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2019 Category Winners

# Spotlight on Excellence



**FOYA** | 20  
19

Facility of the Year Awards



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# FOYA | 2019

Facility of the Year Awards

## Category Winners

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# 2019 FOYA Awards Welcome and Thank You



*Antonio "Tony" Crincoli  
Chair, FOYA Judges Panel*

I am honored to once again work with ISPE to recognize this year's Facility of the Year Awards Category Winners. The FOYA program represents the best of the best—what we call Benchmarking. All companies want to know what is happening on the forefront of technology, innovation, and equipment. ISPE's FOYA program lets the industry know what is happening all in one place, what is truly exceptional, and gives the winners a forum to present it.

ISPE has been recognizing innovations in the pharmaceutical industry through the Facility of the Year Awards (FOYA) since 2004. FOYA submissions are reviewed by recognized leaders from within the industry—leaders from all regions of the world and both small and large pharmaceutical and medical device companies. These leaders have extensive experience in their fields—engineering, manufacturing, supply chain, and quality; most have international responsibilities. Several have lived or worked outside their native countries. They are experienced, knowledgeable, and understand the global landscape.

This group of 20+ leaders have had the privilege of working on a lot of different projects, so they know what goes into producing an innovative project but have also had the benefit of reviewing multiple projects and judging them against the others to find what is a leap above, what is truly unique and truly innovative. Each January the Judging panels converge in a one-day meeting of FOYA submissions. This year, submissions came from all corners of the world and represented projects in the next generation biotechnology, including personalized medicine, digital platforms, modular platforms, continuous manufacturing, and cutting-edge energy project.

Judges review each submission, discuss their individual merits within the submitted category, and consider whether they could qualify for other FOYA categories. This process allows for much dialogue, listening to each judge's assessment, and determining whether the project is novel. This provides judges a forum to discuss new industry trends, and how they are reflected in the submissions. While judges use a template to help them catalog their analyses, they have the freedom to use their expert judgment in reviewing each project. If judges do not identify a project that demonstrates excellence in any one category, they will not award the category that year.



## Facility of the Year Awards 2019 Category Winners Spotlight on Excellence

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The judges' collective expertise and experience is brought to bear during ensuing discussions and evaluations. Once they have screened each submission for compliance with program requirements, judges 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 internal and external networks to benchmark the project information and ensure outcomes as stated were achieved.

One of the areas judges focus on is safety, and whether it was top of mind during project execution. This reflects the judges' experience that projects with a strong safety record will have better overall performance.

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. This year, the category winners were announced at the ISPE Europe Annual Conference in Dublin, Ireland. The Overall winner will be revealed at the ISPE Annual Meeting to be held in Las Vegas in November.

In addition to the defined Category Winners, judges reserve the right to recognize projects with Honorable Mentions. These are clearly successful projects that overcame significant challenges in planning, execution and delivery and are considered worthy of recognition.

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

I would like to thank the 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 project 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 efforts of those that have. ■■■■

*Antonio "Tony" Crincoli is Chair, FOYA Judging Committee and Senior Director, Head Upjohn Global Engineering, Pfizer Inc.*

## Quick Facts

### Project

Dosepak Equipment

### Location

Latina, Italy

### Project Mission

Find an engineering solution to answer the need for equipment not yet available—one that could automatically incorporate multiple requirements on a high volume set of products, and provide results in a flexible and cost-effective way.

# Equipment Innovation

## Janssen Cilag SpA



**FOYA** | 2019

Facility of the Year Awards

CATEGORY WINNER  
Equipment Innovation

## WHY THEY WON

*Janssen's Dosepak Equipment project resulted in the design, installation, and qualification of state-of-the-art equipment, unlike any other in the industry, which integrates advanced robotics and automation into standard packaging process steps and enables lean, flexible, and sustainable manufacturing.*



## Adapting to Consumer Needs

The Janssen Latina SpA factory site produces 3.8 billion tablets and capsules each year. Built in 1983, the factory has undergone renovations and additions over the years to adapt to market needs. One of those changes has been the use of new and innovative Dosepak packaging and I-Smart technology. Currently 20% of Janssen's medications are packaged in blisters and 2.4% in wallets, with this percentage expected to increase to 15% in ten years.

"Erlerada is an example of a medicine that is best packaged in a Dosepak because of safety reasons," said Nello Troccia, Sr. Project Engineer. He says that not only can the packaging be certified as Child Resistant F1, but important information for the patient can be printed on it including calendarization with space to indicate what day the patient should start the medication as well as what time of day it should be taken.

"We know that new products' requirements are rapidly changing from the standard blisters and bottles to more complex packaging," said Marco Minotti, Engineering Site Lead. "Janssen Latina had already started to develop and introduce new, revolutionary machines to give us a high

level of flexibility in our productions as well as the ability to produce the wider range of packaging required by the market when we were given the challenge to develop equipment that would integrate multiple innovative functions into one machine."

## Looking to the Future

Janssen's engineers knew that they wanted equipment that could automatically produce Dosepak and standard wallets, would have I-Smart technology, and be able to process different products as well as blisters and wallets of different sizes. Additionally, Janssen wanted equipment that could address new and evolving needs of patients while keeping production cost low. "Ultimately our ability to transform our products to be more customer-centric was linked to our site's capability to find an engineering solution to the need for a new equipment not yet available on the market," said Minotti.





Since Janssen wanted a machine that could be adaptable to future needs, engineers were faced with some uncertainties during the planning phase. “In order to anticipate the readiness of the company to launch new products on the market as much as possible, the development and construction of the equipment started at a stage where not all the product’s packaging requirements had been defined yet,” said Troccia. “Team members and our suppliers had to demonstrate a great deal of flexibility and adapt to new scenarios.”

## A Winning Collaboration

Janssen Cilag regularly collaborates with external companies when they have an area of expertise that can assist with a new project. For the Dosepak project they brought representatives from the equipment producer, C-Matic srl, the integrator, EECT B.V., the wallet and Dosepak supplier and producer, WestRock, and the designer and producer of I-Smart Wallet, Schreiner-MediPharm, together with their engineering department. Through a series of on-and-off-site workshops and meetings they were able to successfully finish the project on time and on budget.

## Revolutionary Equipment that Saves Time, Money, and Lives

Before Janssen’s Dosepak Equipment it took eight steps, three machines, and four production phases as well as two additional manual steps to produce an I-Smart Dosepak.

The new equipment combines all the multiple steps and phases into one unique production process that integrates advanced robotics and automations into standard packaging process steps and allows Janssen Latina to launch new products with innovative packaging, while keeping production processes lean, flexible, and sustainable.

The new equipment will:

- Start the process by feeding the inner carton or wallet into the machine
- Check the integrity of the I-Smart electronic circuit
- Feed the blister into the machine
- Complete the first sealing step for the blister
- Fold the inner carton or wallet
- Complete the second sealing step of the inner carton or wallet
- Print variable data on the inner and outer carton or wallet as needed
- Seal the label application (for wallet only)
- Build the outer carton (for Dosepak only)
- Insert the inner carton in the outer carton (for Dosepak only)
- Glue the Dosepak
- Activate the I-Smart technology

The automated and fully integrated machine is ten times faster than manual production, reduces the cost of finished goods, reduces the number of head count (HC) needed for the same production volume, increases plant capacity, and increases process compliance and reliability. In addition to the significant industrial and business impact of this project, Dosepak will protect



children from involuntary poisoning, while wallet and calendarized packaging can give additional printed information to the patient to simplify therapy, and I-Smart will increase patient adherence to the medication making treatment more effective.

“Overall, the Dosepak equipment makes the Janssen Latina Plant ready to support the introduction of new life saving products with special packaging requirements,” said Minotti. “ No other equipment combines standard wallet, Dosepak, and I-Smart handling in one single machine while also having the flexibility to process different products and a wide range of blister and wallet dimensions and reduces the amount of time needed to produce a unit, increasing site capacity and reducing labor costs while being designed and built with the highest safety standards for its category. With this equipment we are able to produce medicines in a more efficient and cost-effective way, ensuring higher quality and lower costs to the patients.”

## Key Project Participants

### **Manufacturer/Owner/Construction Manager**

Janssen Cilag SpA

### **Construction Manager**

Janssen Cilag SpA

### **Main/General Contractor**

AKKA

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

C.Matic Srl; ECCT B.V.

## ABOUT THE COMPANY

Janssen is a worldwide group of pharmaceutical companies and part of Johnson & Johnson. A top ten company in global pharmaceutical sales, Janssen has 40,000 employees working on five continents and invests \$4.5 billion in research and development annually. Part of the solid oral products for Janssen are produced at the Janssen-Cilag SpA Latina Plant, which is a Centre of Excellence.



## Quick Facts

### Project

Pfizer Global  
Biotechnology Center

### Location

Hangzhou, China

### Total Facility Size

341,000 sq ft

### Project Mission

Design, construct, qualify  
and deliver a \$195MM  
Biotechnology Campus  
on time and on budget  
with a blemish free  
safety record.

# Facility Integration

## Pfizer Inc.



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Facility of the Year Awards

CATEGORY WINNER

Facility Integration

## WHY THEY WON

*Overall, Pfizer's Global Biotechnology Center had a very high degree of integration from the selection and development of the large molecule network manufacturing platform, to the design of the Hangzhou facility, and to the program that enabled construction completion within 25 months.*



## Biotechnology Center Brings Lifesaving Medications to Underserved Part of the World

Pfizer is known as one of the world's premier innovative biopharmaceutical companies. They opened their first biopharmaceutical center in Dublin, Ireland, in 2006 and followed with ones in Andover, Massachusetts, in 2007 and Sanford, North Carolina, in 2017. Pfizer produces lifesaving cancer medications, monoclonal antibodies (mABs), at the centers and distributes them to more than 100 countries. However, before the Biotechnology Center in Hangzhou was built, most people in China did not have easy access to mABs.

"The cancer mortality rate in China was increasing with lung cancer as the most prevalent cause," said Matt Roberge, Pfizer Senior Director of Technology and Engineering. "Scientists predict the rate of deaths from cancer will continue to increase in China in the short term, reaching as high as 12,000 new cancer diagnoses

daily." Globally, seven of the top 10 selling medicines are biologics and sales are growing. Yet biologics account for only 4% of the medicines prescribed in China.

Based on this underdeveloped biologic market and the growing need for such medicines, Pfizer decided to construct a state-of-the-art Greenfield Biotechnology Center in Hangzhou, China.

This was Pfizer's first modular biological production facility. They partnered with world class companies and top local contractors from the beginning and treated all partners as peers, developed shared goals, and encouraged a philosophy of mutual respect for all people. With an international effort from teams located in many countries around the world, they were able to finish the project on time, under budget, and with an unparalleled safety record. "Our project was led by a small, experienced management team who were focused and empowered to make all decisions," said Chaz Calitri, Vice President for Pfizer Manufacturing Operations.





## Building with Future Needs in Mind

Pfizer Global Engineering took a very novel strategy when developing the site master plan, one that enabled multiple parallel work fronts and flexible expansion of facilities to meet future needs. The new campus includes:

- State-of-the-art Drug Substance manufacturing facility using single-use disposable technology
- State-of-the-art Drug Product manufacturing facility, with an integrated lyo and isolator filling line
- High-Bay Warehouse
- Central Utility Building
- Administration Building, including offices, laboratories and a cafeteria.

The Drug Substance (DS) facility was designed using GE Healthcare's KUBio™ modules. Seventy-seven modules measuring 31 x 14 x 13 feet were built in Stuttgart, Germany, and transported to Hangzhou where they were assembled. The facility has a manufacturing ability of 4000 liters that can easily be expanded to 8000 liters. The capacity is approximately 48 production batches a year with the ability to deliver 96 batches a year when expanded. Depending on the number of products, and the titer, the annual output is in the range of 270 to 540 kg a year. Even though each module was designed and constructed in Germany, they conform to existing local fire protection codes and seismic requirements.

The Drug Product (DP) Facility was built on site. It is a three-floor building adjacent to the warehouse to limit material follow distances and adjacent to the central utilities building to reduce piping lengths. The DP Aseptic Suite is constructed with modular cleanrooms and walkable ceilings. As with the DS facility, it was designed to accommodate multiple products and has a high

degree of future flexibility and expansion. In fact, the entire campus layout was designed to enable expansion for every unit operation and building, either together or independently.

Advanced technology at the site includes an entirely single-use process for both bulk and sterile fill, the first 2,000-liter disposable bioreactors in production by a multinational corporation in China, and the largest modular constructed Biotech Drug Substance Facility to date. The Hangzhou facility is part of a Pfizer manufacturing network and the application of advanced technology enables harmonization of the manufacturing platforms across Pfizer's four biotechnology manufacturing sites.

## Exceeding Industry Standards

Pfizer purchased the land in March 2016 and the facilities were operational by June 2018. "A very accelerated schedule was a key project driver," said Jim Brinkman, Vice President Pfizer Global Engineering. "This required detailed coordination at every level. By streamlining decision making and communication and empowering the team to accelerate activities, we achieved a very fast schedule with very little rework and no scope creep."

Industry cost, schedule, and safety records were broken as a result of the incredible commitment and dedication from the global execution team. Three-thousand-seven-hundred people worked on the Pfizer project over more than 2,700,000 hours with a perfect safety record and no lost time accidents compared to an industry average for similar projects of eight lost time accidents. The Hangzhou project cost of \$195MM was significantly less than similar pharmaceutical projects in China and was completed in 25 months compared to an industry average of 36 to 60 months for comparable ventures.



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“This project was a huge success and was only made possible by the talented colleagues we assembled and empowered,” said Calitri. “Pfizer Global Engineering and our strategic partners delivered a complex biotech facility that will serve patients in China. I’m also thrilled by the safety record of this project, which was by design—we were determined to set a benchmark for others in China. I’m extremely proud of our team.”

## 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.

## Key Project Participants

### Manufacturer/Owner Name

Pfizer Inc., Pfizer Biologics (Hangzhou) Co. Ltd.

### Engineer/Architect (A&E)

Jacobs; EDRI (Wuxi Branch)

### Construction Manager

Cockram

### Main/General Contractor

CNEC

### Piping Subcontractor

Jiangsu YiHuan Group Co., Ltd

### HVAC Subcontractor

Qian

### Automation and Control Supplier

Siemens

### Major Equipment Supplier(s)/Contractor(s)

General Electrical Healthcare Systems; Jindi; Winatech; BWT; Maquet; Austar/Steris; SBM; Merck; Lebal; IMA; M-T; LiangYi; HuChen; F&R; Sartorius-Stedim; Weichi; Dajiang; Fisher; Merck; M+W; Zenith; IMA(Beijing);Maquet; SGS; Pharmatech Associates



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ISPE thanks the **2019 FOYA Judging Committee** for their continued support of the FOYA program.



*L to R: Brian Lange, Gary Schoenhouse, James Dickow, Jian Dong, James Brinkman, James Breen, Jr., Gunter Baumgartner, Francesco Intoccia (back), Sanjit Singh Lamba, David Sternasty (back), Rong Zhang, Lou Kennedy (back), Antonio Crincoli, Simon Shelley (back), Fatma Taman, Sangwon Seo, Sam Kitchell*

## Quick Facts

### Project

New cGMP Clinical  
Manufacturing Facility

### Location

Norwood, Massachusetts,  
USA

### Total Facility Size

200,000 sq ft (approx.)

### Project Mission

Design and construct  
a new, highly-flexible  
facility capable of  
producing materials to  
support its pre-clinical  
and Phase 1 and Phase  
2 clinical development  
programs.

# Facility of the Future

## Moderna, Inc.



**FOYA** 2019

Facility of the Year Awards

CATEGORY WINNER

Facility of the Future

## WHY THEY WON

*Moderna has built a highly automated and digital enterprise to seamlessly integrate and orchestrate cloud-based IT systems to manage and industrialize the complex planning execution of its mRNA pipeline at every stage of development. The company's approach to bringing digital technologies into its workflows and processes, using robotics, automation, artificial intelligence, and cloud-based computing to fulfill cGMP operating strategy, brings the industry to a new level in the digital era.*



## Facility of the Future Creates Medicines of the Future

Messenger ribonucleic acid (mRNA) is an essential biological molecule. It carries genetic code from the DNA in the nucleus of cells to ribosomes where the code is then read and translated in order to produce proteins to perform many critical functions of the body.

However, this genetic information sometimes is incorrect, leading to dysfunctional or missing proteins which can cause a broad array of diseases.

Moderna has developed proprietary technologies and methods to create mRNA sequences that cells recognize as if they were produced in the body. These sequences can serve to generate the missing proteins or even produce new antibodies that can fight or protect against infection—providing the genetic instructions that have the potential to enable the body to effectively create its own medicine.

Since its founding, Moderna has become a leader in mRNA research and development. Today, the company's

pipeline includes mRNA-based investigational medicines for infectious diseases, immune-oncology, rare diseases, and cardiovascular diseases. Currently Moderna has 21 development programs in its pipeline.

Anticipating rapid pipeline growth and recognizing the lack of external capacity to support the company's ambitious timeline, Moderna management decided in 2015 to construct a dedicated manufacturing facility, eventually selecting a site in Norwood, Massachusetts. Designed to current Good Manufacturing Practices (cGMP) specifications, the site gives the company the capacity to develop materials for pre-clinical toxicology studies as well as Phase 1 and 2 clinical development programs and to manufacture, test, and run fill/finish operations for its portfolio of mRNA development candidates. The facility employs more than 200 people in a broad array of roles such as production operations, manufacturing science and technology, quality control, engineering services, supply chain management, and process development.







“Investment in our Norwood manufacturing site was essential to enabling us to support our broad pipeline, while giving us the ability to better manage our supply chain and effectively plan for potential later stage development,” said Juan Andres, Moderna’s chief technical operations and quality officer.

## Breaking Ground and Supplying Individualized Investigational Treatments

Moderna broke ground on its new facility in late 2016 and the state-of-the-art site was completed in July 2018.

Moderna designed the facility to be highly-flexible, adaptable, and capable of manufacturing 100 GMP lots per year for the clinic and 1,000 mRNA orders per month. It leverages a ballroom concept with equipment and digital tracking allowing for individual suites to be quickly and easily reconfigured for various uses based on demand. This is different than traditional biologics manufacturing that relies on larger facilities dedicated to making a specific drug.

“Moderna’s manufacturing platform is designed for rapid development and with Norwood we can leverage fully flexible and reconfigurable ballrooms to help meet these demands,” Andres added. “We believe that the way we have conceived the site, the modularity of the manufacturing floor, and the supporting digital systems, will enable us to accelerate drug development in ways that are unique within our industry.”

The Norwood site also houses production of the company’s personalized vaccine unit, which today enables Moderna to produce mRNA-based immuno-

therapies tailored for individual patients. Its Personalized Cancer Vaccines (PCV) program aims to design and deliver a tailored drug product individualized for a patient’s unique cancer. This starts with sequencing a person’s tumor and using computational algorithms to identify the proteins most likely to elicit a response. The PCV then provides the mRNA sequence encoding for these proteins.

## First Class Digital Infrastructure for Pre-Clinical and cGMP

Moderna’s site is digitally enabled, connecting information systems, robotics, and machinery to allow for the continuous exchange of data and providing information on nearly all manufacturing activities. Using advanced algorithms and analytics, more than 7,000 events are monitored in real time to help increase efficiency, ensure quality, and maintain digital integrity. Moderna also uses technology to remove paper from its manufacturing suites, eliminating many manual and redundant processes. Enterprise and process control systems are integrated in a manner that enables flexibility in a highly-automated landscape that allows the company to:

- Monitor 4,000 environmental and quality metrics data points
- Optimize operations through more than 800 Internet connected devices
- Track mobile assets through hundreds of sensors
- Produce up to 1,000 mRNAs a month with 40 integrated robots

“Moderna has built a highly automated and digital enterprise to seamlessly integrate and orchestrate cloud-



based IT systems. This network allows our company to manage, scale, and industrialize the complex planning and execution of our mRNA pipeline at every stage of development,” said Roland Smith, Moderna’s senior director of GxP digital systems.

## Reducing its Carbon Footprint

Developing the Norwood site also gave Moderna the opportunity to start from the ground up in creating an environmentally sustainable manufacturing facility that minimizes resource consumption and environmental impact. As part of the company’s commitment to sustainability, the Norwood facility was designed to achieve Leadership in Energy and Environmental Design (LEED) certification. Energy use is limited with advanced metering and LED lighting and water use is reduced up to 25 percent compared to similar facilities. The site has charging stations for nearly two dozen electric vehicles and this year will add solar panels to supply renewable energy. Additionally, Moderna chose a brownfield site that had the added benefit of re-energizing an abandoned industrial complex.

“We are excited about the rapid progress we’ve made thus far at Norwood, and we continue to improve and optimize our processes,” said Andres. “Our goal is to ensure this facility fully supports our broad research and development objectives and timelines as we work to bring a new class of medicines to patients.”

## Key Project Participants

### **Manufacturer/Owner Name**

Moderna, Inc.

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

DPS Group; TRIA

### **Construction Manager and Main/General Contractor**

Wise Construction

### **Piping Subcontractor**

Kinetics

### **HVAC Subcontractor**

Harold Brothers Mechanical Contractors, Inc.

### **Automation and Control Supplier**

Hallam ICS; Siemens

### **Owners Project Manager**

Hereva Consultants, Inc.

### **Major Equipment Supplier(s)/Contractor(s)**

RELCO; New England Applied Products; MECO

## ABOUT THE COMPANY

Founded in 2010, Moderna is a clinical stage biotechnology company pioneering messenger RNA (mRNA) therapeutics and vaccines. Ranked by Science as a top 10 biopharma industry employer for the past 4 years, Moderna’s mission is to deliver on the promise of mRNA science to create a new generation of transformative medicines for patients.

## Quick Facts

### Project

Small Volume Continuous Manufacturing Facility for Drug Substance

### Location

Kinsale, County Cork, Ireland

### Total Facility Size

9,294 square feet

### Project Mission

Create a small volume continuous (SVC) GMP facility that can produce new therapies for patients using innovative technologies that are safer, greener, and more productive than traditional ones.

# Process Innovation

## Eli Lilly and Company



**FOYA** | 2019

Facility of the Year Awards

CATEGORY WINNER  
Process Innovation

## WHY THEY WON

*This innovative facility and the process design concepts they use clearly advances the industry in process analytical technology and advanced automation, development of new continuous technologies, and significant improvements in process safety and environmental impact.*



## Lilly Develops First-of-its-Kind Continuous Manufacturing Technology Facility

Batch manufacturing has been the cornerstone of manufacturing pharmaceutical active ingredients (API) for the last century. With the evolution of personalized medicines and advancements in medical research, many of the new medicines are more potent than in the past, which means that much smaller volumes are needed from API manufacturing. This is often impractical in large-scale equipment.

Continuous manufacturing (CM) offers new technologies to pharmaceutical manufacturing and new opportunities for safer and greener chemical processes. Eli Lilly and Company has been recognized as an industry leader in this transition. Lilly's Small Volume Continuous (SVC) Facility combines the practicalities of small-scale processing with the innovations of CM technologies to quickly deliver API. The facility is therefore ideally suited for Lilly's pipeline in therapeutic areas such as oncology and has most recently been used in 2018 to manufacture API for clinical trials of one of Lilly's potential new cancer drug candidates. This took place in conditions that were

safer and more productive than a 'batch process'. Before this advancement it could take months to prepare the API needed, meaning it could take additional months or even years before medications were produced for patients.

"This new facility means that Lilly research and development can apply the most innovative approaches to the design of continuous processes, in the knowledge that these medicines can now be manufactured with better chemical reaction safety than previously possible," said Dr. Martin Johnson, Sr. Engineering Advisor, Eli Lilly SMDD.

## Technology Advances that Transform API Manufacturing

Lilly's SVC facility is unique in the API industry because no other company has applied CM technology to the production of multiple process steps simultaneously including all process separations steps and API crystallization. The guiding principle of the SVC facility is that several GMP steps are coupled together so that one



## ISPE DRUG SHORTAGE INITIATIVE

The Eli Lilly and Company Small Volume Continuous facility is recognized by the ISPE Drug Shortage Initiative for the positive contributions their innovative facility may deliver toward alleviating drug shortages in the future. The strong dimensions of manufacturing of the future this facility exemplifies prepares Lilly Kinsale for flexibility, resiliency, and responsiveness, which are foundational pillars of Drug Shortage prevention.

step flows seamlessly to the next and that all can run at the same time. This allows Lilly to have a much shorter cycle time compared to traditional batch processes and makes the facility more responsive to supply chain demands to meet patient needs. The fully continuous process yielded the first batch of API after two weeks rather than two months.

In order to manufacture multiple steps simultaneously, the facility required a full suite of modular technologies, called skids, to allow uninterrupted CM from start to finish in the chemical syntheses. This required pioneering new continuous technologies as well as creative use of existing technologies in ways never considered by batch processing. For example, Lilly used the well-established kilo-laboratory scale rotary evaporators as solvent swap operations in manufacturing, which eliminated the need to isolate a genotoxic cytotoxic intermediate.

The portable skids can be re-configured and augmented to meet the needs of any current or future process so that it can support products still in development as well as those already commercially available. Thanks to a new automation control hierarchy, the 'plug-and-play' skids are immediately recognized and controlled by the central distributed control system. This innovative equipment can also be adjusted, designed, and installed for new projects at a fraction of the costs needed to upgrade a fixed-asset batch facility.

## Efficient Facility Layout

The simple, yet highly efficient, wheel and spoke layout of the facility is anchored by a central feed preparation

room from which all process streams begin. Lilly worked with its partner suppliers to design dual-access fume hoods that have a total capacity of twenty feed streams at any time. The layout allows operations to maintain process feeds in a central area while making all the feed vessels accessible to the modular CM equipment in the fume hoods. Therefore, the temporary connections between feed vessels and skids in the hoods are shorter, more segregated, and easier to install, follow, remove, and change. In the first SVC process, there were three solution make-ups from solids charging and four liquid solution make-ups with seven drum charging activities, all of which provided fourteen different raw materials feed streams continuously supplied from the central preparation room.

## Improved Control

Lilly's data management system allows for exquisite process control where on-line process analytics technology (PAT) monitors the quality of the product in real time to reduce variation and maintain optimum product quality.

The CM equipment allows access to more robust chemistries that offer improved quality. The equipment can be operated at a steady state with on-line PAT for less operational variability and the reactors can be dedicated or disposable giving extra cross-contamination controls between products. In the first SVC process, the flow-enabled synthetic route was deemed superior to alternative routes for yield, environmental impact, and quality.



## Increased Safety

Not only do patients receive the benefit of safer, quality-controlled medications but also operators or operation personnel have a safer work environment thanks to less materials used, fume hoods, and the state-of-the-art technologies. SVC can achieve the same productivity using much smaller equipment than has been used in the past. If there were an accident, it would be much smaller in scale and be contained in the fume hood. The smaller equipment is more ergonomic and is easier for workers to design, set up, and maintain. Smaller quantities of hazardous reagents are needed to accomplish transformations thanks to new technologies, such as the plug flow reactors, which can be used at wider temperature and pressure operating ranges than traditional batch equipment.

This facility is the first of its kind in the pharmaceutical industry for GMP manufacturing using continuous telescoped steps in series including multiple reactions, solvent exchanges, extractions, and API crystallization. And more molecules are already undergoing design and development for small volume continuous manufacturing in 2019 and beyond.

“Small volume continuous changes the way we make medicine because it truly is stretching all the boundaries. It’s taking away some of the limitations that we’ve had before and actually setting them aside. So that you don’t even need to know what’s coming in the future because you have the flexibility of the skids and the fumehoods, and you know you can deliver,” said Tara Tibbs, Engineering Business Unit Leader at Eli Lilly Kinsale. ■■■■

## Key Project Participants

### **Manufacturer/Owner Name**

Eli Lilly Kinsale Limited

### **Engineer/Architect (A&E) and Construction Manager**

BioPharma Engineering

### **Civil Contractor**

MMD Construction Cork Ltd

### **Cleanroom Paneling Contractor**

Ardmac

### **Piping and HVAC Contractor**

B.M.D. & Company Ltd

### **Skids Mechanical Contractor**

MSL

### **Electrical and Instrument Contractor**

O’Sheas Electrical Limited

### **Skids Electrical and Instrument Contractor**

CIL

### **Major Equipment Supplier(s)/Contractor(s)**

POPE Scientific Inc; Envair Ltd; De Dietrich; Precia Molen; Schneider Electrical Systems; RTD Technology TA Assistec; Johnson Controls; BCD Engineering; ESI Technologies; GPE Industries; De Dietrich Process Systems Limited; Optimal Industrial Automation; Zeton; AP Miniplant GmbH; Flowcon Technology; D & M Continuous Solutions; Waters Chromatography Irl Ltd

## 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.

## Quick Facts

### Project

Pfizer Global  
Biotechnology Center

### Location

Hangzhou, China

### Total Facility Size

341,000 square feet

### Project Mission

Design, construct,  
qualify, and deliver a  
\$195MM Biotechnology  
Campus on time and on  
budget with a blemish  
free safety record.

# Project Execution

## Pfizer Inc.



**FOYA** | 2019  
Facility of the Year Awards

CATEGORY WINNER  
Project Execution

## WHY THEY WON

*The Hangzhou Global Biotechnology Center was completed with a perfect safety record; zero lost time injuries with 2.7 million hours of site activity. The project team trained 3,700 workers on Pfizer's safety program. Additionally, the project was completed on time and on budget.*



## Team Work and Communication Pay Off

In 2015, Pfizer decided to construct a state-of-the-art greenfield biotechnology center in Hangzhou, China, to serve the underdeveloped biologics market in the country. The \$195 million project had many challenges, but thanks to a team-centered approach that focused on communication, collaboration, and delivery, Pfizer was able to meet and exceed their goals.

“When asked why this project is viewed as such a success, the overwhelming response is that it all starts with the team,” said Chaz Calitri, Vice President for Pfizer Manufacturing Operations. “From the beginning of this project, we knew that the only way to overcome challenges was to build and empower a small talented team from inception to startup. They were empowered to make decisions. We used local talent as much as possible and this helped with language, culture, and training.”

The team-bonding efforts were not just limited to those in charge. All workers were treated as part of the team. Pfizer paid contractors on-time or ahead of time,

introduced flexible hours on very hot days and provided extra perks like meals and beverages on site.

## Unprecedented Construction Schedule

Despite a one-month site shut down due to the 2016 G20 Summit in Hangzhou, Pfizer achieved an accelerated construction schedule by streamlining decision making and communication and empowering the management team to develop time-saving solutions. The construction team was part of the early schedule development and worked with the engineering, logistics, and modular teams.

Pfizer broke ground in 2016 and 25 months later what had once been an empty field was home to a state-of-the-art drug substance and product manufacturing







facility with single-use disposable technology, an integrated lyo and filling line, as well as a high-bay warehouse, central utility building, administrative offices, laboratories, and a cafeteria. Additionally, the project was designed to enable expansion for every unit operation and building, either together or independently.

Just a few of the innovative strategies Pfizer used to stay on and ahead of schedule included planning the project to include GE Healthcare's KUBio modular technology, which cut construction time in half for that part of the project, innovative contractor strategies such as separating the piling permit from the construction permit, which saved 4 months, contracts that included a clear scope of work with defined roles and responsibilities, and a multi-national team of experts who were committed to project success and integrating commissioning and qualification early on with a specific handover plan.

Staying ahead of schedule was also easier because Pfizer focused on excellent government relations from the very beginning of the project and obtained buy-in early. Local codes and standards were incorporated early in the design to avoid redesign and schedule delays.

"At the very beginning of the project, Pfizer created effective partnerships with world class companies and top local contractors and treated all partners as peers throughout the project. Excellent government relations based on mutual respect and trust resulted in expedited construction permits, land permits, and efficient fire protection design and approval," said Jim Brinkman, Vice President Pfizer Global Engineering.

Thanks to advanced planning, which included working with the Hangzhou Economic Development Area (HEDA) to make sure all documents were in order and road-testing various ground transportation routes, the KUBio modules from Germany were not delayed at port nor were there any problems with ground transportation, even though these types and quantity of modules had never been shipped or ground transported over such a distance in China.

## Stellar Safety Record

Pfizer had more than 3,700 workers working on the project with a total of 2.7 million hours on site, but thanks to innovative and rigorous safety practices, as well as instilling a safety culture in every project aspect, the project was completed with a perfect safety record, with zero lost time accidents. Similar industry projects have had an average of eight lost time accidents.

The Safety Project Initiative for the project, STOP (Safety First. Think. Organize. Proceed.), promoted an environment of careful consideration and respect for safety practices and was supported by a three-strikes-and-you're-out safety infraction system. To celebrate and promote continuation of safe site activities, the team routinely practiced safety recognition in work areas and organized award events to recognize high-performing teams and individuals. Workers will be able to use the knowledge they gained to recognize hazards and identify necessary risk mitigation efforts to future projects and throughout the course of their careers.

As with other aspects of the project, team



communication was imperative to the safety success of the project. Pfizer communicated safety through regular meetings and posted information and concerns on an open board that all could access and conducted daily, weekly, and monthly safety inspections, walk downs, and fire drills. They also practiced meticulous housekeeping, extreme diligence on lock out/tag out procedures, had flawless barrier and penetration protection, best-in-class scaffolding and fall protection, and at least one spotter for every moving vehicle/machine on-site.

“One of the unique coordination aspects of this project was the concurrent commissioning, qualification, and operation of the drug substance facility in the center of an ongoing, active construction site,” said Bob Myers, Project Director of the Hangzhou Project. “This flexibility, in addition to careful logistical planning and open communication of the schedule generated an unprecedented speed of completion for the Hangzhou Project.”

The first of its kind for Pfizer in China, the Hangzhou Capital project cost of \$195MM was significantly less than similar pharmaceutical projects in China. The center has created more than 150 job opportunities and has established biotechnology expertise that will help strengthen and promote innovation, while modernizing China’s biopharmaceutical industry. ■■■■

## Key Project Participants

### Manufacturer/Owner Name

Pfizer Inc., Pfizer Biologics (Hangzhou) Co. Ltd.

### Engineer/Architect (A&E)

Jacobs; EDRI (Wuxi Branch)

### Construction Manager

Cockram

### Main/General Contractor

CNEC

### Piping Subcontractor

Jiangsu YiHuan Group Co. Ltd.

### HVAC Subcontractor

Qian

### Automation and Control Supplier

Siemens

### Major Equipment Supplier(s)/Contractor(s)

General Electrical Healthcare Systems; Jindi; Winatech/BWT; Winatech; Maquet; Austar/Steris; SBM; Merck; Lebal; IMA; M-T; LiangYi; HuChen; F&R; Sartorius-Stedim; Weichi; Dajiang; Fisher; Merck; M+W; Zenith; IMA(Beijing);Maquet; SGS; Pharmatech Associates

## 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.

# Leaders in Life Sciences

We are honored to share in our client's success and celebrate a long tradition of delivering award winning, innovative projects.

2019 *Facility Integration & Project Execution*  
**PFIZER GLOBAL BIOTECHNOLOGY CENTER**  
Hangzhou, China

2016 *Project Execution*  
**JANSSEN VACCINES AG**  
Bern, Switzerland

2014 *Overall Winner & Operational Excellence*  
**PFIZER IRELAND PHARMACEUTICALS**  
Dublin, Ireland

2013 *Overall Winner & Process Innovation*  
**NOVARTIS U.S. FLU CELL CULTURE FACILITY**  
Holly Springs, NC

*Honorable Mention*  
**NATIONAL INSTITUTE FOR BIOPROCESSING RESEARCH AND TRAINING (NIBRT)**  
Dublin, Ireland

2012 *Sustainability*  
**CHIESI FARMACEUTICI RESEARCH AND DEVELOPMENT CENTRE**  
Parma, Italy

*Facility Integration*  
**CONFIDENTIAL CLIENT, VACCINE BULK MANUFACTURING FACILITY (VBF) PROGRAM OF PROJECTS**  
Durham, NC

*Honorable Mention*  
**SHIRE HGT PROJECT ATLAS (BUILDING 400)**  
Lexington, MA

2011 *Operational Excellence*  
**PFIZER HEALTH AB, PEGASUS BIO7 MANUFACTURING FACILITY**  
Straghas, Sweden

*Overall Winner & Project Execution*  
**GENENTECH EGP1, E.COLI PRODUCTION FACILITY**  
Tuas, Singapore

*Sustainability*  
**PFIZER BIOTECHNOLOGY IRELAND, MONOCLONAL ANTIBODIES (mAbs) SMALL-SCALE FACILITY**  
Cork, Ireland

2010 *Equipment Innovation & Process Innovation*  
**MANKIND CORPORATION, TECHNOSPHERE MANUFACTURING FACILITY**  
Danbury, CT

*Facility Integration*  
**PFIZER IRELAND PHARMACEUTICALS, ASEPTIC MANUFACTURING FACILITY**  
Dun Laoghaire, Ireland

*Finalist*  
**WYETH PHARMACEUTICALS, THE WYETH BIOPHARMA CAMPUS AT GRANGE CASTLE**  
Clondalkin, Ireland

2006 *Finalist*  
**ASTRAZENECA, LSL LARGE LABORATORY**  
Macclesfield, United Kingdom



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# FOYA | 2020

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[www.ISPE.org/FOYA](http://www.ISPE.org/FOYA)

## PROPOSAL DEADLINES

**2020 Deadline**  
22 November 2019

**2021 Deadline**  
24 November 2020

## Quick Facts

### Project

La Fée Verte—The Green Fairy

### Location

Couvet, Canton of Neuchâtel, Switzerland

### Total Facility Size

402,247 sq ft

### Project Mission

Build a new environmentally friendly and sustainable production site that would meet and exceed the stringent Swiss Building Minergie® label requirements and provide long-term, energy-efficient solutions.

# Sustainability

## Celgene Corporation



**FOYA** | 2019

Facility of the Year Awards

CATEGORY WINNER

Sustainability

## WHY THEY WON

*Overall, Celgene's unique and innovative energy-efficient concepts resulted in a reduction of 1,400 metric tons of CO2 per year which is 70% less than a standard installation and building construction. The project also focused on meeting and exceeding Swiss Building Minergie® label requirements and on creating a facility where sustainability was ingrained in daily operations.*



## Commitment to the Environment Reaps Long-term Rewards

Celgene's international headquarters are located in Boudry, Canton of Neuchâtel, Switzerland. In 2015, they decided to build a production facility 30 minutes away in Couvet that would be able to meet the growing demand for their existing products and future needs for developing technologies. While developing plans for the facility, they made a pledge to apply environmentally sustainable philosophies throughout the design.

"Celgene's commitment to sustainability is reflected in our environmental goals," said Rich Bagger, Executive Vice President, Corporate Affairs & Market Access. "By reducing our carbon footprint, increasing the purchase of renewable electricity, reducing water withdrawal, and reducing waste generation, we position ourselves as a more responsible neighbor in the communities where Celgene operates. As much as we show our passion for patients in all that we do, we also take great care to protect the communities where they live."

The Swiss have long been aware of the need to protect their natural resources and their government leaders

regularly adopt environmentally protective policies. Created in the mid-1990s, the Swiss Building Minergie® label requirements are some of the most stringent building policies in the world. Supported by the Swiss Confederation, the Swiss Cantons, and the Principality of Liechtenstein, Minergie standards require a building to have high-grade, air-tight building envelopes and to continuously renew air in the building using an energy-efficient ventilation system. It is estimated that, at present, only 13% of new buildings and 2% of refurbishment projects qualify for Minergie certification. Celgene knew they wanted to meet or exceed these strict requirements.

## Innovative Energy Sources

The site was conceived, designed, and built with a superior energy concept for water heating or cooling based on energy recovery from different heat sources which are normally lost to the environment. This includes heat recovery from underground foundation geothermal





piles, air compressors, chillers, steam boilers, and air handling units. Approximate 59% of the energy required for heating at the site comes from heat recovery and approximate 48% of the energy required for cooling at the site comes from cooling recovery. The remaining heating and cooling requirements are met with chillers and steam boilers.

Data centers have their own cooling system and heat recovery done by an independent chilled water unit which favors the use of geothermal cooling, a more environmentally friendly approach than traditional cooling for data centers.

For 90% of the year, the average temperature in the Canton of Neuchâtel is below 18oC (65oF). For the office and cafeteria buildings, Celgene used the principles of free cooling—an economical method of using low external air temperatures to cool space versus using traditional space air conditioning. The windows in the administration areas and restaurant can be opened to take advantage of free cool air. This has the added benefit of employees being able to control their own comfort and minimizing any air conditioning that might be needed.

Celgene used natural solar exposure for office space heating which they can control through automatic window blinds. The office level is also equipped with a ventilated façade providing an additional air barrier between external and internal façade and windows. This double-skin façade increases energy efficiency.

Thanks to this forward thinking, Celgene's total heat requirements are 22% less and their cooling needs 13% less than those of other comparable buildings.

## Harnessing the Power of the Sun

Celgene installed 662 solar panels which will produce approximately 13 to 14% of the site's annual energy usage. In addition, when planning for office areas, they made sure they were designed to maximize the use of solar heating and natural light.

## Choosing the Right Products

The entire site uses LED lighting technology which has reduced energy usage by 40% compared to fluorescent lighting. They also installed state-of-the art, energy-efficient equipment and material throughout—all of which were selected for cost, reliability, energy efficiency, and environmental friendliness. Throughout the facility, chillers and the geothermal water network use environmentally friendly chemicals.

The building receives extra insulation from metal sandwich panels with mineral wool insulation and insulated concrete walls and slab floors. The roofs of the two administration buildings and the cafeteria are green roofs, which also provide an additional layer of natural insulation.

If something is amiss, an interactive electrical monitoring system provides overall site electrical consumption and allows Celgene to see trends and out-of-normal consumption so that they can troubleshoot as needed.



## Saving the Environment Saves Money

Developing a new facility with environment ally friendly and energy efficient efforts might require extra planning in the beginning, but it can have lasting effects not just on the environment, but on the company's bottom line.

Celgene decided to use Swiss hydroelectric power because of the clear and dramatic environmental advantages to using hydroelectrical power. The total final energy consumption to meet Celgene's requirements is 53% less and the total need of fossil energy (natural gas and fuel oil) is 60% less than that of a standard building.

On October 24, 2018, the Couvet site was awarded a Minergie label. In addition to the extensive list of requirements to be certified, the building must also consume 25% less energy than the average energy consumption of similar construction and 50% less fossil fuel. Not only did Celgene's Couvet site meet this expectation, but they exceeded it as their consumption was 46% lower than the Minergie requirements.

"With this innovative project in energy efficiency, our people feel they are working in a facility that can help to put our planet on the path to sustainable development. They are proud to share this outstanding realization with their families and our local communities," said Jacques Soguel, Vice President, Global Engineering & GMP Facilities. "In addition, optimizing our energy usage not only decreases the use of natural resources, but we also see the benefit of reduced electrical costs compared to other manufacturing sites."

## Key Project Participants

### **Manufacturer/Owner Name**

Celgene International II Sàrl

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

Amec Foster Wheeler (Wood Group—Italy); Bauart Architects; Chammartin & Spricher SA; ALRO Engineering SA; Belthiotherm SA

### **Construction Manager and Main/General Contractor**

BEG SA

### **Piping Subcontractors**

RIEDO Clima AG; Alvazzi Groupe SA; Despraz SA; DES

### **HVAC Subcontractor**

Engie & Winkenbach SA

### **Automation and Control Supplier**

Flückiger Electricité SA; Siemens; Emerson/Vertiv Infrastructure AG; Rotronic

### **Major Equipment Supplier(s)/Contractor(s)**

Rosin Entreprise; BWT AQUA AG; Bosh-Apaco AG; Atlas-Copco—Apaco AG; JAG Jakob AG; Bosch; Müller GmbH; Fette; L.B. Bohle Maschinen GmbH; Mediseal; Marchesini; Ermaflux; Sensusm doo

## ABOUT THE COMPANY

Created in 1986, Celgene is a preeminent global biopharmaceutical company focused on the discovery, development, and commercialization of innovative therapies for patients with cancer, immune-inflammatory, and other unmet medical needs. Celgene operates in more than 60 countries, has production units in the USA and Europe, and employees more than 8,000 people worldwide.



## Quick Facts

### Project

New Compounding Pharmacy for Canton Zürich Hospitals

### Location

Schlieren, Canton of Zürich, Switzerland

### Total Facility Size

115,000 sq ft

### Project Mission

Replace two outdated hospital pharmacies with one state-of-the-art facility that would meet the current needs while remaining flexible enough to adapt to future needs; strengthen consulting services, education, and training of pharmacists; and modernize pharmaceutical hospital standards to comply with the advancements in science and technology.

# Operational Excellence

## Kantonsapotheke Zürich



**FOYA** | 2019

Facility of the Year Awards

CATEGORY WINNER  
Operational Excellence

## WHY THEY WON

*Kantonsapotheke Zürich replaced and integrated two outdated hospital pharmacies, logistics, warehouses and QC/microbiological-labs with facilities that are flexible, adaptable, and easily expandable, to accommodate new functions. All products are manufactured under industrial cGMP conditions and the operators have achieved an astonishing 60-90-minute turnaround time from diagnostic test to patient delivery. Kantonsapotheke Zürich sets new standards for community participation, financial engineering, technology advances, compounding pharmacies, and personalized medicines and last but not least in project speed and management.*



## Meeting the Needs of a Growing Population

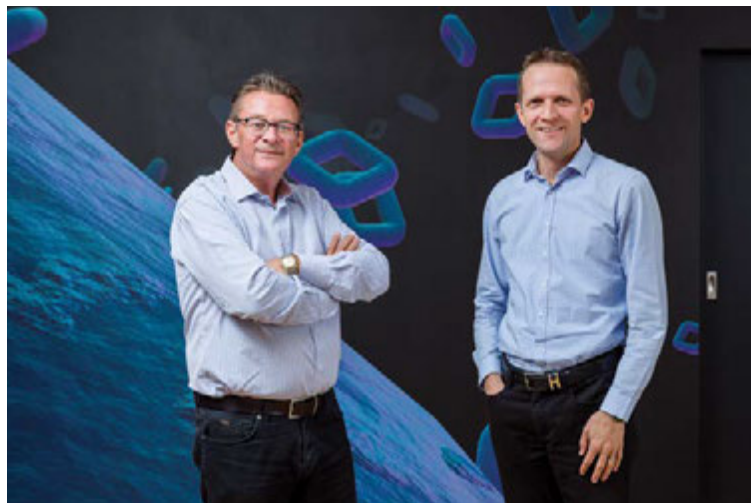
Just a few years ago patients of Schlieren's two largest hospitals often had to wait for a long time before receiving the medicine they needed. "The old facilities were not reliable anymore," said Heinz Obertüfer, a pharmacist, economist, and pharmaceutical manufacturing leader in Zürich. "They had many deviations with the medicines and it always took a long time to investigate and ensure that products were safe and reliable. Sometimes they had to throw batches away; sometimes they did not have the right product available. Today patients are getting the medicine they need on time."

Obertüfer worked with a team of pharmacists, business people, and regulatory officials to develop the over-riding strategy, technical solutions, and business model which would ultimately replace the outdated facilities with one that could meet the current and future needs of the population.

## Setting New Standards

By replacing two outdated hospital pharmacies Kantonsapotheke Zürich (KAZ) is now also capable of producing more than 500 regular formulations of creams, ointments, sterile products, and oral medicines. In addition, KAZ produces over 40,000 cytostatic doses and cytostatic compounds a year, a very important volume that increases about 10% every year. While this production may seem small overall, it is important to note that there is a lot of variability and individuality with the medicine produced at KAZ and everything adheres to the highest level of cGMP.

Integrating the two facilities allowed KAZ to eliminate numerous unnecessary or redundant operations and optimize personnel and material flows with a focus on short distances, unidirectional flows, and a minimal number of transport activities. Along with providing patients at both hospitals with medicine on demand, KAZ also supports clinical studies by offering custom drug manufacturing, maintains an extended stock of drugs, provides expertise to the hospitals, and serves as the main center of pharmaceutical expertise in the region. If needed, KAZ can manufacture various additional advanced therapy medicinal products.



## ISPE DRUG SHORTAGE INITIATIVE

Kantonsapotheke Zürich is recognized by the ISPE Drug Shortage Initiative for the positive contributions their innovative facility may deliver toward alleviating drug shortages in the future. This facility is an inspiring model for pharmaceutical compounding of the future, while at the same time presents advanced capability and flexibility to offset shortage situations or address gaps created by discontinued products.



### An Industry First

“When we were talking about the vial filling during the design process, I knew I wanted to change to robots wherever possible,” said Obertüfer. “As a result, we designed, together with our machine supplier, a vial filling machine that is different from conventional filling machines and operated by robots. It is very easy to changeover and very flexible. This was probably the first machine of its kind on the market.”

This revolutionary robot is used for automated and segregated production of sterile drugs. It enables KAZ to increase production capacity as needed and has helped reduce the number of highly classified containment areas. The machine can handle a broad range of primary containers and be changed from one to the other in less than 30 minutes by staff with limited technological knowledge.

Another very important step was the implementation of robots in the aseptic manufacturing of cytostatic drugs. Two redundant robots replace manual work, previously done in safety workbenches, while making a big step forward in personnel safety and process reliability.

In addition, CIP/SIP systems were introduced to automate cleaning processes. This replaces manual processes by validated ones that are performed overnight, therefore increasing manufacturing day capacity.

Additionally, KAZ has completely removed paperwork from the classified areas by introducing a validated manufacturing execution system that is able to handle records in a secure and compliant manner.

### Improved Layout

Not only did KAZ set up a new pharmaceutical building to meet the current needs of the population but it also reorganized the organizational setup to ensure lean structures and clear responsibilities. It redefined and reengineered all operational procedures and processing steps to achieve full GMP compliance and to ensure that everything was up to the latest standards in operational safety and IT security.

To make sure that operations run smoothly, KAZ is designed with a layout that combines all manufacturing activities on one floor with short distances from each other and a high degree of operational flexibility. This concept brings along the added benefits of improved GMP compliance and reduced operational deviations.

The production floor has four segregated manufacturing areas: one for non-sterile creams and ointments, another for cytostatic drugs, a third for sterile dosage forms that need aseptic processing, and a fourth for manufacturing terminally sterilized products. The design of the space guarantees the shortest delivery time possible and a consistently high level of operator safety and product quality.

The facility was designed with full-height glass wall panels. This allows natural light in and enables employees to see what’s going on throughout the facility, keeping them integrated and informed in the work process and making it easier to exchange information.

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Couvet, Canton of Neuchâtel, Switzerland
- ▶ **Pfizer Project Execution & Facility Integration**  
Bosch Sterilization  
Hangzhou, China
- ▶ **Kantonsapotheke Zürich Operational Excellence**  
Bosch Media Systems  
Schlieren, Switzerland
- ▶ **AveXis Honorable Mention**  
Bosch Fill/Finish  
Chicago, Illinois USA



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## Planning for the Future

KAZ has already increased the standard of living in the Canton of Zürich by giving the community the assurance that a stable supply of specialized medicines will be available when needed. Part of their ongoing mission includes setting a new standard for hospital pharmacy operations in GMP while continuing to pursue new ways to serve patients and to drive further improvements. The facility is ready to adapt to the needs for personalized medicine and new manufacturing techniques and to support the innovation of new drug therapies.

“KAZ will use this project as an example for future ones to improve and standardize manufacturing. The project lifts the basic concept of the hospital pharmacy into the scientific and technological future, creates a benchmark for other pharmacies around the world, and has quickly become a beacon for the way pharmaceutical therapeutics can be effectively delivered to patients,” said Obertüfer. “Overall KAZ embraces some ambitious and noble goals to not only provide a drug supply system to the public health system but also to contribute to scientific advancement and improvement of cGMP standards, to prepare for the provision of novel therapies, and to redefine the profession of pharmacists to become drug knowledge managers and consultants.”

## Key Project Participants

### **Manufacturer/Owner Name**

Kantonsapotheke Zürich

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

LH Partner Architekten AG; Exyte

### **Construction Manager**

Meili Bauconsulting AG

### **Main/General Contractor**

GHZ Schlieren AG

### **HVAC Subcontractor**

Hälg & Co. AG

### **Automation and Control Supplier**

HCS controls AG

### **Major Equipment Supplier(s)/Contractor(s)**

FrymaKoruma AG; Pharmatec GmbH, A Bosch Packaging Technology Company; Steriline S.r.l.; Loccioni, Sede principale; RETEL Neuhausen AG; Getinge; Ortner Reinraumtechnik GmbH; Kiefer technic GmbH; SKAN AG; Mettler-Toledo (Schweiz) GmbH; PLÜMAT PACKAGING SYSTEMS; Müller AG Cleaning Solutions; PAGO AG; Seidenader Maschinenbau GmbH; HCS Controls AG

## ABOUT THE COMPANY

Kantonsapotheke is one of the leading centers of hospital pharmacies in Switzerland. They offer a broad spectrum of pharmaceutical services using the latest technologies and most up-to-date pharmaceutical knowledge. Kantonsapotheke Zürich provides the Canton of Zürich hospital system a range of oral, dermal, and parenteral formulations, often with patient specific recipes.

*G-CON prefabricated cleanroom PODs, a new standard of delivery speed and budget certainty.*

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The G-CON team congratulates AveXis on achieving a major industry milestone. Their passion motivates us and we look forward to continuing our relationship.

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## Quick Facts

### Project

AveXis' Next-Generation Manufacturing Facility for its Next-Generation Medicine

### Location

Chicago, Illinois, USA

### Total Facility Size

49,000 sq ft

### Project Mission

Build a state-of-the-art manufacturing facility where AveXis could produce life-saving gene therapy treatments.

# Honorable Mention

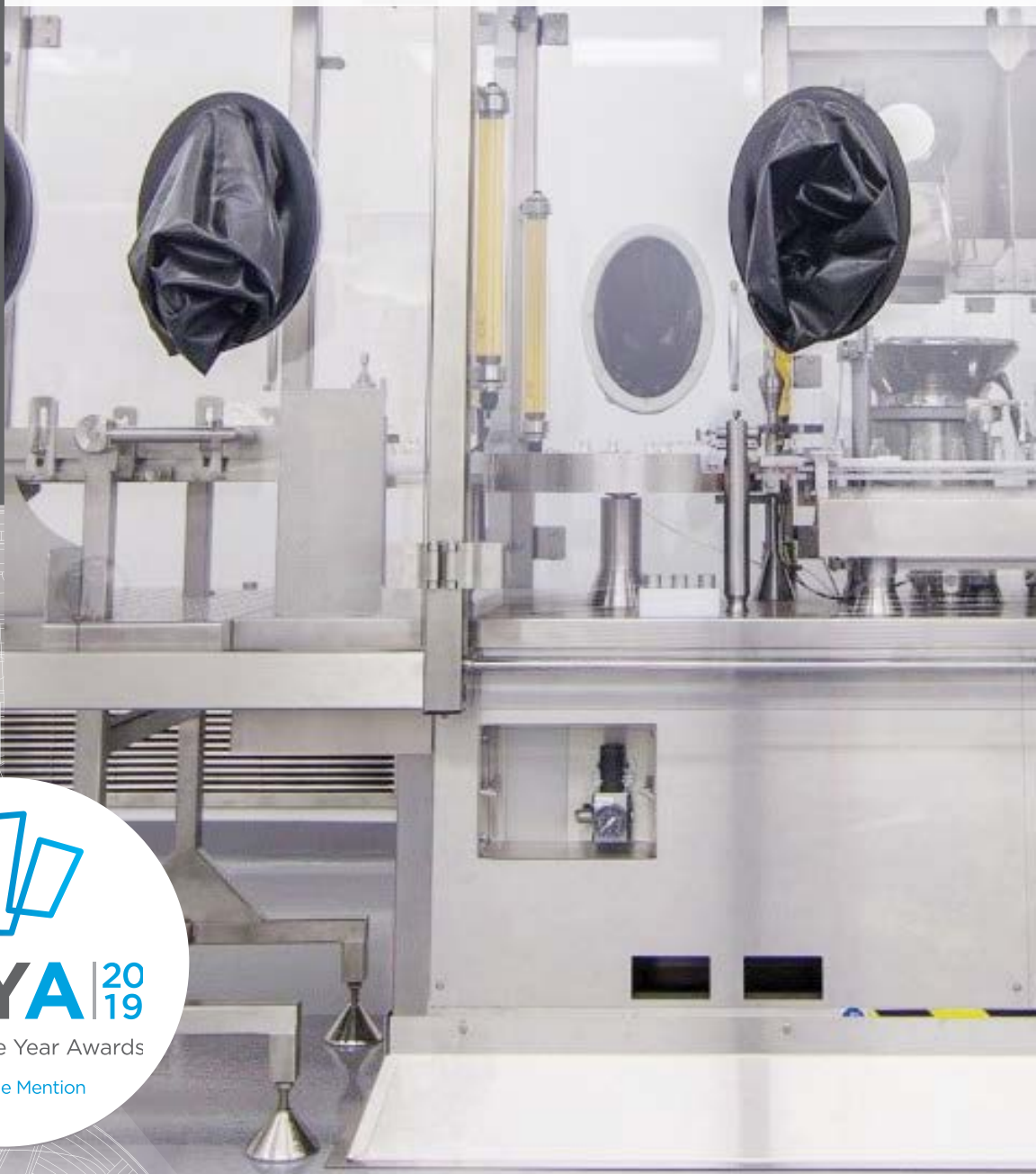
## AveXis, Inc.



**FOYA** | 2019

Facility of the Year Awards

Honorable Mention



## WHY THEY WON

*AveXis is one of the first companies to successfully scale-up the manufacturing process for gene therapy from an academic process to a commercial level. They were able to do so with innovative execution while meeting the deadlines of a very aggressive timeline.*



## AveXis Gene Therapy Facility Makes Next-Generation Medicine Now

AveXis was founded in 2013 to research and develop gene therapies for rare and life-threatening neurological genetic diseases. Two years later, they found themselves with enough promising safety and efficacy data that they were ready to ramp up production of AVXS-101, a one-time dose gene replacement therapy for infants born with spinal muscular atrophy (SMA), the leading genetic cause of infant mortality.

“In order to achieve our mission of bringing change to those devastated by genetic diseases, we knew we had to start moving our gene therapy research out of the lab and into the clinical setting,” said Andy Stober, Senior Vice President, Technical Operations & Chief Technical Officer, AveXis. “Since that time, we’ve treated more than 160 patients with Zolgensma® (onasemnogene abeparvovec-xioi) (formerly known as AVXS-101) and are excited for the future of what one-time gene therapy treatments could mean for patients devastated by rare genetic disease, like SMA.”

## Customized Equipment and Technology

AveXis wanted to make sure that they had a facility that was capable of producing gene therapies for commercial distribution as well as gene therapies needed for ongoing and future clinical trials. The unique manufacturing facility includes modular, single-use technology, and cutting-edge manufacturing equipment in a novel space. Among the more than 200 different pieces of equipment in the facility, the most critical were the modular cleanroom PODs, multiple bioreactors, chromatography and tangential flow filtration (TFF) skids, and fill and finish operations.

AveXis did not have the benefit of case studies to follow and had to forge their own way. They decided to use equipment that had previously only been used for research and development and to partner with the suppliers, G-CON and Bosch, to revamp the equipment for clinical and commercial operations. Much







of the equipment, such as the bioreactors, had to be customized or completely redesigned for the facility. The AveXis leadership team was integrated into every aspect of the equipment redesign.

## New Facility Design for New Generation of Medicines

AveXis' novel manufacturing facility is modular-based with portable cleanrooms, uses cutting-edge equipment and systems that are among the first of their kind in the industry, and is one of the first gene therapy companies to use the specific bioreactors for manufacturing rather than R&D. Because the facility is POD-based, it is portable, and most of the PODs can be shipped to a new facility if needed. The modular cleanrooms were designed to be moveable and scalable to account for future growth and the global demand for gene replacement therapies.

## Meeting Deadlines to Save Lives

Throughout the development and construction phases, AveXis remained focused on the end result—saving the lives of their patients. In an effort to remind everyone of the purpose behind the facility, the leadership team provided the manufacturing team with clinical updates from the ongoing studies in babies with SMA and hung photos of patients in the project team's office.

AveXis wanted to get the new facility up and running as quickly as possible so that they could meet timelines for AVXS-101 regulatory filings and bring this potentially transformational therapy to babies with SMA. AveXis worked in partnership with several other companies with pharma manufacturing expertise, but thanks to in-house knowledge, an early decision to invest in manufacturing, and a commitment to a wholly-owned and operated facility, AveXis was able to create its manufacturing facility for ongoing Good Manufacturing Practice in only 15 months.

Another way that AveXis saved time was by choosing the location and selecting the appropriate equipment simultaneously. The team selected G-CON's modular cleanroom PODs because they were able to supply the cleanrooms in the timeframe needed and even began building the modular cleanroom PODs before the final location was selected.

Because of their dedication and time saving solutions, AveXis was able to develop enough AVXS-101 inventory to be ready for a commercial launch in 2019—the therapy was approved on 24 May, 2019—and they have already helped more than 150 patients.

## Making Gene Therapy History

Historically, gene therapy companies have found it challenging to evolve the manufacturing process



used in research to one scaled to meet commercial demand. AveXis established a foundational process for manufacturing of gene therapies and will be able to replicate it for future gene therapy products including additional types of SMA, Rett syndrome, and a genetic form of amyotrophic lateral sclerosis (ALS). Manufacturing gene therapies in-house, rather than at a CMO, provides AveXis with much needed control, gives them the ability to make decisions quickly, and decreases production costs.

In fact, demand for AveXis' gene therapies is so in demand that they have already replicated their facility and equipment design approach. They are developing a similar facility in Durham, North Carolina, using the same cutting-edge equipment on a larger scale, where they will be able to simultaneously produce gene therapies for SMA, Rett syndrome, and a genetic form of ALS.

“At AveXis, we share a commitment to teamwork, tenacity, and integrity—values that were essential to the design and construction of this state-of-the-art facility,” said Stober. “We are proud to pave the way for the industry and to continue pioneering the research and development of gene therapies for patients with rare and devastating genetic diseases. This is only the beginning for AveXis.”

## Key Project Participants

### **Manufacturer/Owner Name**

AveXis, Inc.

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

George Butler Associates

### **Construction Manager**

CRB Builders LLC

### **Main/General Contractor**

Riley Construction Company Inc.

### **Piping and HVAC Subcontractor**

Martin Peterson Company

### **Automation and Control Supplier**

Matrix Technologies

### **Major Equipment Supplier(s)/Contractor(s)**

G-CON Manufacturing, Inc.; Bosch; Millipore; Pall Biotech

## ABOUT THE COMPANY

Founded in 2013, AveXis, Inc. is a gene therapy company dedicated to developing and commercializing novel treatments for patients suffering from rare and life-threatening neurological diseases including spinal muscular atrophy (SMA), Rett syndrome, and a genetic form of amyotrophic lateral sclerosis (ALS).

## Quick Facts

### Project

Georgia Manufacturing Facility

### Location

Social Circle, Georgia, USA

### Total Facility Size

1,100,000 sq ft

### Project Mission

Build a manufacturing facility that could meet the current demand for Takeda's plasma-derived therapies, expand to adapt to increased demands, and support the emotional, physical, and financial well-being of employees while adhering to strict safety standards.

# Honorable Mention

**Takeda** *(formerly Shire)*



**FOYA** | 2019

Facility of the Year Awards

Honorable Mention

## WHY THEY WON

*The new facility is the cornerstone of a global strategy to ensure patients world-wide have access to Takeda's medications. The project brought together an unprecedented collaborative effort of subject matter experts from around the world to successfully design, develop, and construct a state-of-the-art facility that not only meets Takeda's production goals but positively impacts the wellness of employees and was built with a stellar safety record.*



## The Fight Against Rare Diseases has a New Champion

Every year millions of patients depend upon plasma-derived therapies obtained through plasma fractionation processes. To meet the growing global need for these life-saving therapies, Takeda built a 1.1 million square foot manufacturing facility on 160 acres in Social Circle, Georgia.

### Time Saving Solutions

In order to complete one of the largest greenfield site projects in the United States, Takeda relied upon an exemplary management team, innovative risk management strategies, and excellent communication and brought together experts from around the world—two construction managers, three design firms, and 250 subcontractors.

Even before determining the location of their new facility, Takeda's "volunteer army" was hard at work developing

the design. "A key to the success of the project was the team's ability and ingenuity to deliver a flexible basis of design that could be adapted to any one of the multiple sites being considered," said Eric Schnake, Head of Engineering for the Georgia Manufacturing Facility project. This meant that as soon as the site was selected, Takeda was ready to move to the next stage and immediately begin detailed design and execution; however, even this required quick decision making if they hoped to complete the project on time.

To keep the momentum going, the management team established a system of workshops known as "Jamborees". Once a month, stakeholders, subject-matter experts, and more than 40 design professionals gathered together for a week to make sure everything was moving forward on time and to made design decisions.

Another way that Takeda managed to save time and keep the project on track was through the use of a cloud-based system to manage issues and changes. This made communication more efficient and allowed more than 7,000 issues to be resolved saving hundreds of thousands of dollars and weeks on the project schedule.





## Safety as a Top Priority

From the very beginning of the project the health and safety of everyone involved was a top priority. The project's safety program combined the best practices of each of the construction management companies, formed a voluntary partnership with OSHA, and encouraged leadership to become a driving force for safety through funding of safety initiatives and recognition programs. Because of their success, the project was awarded the 2015 CURT CISE Safety Excellence Award by the Construction Users Roundtable.

"The project's design and execution as well as its impeccable safety record, have set a new standard for the industry. With 2,500 people on the construction site, our commitment to safety was uncompromising and resulted in more than nine million staff hours over a period of four years with zero fatalities and only three cases of lost workdays," said Schnake. Gunter Baumgartner, Head of Global Engineering added, "This year's FOYA Honorable Mention Award for our Georgia Manufacturing Facility project in terms of the highest safety culture and achievement during the construction phase is further great recognition for Takeda's engineering project execution."

Takeda also made sure that safety would be of ongoing importance. State-of-the-art technologies and anti-counterfeit protections put in place increase overall safety of the batches and protect patients. These innovative solutions ensure the facility will be safe and efficient for years to come.

## Designing for Employees

The facility is designed to improve not just the office and amenity spaces, but also the manufacturing and support environments. The facility is surrounded by trees and greenspace and the design incorporates the external environment into interior workspaces so that all workers can view the outside and are exposed to natural light.

## Designing for the Environment

Throughout the design process the project team was committed to sustainability by improving the use of resources and making energy-efficient choices, reducing the environmental impact of the facility, improving indoor quality, and minimizing construction waste. An impressive 89% of construction debris was recycled.

Some of the energy-saving features that were incorporated into the high-performance building include shade systems, an under-floor air distribution system, an active chilled beam system and air rotation towers, and re-use of reject process water. Because of the team's commitment to the environment, the facility has received three Green Globes from the Green Building Initiative.

## Designing for Product Needs

Before they installed any equipment or finalized design plans, the team modeled the manufacturing processes through simulation. This allowed the process engineering team to identify bottlenecks in the operation and propose solutions to eliminate or reduce those impacts.

# We get your facility *online faster.*

**CONGRATULATIONS TO OUR CLIENT TAKEDA  
FOR A 2019 FOYA HONORABLE MENTION.**

**We are proud to have been a part of this successful project!**  
We are excited for what the future holds for Takeda  
and their expanding facilities and capabilities.



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The design team was able to reduce the fractionation cycle time by 18% versus other facilities in Takeda's network, resulting in the ability to produce 18% more batches per year. This increased manufacturing efficiency and utilization and enabled greater flexibility in responding to supply chain needs.

The Takeda Georgia Manufacturing Facility is one of the largest plasma fractionation sites in the world, the facility is licensed by the FDA for distribution in the United States, with future plans for licensing and distribution into China and European markets.

"Designing and delivering a greenfield pharmaceutical facility has been one of the greatest and most satisfying challenges of my career," said Schnake, "seeing it start up and begin commercial manufacturing of life-saving products for Takeda's patients makes me feel very proud of our achievement."  

## ABOUT THE COMPANY

Takeda is a global, values-based, R&D-driven biopharmaceutical leader headquartered in Japan, committed to bringing Better Health and a Brighter Future to patients by translating science into highly-innovative medicines. Takeda focuses its R&D efforts on four therapeutic areas: Oncology, Gastroenterology (GI), Neuroscience, and Rare Diseases. Takeda also makes targeted R&D investments in Plasma-Derived Therapies and Vaccines.

## Key Project Participants

### Manufacturer/Owner Name

Takeda (formerly Shire)

### Engineer/Architect (A&E)

Flad Architects; Affiliated Engineers Inc.; CRB Consulting Engineers

### Construction Manager

Fluor Corporation; Turner Construction Company

### Piping Subcontractor

Kinetics Systems, Inc.; Total Facility Systems

### HVAC Subcontractor

McKenneys Inc.; Ivey Mechanical Company

### Automation and Control Supplier

Emerson Process Management; Honeywell Building Solutions

### Commissioning and Qualification

Commissioning Agents Inc.

### Program Management

Wood Environment & Infrastructure Solutions, Inc.

### Major Equipment Supplier(s)/Contractor(s)

GEA Mechanical Equipment US Inc.; Optima Pharma GmbH; SKAN; Sepragen Corporation; Eastern Rivers; Integrated Process Engineers & Constructors, Inc.; Cotter Brothers Corp.; Inox Industries; Feldmeier; DCI; A & B Process Systems; Electrol Specialties Company; Cotter Brothers Corp.; Babcock & Wilcox MEGTEC LLC; Johnson Controls; MECO, Inc.



“What we do at ISPE is share pharmaceutical knowledge to ultimately save lives. This is our maxim, our reason for being.”

—John E. Bournas,  
ISPE CEO and President