical challenges.

Janssen also won a FOYA Award in the Project Execution Category for this project.

Why Janssen Biologics, BV Won

The Johnson and Johnson (J&J) vaccine supported in resolving an unmet medical need during the COVID-19 pandemic by providing the world with a single-shot COVID-19 vaccine available on a not-for-profit basis for emergency pandemic use. To provide the world with the COVID-19 vaccine, J&J needed to increase production capacity. The constrained timeline for the construction of the VF expansion was one of the requisites for J&J to meet its COVID-19 vaccine supply commitment. An integrated and collaborative project execution approach involving various internal and external stakeholders was required to meet these challenging deadlines.

Quick Response to a Global Crisis

Janssen Biologics provides clinical and commercial manufacturing services of complex medicines and vaccines. As part of the family of companies of Johnson & Johnson (J&J), Janssen Biologics contributes to improving access and affordability of healthcare and creating healthier communities. Vaccines are a major part of this effort. As the COVID-19 pandemic hit, Janssen Biologics expanded its Vaccines Facility, helping J&J to supply its vaccine to the world.

Access and affordability were incorporated in the design and distribution strategy of the vaccine. J&J committed to making its COVID-19 vaccine available on a not-for-profit basis. The vaccine was designed to be convenient and cost-effective to distribute and administer, as it may be stored at regular refrigerator temperatures. These factors are particularly relevant in developing countries where people have remote access to healthcare centers and where expensive ultra-cold storage facilities and cold chain infrastructure are limited.

To provide the world with the COVID-19 vaccine, J&J needed to increase production capacity. Janssen Biologics' Vaccines Facility (VF) in Leiden was identified as having the capacity for expansion. The VF expansion was

a fast-track project to increase the commercial manufacturing capacity of vaccine drug substance at Janssen Biologics. The two-story, 25,000 square foot expansion was completed nine months after the start of the construction and received regulatory approval for commercial production in only twelve months.

In this period, Janssen Biologics upscaled the downstream process to allow large-scale batch processing and an increased manufacturing cadence. The improvements gave Janssen Biologics a significantly increased downstream capacity. The project team worked in extended shifts, including weekends, to meet the challenging timelines and minimize the impact on existing production. Remarkably, the facility expansion activities were performed while small-scale COVID-19 vaccine downstream batches were produced, without any operational impact. "We had a number of things to accomplish simultaneously," explained Erik van Veldhoven, Director of the Vaccines Facility. "We were building a new factory, started up small-scale vaccine production, and worked under new COVID conditions. This demanded a lot from the team and the individual, and I am extremely proud of what we have realized together

combining technology and the knowledge available in the team."

Early contractor engagement and industry best practices resulted in an enormous reduction of the project timelines and increased execution efficiency. This agile approach improved global patient access to the new vaccine. Henri van Drunen, General Manager of Janssen Biologics, emphasizes that the experience of this fast-track facility expansion will help J&J to quickly respond to similar situations in the future. "By expanding our vaccine manufacturing services, we are now able to produce our vaccines on large-scale and deliver them around the world. We are looking forward to continuing our efforts and making a positive impact on communities, today and tomorrow."

When awarding the Social Impact FOYA, the judges said: "This project is an example of a socially responsible response to an urgent public health need."

Safety First

All design and construction activities for involved stakeholders encompassed 600,000 total person-hours, including 150,000 construction hours without a serious safety incident. There were zero lost-work day cases, no serious injuries, A Days Away Restricted Time (DART) value of 0.0, and a Total Recordable Incident Rate (TRIR) of 0.0.

Environmental Designs

The facility is designed to meet LEED silver requirements. It includes water efficiency, HVAC energy recovery, LED lighting, and low emitting materials in building construction. The project includes a biowaste decontamination system (biokill) with a holding tank of 6,000-liter capacity to thermally inactivate process waste and the decision to expand adjacent to an existing site, reduced the need for additional transport and the total carbon footprint.

About Janssen Biologics, BV

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

SUPPLY PARTNERS AND KEY PARTICIPANTS

Manufacturer/Owner Name

Janssen Biologics B.V. (affiliate of Johnson & Johnson)

Engineer/Architect (A&E)

DPS Engineering (Netherlands) B.V. (affiliate of DPS Group)

Construction Manager

John Sisk & Son (Europe) Ltd. (affiliate of John Sisk & Son)

Main/General Contractor

Van Lith Bouwbedrijf B.V.; Kuijpers PHF Services B.V. (affiliate of Kuijpers)

Project Management Services

Plan B Advies B.V.

Clean Room Contractor

Cleangrad d.o.o.

Piping Subcontractor

Engie

Electrical Subcontractor

Elektravon Elektrotechniek (part of De Groot Installatiegroeop)

Automation and Control Supplier + Process Equipment Commissioning and Qualification

Agidens Life Sciences B.V.

Automation and Control Suppliers

Honeywell B.V. (part of Honeywell Building Solutions)

Major Equipment Suppliers/Contractors

WHP; Cytiva Europe GmbH; Merck Millipore Ltd.; Sartorius Stedim Systems GmbH

2022 FOYA Category Award

Pharma 4.0™

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

PROJECT
Takeda Singen Vaccines (TaSiVa)

LOCATION
Singen, Germany

TOTAL FACILITY SIZE
196,817 square feet

PROJECT MISSION
To establish a manufacturing site which would provide reliable in-house manufacturing capacity for the supply of Takeda's Dengue Vaccine Candidate with a focus on implementing digital technologies to increase the level of digital maturity on the existing Singen facility while also providing new employment opportunities for employees working at the site.

Pharma 4.0

Pharma 4.0™ is a new category for the Facility of the Year Awards (FOYA) program. Winners in the Pharma 4.0 category embody the Pharma 4.0 concept. This includes not only implementing at least one technological innovation, but also demonstrating the ability to change the company's culture, processes, and people orienting them towards a 4.0 future. Significant contributions include application of one or more applied science-based solutions or digital innovations like automation, robotics, digital twin, or advanced processing understanding; substantial improvement to operational practices; or technologies widely and strategically implemented across the organization.

Why Takeda Pharmaceuticals International AG Won

The facility was built with state-of-the-art process equipment and then layered with advanced digital technologies in several key areas. A complete IT (Information Technology) infrastructure upgrade was completed at the site during the early phase of the project thus providing the platform to utilize advanced information technology (IT)/ operational technology (OT) solutions as part of the project delivery. The Takeda TaSiVa project exemplifies how the application of innovation in advanced digital technologies leads to improved outcomes in terms of safety, product quality, and productivity in a pharmaceutical manufacturing facility.

Digital Innovations Improve Vaccine Production

According to the World Health Organization, the number of reported dengue cases has dramatically increased over the last two decades, from 505,430 cases in 2000, to over 2.4 million in 2010, and 5.2 million in 2019. Reported deaths between the year 2000 and 2015 increased from 960 to 4,032, affecting a mostly younger age group.

Dengue is caused by four distinct but closely related virus serotypes. Takeda's vaccine candidate, TAK-003, is designed to protect against all four types of the virus. When Takeda decided to expand manufacturing capacity for their vaccine, they decided that machine learning, artificial intelligence, and an elevated level of systems integration were integral to the project. From the beginning, the team introduced digital solutions with the objective to identify innovative Pharma 4.0™ technologies which would support the delivery of the project by increased productivity, quality, and efficiency of processes within the plant. They also conducted a significant IT infrastructure upgrade to ensure that the facility was fit for purpose to operate as a highly automated facility.

"This project was a significant investment within Takeda`s global manufacturing network. The Singen site in Germany was selected for this

investment as the site employees have vast experience in lyophilization technology, which is key for the manufacturing process of Takeda's dengue vaccine candidate," said Thomas Wozniewski, Global Manufacturing & Supply Officer, Takeda.

The facility is connected to a central logistics spine on the Singen site. The spine connects all the existing and new manufacturing areas to the finished product warehouse on the existing site. The temperature-controlled requirements of the vaccine candidate presented a unique challenge which the team solved by re-engineering the facility; introducing a two-way logistics flow and increasing the level of automation which included the introduction of autonomous mobile robots (AMRs). The AMRs form part of the Singen warehouse management system, which is interfaced to the manufacturing execution system in the facility. The result is seamless automated transport of raw materials to production areas as well as the final transfer of finished goods to the warehouse.

The full automation strategy was also applied to the packaging process. The packaging hall is divided into two packaging lines which pack the final product. Before and during the project, Takeda's Global Manufacturing and

Supply organization was already undergoing a significant digital and data transformation which led to the modernization and standardizing of platforms for the enterprise and a move toward a more scalable, secure, and flexible cloud architecture. By utilizing Takeda EDB (Enterprise Data Backbone), coupled with the electronic batch record system, the performance of the plant can be monitored in real time via the facility's control tower.

The project has a high degree of vertical and horizontal systems integration which enabled the project team to identify opportunities where machine learning and artificial intelligence could be developed to support the manufacturing process. The project team identified three machine learning opportunities for both operations and quality control: drug substance bag selection, including automated dosing, automated FOCI counting in QC, and semi-automated visual inspection.

"At Takeda, we continue to advance manufacturing capabilities by introducing new digital and data solutions to our manufacturing network across the globe," said Wozniewski. "Many of the technological advances at the TaSiVa plant come from effective partnership and collaboration within Takeda and with our suppliers and partners. With many of these initiatives we immediately assess and share the practices with other sites, further enhancing our manufacturing capabilities for our existing products as well as future proofing our manufacturing network for the future needs of Takeda, and our patients."

Safety First

Human error contributes significantly to the quality and safety of any pharmaceutical operation. The high use of automation throughout the facility, from automated dosing in formulation to automated logistics at the end of the process results in a significant reduction

in human error and supports a “right first time” culture at the site. The automated processes in both packaging and logistics significantly improve the safety of the workplace and the use of collaborative robots throughout the facility improves ergonomic work conditions for the team at the plant.

Environmental Responsibility

In alignment with Takeda’s overarching sustainability commitment, careful consideration was given to the efficient utilization of utilities to reduce the Singen campus carbon footprint and lifecycle operating cost including the installation of solar panels.

About Takeda

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by our commitment to patients, our people, and the planet.

SUPPLY PARTNERS AND KEY PARTICIPANTS:

Manufacturer/Owner Name
Takeda GmbH

Engineer/Architect (A&E)
HHP Architecture; M+W

Construction Manager
Implenia Regiobau

Piping Subcontractor
Fuchs Haustechnik

HVAC Subcontractor
Bühr Lufttechnik

Automation and Control Suppliers
Schneider Electric GmbH

Major Equipment Suppliers/Contractors
Groninger; Metall+Plastic; GEA Lyophil; Fedegari; Syntegon Packaging Systems AG; UHLMANN Packaging Systems GmbH

2022 FOYA Category Award

Supply Chain

TAKEDA PHARMACEUTICALS INTERNATIONAL AG

PROJECT
Alofisel Global Program

LOCATION
Madrid, Spain; Osaka, Japan; Thousand Oaks, California, USA; Grange Castle, Ireland

PROJECT MISSION
To develop a supply chain and engineering solution to deliver product in less than 72 hours to patients.

Supply Chain

The Supply Chain category honors projects that exemplify the novel application of process manufacturing techniques, innovative design concepts, new technologies, and unique solutions that exemplify the next generation of agile, flexible, efficient, and effective new and existing pharmaceutical and biotechnology facilities. This includes implementation of commercially available and custom developed equipment which yielded superior results, improved competitive position, and/or demonstrated imaginative collaboration with vendors/suppliers/manufacturers.

Why Takeda Pharmaceuticals International AG Won

Takeda's medicine Alofisel is a first-in-class stem cell therapy product and the first allogeneic mesenchymal stem cell therapy to receive approval by the European Medicines Agency. The project was designed with a product shelf life of only 72 hours and requires seamless cold chain transportation. Takeda had to completely rethink the supply chain to get the product from the plant to the hospital to be administered to the patient within a short time frame. The program is recognized in this year's awards for its novel and innovative approach to end-to-end supply chain management as well as the program's innovative design in expanding the Alofisel manufacturing network from its initial plant in Madrid, Spain, to other regions across the globe with new facilities in the US, Japan, and Ireland. It exemplifies the application of novel and innovative supply chain management in bringing this product from "plant to patient" in 72 hours.

Innovative Supply Chain Benefits Patients

Takeda's stem-cell therapy is a live human mesenchymal stem cell treatment used to treat adult patients with non-middle active luminal Crohn's disease, when fistula have not responded to conventional or biologic therapies. Mesenchymal stem cells are adult stem cells isolated from various sources that can differentiate into other types of cells. Because of the nature of this living cell formation, the shelf life for the product is 72 hours.

"There has been significant growth and investment in this space in the last five to ten years and this will continue into the next decade. This type of manufacturing and the very nature of the products produced will continue to challenge manufacturers and suppliers to be innovative in their manufacture, delivery, and supply of these products. This is only one of the many technological advances we will see and continue to see as we broaden the supply of these products across the globe," said Thomas Wozniewski, Takeda's Global Manufacturing & Supply Officer.

The entire finish product process for Alofisel is up to ten days long and is truly a make-to-order process where doctors can order patient treatment directly via a web portal and track when the treatment is ready for shipment and anticipated delivery date. The innovative and highly integrated approach from enterprise to equipment was made possible through solution standardization and strong cross functional collaboration across different departments and facilities within Takeda.

"This project was critical to secure the supply of our allogeneic cell therapy project to local markets due to its short shelf life. In addition, the innovative supply chain scheme overcame the challenge of delivering a short shelf-life product, required for surgery at a certain time point in the future. By doing so, Takeda changes the paradigm for how we supply this type of product to our patients globally and effectively brings the patient to the very center of our manufacturing and supply for this product," said Thomas Wozniewski.

In addition to the supply chain advancements, Takeda combined and implemented innovative technologies. One major advancement in the manufacturing process was the achievement of a parametric release to enable real time

batch release, reducing the need for detailed retrospective batch review. Given the short shelf life of the product, four rapid and real time test methods give early warning signs of any production issues, days, if not weeks, earlier than traditional test methods.

"We have launched this product in Europe and, recently, in Japan. Teams across the globe continue to collaborate as we expand the Alofisel manufacturing footprint across the globe. Indeed, for all operations and projects teams working on the project, there is an immense pride in being able to transfer this product from site to site and meet the demanding logistics and supply chain challenges in getting this product to our patients," said Wozniewski. "Across the industry, the spectrum of products that we produce, from high throughput high volume products to personalized, small batch products will continue to challenge the industry and, in some instances, require a paradigm shift to how we supply products to our patients. I think the Alofisel project exemplifies this, where an innovative and new supply chain scheme must be created to meet the requirements of the product."

Environmental Responsibility

In alignment with Takeda's' overarching sustainability commitment, the facility expansion in Grange Castle, Dublin, Ireland, embodies the latest in designs for the efficient utilization of energy, water, and materials to reduce the facility's carbon footprint and lifecycle operating cost. Takeda focused on carbon reduction throughout the design process. The entire Grange Castle site is supplied with certified renewable electricity, the expansion uses air to water heat pumps to provide both low pressure hot and chilled water supplies to the facility, without the need for a gas or oil boiler resulting in zero carbon emissions. The roof structure was reinforced, and the electrical system upgraded, during the design phase, to facilitate the future installation of photovoltaic panels on the entire south facing roof.

About Takeda

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to discover and deliver life-transforming treatments, guided by a commitment to patients, people, and the planet.

SUPPLY PARTNERS AND KEY PARTICIPANTS

Manufacturer/Owner Name

Takeda Ireland Ltd (Grange Castle, Ireland)

Takeda Pharmaceuticals (Thousand Oaks, California, USA)

Takeda Pharmaceuticals (Madrid, Spain)

Takeda Pharmaceutical Company Limited; Osaka Plant (Osaka, Japan)

Engineer/Architect (A&E)

McElroy Associates

Tandem Project Management

KLINEA; Axiom; ESTUDIO G&B; Taisei Corporation; CRB Engineers

Construction Manager

John Sisk & Son (Holding) Limited; Axiom; Taisei Corporation; CRB Engineers

Main/General Contractor

ALBIAN (INGECLIMA, SL); Taisei Corporation

CRB Engineers

Piping Subcontractor

AFARVI; Taisei Corporation; Pan Pacific Mechanical

HVAC Subcontractor

ALBIAN (INGECLIMA, SL); Taisei Corporation; Pan Pacific Mechanical

Automation and Control Suppliers

OASYS; Johnson Controls, K.K.; Taft Electric

Major Equipment Suppliers/Contractors

SKAN AG; Ortner Reinraumtechnik GmbH; Telstar; BSC etc.; Azenta Life Sciences; SKAN Japan

2022 FOYA Category Award

Honorable Mention

IOVANCE BIOTHERAPEUTICS, INC.

PROJECT
Iovance Cell Therapy Center

LOCATION
Philadelphia, Pennsylvania, USA

TOTAL FACILITY SIZE
136,000 square feet

PROJECT MISSION
Impact the lives of thousands of patients each year by building a centralized, scalable, state-of-the-art manufacturing facility dedicated to producing TIL (Tumor Infiltrating Lymphocytes) cell therapies for patients with solid tumor cancers.

Honorable Mention

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

Why Iovance Biotherapeutics, Inc. Won

Unlike a typical manufacturing facility that is designed to produce millions of identical products, at the Iovance Cell Therapy Center each product is made from the starting material of an individual patient and is unique. A mistake or production failure can leave a patient without potentially life-saving treatment. This is the first facility in the world dedicated to producing this kind of personalized cancer treatment and it sets the bar for this next-generation approach to personalized cell therapies.

Patient-Centric Facility

Iovance is a late-stage oncology company that is focused on developing, manufacturing, and commercializing novel cancer immunotherapies based on tumor infiltrating lymphocytes (TILs), treatment. Until now this treatment has proven to be a challenge to deliver to patients in a scalable, timely commercial manner. While traditional facilities work with the aim of producing consistent, repeatable products, the Iovance Cell Therapy Center (iCTC) is designed to produce individual TIL cell therapies for thousands of patients a year. The facility is designed to maintain the quality and integrity of the product throughout its journey at iCTC. Additionally, Iovance has cut the process time to become the first facility in the world with the capability to produce this type of personalized cancer treatment at a commercial scale.

“Establishing our internal manufacturing capabilities was a top priority at Iovance to support our goal to ensure broad access to Iovance TIL and reduce the costs of Iovance TIL cell therapy,” said Igor Bilinsky, Chief Operating Officer, Iovance.

The iCTC was built with multiple processing rooms, each equipped with the process equipment required to perform any of the operating parts of the process. To reduce cross-contamination, each 214 square foot workstation has its own dedicated air handling unit, and the overall flow of the facility is unidirectional.

Because each sample is patient-specific, the reliability of the facility, the process utilities,

and of the process itself is of the utmost importance. Any failure that would interrupt the progeny, any failure that would interrupt the process, could potentially result in devastating consequences for the patient. To reduce this risk, N+1 redundancies were built into every critical component from the process equipment, storage facility, and power infrastructure to ensure an “always on” state. Since the facility is designed to function 24 hours a day, every day of the year, it was essential that building utilities, systems, and equipment would be able to function in this way and the power system was designed so any single outage would not affect the whole building.

The process of creating TIL therapy starts in the hospital operating room, where a surgical oncologist removes tumor specimens from the patient. The specimens are then shipped via a specialty medical courier to the iCTC where TILs are isolated and multiplied to generate billions of TILs over a 22-day process. The final product is frozen and shipped back to the hospital. Iovance had to not only successfully design a facility that would develop one-of-a-kind treatments, but also develop a logistical model that would factor in the schedules of surgeons, oncologists, specialty couriers, and airlines. Iovance’s in-house team developed proprietary chain of

custody (COC/COI) software that tracks the patient sample from the hospital to the iCTC, the product throughout the iCTC and the final product back to the hospital and patient. They worked with vendors to develop a solution that would be best-in-class in providing end-to-end visibility to customers and regulators.

To plan for future growth, lovance used a "butterfly" design so that the facility could eventually double its capacity. The core, staging, corridors, incubators, and workstations for phase two will be an exact mirror of the first. The building shell is already built for this crucial second phase.

Another first, the iCTC welcomes visitors to explore on-site learning kiosks. Narrated videos describe what visitors are seeing in the viewing windows across from them, for example, how to behave in aseptic environments, a background into the science and data of TIL therapy, an overview of the manufacturing process, and patient stories. For privacy, lovance used switchable glazing on viewing windows. With this innovation, a film is placed between two panes of glass. When current is applied, the film turns opaque; when it is removed, the view is clear.

"We built iCTC to lead the next chapter in manufacturing and delivering novel cell therapies for patients with cancer," said Sumit Verma, SVP, Commercial Manufacturing, lovance.

Safety First

With an active operational facility and two

construction companies working side-by-side on the build, the complexity of this project was exceptional. Project leadership instilled safety into the workplace culture by incorporating safety into weekly coordination meetings and celebrating safety milestones, giving equipment demonstrations and protocol walkthroughs, and leveraging onsite and offsite prefabrications to eliminate construction hazards. They also developed a proactive COVID response plan to ensure a clean, healthy site and a quick response to isolate infected workers and minimize disease transmission.

Environmental Responsibility

The iCTC core and shell were pre-selected to meet LEED Silver standards. The Building Management System monitors HVAC to track and manage the power used for each system and the manufacturing HVAC system uses a glycol run-around loop to recover energy from exhaust systems. HVAC systems across the facility use "free cooling" when appropriate. The construction of modular cleanrooms reduces overall leakage within manufacturing and reduces the airflow required for pressurization.

About Iovance

Iovance Biotherapeutics aims to be the global leader in innovating, developing, and delivering tumor infiltrating lymphocyte (TIL) therapy for people with cancer. They are pioneering a transformational approach to treating cancer by harnessing the ability of the human immune system to recognize and attack diverse cancer cells in each patient. Their lead, late-stage TIL product candidate, lifecycle for metastatic melanoma, has the potential to become the first approved one-time cell therapy for a solid tumor cancer. The Iovance TIL platform has demonstrated promising clinical data across multiple solid tumors. They are committed to continuous innovation in cell therapy, including gene-edited cell therapy, which may be a promising option for patients with cancer.

SUPPLY PARTNERS AND KEY PARTICIPANTS

Manufacturer/Owner Name
Iovance Biotherapeutics, Inc.

Engineer/Architect (A&E)
CRB Group, Inc.; Digsau; Pennoni Associates

Commissioning Qualifications & Validation Services
AEI Affiliated Engineers, Inc., IPS and Project Pharma

Construction Manager
CRB Group, Inc.

Main/General Contractor
Plumbline Construction, Inc.

Piping Subcontractor
A.T. Chadwick Company, Inc.

HVAC Subcontractor
WM. J. Donovan Company

Automation and Control Suppliers
Siemens Industry, Inc.

Major Equipment Suppliers/Contractors
AES Clean Technology, Inc.; Hatzel & Buehler, Inc.

DPS Better Engineered Solutions

Delivering success at the speed of science

We're fully invested in creating inventive, collaborative, and client-centered solutions to every project, at every stage:

Architectural and engineering design
Commissioning, qualification, and validation
Construction management
Technical services
Strategic consulting
Managed services

Congratulations to our clients—category winners of the 2022 ISPE Facility of the Year awards

CRISPR Therapeutics

FOYA 2022 ISPE Facility of the Year Awards

CATEGORY WINNER
Innovation
Supply Partner

Janssen Biologics

FOYA 2022 ISPE Facility of the Year Awards

CATEGORY WINNER
Project Execution
Supply Partner

FOYA 2022 ISPE Facility of the Year Awards

CATEGORY WINNER
Social Impact
Supply Partner

Learn more at dpsgroupglobal.com