



**FOYA** | 20  
20

Facility of the Year Awards

2020 Category Winners

# Spotlight on Excellence



Europe | USA | Asia



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**FOYA** | 2020

Facility of the Year Awards

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# 2020 FOYA Awards Welcome and Thank You



*Antonio Crincoli  
Chair, FOYA Judges Committee*

For the past 7 years, I have been honored to collaborate with ISPE to recognize Facility of the Year Awards (FOYA) Winners. While this year has presented new and unique challenges for us all, the FOYA program continues to represent the best of the best, and gives our industry information about truly exceptional projects and 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 pharmaceutical industry since 2004. Submissions are reviewed by recognized leaders from within the industry - 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 have international responsibilities. They are experienced, knowledgeable, and understand the global landscape. They have had the privilege of working on many different projects and know what goes into producing an innovative project.

This year, submissions came from all corners of the world and represented projects that included breakthroughs in continuous manufacturing, first class in vivo research, and dedication to developing medicines for unserved communities.

## How Are The Submissions Reviewed?

The Judging panels meet each year in January to review the submission and discuss their merits. We start by assessing each project and determining whether it is novel. The judges discuss new industry trends and how they are reflected in the submissions. While we use a template to help catalog analyses, judges have the freedom to use their expert judgement in reviewing each project. If the group does not identify a project that demonstrates excellence in any one category, they will not award the category that year.

*continued on page 4*



## 2020 Facility of the Year Awards Category Winners Spotlight on Excellence

**Barbara Peck:** Manager, Community and Industry Recognition

**Marcy Sanford:** Contributing Writer and Editor

**Alisa Pachella:** Sales Account Manager

**Dawn Arbetello:** Design and Layout

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*continued from page 3*

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

Judges then select the overall winner from among the category winners. The process involves several rounds of discussions, often very passionate, 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 these 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 of business at each facility, so we focus on and award projects that demonstrate innovation.

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 the 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, Chair, FOYA Judges Committee*

*Senior Director, Head Upjohn Global Engineering, Pfizer Inc.*

ISPE thanks the **2020 FOYA Judging Committee** for their continued support of the FOYA program.



**L to R (Back Row):** David Sternasty, Joydeep Ganguly, Felix Velez, Francesco Intoccia, Frank Vanermen, Sangwon Seo, Georgia Keresty, Simon Shelley, James Breen, James Brinkman, Brian Lange, Jian Dong, Lou Kennedy. **L to R (Front Row):** Antonio Crincoli, Jorgen Falkboll, Rong Zhang, Carla Boragno, James Dickow, Gunter Baumgartner, Parag Sane, Gary Schoenhouse.

# FOYA Planning Committee

As the premier global awards program recognizing innovation and creativity in the pharmaceutical and biotechnology manufacturing industries, ISPE's Facility of the Year Awards (FOYA) Program and its honorees represent the future of pharma. They are risk takers who are solving tomorrow's problems and whose innovations will transform the way we manufacture medicines, deliver products, and protect patients.



*Avril Vermunt*  
**Chair, FOYA Planning Committee**  
**Cytiva, Strategic Technology Director**

I was a member of ISPE for several years and involved with my local chapter before I began volunteering on the FOYA Committee. Each year I would read about the winners' projects in PE magazine to find out which projects had won and to see if there was any way I could apply some of their projects' innovations to my own company. While we typically have to keep much of our company's work confidential, FOYA gives us the opportunity to showcase what we are doing and inspire our colleagues to push themselves as well. As a FOYA Chair and committee member, I've learned so much from the other members and award submissions. If you are looking for ideas for your company's next project or ways to improve your company's processes, you will find inspiration through FOYA.

The FOYA award categories include Equipment Innovation, Facility Integration, Facility of the Future, Operational Excellence, Process Innovation, Project Execution, and our newest one, Social Impact, which honors projects that have applied new approaches, standards, and practices to increase patient access and prevent drug shortages, implemented cost-effective strategies to reduce the cost of drug products, or accelerated a shift to sustainable facility design.

Projects that have won a FOYA award include 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 2018 and 30 November 2020, I would encourage you to apply 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.

I'd like to congratulate the companies that won a 2020 FOYA 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 2021, visit [ispe.org/FOYA](https://ispe.org/FOYA) for submission requirements. ■■■



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**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Equipment Innovation

# Equipment Innovation

## F. Hoffmann-La Roche Ltd.

Equipment Innovation recognizes the novel application of commercially available and custom developed process manufacturing and facility management tools, which yielded superior results, advanced processing understanding, and improved competitive position including imaginative collaboration with vendors, suppliers, or manufacturers.

### Quick Facts

**Project**

Building 98 (B098)

**Location**

Basel, Switzerland

**Total Facility Size**

191,414 sq. ft.

**Project Mission**

To design and build a unique environment for housing all activities involving live animals.



## WHY THEY WON

*“The New In-Vivo Building brings innovation to one of the lesser understood parts of the pharmaceutical discovery and development process. The equipment innovation that is found in every part of the project aims to protect researchers and animals, drive efficiency, and set new industry standards for animal research.”*

### A Researcher’s Dream Come True

In most countries it is a legal requirement that any new human medication be tested on animals. However, animal facilities are not typically talked about or usually lauded. F. Hoffmann-La Roche strives to be an industry leader in every aspect of the pharmaceutical industry and that includes animal research. In order to build a new facility, Roche had to demolish an existing building on their site and extend the pit. Before the new facility, Building 98 (B098), animal husbandry was split over various buildings of the Basel, Switzerland, site, some of the infrastructure was outdated, and productivity and efficiency was not optimal.

Thanks to a team dedicated to exploring new ways to improve the status quo, Roche was able to discover clever and unorthodox solutions to common issues found at in vivo facilities and create a technological masterpiece that sets a gold standard for future laboratories.



### Increasing Light, Reducing Allergens

Since animals require a light schedule that is often at odds with humans’ day-night cycle, in vivo facilities are often found in the basement bathed in artificial light. Roche wanted to house the lab on the upper floors so that their employees would be able to enjoy natural light. They decided to test the common belief that rodents cannot perceive red light. They tested different foil types to determine the wavelength and brightness of filtered light that was either consciously perceived by the animals or subconsciously affected their physiological rhythm and found that not all red foils sufficiently shielded the animals. Based on these studies, the glass partitions in the animal holding and study rooms were coated with the optimum foil type.

“Some of the innovative solutions we realized in B098, you will find in other buildings too,” said Nora Denk, Roche In Vivo Researcher and Veterinarian. “But I am not aware of any other animal facility which brings everything together so perfectly. We did not have to make one single compromise.”

Roche also used technology to protect its researchers. Rodents produce high allergenic particles that can cause respiratory disorders in humans. B098 has intelligent ventilation and fully automated logistics and cage handling outside the barrier zones thus reducing researchers’ exposure to allergens and physical strain.

### Future Flexibility

All study and animal housing rooms have a modular structure and can be reconfigured from a small study room with anteroom into a large animal housing unit or any type of room in-between. The system allow modules to be reconstructed and refitted in 2 -3 weeks, almost silently, and without disturbing adjacent areas. Backup corridors provide space for utility supply lines, separate the study rooms from the building shell, allow individual refitting of each room, without disturbing the hygiene or work in the rest of the space, and offer access for visitors.





Additionally, all furniture and equipment is mobile and can be set up anywhere on the laboratory levels and easily attached to the supply network with connecting “plug and play” hoses for electricity and media supply.

“Research navigates in an ever-changing environment, so we do not know exactly what studies will be required in the upcoming months,” said Rolf Melcher, Building Engineer, Real Estate Management. “Given the unmatched flexibility in B098, we trust that it will sustain a top-notch, state-of-the-art research facility for years to come.”

## Automation for Creativity



Roche completely redesigned automation and robotics for the building and, along the way, set new pioneering technological standards. They

combined animal management subtasks into a circular system that runs almost without human intervention.

Some of the top features include:

- 15 Automated Guided Vehicles (AGVs) to provide full automation of animal supply processes throughout the building
- 4 robots with 7-axis to perform the mechanical steps of cage cleaning

- 155 wash and transport trolleys designed and custom built by Roche engineers to work with the AGVs

“We started from scratch and were free to come up with our own solutions, often inspired by other types of buildings like hospitals or even factories,” said Achim Heudtlass, Project Lead Automation, Roche. “It’s very rewarding to see that these solutions are being highly valued by the internal and external expert community.”

## Transformational IT Integration

A conventional IT system would not work for Roche’s needs so they merged third-party IT products with Roche-specific IT solutions to develop the Roche In Vivo Building IT System (RIBIS). Considered an operating system for the building, RIBIS integrates and controls key IT systems of the facility and seamlessly presents information to users. RIBIS’ features include:

- Can connect and interact with all key integrated IT systems
- Keeps track of permissions and restrictions
- Supports and manages changing architecture setups
- Locates furniture and devices in the building
- Transfers monitoring data and control criteria to searchable database
- Runs on any device

“With B098 the first truly smart building was created for Roche,” said Angelo D’Annunzio, Roche Pharma



Research & Early Development Informatics. “It is very rewarding for us to see that RIBIS found its place within corporate IT and is referenced by colleagues around the world.”

## Classic Solutions for a Changing Environment

Every aspect of B098 was touched in some way by innovative solutions but Roche did not lose sight of their core values and in one instance brought back an “old school” information delivery system. A pneumatic tube system is used for the swift transport of material between B098 and other research buildings.

B098 was designed and built to adhere to the highest standards of energy conservation and sustainability. Environmentally friendly products were used throughout the project. In conjunction with their supplier, empty supply bags are used to dispose of dirty bedding from cages thus reducing plastic waste.

Throughout the planning of B098, Roche paid attention to the importance of soft factors. The top 6 floors of the 10-story facility are connected by an atrium, which allows natural light to filter in throughout the building and the elegant architecture connects with the neighborhood.

“The project demanded intensive collaboration and problem-solving skills from everyone involved,” said Christof Specht, Roche Project Manager “Our employees have told us that B098 is, ‘an in vivo researcher’s dream come true, even beyond imagination.’ Roche is proud to be leading a new era of novel therapeutic modalities.”

## Supply Partners and Key Participants

### Manufacturer/Owner Name

F. Hoffmann-La Roche AG

### General Design Contractor

Pharmaplan AG

### Architect

hammeskrause

### Construction Manager

S+B Baumanagement

### Major Equipment Suppliers/Contractors

Erne AG; Novisol AG; Aepli Metallbau AG; Tecton-Fladag AG; Hemmerlein GmbH; Selmoni Installation AG; Siemens Schweiz AG; Bouygues E&S InTec Schweiz AG; Tschantré AG; Schindler Aufzüge AG; RWD Schlatter AG; CLEANTEK Reinraumtechnik GmbH+Co.KG; Walo Bertschinger AG; Stamm-Bau AG; durrenberger maler ag; Ortner Reinraumtechnik GmbH; MMM Sterilisatoren AG; Indulab AG (ab 1.1.2020 Tecniplast Schweiz); Swisslog AG; Bicasa SRL; Skan AG; Scanbur BK A/S; Tem Segal; Inrabau AG; Pharmaplan AG, Basel; S+B Baumanagement AG, Pratteln; F. Hoffmann-La Roche AG, Basel; Roche Polska Sp. z o.o.— Roche Global IT Solution Centre

## ABOUT THE COMPANY

Founded in 1896, F. Hoffmann-La Roche is a global pioneer in pharmaceuticals and diagnostics focused on advancing science to improve people’s lives. With about 98,000 employees worldwide, F. Hoffmann-La Roche is the world’s largest biotech company, the leader in personalized healthcare, the world leader in in vitro diagnostics and tissue-based cancer diagnostics and has been recognized as one of the most sustainable companies in the pharmaceutical industry.



**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Facility Integration

# Facility Integration

## Pfizer Inc.

Facility Integration honors projects that exemplify the application of good design practices and superior conceptual planning which lead 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

Andover Clinical  
Manufacturing Facility

#### Location

Andover, Massachusetts,  
USA

#### Total Facility Size

175,000 sq. ft.

#### Project Mission

To build a new, state-of-the-art clinical manufacturing facility to house existing clinical manufacturing capabilities and provide room to support the growing portfolio demands of Pfizer's new GMP-compliant, clinical bulk drug substance, biological products.



## WHY THEY WON

*“The Andover Clinical Manufacturing Facility proves that a sustainable, flexible, configurable, and wireless clinical manufacturing facility can achieve complete integration into a dynamic, high-performance process development flow today and preserve that integration no matter how biologic drug development may evolve in years to come.”*

### New Standard for Physical, Operational, and Intellectual Integration

Thanks to careful planning and astute attention to detail, Pfizer’s new Andover Clinical Manufacturing Facility (ACMF), built on their master-planned 70-acre Andover campus, looks as if it was always meant to be there. They relocated existing manufacturing capabilities from Chesterfield, Missouri, to the new facility in Andover, Massachusetts, which allowed them to integrate research and development and expand biological products from 14 campaigns to a future maximum capacity of 21.

“The Andover Clinical Manufacturing Facility plays a critical role in Pfizer’s mission to drive the cost of medicine down and drive medicines and therapies to the patient faster,” said Lauren Gomes, Director, Clinical Manufacturing, Pfizer.



### Seamless and Immediate Connections

Pfizer added the 175,000 square foot clinical manufacturing facility to their Andover site without growing their carbon footprint – they did not have to add any new core utilities, support systems, or amenities to bring the facility on-line. They also deliberately oriented the facility on a true northeast/southeast axis to take full advantage of heating and lighting benefits from the sun.

“To look at an aerial photograph, the ACMF looks like it has always been there, perfectly integrated – environmentally and aesthetically into the Andover site. This, of course is by design,” said Curtis Steenstra, Lead Project Engineer, Pfizer.

The 5-story building houses 5 independent manufacturing suites dedicated to the development of new biotherapeutics and vaccines to support trials in disease areas including oncology, rare diseases, infectious diseases, hemophilia, and rheumatoid arthritis. Each suite operates completely independently of the others and all 5 can operate simultaneously. To reduce the risk of cross-contamination, there are no crossties between the suites. The required physical connections to upstream and downstream processes are accomplished by the most fundamental of flexible facility integration strategies – a network of lower classification corridors enabling unrestricted media and buffer moves via totes and pass-throughs rather than transfer lines. In fact, there is almost no fixed equipment deployed in the ACMF – almost everything is on wheels or skids.

### Designed for Today and Tomorrow

Designed to be Pfizer’s premiere clinical manufacturing facility, the ACMF is a center of excellence that was built and fitted out to meet current and projected needs for clinical drug substances and products and is ready to accommodate the anticipated advances in process development and easily adapt to future innovations.



Pfizer developed a unique strategy of flexible facility integration for the ACMF that includes:

- **Multi-Host** – the ACMF runs both microbial and mammalian processes. Strict product segregation protocols were implemented in the building design and main upstream and pre-viral areas are combined into a single room. All media and buffer moves are made with totes which eliminates bottlenecks and reduces transfer times by up to 70%.
- **Multi-Platform** – 3 of the suites at the ACMF deploy single-use plastic while the other 2 are set up for stainless-steel technologies. Because each biologic product is unique in so many ways, Pfizer needed the flexibility to make and execute on decisions at any point in the process development life cycle. The multi-platform mandate enables Pfizer to make high confidence, real-time determinations as to the best platform best suited to launch any given product.
- **Configurable Suites** – with almost no permanent installations and with all equipment and process control systems on wheels or skids, each suite can be configured to handle even complex steps like refold reactions and homogenization. Upstream and downstream process rooms are segregated to allow Pfizer to purify one drug substance in the downstream room while running a different drug substance in the upstream room in the same suite.
- **Wireless Controls** – to maximize suite configurability and support the integration of new and varied processes, the ACMF is a wireless DeltaV facility. Manufacturing Control System (MCS) equipment accompanies processing equipment wherever it is needed. Wireless asset tracking also makes it easier

to manage and quickly deploy equipment. Fully portable process control equipment on “plug and play” skids can be wheeled anywhere in the ACMF and the MCS knows exactly where they are, even when they not in use.

## Connected Workforce

“In addition to the physical and operational integration innovations of the ACMF, lies a different type of integration – one of intellectual capital,” said Gomes. “Pfizer has brought R&D, clinical manufacturing, and commercial manufacturing people together and all of the knowledge, expertise, and insights acquired over 3 decades of biologic drug development experience.”



DISCOVER WHERE TOMORROW GETS ITS

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Pfizer promotes exchange of knowledge and skills with formal cross-staffing programs which place commercial manufacturing personnel in clinical manufacturing roles. Additionally, Pfizer's Historian captures data and information generated by all process development activities at the Andover campus and provides site-wide access to the lessons-learned.

Biologic drug development processes are always evolving and if Pfizer had restricted the ACMF to a single modality or technology, it would almost certainly have led to early facility obsolescence. Instead, Pfizer's bold but carefully calculated commitment to flexibility has resulted in a facility that is ready to integrate new technologies and processes without any major modifications.

"A project like this is really months of preparation for the day you will go live - the day you become a productive contributor to human health and wellness and to Pfizer's mission," said Gomes. "As of June 2020 all suites within the facility are fully operation. The flexibility of the facility and the ensuing relationships with collaborating teams have enabled us to complete technology transfer of complex processes within 2 months. One of our upcoming projects will be producing a drug substance for pandemic supply of the COVID-19 mRNA vaccine." ■■■■■

## Supply Partners and Key Participants

### **Manufacturer/Owner Name**

Pfizer Inc.

### **Engineer/Architect (A&E)**

CRB

### **Construction Manager**

Lendlease

### **Piping Subcontractors**

Decco, Inc. (process)

TG Gallagher Mechanical Contractors

### **HVAC Subcontractor**

McCusker Gill Inc.

### **Automation and Control Suppliers**

Schneider Electric (Building Automation)

Hallam-ICS (Instruments & Controls)

### **Major Equipment Suppliers/Contractors**

Aqua Chem Inc.; Integrated Process; Engineers and

Constructors Inc. (IPEC); A&B Process Systems Corp.;

GE HEALTHCARE

## ABOUT THE COMPANY

Pfizer is a research-based, global pharmaceutical corporation founded in 1849. One of the world's largest pharmaceutical companies, Pfizer discovers, develops, and manufactures health care products including medicines and vaccines for a wide variety of illnesses as well as many of the world's best-known consumer healthcare products.

# CONGRATULATIONS TO SANOFI



**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER

Facility of the Future  
Supply Partner

## ISPE FOYA Winner 2020 Facility of the Future

- > Proud to be part of this **award winning** project delivery team
- > Providing the **automation & controls** for this **digitally enabled**, continuous, biomanufacturing facility
- > Delivering efficient processes, better control & **increased quality**
- > Achieving **higher capacity** with a smaller footprint

We are excited to see what the future holds for this cutting-edge facility. Well done to the team!

[www.zenithtechnologies.com](http://www.zenithtechnologies.com)







**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Facility of the Future

# Facility of the Future

## Sanofi

The Facility of the Future award recognizes the application or implementation of innovative design concepts, new technologies, and unique solutions that exemplify the next generation of agile, flexible, efficient, and effective Life Sciences facilities.

### Quick Facts

#### Project

Digitally-Enabled,  
Integrated Continuous  
Biomanufacturing  
Facility

#### Location

Framingham,  
Massachusetts, USA

#### Total Facility Size

168,839 sq. ft.

#### Project Mission

Sanofi is driven by a single purpose; work passionately, every day, to understand and solve healthcare needs of people across the world. This project aspired to leverage engineering, science, and technology to transform the way Sanofi manufactures biologics products. The facility was designed to be most advanced digitally integrated manufacturing facility in the Sanofi network and one of the world's first using continuous biomanufacturing for commercial biologics production.



## WHY THEY WON

*“Sanofi pushed the concepts of digitization to fully integrate process control, data collection, and analytics and built a fully integrated bioprocessing facility that takes the application of disposable process technology and flexible facility design to a new level. They used the best of already proven technology and design and expanded the use to allow design and construction of a facility that enables continuous processing. Through an innovative collaboration with equipment suppliers they were able to expand the use of single-use technology to include, media and buffer preparation, upstream, downstream, and column packing. This combined with a commitment to a ‘born lean’ design philosophy has created an industry factory 4.0 lighthouse.”*

### Facility Flexibility Reaps Rewards

Sanofi is a pioneer in continuous biologics processing and has several rare disease enzyme replacement therapies that are produced using large scale perfusion reactors and novel cell separation technologies.

“Over the past four years, Sanofi has expanded our biologics manufacturing capabilities by introducing new technology and the commercialization of integrated continuous biomanufacturing,” said Franqui Jimenez, Head of Second-Generation Process Development, Global Manufacturing Science and Technology at Sanofi. “We have seized an opportunity to go beyond traditional lifecycle improvements and have developed our second-generation processes; transforming the way we manufacture currently approved commercial products and enabling a flexibility for future product introductions.”



### Innovative Process + Factory 4.0 Concepts = Breakthrough Performance

Sanofi used a wide range of cutting-edge manufacturing technologies to develop an efficient, flexible, and sustainable manufacturing platform. One of the most significant aspects of their design is the commercial implementation of Integrated Continuous Biomanufacturing (ICB), which made it possible for them to adopt a modernized perfusion-based cell culture process where smaller single-use technologies replace traditional large-scale stainless-steel reactors and capture equipment.

Some of the key ICB process benefits include:

- Significant reductions in reactor volumes, enabling single-use bioreactors
- Cell separation technologies provide for single-use perfusion systems
- Single-use mixers and totes replace large stainless-steel tanks, eliminating the need for CIP/SIP
- Continuous chromatography significantly reduces column diameters and enables use of single-use pre-packed capture columns
- Continuous production in a fully automated fashion with minimal user intervention

Ultimately the ICB process results in improved product quality and consistency, increased process robustness, the generation of massive process data analytics, with 770 million data points sampled each day, and reductions in processing footprint, raw material usage, and energy consumption.

Sanofi developed new and innovative ways to use single-use technologies, many of which had never been commercially implemented. They partnered with a single-use mixer supplier to develop a novel single-use slurry mixing application. They used single-use mixing and



powder handling technology, along with a custom library of single-use fluid management assemblies, to replace traditional stainless-steel systems. The new set up provides the building blocks to use pre-sterilized single-use tubing and manifolds equipped with single-use aseptic connection devices to provide a wide range of operational flexibility.

The facility has a dedicated solution preparation area with single-use mixers ranging in scale from 100 up to 3,000 liters. Once prepared, fluid is moved in portable totes containing single-use liners. The totes can be moved anywhere in the facility and use wireless technology to monitor parameters like volume level, temperature, and physical location. The design allows for flexibility in operations and eliminates the need to clean tanks and transfer piping. Thanks to single-use technology, the same totes can be used for a variety of different solutions.

The facility was designed for flexible operations, rapid changeovers, and multiproduct operations. The layout and material workflows were designed to prevent waste in material movement and waiting times. The facility infrastructure was designed to maintain greater than 99% facility uptime.

“The facility includes many of the traditional concepts of flexible facility design including single-use technology and flexible ‘ballroom’ designs, accommodating a wide variety of equipment design and scale. Utilizing digital technologies enhances the flexibility of the facility, enables reconfiguration in response to changes in product demand, and creates a shop floor experience that is intuitive to the operator. We believe that we have pushed these concepts to new levels with our novel processes, deployment of technology, and digital integration,” said Navin Tiwari, Head of Digital Shop Floor and Automation for Sanofi.

## Born Lean and Digitally Advanced

Throughout the project, Sanofi focused on lean manufacturing principles and operational excellence. “The facility was designed to be ‘born lean’ and engineered using the Sanofi Manufacturing System,” said Dean Morris, Program Director of Capital Investment and Operations at Sanofi. “This system is based on lean manufacturing principles to ensure that people, product, and waste flow through the facility are optimized and continuously improved to reduce non-value-added activities and waste.”

The facility is equipped with large touch screen displays that help maintenance and operations staff accomplish their daily activities. The tools provide:

- Real time visualization of process performance data
- Daily performance metrics
- Capacity management
- Immediate issue escalation
- Real time monitoring of safety, quality, and delivery metrics
- Historic trending of key metrics

Sanofi created a digitally integrated, paperless ecosystem. Some of the advancements in the digitalization enable plant operational efficiency include:

- Process control system (PCS), manufacturing execution system (MES), historians, and enterprise resource planning (ERP) systems operate together automatically initiating process orders and embedding records
- Full integration of online/at-line testing into MES (no data transcription)



- Wireless instrumentation and RFID
- Real time visualization on the shop floor
- Digital touchscreens for performance tracking and data visualization
- All data is available on the shop floor, eliminating the need to wait for results from Quality Control for in-process samples

Sanofi provides electronic work instructions that are operation specific and include clear, visual instruction with pictures and instructional videos. As a result initial training has been more efficient, consistency among operators is ensured, and the chance for human error has been drastically reduced.

Additionally, the move to a Digitally-Enabled, Integrated Continuous Biomanufacturing Facility reaped rewards for the environment. Sanofi’s utility systems were designed using the latest technologies to perform at the highest energy efficiency. They were able to reduce their chemical usage by 94%, reduced energy consumption and CO2 emissions by 80%, water usage by 91%, and saved 321 tons of waste from the landfill annually.

“The vision for a flexible, agile facility could not be realized without maintaining a focus on our core values. We remained committed to supplying our patients with the highest quality products while also maintaining our commitments to environmental sustainability,” said Morris. “With a process that is 80 times more productive, we can reach twice as many patients with a fraction of the raw material, chemical, and energy usage of traditional processes.”

## Supply Partners and Key Participants

### Manufacturer/Owner Name – Headquarters

Sanofi

### Engineer/Architect (A&E)

Jacobs Engineering

### Construction Managers

Skanska USA; The Cardinal Group

### Main/General Contractors

Skanska USA; The Cardinal Group

### HVAC Subcontractors

CP Blouin

Worcester Air Conditioning

### Automation and Control Suppliers

Zenith Technologies; Honeywell

### Major Equipment Suppliers/Contractors

BioPharm Engineered Systems; EMD Millipore; Thermo Fisher; Cotter Brothers; GE Healthcare

## ABOUT THE COMPANY

Sanofi is dedicated to supporting people through their health challenges. They are a global biopharmaceutical company focused on human health, preventing illness with vaccines, and providing innovative treatments to fight pain and ease suffering. They research and develop treatments for the few who suffer from rare diseases and the millions with long-term chronic conditions. With more than 100,000 people in 100 countries, Sanofi is transforming scientific innovation into healthcare solutions around the globe.



**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Process Innovation

# Process Innovation

## Janssen Pharmaceuticals

Process Innovation recognizes winners who have applied novel process manufacturing techniques on existing or new facilities, including fundamental scientific processing approaches and related applied science-based solutions to existing and new challenges.

### Quick Facts

**Project**

Mirror 1: A Continuous Manufacturing Platform

**Location**

Beerse, Belgium

**Total Facility Size**

5,547 sq. ft.

**Project Mission**

To develop and implement an End-to-End strategy in order to develop, launch, and commercialize a new product portfolio on a common continuous manufacturing platform.



## WHY THEY WON

*“Janssen’s Mirror 1 Continuous Manufacturing Platform project represents a significant step in process innovation. Mirror 1 incorporates and integrates 3 different process technologies, includes 7 PAT applications, a sophisticated automation control system, and is complemented by a SynTQ data management system. This integrated system allows Janssen to effectively execute a continuous manufacturing control strategy.”*

## Changing Strategy to Change the Future of Drug Delivery

Until recently Janssen developed and manufactured all tablet formulations in a multi-purpose batch facility. However, as the company formulated a mission that focused on making the patient the center of all decisions, improving quality, reliability, and control, and reducing development and scale up cycle times, they found that the batch platform did not support their vision. Janssen decided they had to completely change strategy in order to support their new mission and embarked upon an end-to-end (E2E) strategy that included investing in continuous manufacturing (CM) as their preferred technology platform for all future oral solid dosage formulations.

“Continuous manufacturing is becoming a new standard within the pharmaceutical industry, consistent with healthcare authorities’ expectations to deliver greater process understanding and enabling continuous verification,” said Dirk De Smaele, Global Head, Small Molecule Product Development for Janssen. “There are many benefits of continuous commercial manufacturing

including increased yield, quality, and controls and lower inventory, labor costs, and energy consumption but Janssen considers the benefits that continuous manufacturing generates for the R&D process to be equally important. These include faster development and speed to market, reduced API-consumption, reduced QC-testing, simplified tech transfers with fewer bioequivalence/stability studies, and enhanced ability to generate significantly more meaningful process data by use of PAT tools, resulting in stronger CMC dossier submissions.”

## Technological Advances for CM

To support their new E2E strategy and commitment to CM, Janssen designed, installed, and qualified a new CM line, Mirror 1, at their Drug Product Pilot plant in Beerse, Belgium.

Mirror-1 will be used to support all development and clinical manufacturing activities and an identical CM line, Mirror-2, is under construction at Janssen’s commercial site in Latina, Italy. Since Janssen planned from the beginning to build an exact copy of Mirror-1 at a different location, they had to consider the requirements and limitations of both facilities when developing the line. Together the 2 identical lines will enable seamless 1/1 tech transfers, without additional scale-up efforts and result in over-all benefits such as shorter timelines and reduced API-consumption.

“We strongly believe that our unique strategy will accelerate the development of new medicines, with a significant increased level of process understanding and controls, providing more robust processes and delivering better and safer products,” said Luca Russo, Global Head, Clinical Supply Chain, Janssen.

The Mirror lines will incorporate 3 different technologies:

- Wet Granulation (twin screw)
- Dry Granulation (roller compaction)
- Tablet Compression

The wet and dry granulation platforms are equipped with a joint continuous feeder/blender platform. The





tablet press is equipped with a double continuous feeder/blender platform to allow for continuous direct compression or to allow this set-up to be used as the down-stream part of the wet/dry granulation process trains. The line has been designed to handle high potent compounds (OEL-level 3).

The Mirror-1 line can handle up to 7 process analytical technology (PAT) applications, is operated through a fully automated process control system (WinCC), and is linked to the plant's OSI-PI system for data trending. The line is also complemented with a SynTQ data management system, allowing it to process complex PAT and/or process models and orchestrations, as part of the CM control strategy. The line is designed in a vertical set-up to maximize product flows by gravitation and minimize product transfer through pneumatic or conveying systems, as the latter could expose the product to additional risks.

The Mirror-1 line was integrated into an existing drug product plant which presented a number of challenges. The entire building and facility had to be revamped to enable the introduction of the vertically designed line. Design teams had to work around pre-existing building constraints, such as support beams, when designing and building the process equipment line, clean rooms, HVAC-systems, GMP staircases, GMP elevator, and safety escape doors. The entire installation project and introduction of the CM-line was completed upholding Janssen's highest safety standards and with zero lost work day cases.

## Collaboration Helps Strategy Succeed

Not only did Janssen develop a new CM-line but they set up cross-functional initiatives to make sure they were ready to start developing new compounds once the Mirror-1 line was complete. They collaborated with academics, partnered with other pharmaceutical companies, and established connections with health authorities worldwide to help them formulate renewed development strategies and best practices and to establish new methodologies including:

- Establishing material databases in order to optimally design CM-formulations
- Establishing predictive modelling tools to support process understanding, monitoring, and control
- Establishing API-reduction strategies
- Developing the API/DP-interface to further optimize the engineering of the final API in view of CM
- Incorporating and consistent integration of 7 in- and at-line PAT-tools as part of process development
- Developing secure product traceability as part of the process controls
- Increasing experience in data management systems
- Re-defining established concepts of batch, batch size, and scale
- Developing a strategy for the implementation of real-time release testing



## CM Mirror Line Exceeds Expectations

The implementation of this innovative and unique E2E-strategy for a CM platform will lead to multiple benefits for development, clinical manufacturing, and supply chain. It will also create benefits for society, both for patients and for sustainability.

“We estimate our strategy will create an efficiency improvement of around 30-50% in late development and this will free up resources which can be used to support our promising and growing pipeline of products in development,” said De Smaele.

Additionally Janssen’s pioneering Mirror concept:

- Reduces API-needs, which will reduce costs
- Produces consistent product quality throughout development and scale-out/transfer, which can minimize unexpected issues
- Reduces the number of clinical bioavailability and bioequivalence trials, again reducing cost
- Improves tailoring of supply versus demand
- Enables further scientific strengthening of new drug product submissions

“We choose an extremely ambitious holistic strategy towards the implementation of a CM-strategy, requiring cross-functional interactions at all levels, acting in a global environment,” said Russo. “Patients worldwide will have access to safer and more affordable products. In addition, the unique advantages of introducing an E2E platform also used in the R&D stages gives an additional potential to support the development of more products which would otherwise not be possible, thereby supporting the introduction of new and improved drugs on the market.”

## Supply Partners and Key Participants

### Manufacturer/Owner Name

Janssen Pharmaceutica n.v.

### Engineer/Architects (A&E)

dbv-architecten

Sweco Belgium nv (previously Grontmij),

### Construction Manager

Arcadis Belgium nv/sa

### Main/General Contractor

Groep Van Roey nv

### Piping Subcontractor

Hyline

### HVAC Subcontractor

ENGIE Axima HVAC – Aartselaar

### Automation and Control Supplier

GEA Pharma Systems

### Major Equipment Suppliers/Contractors

GEA Pharma Systems; Gerteis Maschinen + Processengineering AG; Optimal Industrial Automation Ltd; Bruker Optik GmbH

## ABOUT THE COMPANY

Janssen Pharmaceutical Companies of Johnson & Johnson focuses on areas of medicine where they can make the biggest difference including oncology, infectious diseases and vaccines, cardiovascular and metabolism, immunology, neuroscience, and pulmonary hypertension. Janssen’s more than 40,000 employees worldwide are working to create a future where disease is a thing of the past by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart.





Facility of the Year Awards

CATEGORY WINNER  
Project Execution

# Project Execution

## Bristol Myers Squibb

Project Execution recognizes companies that have implemented novel tools and approaches to improve efficiency, overcome an unusual challenge, and promote effectiveness and have organized stakeholders and project team participants in ways that led to successful outcomes.

### Quick Facts

#### Project

Cruiserath Biologics  
Campus

#### Location

Cruiserath Campus,  
Tyrellstown, Dublin 15,  
Ireland

#### Total Facility Size

500,000 sq. ft.

#### Project Mission

To transform an existing  
Bristol Myers Squibb  
Active Pharmaceutical  
Ingredient site into a  
state-of-the-art Biologics  
Drug Substance  
Manufacturing  
Campus that includes  
consideration for future  
commercial projects.



## WHY THEY WON

*“The project demonstrated an exemplary, positive collaboration between all project stakeholders and team members. The project was extremely fast-tracked, with mechanical completion achieved for the manufacturing building within 26 months of start of detailed design, which coincided with the start of construction on site. The project was completed safely, on time, on budget, delivered a successful Process Performance Qualification campaign, achieved LEED Silver rating, and is well on the way to delivering product to patients. The facility now serves as a much sought-after employer in the area and provides a comfortable, aesthetic work environment for employees.”*

# Billion Dollar Commitment to Biologics

## Renovations for the Future

The biopharmaceutical industry is thriving in Ireland and Bristol Myers Squibb’s (BMS) Cruiserath Biologics is at its forefront. In 2014, BMS closed its Dublin-based Active Pharmaceutical Ingredient site and announced a \$1 billion commitment to building a new world-class biologics manufacturing facility in its place. The investment helped BMS increase its biologics manufacturing capacity and played a central role in its global manufacturing network. At the time, the project was the largest single investment by BMS outside of the United States and the second largest life sciences sector investment in the history of the Irish state.

BMS’s primary goal was to build a fully operational and qualified facility capable of commercially manufacturing cell culture product by January 2019 and process performance qualification batches by September 2018. They did so while staying on budget and meeting all cGMP, environmental, safety, local authority requirements, and European and United States safety and regulatory compliance standards.

Construction was complete in 3 years and now BMS Cruiserath employs more than 400 full-time employees, all of whom work collectively to deliver innovative medicines to patients.

The project team was purpose-built starting with a small group of BMS employees. Jacobs was hired as the Engineering firm and later for full Engineering, Procurement, and Construction Management to transform the site into a new state-of-the-art Biologics Drug Substance Manufacturing Campus. Four new buildings were constructed including the Multi-Product Cell Culture manufacturing building, the Laboratory, Office, Cafeteria building, the Central Utilities building, and a large addition to the existing warehouse. Some original site infrastructure including utilities, warehousing, and waste water treatment were upgraded, retrofitted, and/or re-utilized to support the new Biologics functions.

## Innovative Design Concepts

The result of this \$1 billion investment is a new biopharmaceutical campus manufacturing immuno-oncology medicines for patients worldwide. The large-scale site (6 x 15,000L bioreactors) will produce multiple biologic medicines annually on a rapid-turnover, campaign basis for high efficiency and throughput. It is designed for future expansion into a concurrent-campaign multi-product facility.

Innovative concepts were applied to the facility design to facilitate higher throughput and rapid product changeover while minimizing equipment redundancies and maintenance shutdowns. Some key initiatives implemented for rapid product changeover include:

- Extra media and buffer preparation capacity
- 3D transfer panels
- Additional CIP skids and distribution manifolds





- Parallel inoculum and harvest suites
- Segregation capability of the ballroom-style purification suites
- Use of buffer concentrates
- Remote column packing and mobility system
- Hybrid design using single-use and stainless-steel equipment

The Manufacturing Execution System design integrates with the production automation system and collectively utilizes flexible and lean recipes. This allows for easy and quick configuration of the system for the next product to be produced.

## “One Team” Philosophy Reaps Rewards

One of the reasons the project was successfully completed on time, on budget, and with a stellar safety record was the “One Team” project philosophy BMS promoted from the outset. All team members partnered with a focus on open communication, transparency, collaboration, flexibility, fairness, rapid and local decision making, and safety.

## Working Together to Save Lives

The project was at one time the largest pharmaceutical project being undertaken in Europe with the site peaking at more than 2,200 people. A robust safety culture centered on collaboration was one of the keys to delivering an exemplary safety record with more than

6,500,000 site hours worked and a TRIR rate of 0.68 (less than ¼ of the industry norm).

The project team implemented several novel safety initiatives including linking the safety program to the innovative medicine that would be manufactured at the facility.

“Every individual coming onto site, from site contractors, equipment vendors, design engineers, CQV contractors, and new BMS personnel, were brought through an induction program focusing on the big picture of bringing innovative medicines to patients worldwide,” said Anthony Carter, BMS, Project Director, Capital Governance and Controls.

Site Inductions opened with a personal project introduction by a senior member of the project leadership team, a “meet and greet” with the site medic and security manager, a project descriptive video, and a site walk to familiarize new starts with the size of the site and location of key areas.

## Accelerated Schedule to Meet Growing Demands

“With growing demands for its immuno-oncology medicine, Bristol Myers Squibb needed to build a facility for the future,” said Koti Vadlamudi, Jacobs Senior Vice President, Advanced Facilities. “The project is a huge success for Bristol Myers Squibb, Jacobs and ultimately the many patients that rely on these medicines produced in the Dublin campus.”

With a goal to begin making innovative biologic medicines for cancer patients as soon as possible, BMS set an aggressive timetable for the project’s completion.

They conducted an extensive benchmarking study of comparable facilities to learn lessons from those projects' successes and failures.

Design was implemented in multiple locations including Ireland, India, and the U.S. and used state-of-the-art design tools and collaboration platforms. Similar innovation was applied during the construction phase. Much of the specialist biotech equipment was ordered in advance of the detailed design phase to support the aggressive project schedule. Other concepts used to deliver the project rapidly included the use of super skids and modules for process/utility equipment, multi-shift field construction, and the construction of a temporary data center. The Commissioning, Qualification, and Validation team was mobilized early and embedded in the design reviews. An additional, and innovated tactic, was to hire new college graduates and train them via a new program developed jointly with Ireland's National Institute for Bioprocessing Research and Training (NIBRT). This approach allowed the site team to quickly grow to 400 members who were ready to operate the new facility.

## Focus on Sustainability

The new facilities were designed and built with environmental sustainability in mind. Approximately 50% of the campus area is designated as vegetated open space. BMS promoted resource efficiency and waste minimization during construction - 15% of materials were made from recycled content and 30% were manufactured within the region, reducing the environmental impact of transportation and supporting the local economy. In April 2018 the project was awarded a U.S. Green Building Council LEED Silver Rating.

"The Cruiserath campus represents the largest ever capital investment for the company and is the first Bristol Myers Squibb biologics manufacturing facility in Europe. We set out with a vision to build a world class Biopharma Campus and state-of-the-art facility; to receive this highly coveted and industry recognition indeed signifies we are well on our way in this endeavor," said Noel Heaney, General Manager, Cruiserath Biologics and Executive Director, EU Biologics. "The facility and overall project met the design intent to be a flexible, multi-product manufacturing operation able to produce biopharmaceuticals for patients who rely on us. This project re-purposed an existing, but redundant site into a new biologics campus that has the capability and capacity to meet our global single vision of transforming patients' lives through science."



## Supply Partners and Key Participants

### **Manufacturer/Owner Name**

Bristol Myers Squibb

### **Engineer/Architect (A&E)**

Jacobs

### **Construction Manager**

Jacobs

### **Main/General Contractor**

Jacobs

### **Piping Subcontractors**

Jones Engineering  
Mercury Engineering  
Leo Lynch & Co

### **HVAC Subcontractor**

Rockwell Engineering

### **Automation and Control Supplier**

Sirus

### **Major Equipment Suppliers/Contractors**

Techniserv; IPEC; PALL Corporation; Steris Ltd; Millipore; FlowTech; Radley Engineering Ltd; BCD Engineering

## ABOUT THE COMPANY

Bristol Myers Squibb is a global biopharmaceutical company whose mission is to discover, develop, and deliver innovative medicines that help patients prevail over serious diseases.



**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Social Impact

# Social Impact

## GlaxoSmithKline

New for 2020, the Social Impact Award recognizes companies who have developed new standards and practices that have prevented drug shortages and increased patients access to medicine, reduced the cost of drug products through the use of new tools or techniques, or accelerated a shift to sustainable facility design which has significantly reduced environmental impact.

### Quick Facts

**Project**

Attachment Inhibitor (AI) Project

**Location**

Parma, Italy

**Total Facility Size**

14,410 sq. ft.

**Project Mission**

To successfully design, construct, and commission a new greenfield facility to support a new product introduction for HIV in an unprecedented time frame.



## WHY THEY WON

*“The team used the novel delivery approach of ‘Integrated Project Delivery’ (IPD) never used before in Italy and were able to build a fully finished facility in 15 months. They paid attention to creating a ‘can do’ attitude and culture whilst implementing accelerated delivery tools such as building information modelling and 3D visualization. This pre-construction project visualization improved coordination of scheduling and sequencing throughout the project and contributed to an excellent safety performance of zero reportable incidents. As a result, GSK and ViiV Healthcare ensured the continuity of supply of fostemsavir for clinical trials and allowed the submission of a new drug application to the FDA and CHMP.”*

## Accelerated Delivery to Meet Critical Need

GSK has a broad portfolio of innovative and established medicines. When they partnered with ViiV Healthcare to develop a newly acquired investigational HIV product, fostemsavir, one of the first things they needed to do was develop a new facility to handle production of the first-in-class HIV treatment. Since the drug is typically used by patients with previous viral failures, who have limited or no treatment options remaining, time was of the essence. GSK met the challenge and in just 15 months, the project team constructed and commissioned a new greenfield NPI facility for high containment.

Due to limited available product knowledge, GSK’s team collaborated closely with colleagues across all development functions and regulatory authorities to understand the impact of the drug on facility design and operation. Through collaboration with the FDA, they knew the facility needed to:

- Be a standalone facility, segregated and dedicated to the manufacture of fostemsavir
- Have dedicated staff with discrete changing regimes on entry and exit to and from the manufacturing area

- Have a dedicated laboratory inside the GMP area
- Have contained equipment and materials transfer to protect operators and product

GSK also wanted a facility that could be adapted to meet future needs or scaled down to reduce the risk of under-utilization.

The accelerated schedule drove the need for a highly integrated program including concurrent design, construction, and commissioning. For the first time in the Italian industry an Integrated Project Delivery (IPD) approach was used. Designers, contractors, and suppliers from diverse backgrounds and experiences worked together to capitalize on the talents and insights of everyone on the team.

The fostemsavir project team was deliberately kept small to maintain focus and shorten decision making time. “We wanted to get this new medicine to the patients who need it as soon as possible, so we started by working closely with our development colleagues and the regulatory authorities to understand the nature of this new product and the control strategy for manufacturing, and hence the specialized facility we would need to create to accommodate it. Using an IPD approach, we created a unified team, where every individual took full accountability for their tasks, mindful of the impact successful delivery would have on human lives. IPD generated a ‘can do’ attitude and culture, having a really positive impact on problem-solving and fast, informed decisions. A key factor in this was the early decision to co-locate all members of the team, which created instant communication that could address issues on the spot,” said Mike Mungall, GSK, Vice President, Global Capital Projects.

## Novel Technical Solutions

The GSK team reduced the overall design time by overlapping the design, procurement, and construction phases thus changing the inherently iterative nature of





the design process. Interactive and decision-making workshops were held to evaluate different layout, facility, and process manufacturing options.

“When we were examining design choices, we kept asking ‘What options would allow the quickest delivery of the project?’ By focusing on this, we were able to find smart engineering solutions that shortened the construction schedule,” said Nick Furnston, GSK, Head of Front-End Design, Global Capital Projects.

Some of the key technical choices the team made included:

- Adopting modular design principles in the layout and process equipment design development to maximize adaptability
- Minimum footprint to make operations of the high containment facility more manageable
- Small basement and walk-on ceiling allowed for parallel construction
- Concrete versus a steel-framed and clad building

The team used 3D Building Information Modeling (BIM) from the early stages of design which proved to be extremely effective and offered several advantages. At the beginning of the design phase, the 3D model helped stakeholders to visualize the design and specify requirements more accurately. During the bidding phase, the model gave construction bidders a clearer overview of the scope of the work. It also helped identify any constructability issues which resulted in significant monetary and time savings.

## Accelerating Delivery of Long-Lead items

While the design for the building was being developed, the team identified equipment that could take a long time to procure – in some instances up to 12 months. To mitigate the risk of having a facility ready but no equipment, the process equipment team developed a strategy to develop User Requirement Specifications so that equipment could be ordered at the end of concept design. This meant that equipment was able to be ordered before the design of the facility and layout was completed and arrived on-site earlier than is typical with a similar project.

## Different Approach to Construction Planning

The building was divided into 3 separate construction zones each operating simultaneously. The planning of each zone was managed individually with each focusing on workers’ safety, contractor availability, reduction of labor downtime, dynamic planning “scrums,” and constant reviews of materials and delivered process equipment.

There were daily and weekly meetings with transparent communication of potential re-planning requirements, including four-week-look-ahead interactive sessions. Dedicated field engineers were on site to review the 3D model with contractors and monitor the progress for the facility works.



## Accelerating Commissioning and Qualification Stages

Due to constraints linked with compliance requirements and the technical/quality risks associated with the commissioning and qualification (C&Q) stages of the project, finding ways to accelerate it was difficult. However, four key factors kept C&Q aligned with the pace of the project.

1. A C&Q schedule analysis was performed early on to identify which validation activities were on the project critical path
2. Site Acceptance Testing (SAT) was leveraged into IQ/OQ protocols to avoid test repetition
3. Every process engineer was supported by a dedicated validation engineer and a computer system engineer to balance workload and enhance technical collaboration
4. The extensive participation of production, maintenance, and EHS personnel in FAT and SAT activities helped identify issues early on

In addition to the successful design, construction, and commissioning of a new greenfield facility in an unprecedented time frame, the AI project was on budget and had zero reportable safety incidents.

“In December 2019, we filed for FDA approval for fostemsavir, after our fastest ever project build,” Mungall said. “The project team, the Parma site, and everyone who had a part in making this happen, is proud to be involved in developing a new treatment that could help people who are living with HIV, but are not able to suppress their virus with other medicines and who could be left with few or no treatments available.”

## Supply Partners and Key Participants

### Manufacturer/Owner Name

GlaxoSmithKline

### Engineer/Architects (A&E)

Techniconsult

Bryden Wood

### Construction Managers

Techniconsult

Oneplan

### Piping Subcontractor

Idroinox

### HVAC Subcontractor

Omega

### Automation and Control Suppliers

SIA

ER Sistemi

### Major Equipment Suppliers/Contractors

Leistritz Markgrafenstr 29-39; IMA; Korsch; Comecer

## ABOUT THE COMPANY

GSK is a science-led global healthcare company with a special purpose: to help people do more, feel better, live longer. GSK's HIV research and medication is managed through ViiV Healthcare, a global specialist HIV company focused on advancing science into HIV treatment, prevention and care.





**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Social Impact

# Social Impact

## United Therapeutics

New for 2020, the Social Impact Award recognizes companies who have developed new standards and practices that have prevented drug shortages and increased patients access to medicine, reduced the cost of drug products through the use of new tools or techniques, or accelerated a shift to sustainable facility design which has significantly reduced environmental impact.

### Quick Facts

#### Project

Dinutuximab Dedicated Oncology Medical & Analytical Laboratory (DDOMAL)

#### Location

Silver Spring, Maryland, USA

#### Total Facility Size

31,486 sq. ft.

#### Project Mission

To build a facility that would integrate into the existing United Therapeutics campus and the Silver Spring community, where United Therapeutics could increase the production of Unituxin® to provide it to patients with a rare pediatric cancer and to conduct research for numerous other life-threatening illnesses.



## WHY THEY WON

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*“This project faced unique challenges and obstacles to build the facility but never lost focus on why they were doing this work – to provide medicine for an unmet medical need. The project also took the time to consider the impacts to the community both during and after construction, even including external artwork for the facility.”*

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### A Company Built from Love

United Therapeutics was founded because of a parent’s love, a tireless mission to save lives, and a willingness to break convention to do so. In 1994 Dr. Martine Rothblatt, an American attorney, author, and founder of SiriusXM, learned that her 7-year-old daughter had pulmonary arterial hypertension, a life-threatening orphan disease, with no viable medicine on the market. Since orphan diseases affect a small percentage of the population, cures are not typically being researched so Dr. Rothblatt took matters into her own hands and made it her life’s mission to find a lifesaving treatment. She and her team at United Therapeutics were successful and several years later they expanded their focus to include the development and commercialization of unique products to address more unmet medical needs, including those of children with chronic and rare life-threatening conditions.

One of those products is Unituxin®, which has proven effective in treating and reversing high-risk neuroblastoma, a rare form of cancer that typically forms on immature nerve cells in children under the age of 5 and affects approximately 800 children a year. Unituxin® has been shown to provide event-free survival for 6 years in

25% of the patient population and it also has the potential to treat other rare forms of cancer. United Therapeutics’ manufacturing and research capability was limited due to its existing biologics manufacturing capacity. In order to treat more pediatric patients, conduct research on other life-threatening illnesses, and bring hope to more families, United Therapeutics knew they had to expand their operation and so they decided to build a new facility – the Dinutuximab-Dedicated Oncology Medical & Analytical Laboratory (DDOMAL).

### Challenging Site Location

United Therapeutics wanted to build adjacent to its existing campus. This would not only allow employees to stay connected to one another but would also keep them integrated in the Silver Spring community and enhance the downtown area. Additionally, choosing a site the company already owned saved approximately 6 months of acquisition time and, more importantly, reduced the need for redundant administrative space and costs – therefore helping United Therapeutics to dedicate 100% of DDOMAL to the production of medicine. However, the site did impose several challenges including a limited footprint and local government ordinances.

United Therapeutics needed 25,000 square feet for the facility but only 14,000 was available on site. The company partnered with local government to overcome this challenge and was able to convince officials to pass legislation that allowed for the floor area housing mechanical, engineering, and plumbing equipment required to support the drug manufacturing process to be exempt from the total gross square foot calculation. This legislation not only made the project feasible, but will promote the future development of the life science industry in Montgomery County, Maryland.

“Creative and innovative design was essential to work around the limited footprint,” said Avi Halpert, VP, Corporate Real Estate. “Because of the space limitation the building was designed far below grade as well as above. The new facility went so far below grade that municipal utilities had to be rerouted and huge





efforts made to shore and pump the site to keep out groundwater. Everyone involved, including Montgomery County, Maryland, officials, residents, and local construction partners, made an unprecedented effort to make this seemingly unfeasible facility a reality.”

Pioneering design solutions were created early on such as using space trusses to avoid interior columns, optimizing manufacturing space, and segregating the elevator and stairwell from the process areas. The construction team excavated down almost as far as they built up and every possible inch of space has a purpose including the cellar for process utility equipment and the roof for black utilities.

DDOMAL is capable of producing eight times the capacity of the previous production site, which will significantly increase the amount of Unituxin® available to patients and allowed United Therapeutics to conduct clinical trials and support commercial markets for other rare diseases.

## Project Management for an Aggressive Timeline

United Therapeutics used a partnered design/build approach which enabled quick decisions based on science, constructability, cost, and schedule. The

company was able to determine the critical path through design, construction, commission, and validation to keep the building timeline on schedule. The United Therapeutics team identified when all key long-lead equipment would be needed on site and had it shipped ahead of schedule to a local staging area so it could be installed at the precise time needed. In addition, the company partnered with a skid manufacturer early on to have stainless-steel bioreactors designed before integrating them into constructed building systems.

## Leveraging New Technology

Throughout the project, teams used building information modeling (BIM) and virtual reality (VR) software to stay on track, coordinate between teams, and ensure all equipment would fit into the atypical space. An LOD 400 BIM model allowed key contributors to see where engineering and structure integrated and allowed the team to visualize the construction process early in the project to reduce utility conflicts and optimize quality control. VR technology allowed laboratory technicians to interact with the look and feel of the facility and identify problematic areas. The team was able to experiment with different locations for equipment and create a functional, well-thought-out layout ahead of time which saved time and money by reducing changes and rework once physical construction was complete.

*Congratulations to the ISPE FOYA winners*



**United Therapeutics**

Dinutuximab-Dedicated Oncology  
Medical and Analytical Laboratory  
*Silver Spring, MD*

**Janssen Pharmaceuticals and  
Legend Biotech**

CAR-T Clinical Manufacturing Facility  
*Somerset, NJ*

**Sanofi**

Digitally Enabled Integrated Continuous  
Biomanufacturing Facility  
*Framingham, MA*





## Supply Partners and Key Participants

### **Manufacturer/Owner Name**

United Therapeutics

### **Engineer/Architects (A&E)**

IPS-Integrated Project Services, LLC  
EwingCole

### **Construction Manager**

The Whiting-Turner Contracting Company

### **Main/General Contractor**

The Whiting-Turner Contracting Company

### **Piping Subcontractor (HVAC, Plumbing, Lab Gas Piping)**

Heffron Company

### **Piping Subcontractor (Process Piping)**

High Purity Systems

### **HVAC Subcontractor**

Heffron Company

### **Automation and Control Supplier - Process Controls**

Omni Instrumentation & Electrical Services;  
Avid Solutions, Inc.; BAS - Critical Systems by  
Schneider Electric

### **Major Equipment Suppliers/Contractors**

ABEC; Millipore Sigma

## Community Connections

From the beginning, United Therapeutics wanted to stay connected to their local community – and the company did not lose sight of that during or after construction. Throughout the project, the team went above and beyond to create a positive experience for those around them by installing covered walkways, organizing social events for the local community to discuss the project, installing a project signboard to inform neighbors of what they should expect to see, hear, and smell, and providing noise-cancelling headphones to residents of a nearby nonprofit Catholic organization.

“DDOMAL was born of a mission to improve the lives of patients,” said Patrick Poisson, EVP, Technical Operations. “Against all odds, the DDOMAL team showed an unparalleled commitment to getting Unituxin® into production and to market, building strong local relationships, and executing the project to an outstanding level. It is an exceptional example of how a valiant team effort across the board can lead to an innovative and well-functioning pharma manufacturing facility that respects all stakeholder and quickly produces medicine that saves children’s lives.”

## ABOUT THE COMPANY

United Therapeutics, a public biopharmaceutical company, was established in 1996 to focus on the development and commercialization of unique products to address the unmet needs of patients with chronic and rare life-threatening conditions. As of 2020, United Therapeutics markets five FDA-approved medicines – Adcirca®, Orenitram®, Remodulin®, Tyvaso®, and Unituxin®.



# ISPE Members Globally Cultivate A Culture of Collaboration and Support

## Top Reasons to Join ISPE

- Networking and Knowledge Sharing
- Broaden and benchmark your work with industry
- Have a seat at the table with Regulatory groups
- Gain exposure to new and advanced technology
- Become a Subject Matter Expert
- Be part of a membership that provides collaboration and support



**FOYA**  
Facility of the Year Awards  
An ISPE Program

ISPE would like to congratulate all the 2020 FOYA Category Winners!





**FOYA** | 2020

Facility of the Year Awards

CATEGORY WINNER  
Operational Excellence

# Operational Excellence

## Eli Lilly and Company

Operational Excellence recognizes winners who have applied modern management techniques to improve operation efficiencies, promote excellent quality and consistency, and yield competitive cost of goods from existing and new facilities, processes, and manufacturing operations.

### Quick Facts

**Project**

Lilly Innovation  
Development Center

**Location**

Indianapolis, Indiana,  
USA

**Total Facility Size**

130,713 sq. ft.

**Project Mission**

Construct a flexible  
development laboratory  
for Eli Lilly and Company  
product and research  
development.



## WHY THEY WON

*“By embracing optimized work processes and providing workspace to agilely adapt not only to laboratory needs, but to the most appropriate processes for collaboration and workspaces, the Center established itself as a model for rapid pharmaceutical development, proving to the industry that it is possible to bring successful therapies to market faster than ever before.”*

### Improving the Drug Discovery Process

As a global healthcare leader, Eli Lilly and Company employees strive to discover and bring life-changing medicines to those who need them. In support of this mission, Lilly spent several years examining the traditional industry accepted belief that drug development is a drawn-out, time-consuming process characterized by complex challenges and long delays and set out to determine what facility factors could help improve the pharmaceutical development process. They analyzed many of the basic assumptions of the development process and as a result implemented leading-edge improvements throughout their new facility, the Lilly Innovation Development Center.

Located at the center of Lilly’s Indianapolis, Indiana, campus, the new Center brings modeling, analytical, and formulation scientists together with organic chemists and engineers in a collaboration-centric workspace and enables Lilly to effectively accelerate traditional time scales – reducing the development time from years to mere months.



### Knocking Down Road Blocks

One of the most common delays development teams face is the need to reconfigure a laboratory to support a new approach. Sometimes, the progress of the candidate compound is put on hold while the team works to design a new lab which then has to be constructed before the development process can continue. Previously, Lilly estimated they spent \$2.7 million over a period of 3 years reconfiguring 42 hood arrangements.

Lilly’s Innovation Center was designed so that researchers could transform their laboratory to support new or revised processes in a matter of days. The innovative design also eliminates the costs of involving a laboratory architect and general contractor.

Some of the flexible solutions include:

- An open-grid ceiling which allows easy access to distribution panels for ventilation and piped services
- Pre-installed taps which allow technicians to quickly connect and disconnect hood ventilation lines
- Fabric duct socks to ensure even distribution of air flow and allow maximum lab arrangement and experiment flexibility
- An electrical bus duct system allowing electrical connections to be made anywhere along the “busway”
- Custom fume hoods that can be easily reconfigured and moved throughout the facility







Thanks to the innovative hood design and rapidly adjustable ventilation and piped systems, any researcher can determine what is needed for their specific experiment and if it is not already available in the facility, they can easily have a space adjusted to their needs. Instead of the costly, drawn-out process of fully renovating a laboratory, the researcher only needs to submit a simple work order and once approved, the adjustments can be made in as little as one workday.

Researchers can search the system to see if there is a hood that meets their project's needs or configure an unused one. Approximately 4,000 pieces of equipment are tracked using a Radio-Frequency Identification (RFID) tracking system. In the first 18 months of operation, 10 percent of the hoods at Lilly's Center were reconfigured or relocated in a matter of days at no additional cost.

## Effective Collaborations

Early in the project, Lilly's team determined that they wanted the building design to help make collaboration easy and effective. As with the laboratories, workspaces were designed to be flexible and easy to configure based on the users and their needs. There are no assigned workspaces at the Innovation Center; employees can work wherever is best suited for their current activities.

Teams are able to organically formulate project groups on a day-to-day basis in areas that match and support what is happening in the lab. Each staff member has an ergonomic number that they can enter into a work station for either sitting or standing so that it will adjust to their height.

The Center was even designed to support employees when they are working off site. Every laboratory in the facility is supported by a Distributed Control System (DCS), allowing researchers to monitor and control their experiments. The system can remotely monitor, control, and log data from weigh scales, temperature transmitters, level sensors, pressure transmitters, pump flow rates, stirring on/off, and opening and closing valves in any lab hood. Researchers can customize their design and have the ability to receive mobile messages on each key step of the experiment. As an added benefit, experiments can run 24-hours a day, 7-days a week eliminating delays associated with starting and stopping reactions based on work schedules.

"The automation and remote monitoring allows me to continue my research while I'm away from the lab," said Martin D. Johnson, Senior Engineering Advisor, Small Molecule Design and Development, Eli Lilly and Company. "I can run my experiment sitting in my kitchen at home or monitor its progress using Wi-Fi at my favorite coffee



shop.” This remote access to ongoing processes allowed for the continuation of development activities during the COVID-19 closure periods.

## Eliminating Waste

The Center incorporates features that promote responsible use of resources and reduce energy consumption by 46% compared to a typical laboratory and thanks to the renovation flexibility of both work and lab spaces, materials that might be tossed away in a traditional reconfiguring are re-used at Lilly and never enter the waste stream.

## The Art of Science

Lilly’s Innovation Center showcases the research being conducted in its laboratories and offers opportunities for students, employees, and patients to see the life-saving work Lilly researchers are doing. Throughout the building art work interpreting science and healing hangs on the walls but The Lilly Oncology on Campus program, a compelling art collection of pieces created by people affected by cancer, really reinforces the importance of the work being performed within the facility and its impact on individuals.

“Since we moved to the Innovation Center we have seen time and time again how it has allowed colleagues across multiple functions to co-locate and interact directly with each other, ultimately helping to further accelerate development of our new medicines. It truly is a very special place to work,” said Sarah O’Keeffe, Lilly’s Vice President of Small Molecule Design and Development. ■■■■

## Supply Partners and Key Participants

### Manufacturer/Owner Name

Eli Lilly and Company

### Engineer/Architects (A&E)

Flad Architects

BSA LifeStructures

### Construction Manager

Messer Construction

### Main/General Contractor

Messer Construction

### Piping Subcontractor

North Mechanical

### HVAC Subcontractor

Bright Sheet Metal Co.

### Major Equipment Suppliers

Scott Laboratory Solutions; Industrial Electric, Inc. (IEI)

## ABOUT THE COMPANY

A global healthcare leader, Eli Lilly and Company was founded in 1876 in Indianapolis, Indiana, USA, by Colonel Eli Lilly, a man committed to creating high-quality medicines. Lilly employs about 33,000 people worldwide with almost 8,000 people committed to research and development of new medicines.



**FOYA** | 2020

Facility of the Year Awards

Honorable Mention

# Honorable Mention

## Boehringer Ingelheim Biopharmaceuticals China Ltd.

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**  
OASIS

**Location**  
Shanghai, China

**Total Facility Size**  
25,419 sq. ft.

**Project Mission**  
To build a manufacturing facility to support the growing need for biopharmaceutical medicines in China.



## WHY THEY WON

*“Boehringer Ingelheim’s facility, OASIS, is designed to fulfill a maximum degree of flexibility: this includes a modular approach to fit out distinct manufacturing modules sequentially and implementing a single-use bioreactor design to react to various customer needs. The interior installations, as well as the enabling utilities, are set-up in such a way to allow for further expansions. The spatial layout of the equipment in each floor of the site’s heart, the production building, is arranged to synergistically merge procedures and building. The closed proximity ensures operational efficiency and, in the end, secured product supply.”*

## Changing Laws to Change Lives

Boehringer Ingelheim’s commitment to bring life-saving medication to meet increasing needs, included not just building a new facility, but also working with local government to change regulations. “Until very recently Chinese regulations did not permit contract manufacturing of biopharmaceuticals at all,” said Dr. Jiali Luo, General Manager and Site Head of Boehringer Ingelheim Biopharmaceuticals China. “The rule was, if you own the drug, you have to manufacture it yourself and are not allowed to outsource the manufacturing to a third party.”

In 2013 Boehringer Ingelheim began supporting the China National Medical Products Administration (NMPA) efforts to revise the regulations. Years of hard work and diplomacy led to China’s Standing Committee of the National People’s Congress approving a significant revision of the Drug Administration Law in 2019, the Marketing Authorization Holder (MAH) system. The new

system makes it easier for drug developers to bring new drugs to market, while increasing their responsibility to ensure the safety of those drugs. The MAH-based drug approval system allows drug researchers, research institutes, and biotech companies with innovative technologies to launch and commercialize drugs by outsourcing production instead of requiring in-house manufacturing. The newly established MAH/CMO regulatory framework enhances innovative drug discovery and development, and also provides opportunities for the industry to increase the level of drug quality in general. The allocation of core competences in partnering companies allows for example, biotech the opportunity to focus on research and development (R&D) only without having to establish manufacturing capabilities and capacities on their own, which strengthens the research capability and in the end eventually improves access of innovative drugs to patients.

In addition to changing the future of medical care in China, Boehringer Ingelheim built a modern facility that can be expanded to meet patient, business, and market needs and incorporates environmentally friendly systems.





## Flexible Facility to Meet Future Needs

The OASIS GMP facility is located directly in the heart of Zhangjiang Hi-Tech Park in Shanghai, China. The OASIS facility is set up in a modular approach with module 1 covering first bioreactors including an auto isolator fill and finish line and an expansion option for module 2. The site includes:

- Production Building
- Central Utility Building
- Dangerous Goods Warehouse
- Fire Fighting Pump House
- Waste Water Treatment Plant
- Security Guard House

The Chinese society, economy, and political environment are changing rapidly and OASIS was constructed with this in mind. Boehringer Ingelheim used a modular approach so that some productions could be up and running while other areas were still being built. Even with technology, the focus is on maximizing flexibility. The entire production is based on single-use equipment to be put together following a toolbox concept, which allows for various combinations and can cope with the requirements of different processes. The bioreactors and

vessels are connected through a flexible tube system instead of pipes, offering options for putting together equipment independent of hardware installations. Additionally, the site is the only biopharmaceutical site of a multinational company on the Chinese market offering contract manufacturing that meets global standards.

## Small Ecological Footprint; Big Social Impact

The modular fit allows Boehringer Ingelheim to only expand utilities and manufacturing areas when demand requires it which allows for the most efficient use of resources at the site. The project embraced energy efficiency and environmental impact throughout the detailed design to fulfill Boehringer Ingelheim's standards and practices to reduce carbon emissions. Examples of energy efficient design used in the facility include variable air volume (VAV) HVAC systems, exhaust air heat recovery, optimized/limited air duct velocity, and reduced ductwork resistance. Variable Frequency Drives (VFD) and high efficiency motors were used for the drives and pumps. Metering was also installed throughout the facility to provide accurate monitoring of energy and clean media consumption and to enable continuous improvements in energy efficiency and waste reduction.



In December 2019, in collaboration with BeiGene Ltd., Boehringer Ingelheim Biopharmaceuticals China began manufacturing tislelizumab, a monoclonal antibody, which was the first biopharmaceutical manufactured by a multinational contract manufacture service provider in China and the first innovative biopharmaceutical commissioned under the new MAH model in China.

“We were very proud to become the first company starting commercial biopharmaceutical manufacturing under the MAH model in China,” said Luo. “The trial project was smoothly conducted and has now proven successful. The newly established model can be of great benefit for the Chinese health care system and provide Chinese patients broader access to more innovative medicines.”

## Supply Partners and Key Participants

### **Manufacturer/Owner Name**

Boehringer Ingelheim Biopharmaceuticals China Ltd.

### **Engineer/Architects (A&E)**

The IT Electronics Eleventh Design & Research Institute Scientific and Technological Engineering Corporation Limited; Jiangsu Super Clean Electronics System Engineering Co., Ltd.

### **Construction Manager**

NE (Tianjin) Engineering Co., Ltd Shanghai Branch

### **Main/General Contractor**

Jiangsu Construction Group Corporation

### **Piping Subcontractor**

Actemium; Ensysta Piping Systems Engineering (Shanghai) Co., Ltd.

### **HVAC Subcontractor**

AL-KO Air Technology (Suzhou) Co., Ltd.

### **Automation and Control Supplier**

Schneider Electric (China) Co., Ltd.

### **Major Equipment Suppliers/Contractors**

Thermo Fisher Scientific; Sartorius Stedim Biotech GmbH

## ABOUT THE COMPANY

Family-owned since it was established in 1885, Boehringer Ingelheim is one of the pharmaceutical industry's top 20 companies and one of the world's largest manufacturers of biopharmaceuticals. Represented by the brand Boehringer Ingelheim BioXcellence™, it offers tailor-made contract development and manufacturing services to the industry, providing the entire production technology chain from DNA to fill and finish.



**FOYA** | 2020

Facility of the Year Awards

Honorable Mention

# Honorable Mention

## J&J, Janssen Pharmaceuticals, Inc.

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**

Raritan CAR-T Clinical Manufacturing Facility

**Location**

Raritan, New Jersey, USA

**Total Facility Size**

130,713 sq. ft.

**Project Mission**

To construct a facility in rapid fashion where a cell therapy (JNJ-4528) for patients with multiple myeloma can be manufactured for clinical studies and commercial launch, in conjunction with Legend Biotech.



## WHY THEY WON

*“The Janssen Pharmaceutical Companies of Johnson & Johnson used an innovative Commissioning, Qualification, and Validation and hybrid parallel construction approach on the project. The project team expertly executed the innovative Johnson & Johnson Specification, Design, and Verification (SD&V) program for manufacturing systems and equipment and designed utility systems with a focus on sustainability. They were able to complete the project on an aggressive time schedule with zero reportable incidents and a perfect Total Recordable Incident Rate score of 0.”*

## Advancing a Next Generation Cell Therapy for Blood Cancer

With the current treatment options on the market, the 5-year survival rate for patients with multiple myeloma is approximately 50%. Although treatment may result in remission, most patients will relapse as there is currently no cure for the blood cancer multiple myeloma. However, Janssen and Legend Biotech’s innovative BCMA-targeted chimeric antigen receptor T (CAR-T) therapy, currently in global clinical development, is offering hope to patients with multiple myeloma and their families.

CAR-T therapy uses the patient’s own immune system to identify and attack tumor cells. After collecting the patient’s white blood cells, the T-cells are genetically engineered to produce CARs on their surface which enables the T-cells to recognize tumor cells. The re-engineered CAR-T cells are expanded and formulated in

a cleanroom environment before returning to the patient for infusion. The CAR-T cells attack the cancer and stimulate the immune system to recognize the cancer cells if they return.

## Aggressive Timeline to Begin Transforming Patients’ Lives

Speed of implementation was the driver for this project as Janssen and Legend Biotech wanted to provide this innovative therapy to patients as soon as possible with no compromise to the companies’ standards for quality. Two project design teams, one to design the cleanroom PODs and the other to design the stick-built modular facility, worked closely together to ensure both elements came together seamlessly. They used hybrid construction and a unique combination of on-site and off-site modular construction to help them meet their timeline and were able to achieve mechanical completion in just 9 months.

Mobile and modular PODs are used as cleanrooms. These PODs were fabricated at an off-site factory in parallel with demolition and subsequent construction of Grade C, Grade D, and support infrastructure onsite at Raritan.







The PODs were built such that mechanical and electrical maintenance could occur without entering the cleanroom and were designed to slide into place and integrate into the host facility immediately upon arriving on site.

## Advances in Commissioning/ Validation Technology

The project team used Johnson & Johnson's Specification, Design, and Verification (SD&V) program for manufacturing systems and equipment. This methodology ensures that product and process knowledge is integrated into system design and testing to reduce risks to product quality and patient safety.

The 2 key differences in the SD&V process versus traditional approaches are:

1. A fundamental shift for what it means to qualify equipment and systems, including automation
2. The use of quality risk management (QRM) principles to focus the specification, design, and verification process.

Because of the SD&V program, Janssen and Legend Biotech were able to:

- Implement a novel out-of-place testing procedure that facilitated qualification of equipment prior to move-in

- Increase focus on product and process requirements
- Deliver higher quality equipment and systems
- Increase project efficiency (cost and schedule)
- Improve equipment and system start-up
- Improve regulatory compliance documentation

While projects following a traditional C&Q approach average cost of 7.9% Total Installed Cost (TIC), the CAR-T projects' risk-based qualification cost was 3.5% TIC, a 55% reduction.

## Process Improvement

"The challenges around scale-up of 1st generation CAR-T processes are many, and the teams have been able to advance their thinking and improve their processes with each milestone, using technology and sound engineering to reduce the manual manipulations of patient samples through cell expansion, harvest, purification, and filling." said Jeff Reinhardt, Program Delivery Lead, Advanced Therapies. "As this product moves towards the prospect of approval and commercialization, a robust, essentially closed manufacturing process has been developed to bring hope to as many patients as possible."

## Flexibility for the Future

At the core of the facility design was a strategy for flexible expansion. Subsequent phases of growth can be built and validated without impacting ongoing operations in adjacent manufacturing spaces. This will be critical to support clinical ramp-up and to prepare for commercial manufacturing.

## Strict Safety and Quality Standards

Before starting work, all workers received site-specific training. Subcontractors were also required to follow the same strict requirements including following a permit-to-work system and understanding the site-specific emergency plan. The extensive safety program resulted in no lost-time injuries.

Additionally, the facility was designed to meet all Janssen and Legend Biotech internal quality standards, Current Good Manufacturing Practices (CGMP) guidelines, and industry standards.

Some of their innovative approaches to CGMPs include:

- Traceability – Chain of Identity for patient samples is critical to establishing a robust manufacturing environment that minimizes human error and serializes the flow of product safely through the process
- Proactive or predictive quality systems
- Preventative maintenance on HVAC equipment
- Redundancy built into the chilled water utilities, the electrical system, and UPS system to protect the IT servers

## Ring the Bell

At the conclusion of the project a bell was installed within the open meeting space. Employees ring “The Hope Bell” weekly for each dose of CAR-T therapy being provided to a patient.

“Initially the sound of the bell was rare. As a result of tireless efforts to develop personalized treatments for more patients, this bell ringing has become a weekly ritualized event where it is rung numerous times, and each time with deep, personal meaning for everyone involved,” said Eric Niebling, Vice President Advanced Therapies. “The sound of The Hope Bell is a celebration for every patient and for every employee who has worked passionately to develop each treatment.”



## Supply Partners and Key Participants

### Manufacturer/Owner Name

Janssen Pharmaceutical Companies of Johnson & Johnson; Legend Biotech USA Inc.

### Engineer/Architect (A&E)

IPS-Integrated Project Services, LLC

### Structural Engineer

Mainstay Engineering Group, Inc.

### Civil Engineer

David A. Stires Associated, LLC

### Construction Manager

HSC Builders & Construction Managers

### Main/General Contractor

HSC Builders & Construction Managers

### Piping Subcontractor

Binsky Mechanical

### HVAC Subcontractor

Central Sheet Metal Fabricators Inc.

### Major Equipment Suppliers

Honeywell Building Solutions; Siemen's Industry Inc.; MDT Infrastructure Solutions; Forest Electric; G-CON Manufacturing, Inc.; AES Clean Technology, Inc.; Miltenyi Biotec B.V. & Co. KG

## ABOUT THE COMPANY

Janssen's mission is to create a future where disease is a thing of the past. Part of the Pharmaceutical Companies of Johnson & Johnson, they are working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. They focus on areas of medicine where they can make the biggest difference: cardiovascular and metabolism, immunology, infectious diseases and vaccines, neuroscience, oncology, and pulmonary hypertension.



# FOYA

Facility of the Year Awards  
An ISPE Program

## 2021 Program

We are accepting applications for the 2021 Program.

**The deadline to submit is Friday, 20 November 2020.**

## Facility of the Year Awards (FOYA)

ISPE's **Facility of the Year Awards** is an annual program that recognizes state-of-the-art projects utilizing new, innovative technologies to improve the quality of products, to reduce the cost of producing high-quality medicines, and demonstrate advances in project delivery.

### You're Invited

Join us on **3 November 2020** during the ISPE Virtual Annual Meeting for **TWO** FOYA Education Sessions and the Virtual Banquet. All members and conference attendees are invited to attend. Registration information at: <https://ispe.org/conferences/2020-annual-meeting-expo>.



**Learn more at [ISPE.org/FOYA](https://ispe.org/FOYA)**



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## **CONGRATULATIONS** to the 2020 FOYA winners!

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