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18

Facility of the Year Awards

2018 Category Winners

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Facility of the Year Awards

## Category Winners

Facility Integration <b>Shire</b>	5
Facility of the Future <b>Vetter Pharma-Fertigung GmbH &amp; Co. KG</b>	9
Operational Excellence <b>Shire</b>	15
Project Execution <b>BioMarin Pharmaceutical Inc.</b>	19
Sustainability <b>Wyeth Pharmaceuticals Co., a Pfizer Company</b>	25
Honorable Mention <b>Emergent BioSolutions, Inc.</b>	31
Honorable Mention <b>Government Pharmaceutical Organization (GPO)</b>	35

## Advertiser Index

Airplus Apply Co., Ltd.	34
Commissioning Agents, Inc.	Inside Back Cover
CRB	Back Cover
Factorytalk Co., Ltd.	34
Government Pharmaceutical Organization (GPO)	13
ISPE	38
Kinetics	29
MECO	24
Novo Construction, Inc.	20
PM Group	Inside Front Cover
Rosendin Electric, Inc.	30

# 2018 FOYA Awards: Honoring Innovation



*Antonio "Tony" Crincoli*

This is the fourteenth year that pharmaceutical industry leaders have convened to consider contributions from individual projects submitted for the annual Facility of the Year Awards (FOYA).

FOYA winners represent organizations large and small in the pharmaceutical, life sciences, and medical device industries. FOYA judges have extensive experience in engineering, manufacturing, supply chain, and quality; most have international responsibilities. They are experienced, knowledgeable, and understand the global landscape.

## The Judging Process

The process starts each January with a one-day meeting to review submissions that are submitted to ISPE in the fourth quarter of the preceding year. Submissions come from all corners of the world and represent projects in the pharmaceutical, medical, and biologic fields. Judges nominate one project for each award category; if no project is found to demonstrate excellence in a category, it is not awarded that year.

Judges review each submission, screening for compliance with program requirements and determining whether the project is novel. They then discuss each project's merits within the category, and consider whether it could also qualify in another category. Using a template to help them catalog their analyses, each judge's assessment is weighed and reviewed in detail. This process allows for much dialogue, listening to each judge's input, as well as assessing and determining whether the project is novel. It also provides an opportunity for them to apply their expert judgment, discuss industry trends, and consider how they are reflected in the submission.

Judges apply 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? Judges also use their internal and external networks



## Facility of the Year Awards 2018 Category Winners Spotlight on Excellence

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to benchmark the project information and ensure the stated outcomes were achieved. Safety and its role during project execution are key areas of focus. This reflects the judges' experience that projects with a strong safety record will have better overall performance.

After identifying the winners for each category, judges choose one as the Overall Winner. The selection of the Overall Winner includes several rounds of discussions, followed by a series of secret ballots. Once winners have been selected, judges are sworn to secrecy.

## And the Winners Are ...

This year, the category winners were announced at the 2018 ISPE Europe Annual Conference in Rome, Italy. The Overall Winner will be revealed in November during the ISPE Annual Meeting & Expo in Philadelphia, PA, USA.

FOYA winners vary—most are smaller projects that improve quality and efficiency, reduce cost, improve transfer of new products, or implement new information technology solutions. Entrants are not required to be large companies. Judges understand that these projects are critical to the success of the business at each facility, so innovation is a central focus, not the size of the organization.

While there are defined category winners, judges reserve the right to recognize projects with an honorable mention. These are clearly successful projects that overcame significant challenges in planning, execution, and delivery. In 2018, there were two Honorable Mention awards.

## Lessons Learned

Although I've been part of the FOYA Judging Committee for several years, this was my first year leading the committee. Many thanks to Jim Breen for doing so over the past five years. Having a group of leaders at these sessions allows us to share industry trends, discuss lessons learned from these projects, and explore how we can communicate these best practices across the entire ISPE membership to advance the industry. I believe all the judges have learned a great deal in reviewing these projects from technical and execution points of view. We will all perform our duties better and more efficiently leveraging the collective industry knowledge.

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 increases.

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. FOYA allows us to recognize efforts of those that have done so.

*Antonio "Tony" Crincoli is Chair, FOYA Judging Committee and Vice President, Global Engineering, Glenmark Pharmaceuticals*

# Facility Integration

## Shire



## New Plasma Fractionation Facility Fits Right In

Building a new facility to relocate existing processes is a major undertaking. Now consider the challenge of building that facility a) within a confined space, b) without disrupting existing operations, c) while staying under budget, and d) adding new capabilities. Shire, a global biotech company focused on developing treatments for underserved patient communities, especially those living with rare diseases, did just that at its campus in Los Angeles, California. The facility is one of the largest plasma fractionation sites in the world.

### Tight Quarters

The campus is situated on 11.6 acres in a light industrial zone on the edge of Los Angeles. Before the new construction was commissioned in 2010, the complex was home to seven buildings and a parking garage. Building 8, a 120,000 square foot facility, was added to house the purification process for two commercial products. The project was also designed to improve material and personnel flows.

## Quick Facts

**Category Winner**  
Facility Integration

**Project**  
Los Angeles Building 8

**Location**  
Los Angeles, CA, USA

**Project Mission**  
Construct and license new purification suites to replace current capacity with more efficient operations in a more robust building.

## JUDGES' PANEL CONCLUSION

*Application of excellent and innovative design practices as well as superior planning led to the successful integration of this new facility into an existing operational campus.*



Prior to the construction of Building 8, the purification steps for these products were performed in Building 1, a structure that predates acquisition of the property in 1952. “Building 1 was constructed in the 1930s and was originally a warehouse,” says Brian Danahy, Engineering Director at Shire. “You can imagine that over the years, with process changes and equipment changes, along with expansion, it got to the point where the facility wasn’t the most optimal and efficient. So that is really what drove us to create Building 8, the purification building.”

*“Project execution success factors included lean construction concepts”*

Additional challenges were space constraints in every direction (north, south, east, west, elevation, and excavation), as well as occupancy limitations, which compressed the building layout to two above-ground floors. Ongoing manufacturing operations had to continue during construction, as well, which provided multiple opportunities for creativity and innovation.

The land on which Building 8 would sit was full of underground utilities such as electrical power distribution lines, a main sewer line, and main

site fire-protection distribution water line. “In the footprint of where Building 8 is now, there used to be a 100,000-gallon underground fire water storage tank. There were also temporary trailers on-site and utilities running under the driveway. All of those needed to be rearranged, and some of them had to be resized,” explains Danahy. Shire used the annual plant shutdowns to relocate and reroute underground utilities.

### Advanced Technologies

Project execution success factors included lean construction concepts such as working in a co-located space and utilizing advanced technologies. Offices for the entire Building 8 team, including the owner, designers, construction manager, key subcontractors, and the automation contractor, were co-located to accelerate decision-making and to promote the use of the latest in design and construction technologies. This saved time, saved money, and improved quality.





The project team used building information modeling (BIM) to model systems including conduit, hanger rods, and seismic bracing. Since designers and detailers worked side-by-side in the project's "BIM cave", the team was able to resolve over 10,000 "clashes" per week during the design phase. Users were able to review the 3D process design weekly and could even "fly through" the model to adjust equipment access and optimize process flow. As a result, complex system field installations were completed without any costly rework.

"BIM provides a 3D model so that you can locate all of the different parts in the building," explains Danahy. "In this project, we really took it to the level where we could see the individual rods that hold up the piping and the electrical outlets and conduits. It was really helpful in design to avoid clashes, but it was interesting in construction as well; they had a neat little device called a 'trimble' that uses lasers to pinpoint exactly where something is supposed to go. So it will show the guy in the field, for example, that this little laser spot is where the electrical outlet goes."

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*"The facility is one of the largest plasma fractionation sites in the world"*

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"The way BIM supported construction was really impressive," says Sam Kitchell, Vice President of Engineering at Shire. "I remember walking through and looking around for all of the changes, but there were virtually none because every wire, every pipe, and every conduit was already identified in the exact location. It was a very new look in observing the construction progress."

Perhaps the most unique management tool used by the project team was a proprietary Monte Carlo-based risk modeling software that allowed the team to simulate thousands of outcomes of potential problems. The models produced very accurate predictions of the likelihood and severity of schedule and cost impacts, allowing the team to develop mitigation plans to prevent them from affecting the project.

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*"The way BIM supported construction was really impressive"*

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One identified problem was the existing underground fire water storage tank, located directly within the new building's footprint. Although they explored multiple mitigation options, the team decided to build around the existing tank and keep it in operation until a new one was built adjacent to the building and commissioned. The old tank was then removed, and construction resumed without affecting plant operations or the building schedule.

## New Capabilities

In addition to purification processes, Building 8 includes a full GMP pilot plant that was built using modular construction to provide an extremely flexible operating environment. The HVAC, for example, allows any room to be operated at ambient to cold processing (< 0°C) temperatures. Critical utilities—WFI, compressed air, nitrogen, alcohol, and clean steam—are available via utility panels on the walls of the main production rooms. The ceiling was constructed in a grid to allow for easy relocation of lights and HEPA filters.



This pilot plant has already been used to create a bulk batch of an orphan drug. Only one bulk batch of this product is created every five years, so the flexible design of Building 8 GMP pilot plant was an ideal location to produce this product.

“We plan to use that area for future products and future clinical material as well,” says Danahy. “So I think that is a really nice flexible space that the campus will be able to use to create new products and to manufacture small batch products.”

## IN THEIR OWN WORDS

Building 8 was designed and built with significantly improved process, material, and people flow. Buffer preparation was removed from purification manufacturing and is performed in a dedicated area adjacent to the receiving area for quick transportation of raw materials. The west side of building on both production floors is utilized for people access and east side is used for equipment and material flow. This led to improved safety and efficiency of motion.

A major goal of the project was to not interrupt the ongoing operations at one of the largest plasma fractionation sites in the world. The project posed significant challenges with construction occurring in the center of an already congested 11-acre campus. There were no laydown areas and Building 8 wrapped around an existing building.

## Key Project Participants

### Manufacturer/Owner

Shire, Los Angeles, CA

### Engineer/Architect (A&E)

HDR, Pasadena, CA

CRB, Kansas City, MO

### Construction Manager and Main/General Contractor

DPR, Pasadena, CA

### Piping Subcontractor

Murray Co., Rancho Dominguez, CA

### HVAC Subcontractor

ACCO, Glendale, CA

### Automation and Control Supplier

Sasco, Fullerton, CA

### Major Equipment Suppliers/Contractors

Holloway, Springfield, MO

Sanimatic, Madison, WI

Central States Industrial Equipment, Springfield, MO

ABEC Inc., Bethlehem, PA

IEDCO, Turnersville, NJ



**FOYA** | 2018

Facility of the Year Awards

CATEGORY WINNER  
Facility Integration



# Facility of the Future

## Vetter Pharma-Fertigung GmbH & Co. KG



## Vetter Facility Sets New Standards

When organizations make capital investments to ensure the future, many choose to do what's necessary. Others decide to go above and beyond. Vetter Pharma-Fertigung GmbH & Co. KG chose the latter for its Center for Visual Inspection and Logistics, a state-of-the-art storage, inspection, and material testing facility that has set new standards for the pharmaceutical industry.

Vetter is a leading contract development and manufacturing organization in aseptic filling and packaging. The company supports customers from around the world from the early stages of clinical development to market launch and beyond. With industry projections pointing toward both increased demand for prefilled injection systems and increased global regulatory requirements, Vetter decided to build its RVW (Ravensburg Vetter West) facility.

## Beyond State-of-the-Art

Construction planning started in 2009. "We ran out of space at one of our existing sites and we needed additional capacity for growth, so the company decided to erect a completely new facility," says Thomas Ruebekeil, Vice President, Project Management. "We also wanted to improve all processes which were implemented there. We took the opportunity to build a new facility that

## Quick Facts

**Category Winner**  
Facility of the Future

**Project**  
Vetter's Center for Visual Inspection and Logistics

**Location**  
Ravensburg, Germany

**Project Mission**  
To erect an innovative center for visual inspection and logistics for the supply chain processes of tomorrow.

## JUDGES' PANEL CONCLUSION

*Application of excellent and innovative design practices as well as superior planning led to the successful integration of this new facility into an existing operational campus.*

is more than state of the art, where we would run extremely efficient processes and be flexible enough for further growth.”

The plan was to erect an autonomous site in Vetter's headquarters city of Ravensburg, Germany, that could act as a central hub for the company's logistical processes. The first construction stage was commissioned in 2012, followed by the second in 2016.

The concept for RVW is a supply chain with optimized product flows that incorporates perfectly harmonized processes. The site provides warehousing for cold-storage and room temperature products, capacity for freezers, constant-climate chambers, and state-of-the-art incubation chambers. Visual inspections can be performed manually or automatically.

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*“The concept is a supply chain with optimized product flows that incorporates perfectly harmonized processes”*

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Unlike many facilities, optimization starts from the moment materials arrive.

“We ensure the security of our customer's products, which arrive refrigerated between 2 and 8 degrees Celsius, as we have a seamless temperature door that is also refrigerated to between 2 and 8 degrees. This is quite unique for a warehouse,” explains Michael Schmitz, PhD, Vice President Planning and Logistics.

RVW also features a lab for packaging-materials testing, storage space for auxiliary materials, a central archive, and 200 office work stations. Departments and staff from an existing Vetter building were moved into the new location in 2017.

### Securing the Supply Chain

Guaranteeing cold-chain integrity for cold-storage products is crucial. Vetter achieves this through a variety of systems that are deployed and linked intelligently, guaranteeing predefined temperature

areas that are matched with the stringent requirements for pharmaceutical products.

The facility's high-bay storage area is divided into two temperature zones with automatic temperature and humidity control. There are 26,500 pallet spaces for room temperature products and 7,100 for cold-storage products. This allows substances, primary packaging materials, and filled-and-finished injection systems to be stored under current good manufacturing practice (cGMP) and consistent-climate conditions. “That means we have a cold zone (2-8°C) and we have a room temperature zone. And you will never find pallets mixed in any temperature zone,” explains Schmitz.

“For the logistical flow, we have short routes—direct connections between areas and automatization with conveyor belts in place,” Schmitz continues. “For example, we have a direct connection from the warehouse to the visual inspection area, which consists of manual visual inspection plus automatic visual inspections (AVI) machines. We have implemented a just-in-time process to supply the visual inspection so that we have very limited number of pallets sitting in front of the rooms or machines; we just have one-hour stock, and when the visual inspection is finished the pallets are put back into the warehouse immediately.”





In addition to the storage areas, RVW also has freezer capacity used for active pharmaceutical ingredients (API). There are seven chambers for storing raw materials, enough space for a total of 317 chest freezers. Each chest has a volume of 556 liters and storage temperatures that range from -20 to -80°C. The highly sensitive and very valuable pharmaceutical substances are stored in these chests under strict safety standards. To make sure the freezers are always in operation, RVW offers multiple emergency power supplies and backup chests.

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*“The facility sets new industry standards for transportation, warehousing, and quality assurance of pharmaceutical products”*

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To ensure the round-the-clock integrity of all products and processes within the facility, the Vetter team implemented an energy-supply system with an incredible six levels of backup. The facility’s basic power comes from two separate connections to the public grid. In the event of a failure, autonomous standby units can power the entire facility. Should these also fail, additional standby units, including a mobile 400-volt power unit, are available to supply all temperature-critical areas. “Each chest freezer is also connected to an automatic emergency liquid nitrogen supply,” explains Schmitz. “If all other backups fail and the power goes away, then we have a very big tank of liquid nitrogen outside and the system would then spray into the chest freezers so that the APIs do not thaw.”

In addition to its operational excellence, RVW was designed to operate in a highly sustainable,

environmentally friendly, and efficient manner. The basis for this is an ISO-certified environment, health, and safety program implemented throughout the company. The building’s holistic energy concept uses renewable energy sources and makes extensive use of recycled waste heat. Vetter was also able to improve on Germany’s strict energy-savings norms while meeting all regulatory guidelines.

International regulatory agencies have certified RVW’s cGMP quality standards. Since the facility was first commissioned in 2012, it has been inspected 19 times; 16 were completed successfully. Three others, including one by the US Food and Drug Administration and one by a local German authority in 2017, are still “waiting for acceptance.”

## Future Expansion

RVW was built with modular components, and has space available for future expansion, if required. “Our market leadership comes from our quality, so for us the quality of our processes is number one,” says Ruebekeil. “When we constructed and planned the facility, we looked at future trends, such as digitalization or smaller batch sizes, as well as trends from the regulatory side. What we have here at RVW is for the next 30 years, and I would say we can fulfill the upcoming requirements. But we don’t want to stop now; we are looking to see where we can further improve our processes. And that is what is happening now as we set the stage for the third planning phase.”

Vetter expects planning for the third RVW construction phase to take place in 2018. ■



## IN THEIR OWN WORDS

Vetter's RVW facility sets new industry standards for transportation, warehousing, and quality assurance of pharmaceutical products. It goes beyond simply meeting official worldwide norms and regulations, and takes these standards to a new level of excellence.

- RVW combines intelligent facility layout, state-of-the-art technologies, and innovative processes, so customers from around the world can be assured of the highest levels of efficiency, flexibility, quality, and safety in the supply chain.
- The facility has carefully designed space and optimal working conditions to guarantee that the visual inspection section produces a uniformly high level of quality and faster throughput times, regardless of batch size.
- The building's modular design allows for simple and gradual creation of more space without expansion work affecting operations. This architecture is a direct response to increasing customer demand for more capacity.
- Comprehensive safety and security measures and complex backup systems protect products from a number of potential risks, ensuring integrity of facility operations and supply.
- The facility's design concept includes rigorous energy efficiency and environmental friendliness, which guarantees sustainable, extremely safe, and hence future-oriented supply chain processes.

## Key Project Participants

### Manufacturer/Owner

Vetter Pharma-Fertigung GmbH & Co. KG,  
Ravensburg, Germany

### Engineer/Architect (A&E), Finishing Trades

Wassung und Bader Architekten, Tettnang, Germany

### Civil Engineers

Fassnacht Ingenieure GmbH, Wurzach-Arnach,  
Germany

Matthäus Schmid Bauunternehmen GmbH & Co KG,  
Baltringen, Germany

### Technical Building Equipment

Ingenieurbüro Sulzer GmbH & Co. KG, Vogt,  
Germany

### Electrical Engineering Measurement and Control

Ingenieurbüro Werner Schwarz GmbH, Ravensburg,  
Germany

### Monitoring

Yokogawa Deutschland GmbH, Mainz, Germany

### Piping Subcontractor Technical Building Equipment HVAC Subcontractor

Siegle u. Epple GmbH & Co. KG, Stuttgart, Germany

### Major Equipment Suppliers/Contractors

Brevetti CEA, spa, Sovizzo, Italy



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

## PROPOSAL DEADLINES

**2019 Deadline**  
28 November 2018

**2020 Deadline**  
18 November 2019

# Operational Excellence

## Shire



## State-of-the-Art QC Lab

Determined to deliver faster and more economical results and to instill a lasting culture of continuous improvement, global biotechnology company Shire is reinventing its world-class plasma manufacturing campus in Los Angeles. As part of that initiative, the company relocated its quality control (QC) lab to another building to thoroughly examine and refine its QC processes and design a next-generation lab that may set a benchmark for the pharmaceutical industry.

Founded in 1986, Shire focuses on developing treatments for underserved patient communities, especially those living with rare diseases. The Los Angeles campus, which manufactures treatments for primary immunodeficiency, hemophilia A, fluid imbalance, emphysema, and infant botulism, is one of the largest plasma-fractionation sites in the world. The complex and sensitive nature of these processes mean that the company is highly dependent on its internal quality control capabilities.

With the existing QC lab located in a building slated for demolition, the company selected a 16,000-square-foot area within an office building as its new home. The new location will permit future expansion. In addition to supporting the Los Angeles manufacturing operations, this QC lab will support other Shire facilities.

## Quick Facts

**Category Winner**  
Operational Excellence

**Project**  
Shire Los Angeles  
Quality Control  
Laboratory

**Location**  
Los Angeles, CA, USA

**Project Mission**  
Build a new QC lab to replace current capacity with a modern, lean, innovative, and efficient QC laboratory.

## JUDGES' PANEL CONCLUSION

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*We were impressed by the various elements of the project, which were all grounded in the spirit and ethos of operational excellence. The project was developed in a thoughtful, methodical manner and relied heavily on incorporating lean principles in every aspect of project execution, as well as in the day-to-day operation of the laboratory*

---

To enable this capability, Shire has fully decoupled the QC lab from Los Angeles manufacturing operations and infrastructure.

### Deconstructing All Processes

From the project's inception in April 2015, the goal of the Shire QC team was clear: Redesign their QC operation to deliver faster and more economical results while instilling a culture of continuous improvement.

Under the mentorship of their Lean Six Sigma Master Black Belt, the team went through a series of kaizen\* events to map out current operational flows, identify improvement areas, and eliminate wasteful practices. Together, the team developed the guiding principle that all processes had to be simple and clear, with direct customer-supplier connections.

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*“The team used kaizen events to map out operational flows, identify improvement areas, and eliminate wasteful practices”*

---

“We put together a task force made up of lab analysts, supervisors, managers, the QC lab director, and myself to go through every aspect of the QC lab,” says Bert Chai, Associate Director of Engineering at Shire. “There are three main areas of our QC lab—a biochemistry lab, a microbiology lab, and lab support, which supports the incoming samples materials and how they flow. We looked at how many samples we needed to test. We looked at how samples arrive, in what format, and by what transportation method, and then recorded how many samples are coming in at a time, how much space we needed, and so on. We painstakingly analyzed every step of the process.”

---

\*Kaizen (Japanese: “change for better”)—the practice of continuous improvement; industrial or business techniques for implementing continuous improvement; “kaizen events” are short-duration projects with a specific aim for improvement.

“It took a few months to come up with a solid game plan,” continues Chai. “Then we started doing spaghetti diagrams and realized that we have waste in our process from lack of flow. So we went through and finally came up with very efficient unidirectional flow diagrams. Then, with the designers, we went through many different iterations of the floorplan. And that’s how we came up with the efficient layout.”

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*“We painstakingly analyzed every step of the process”*

---

Construction began in January 2017 and was completed in seven months. The design was developed with exceptionally clear lines of sight, offering increased safety, quality, and efficiency. Management stations at a central hub in the transparent facility enable management to identify and respond to issues rapidly.

While the traditional isolated, low-visibility laboratory concept required the use of a two-person “buddy system” to ensure safe operations, the new design







allows team members to pursue individual tasks while being visually connected to the entire group. Not only do these connections promote a shared sense of pride in team accomplishments, but the natural light and breathtaking views of the city and hillsides elevate the work environment.

“We are very pleased with the end result of how the physical lab came together,” says Chai. “We are pleased with the aesthetics of the lab—it is very bright, open, and cheerful—as well as its efficiency. We use a just-in-time process, so anything that we don’t need in this lab can be stored in the warehouse or at our supplier’s warehouse. So we really don’t have a lot of waste. We have computerized as much as we can and there are a lot of visual displays to communicate. We are proud of what came out of our whole team effort.”

## Optimizing Space

The QC team also evaluated the space required for each analyst. As part of their effort to eliminate as much waste as possible, they decided to move away from the one-desk-per-person model found in most laboratory operations. “We came up with the whole idea of a hoteling concept,” says Chai. “Rather than each person having their own dedicated lab space, we decided to give everybody a laptop and have them share workspaces. Since this is a 24/7 operation, once analysts’ shifts are done, they take their belongings and laptops home with them.” This shared workspace or “hoteling” approach reduced capital investment and reinforced teamwork while conserving space and maintaining the showcase appearance of the new lab.

The results have been well received by all involved in the lab’s day-to-day functioning. “The satisfaction and acceptance of the people who are now working in this different paradigm is incredibly high, and I think that is because of the exceptional collaboration of the end users,” says Sam Kitchell, Vice President of Engineering at Shire. “They see their fingerprints all over this project just as much as the project team. They are now getting to live and work in the environment that they helped create, and that is a special thing, from my perspective.”

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*“Shared workspace reduced capital investment and reinforced teamwork”*

---

“This is true teamwork and the entire team contributed to the design” says Chai. “It’s not like we asked people for their help to come up with ideas or said, ‘Come to our kaizen event so we can make sure that we are lean and mean without any waste.’ No, they were all very happy to come and help. We discussed everything, and we challenged people and departments, so it was cooperative team effort, and everyone was happy to do it -- and they are certainly happy to have this new lab on-site.”

A benefit not initially envisioned by the project team is increased capacity. “When we first started discussing this move,” says Kitchell, “in the context of the lab, we were concerned about whether or not we could handle the capacity for just that location. By the end of the project, through all of the activities that led to this very efficient design, we actually found that we could now take testing volume from other sites. So by changing the way we work, we not only met existing capacity needs, but created



additional capacity through efficiency. For me, that's one of the tangible outcomes that makes me most proud.

"At Shire," Kitchell concludes, "we have to invest our capital wisely to create the infrastructure we need. This project was really a great example of making dollars count—not just to meet the immediate needs of the business, but to drive improvement and better serve our patients." ■■■■

## IN THEIR OWN WORDS

To deliver faster and more economical results than current industry QC laboratory workflow models, as well as to embody a lasting culture of continuous improvement, Shire's QC team used this opportunity to reevaluate their entire operation through a lean perspective. As a result, the team developed the guiding principles that governed the development of the facility's design and operation—all processes need to be simple and clear, with direct customer-supplier connections.

Shire's new quality control laboratory not only embodies our industry's future through its planning process, strategically open plan, and transparent design, it expresses an innovative operational model, enables lean processes, and exemplifies advancement and ingenuity in quality testing environments for the pharmaceutical industry. Through automation, continuous processing, and increased connectivity, the design team utilized many opportunities to adopt emerging and current technologies to enable a faster and more efficient operation.

## Key Project Participants

### **Manufacturer/Owner**

Shire, Los Angeles, CA

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

Flad Architects, Madison, WI

CRB, Carlsbad, CA

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

DPR Construction, Newport Beach, CA

### **Piping Subcontractor**

Murray Company, Rancho Dominguez, CA

### **HVAC Subcontractor**

Limbach, Seal Beach, CA

### **Automation and Control Supplier**

Siemens Industry, Inc., Cypress, CA

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

Morrow Meadows Corporation, Walnut, CA

LabCrafters, Inc., Ronkonkoma, NY



**FOYA** | 2018

Facility of the Year Awards

CATEGORY WINNER  
Operational Excellence

# Project Execution

## BioMarin Pharmaceutical Inc.



## Keeping the Faith

### Gene-Therapy Facility Completed in 11 Months

Based in Novato, California, biotechnology company BioMarin Pharmaceutical is a leader in the development and commercialization of biopharmaceuticals for rare diseases with genetic causes. Its pipeline is robust, with several therapies at various stages of development and trials.

In the summer of 2016, as development of their investigational gene therapy for hemophilia moved forward, the company embarked on a project to construct a new manufacturing facility within a seemingly impossible time frame. The resulting facility, built, and commissioned in only 11 months, demonstrates that the impossible can be achieved with dedicated people, a solid plan, and the right amount of faith.

### On a Fast Track

The company launched Project FAITH on 2 August 2016. One year later, BioMarin announced that valoctocogene roxaparvovec, its AAV-factor VIII vector investigational gene therapy for hemophilia A, was ready for Phase III trials. The

## Quick Facts

**Category Winner**  
Project Execution

**Project**  
Project FAITH

**Location**  
Novato, CA, USA

**Project Mission**  
Develop the processes, systems, operations team, and site to deliver Phase III clinical material in 18 months.

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AND DESIGN TEAM:



RANDALL LAMB





## JUDGES' PANEL CONCLUSION

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*Demonstrates how, when teamed with the industry's best people, equipped with the right technology, and energized by the right motivation, an impossible project is made possible. The execution of Project FAITH represents a spectacular display of pharmaceutical engineering and professionalism.*

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building project was fast-tracked for both business and therapeutic reasons, with the new facility targeted to support clinical trials before the end of 2017. To meet this goal, BioMarin elected to repurpose their existing office/warehouse building in Novato.

Because therapies such as valoctocogene roxaparvovec have lifechanging potential, the Project FAITH team understood the need to work quickly while keeping their eyes on longer-term objectives. "Although it has a specific purpose right now, the intent is that this facility will be flexible and able to expand to meet not only our current manufacturing needs but also our future needs for other gene therapies," said Carl Albertson, Director of Capital Projects at BioMarin.

While many gene-therapy firms farm out virus production, the fierce demand for these specialized services often results in delays. To avoid these problems, BioMarin plans to use the facility to manufacture viruses for its products, said Dr. Robert Baffi, BioMarin's Executive Vice President of Technical Operations, in a 2017 New York Times article. "The new facility also will give the company complete control over manufacturing," he added.

### An Impossible Time Frame

BioMarin's project team was tasked with developing a plan to repurpose the existing office/warehouse building within the desired time frame. The new facility would include allocations for manufacturing and quality control testing, as well as filling and

packaging suites. It also included new utilities, material staging, a loading dock and site-access modifications. To accomplish this, several parallel critical paths were swiftly set into motion.

"We held a kickoff meeting and then the next day we started demolition drawings, which were completed in two weeks," explained Logan Kelley, Senior Project Manager at BioMarin. "By the third week we had started demolition, and at that point, we'd already started our structural drawings and our underground drawings to complete the core and shell. We had those done in approximately six weeks and submitted them to the city so we could start the work."

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*“Key to the project's notable success was getting everyone involved and moving in the same direction”*

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Much of the existing facility was gutted, with only about one-third of the office space maintained. The roof was reinforced to support new HVAC requirements and the building shell was strengthened to surpass seismic codes for the area, which is prone to earthquakes.

While the exterior work and site access were still under construction, the building's interior was outfitted and connected to the good manufacturing (GMP) utility systems. This enabled the process development team to commence their critical test runs in May 2017; these included two process development runs, an engineering run, and three

successful media fills, followed by GMP release for production in August 2017.

“A key piece of our success was that we had an overarching vision; we knew we needed to separate the packages to stagger design and construction activities, so they could overlap each other and we could achieve our aggressive schedule,” said Kelley.

## Defining a New Process

“One of the decisions that turned out to be a blessing was that we dedicated all our key resources and co-located them in the same area with the contractors and consultants, so that everybody just focused on talking to each other as opposed to emailing or calling or trying to set up a meeting. We could make decisions and communicate on the fly and have morning huddles to make sure everybody knew what everyone else was doing,” said Albertson.

“And while we were constructing the building,” he continued, “we were concurrently doing manufacturing for process development and testing in the same facility. So we had to coordinate the activities and keep everyone safe while we were doing multiple tasks in this building.”

Bringing BioMarin’s first-ever sterile filling and packaging suite online in the prescribed time frame presented its own unique technical challenges. The operational readiness team met this challenge head-on, hiring and training new staff in parallel while

construction took place. Operators were trained on the filling equipment as it was being installed, and were given a full-scale wooden model of the isolator to help them refine their procedures while preparing for the finished equipment train.

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*“The project was completed on scope, on budget, and amazingly, on time”*

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In keeping with industry trends, the validation team quickly set to work as design documents were developed, allowing factory and site acceptance testing to be leveraged. BioMarin also quickly formed strong relationships with their raw materials suppliers, which helped them understand and overcome challenges in setting up critical supplies for start-up testing as well as GMP runs. In total, BioMarin developed and approved 1,546 GMP documents to support the fully operational facility in under eight months!

## Hallmarks of Success

The fact that Project FAITH was completed within 11 months is remarkable. That it was accomplished on spec is even more impressive. Final cost for the project came in at an amazing 1% above the approved budget.

According to Kelley, the key to the project’s notable success was about getting everyone involved and moving in the same direction. “We brought in representatives from every department and external partnership,” he said. “In the first few weeks, we did a four-hour workshop every morning with people from process development, engineering, architectural, project engineering teams, contractors, pipe fitters, along with the quality, operations, and facilities people. At first, people were a little tepid, not trying to step on anybody’s toes. But soon the leadership team formed, and by the end everybody was speaking their mind in a very positive, proactive manner.”

In the end, Albertson said, completing Project FAITH is about positively affecting the health and quality of peoples’ lives. “We had the mother of a child afflicted with hemophilia A visit our facilities several times and when she spoke, she had tears of joy that there’s somebody doing something somewhere down the road that could help her son. When I looked at that, I couldn’t help but feel that I’m doing something that’s helping someone. And that really motivated a lot of us.”





The project was completed on scope, on budget, and amazingly, on time. Albertson says the BioMarin team always knew they could accomplish it, hence the name: FAITH. “The name was a motivating-type tool,” he says. “We would joke about it, but it really did help, and I think it represents believing in the impossible.”

## IN THEIR OWN WORDS

The execution of Project FAITH represents a spectacular display of pharmaceutical engineering and professionalism. It demonstrates how, when teamed with some of the industry’s best people, equipped with the right technology, and energized by the right motivation, an impossible project is made possible.

The time frame alone indicates how well the project was executed. From design to construction to schedule and change control, three parties involved—BioMarin; Project Architect and Engineer, CRB; and General Contractor, NOVO Construction—brought an intensive professionalism to Project FAITH that ultimately achieved success.

Project FAITH created a common, shared belief among all its participants that with will, wisdom, and professionalism, they could achieve one of the fastest and most successful implementations of new biopharmaceutical manufacturing capacity ever seen in the industry. The precedents and practices established by this project may influence the delivery of biopharmaceutical innovation and support of the supply chain for years to come.

## Key Project Participants

### Manufacturer/Owner

BioMarin Pharmaceutical Inc., Novato, CA

### Engineer/Architect (A&E)

CRB, Emeryville, CA

### Main/General Contractor

NOVO Construction, Menlo Park, CA

### Piping and HVAC Subcontractor

ACCO Engineered Systems, San Leandro, CA

### Automation and Control Supplier

Powers of Automation, Inc., Bend, OR



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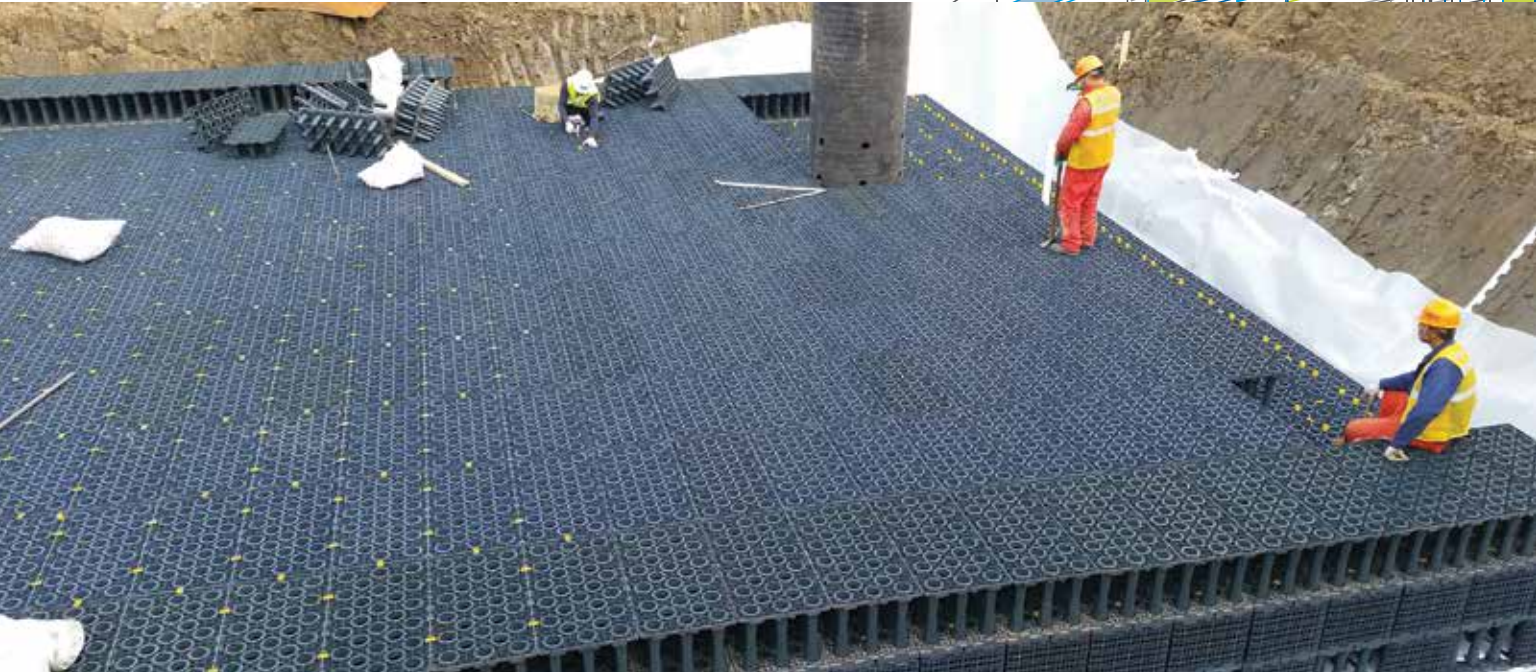
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# Sustainability

## Wyeth Pharmaceuticals Co., a Pfizer Company



## OSD Facility: Worldwide Model for Sustainability

Pfizer Consumer Health has manufactured oral solid dosage (OSD) pharmaceutical and health supplement products at its facility in Suzhou, China since 1995. In recent years demand for the Caltrate and Centrum health supplements manufactured there has increased rapidly. To meet the demand and to plan for future growth, the company decided to build a second manufacturing facility in Suzhou. The new facility has become a model for sustainable design, not just for China and not just for Pfizer, but the pharmaceutical industry as a whole.

### Committed to Sustainability

From the beginning of the project to construct the second facility, the project team highlighted environmental sustainability as a key driver, in alignment with Pfizer's corporate objectives.

In its 2017 Annual Review, Pfizer Inc. reiterated its commitment to protecting the environment through its Environmental Sustainability Council, which focuses on three core areas: "mitigating climate change and its impact through reductions

### Quick Facts

**Category Winner**  
Sustainability

**Project**  
Project Diamond

**Location**  
Suzhou, Jiangsu Province, China

**Project Mission**  
A greenfield site for over-the-counter OSD products for 2.6 billion tablets a year

## JUDGES' PANEL CONCLUSION

*This project has set a new bar, creating a facility that embraces a holistic approach to sustainability going far beyond application of GEP to include proactive planning for sustainable operations and thoughtful stewardship of the surrounding environment.*

in our greenhouse gas emissions; reducing waste through the lifecycle of our products; and reducing water use.”

Paul Chiu, Global Engineering, explained that “at Pfizer, Senior Management in the United States pushes all sites to think about sustainability, and they want to see it reflected in facility design” says. “Very early in the project, we set an initial objective to achieve LEED (Leadership in Energy and Environmental Design) Gold for the site, for both the manufacturing building and for the office building.”

Project leaders also recognized the potential to set a new benchmark for the industry in a region with serious sustainability and environmental challenges. “On one side we are responding to Pfizer’s objectives, but in parallel we are also responding to the Chinese government’s expectations of how western companies in China should be performing,” says Chiu. “It is not unusual for the government to expect western companies like Pfizer to set a higher standard in the hopes that we will influence the local companies to follow.”

### Beyond GEP

“I commend our team in China for their thoughtful approach to this project, incorporating energy conservation and environmental protection technologies, including highly efficient equipment,

solar power generation, a water recycling system, a heat recovery system, and a smart rainwater harvesting system,” said Kirsten Lund-Jurgensen, President, Pfizer Global Supply.

*“The project team highlighted environmental sustainability as a key driver”*

Led by Yuyi Meng (Engineering Leader) and Jianlong Xie (Utilities Leader), the local team worked closely with Pfizer’s subject matter experts in the United States and Europe. Corporate practices advocate that all Pfizer engineering projects include good engineering practices (GEP) for environmental sustainability.

For the Suzhou facility, these included but were not limited to:

- Energy-efficient mechanical equipment, such as chillers, cooling towers, air compressors, and air handlers
- Efficient water-conservation equipment, such as cooling towers, laundry washers, toilets, and shower fixtures
- Air, water, and steam discharge systems to maximize energy recovery, such as steam condensate heat recovery to preheat hot water for processes and domestic use
- LED lamps throughout the facility
- Parameters that challenge the air-conditioning systems to allow for the widest possible temperature and humidity ranges without compromising GMP or product requirements

As the plant becomes operational, energy and water utilization will be reviewed for additional opportunities in design and operational practices.

To push the boundaries of sustainable design, Meng and his team consulted with employees from the first Suzhou facility. “The idea was to get the entire plant staff to be engaged in support of an energy-saving design,” explains Chiu. “The team received many submissions from employees making suggestions on how we could make contributions. However, the goal





was not just to solicit ideas but also to make them feel that they are part of a very noble effort.”

Many employees’ ideas were adopted in the new facility design, including:

- Solar power generation with photovoltaic cells. The team included allowance for solar panel installation in its roof structural design, and future connection allowance in its electrical distribution design. To maximize the 8,000 square meters of roof surface, a canopy structure was added to the parking lot. The team aggressively pursued third-party funding and found a renewable energy company willing to invest in solar power generation and operate the facility for 25 years. The facility includes 2,900 panels with close to 0.8-megawatt capacity. The solar power facility should be ready for generation in mid-2018.
- Rooftop solar panels for domestic water heating and rainwater harvesting for lawn and plant irrigation.
- A green roof and wall on the Administration building provides additional insulation for the building, and communicates a very visual statement of the site’s green commitment.
- Charging stations in parking lots for electric vehicles.
- Zero nitrogen and phosphorous in wastewater discharge protect the second largest freshwater lake in China, which is located nearby.

## LEED Platinum

As the team finished their design, they realized that in surpassing GEP, they were also able to move beyond their initial target of LEED Gold certification.

“By the time we were done with the design, we realized that what the team had done was good enough to

achieve LEED Platinum,” says Chiu. “We received LEED Platinum certification in the fourth quarter of last year as the project came close to completion.”

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*“The facility is the world’s first LEED Platinum-certified pharmaceutical manufacturing campus”*

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Both the manufacturing and the office and laboratory building were certified, making the Pfizer Suzhou facility the world’s first LEED Platinum certified pharmaceutical manufacturing campus. It also received the China Two Energy Star certification for a manufacturing site, with requirements very similar to LEED Platinum. As the new site prepares for commercial operation, the project team has met management’s challenge and delivered a first-class environmental sustainable manufacturing site that sets a new global benchmark, and serves as a concrete example to the local community, government, and industries in China.

## Going the Extra Mile

While the new site is destined to produce health supplements, Chinese regulations classify it as a pharmaceutical plant, no different that if it was producing prescription drugs.

“Our sustainable design has enabled us to reduce the carbon emissions by 4,000 tons per year, which is equivalent to planting 235,000 trees,” says Meng. “In addition, our water consumption is reduced by 40,850 tons per year.”

Chiu believes that it was the passion of senior management and the local team that allowed the project to go the extra mile to achieve LEED Platinum certification. And it was well worth the



effort: “Some people think that you have to spend a lot of extra money to achieve that Platinum standard, but I don’t think we spent more than 0.5% of the project budget to achieve this certification.”

The new Pfizer Suzhou facility has been producing performance lots since October 2017; it expects to receive certification from the Chinese authorities to enter full production in the second quarter of 2018.

“What was unique about this project,” says Chiu, “is that it was 100% built by the local team. Normally, when a western company builds a new facility in China, you would expect to find a high percentage of ex-pats on site, people coming from outside of China to be on site managing the project. I am not sure if I know of any other greenfield facilities in China built by western companies that are 100% entirely built by the local team.”

## IN THEIR OWN WORDS

The new Pfizer Consumer Health manufacturing facility in Suzhou, China, fully embraces all good engineering practices and latest environmental sustainable design features, resulting in a contemporary facility recognized by the prestigious international certification body LEED as the world’s first LEED Platinum pharmaceutical manufacturing campus. This achievement is particularly meaningful for a facility located in China, where environmental sustainability is a difficult challenge facing its government, citizens, and industries. The site hopes to make a long-lasting contribution to the local community by setting a high benchmark as a pioneer, demonstrating a viable solution, and encouraging other companies to join the journey to long term environmental sustainability.

## Key Project Participants

### Engineer/Architect

The IT Electronics Eleventh Design & Research Institute, Scientific and Technological Engineering Corporation, Ltd., Wuxi, Jiangsu Province, China

### Construction Manager

Cockram Projects Construction & Engineering Co., Ltd.

### Main/General Contractor

ZhongYiFeng Construction Group Co., Ltd., Suzhou, Jiangsu, China

### Piping and HVAC Subcontractor

BOTH ENGINEERING CO., LTD, Wuxi, Jiangsu, China

### Automation and Control Supplier

Rockwell Automation

### Major Equipment Suppliers/Contractors

Fluid Air/Spraying Systems Co., Aurora, IL  
GEMCO, Middlesex, NJ



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*L to R: Gunter Baumgartner, Antonio Crincoli, Peter Larsson, Samuel Kitchell, Simon Shelley, Rong Zhang, Britt Petty, Frank DeMarinis, James Breen, Jr., Gary Schoenhouse, Frank Vanerman, David Sternasty, Joseph Sullivan, James Dickow, Lou Kennedy, Joydeep Ganguly, David Yoon, Charles Calitri, Brian Lange, Jian Dong*



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# Honorable Mention

## Emergent BioSolutions, Inc.



## New Facility Protects Against Public Health Threats

Since 2000, the United States has endured biological attacks with anthrax-laden letters; natural outbreaks of diseases like severe acute respiratory syndrome, Ebola and Zika; as well as influenza pandemics. In response to such national emergencies, the Biomedical Advanced Research and Development Authority (BARDA) in the Office of the Assistant Secretary of Preparedness and Response within the US Department of Health and Human Services, set out to enhance the government's ability to develop and manufacture medical countermeasures to address these and other threats using the public-private partnership model.

In 2012, BARDA entered into a 25-year partnership with Emergent BioSolutions, a global life sciences company that provides specialty products to address accidental, intentional, and naturally occurring public health threats. Emergent was designated one of three national Centers for Innovation in Advanced Development and Manufacturing (CIADM), a network of sites designed to provide development and manufacturing capabilities for rapid deployment in response to public health emergencies.

## Quick Facts

### *Honorable Mention*

#### **Project**

BARDA—Emergent Center for Innovation in Advanced Development and Manufacturing (CIADM) Baltimore Facility Expansion

#### **Location**

Baltimore, MD, USA

#### **Project Mission**

Bolster the nation's existing manufacturing surge capacity with more rapid, nimble, and flexible vaccine manufacturing for pandemic influenza and provide readiness to produce other products routinely and in an emergency to counter known and unknown threats.

# JUDGES' PANEL CONCLUSION

*The facility represents a unique partnership between industry and government that can act rapidly to stop significant public health threats.*

“Our FOYA project was centered around being able to make 50 million doses of pandemic flu vaccine within four months of pandemic declaration [by the World Health Organization],” says Scott Battist, VP, General Manager and Site Head for Emergent’s Bayview site. “We knew we needed a facility with significant capacity that could run a wide range of processes, but we didn’t know on which specific expression platform (microbial, mammalian or insect cell culture, viral vector, etc.) the pandemic flu vaccine would best be developed.” This upstream uncertainty demanded flexibility to handle a wide range of downstream processing requirements.

## Designing for the Unknown

In mid-2013, the Emergent team began conceptual design for a 56,000-square-foot CIADM facility to be built adjacent to its existing Bayview facility in Baltimore, Maryland. Design and site work began in 2014, followed by construction in the summer of 2015. As of early 2018, the facility is in the final stages of commissioning and qualification.

In engineering this building, Emergent defined a new type of biotech facility: one that is operationally agile enough to change product campaigns quickly, with minimal limitations. The iterative design process was instrumental in delivering the flexible, responsive, process-agnostic platform that BARDA demanded while still giving Emergent a facility that could meet internal needs.

Flexibility is a key design feature. Unlike most pharmaceutical production facilities, Emergent did not design for a specific process, but instead considered a variety of processes that it could potentially run in the future. “It could be anything covering microbial, cell culture, or viral expression systems to produce the bulk vaccine,” says Battist.

As a result, the facility’s scalable space, coupled with a singular focus on single-use technologies, can accommodate varied process platforms and is ready for the plug and play of current standard cGMP equipment trains. If demand and supply timelines

require higher downstream throughput, for example, the operations team has the capacity to run parallel units to meet the required productivity. The utilities and space are available, and in most cases, existing equipment can be moved to accommodate any necessary new equipment.

## Flexible Production

BARDA’s partnership with Emergent requires the company to react quickly to declared emergencies. “If a flu pandemic were declared, we would receive notification from BARDA to start vaccine manufacture and would be expected to produce 50 million filled, final doses of vaccine within four months, with first doses being delivered within 12 weeks of the notification from BARDA,” says Battist

Once a platform is validated, the pandemic production schedule includes:

- Bulk antigen production
- Bulk antigen quality control release
- Final filling
- Final drug product release

BARDA’s partnership also requires that the government keep the CIADM facility busy for six months of each year. This includes work on influenza viruses as well as other clinical trial material. “In addition to pandemic flu vaccines, the facility is also capable of manufacturing other medical countermeasures for the US government under the same CIADM contract with BARDA. To date these have included production of anti-Ebola therapeutic monoclonal antibodies from a CHO (Chinese hamster ovary) cell line. This facility-flexible approach also allows the site to accept contract manufacturing work as well as produce its own products, and has been building a strong business around all three sources of work. The facility is capable of manufacturing products from a variety of platforms including microbial, cell culture, and viral/cell culture for their customers and stakeholders,” explains Battist.





The company recently adapted the facility in response to its acquisition from GSK of raxibacumab, the only monoclonal antibody therapeutic licensed by the US Food and Drug Administration to treat and prevent inhalational anthrax. This product, which will serve as the site's anchor commercial product, will be produced using Emergent's first-in-kind 4,000-liter single-use bioreactors, an equipment capability that was neither considered nor discussed during facility design. It was easily accommodated, however, by the flexible nature of the facility, which allows these systems to be installed with minimal utility distribution systems modifications and no necessary changes to building architecture, structure, or infrastructure. ■■■■

## IN THEIR OWN WORDS

BARDA's mission, combined with Emergent's vision of "protecting and enhancing 50 million lives by 2025," created a unique opportunity to join the search for the next generation of future facilities. While its demands were great, BARDA put tremendous trust in Emergent's capabilities and expertise, and Emergent delivered.

The BARDA-Emergent CIADM Bayview Expansion Project has ushered in a new era of biomanufacturing facilities, creating a true "facility of the future" model that provides benchmark examples of how companies can rapidly deploy manufacturing capacity nimble enough to meet the future uncertainties of biopharmaceutical markets and capital financing, yet capable of providing cost effective capacity and readiness to face the future.

## Key Project Participants

### Manufacturer/Owner

Emergent BioSolutions, Baltimore, MD

### Engineer/Architect (A&E), Construction Manager, Main/General Contractor

CRB, Rockville, MD

### Piping Subcontractor

Kinetic Systems, Frederick, MD

### HVAC Subcontractor

Pro-Air, Inc., Washington, DC

### Automation, Control System Integrator

Automated Control Concepts (ACC), Neptune, NJ

### Instrumentation and Control Supplier

Omni Instrumentation Services, Inc., South Plainfield, NJ

### Major Equipment Suppliers

Rosendin Electric, Glen Burnie, MD





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# Honorable Mention

## Government Pharmaceutical Organization (GPO)



### GMP Facility Secures a Sustainable Supply of HIV Medicines

Despite much progress, HIV/AIDS continues to be a global health issue. The problem is particularly severe in Thailand, which accounts for approximately 9% of cases in the Asia-Pacific region. Out of a national population of 66 million in 2016, an estimated 450,000 people were living with HIV and 6,400 died of AIDS-related illnesses. The situation is compounded by the high cost of importing HIV drugs as well as the difficulty of producing enough medicine domestically.

The Government Pharmaceutical Organization (GPO) has responded to the challenge by building a new facility that follows international best practices to greatly increase its ability to produce cost-effective, high-quality, much-needed HIV drugs.

#### Adopting Best Practices

GPO is the largest pharmaceutical producer and distributor in Thailand. GPO purchases API from countries such as India, China, and the EU to produce and package drug products, then distributes them to hospitals, clinics, and its own retail outlets.

### Quick Facts

#### *Honorable Mention*

##### **Project**

The Government Pharmaceutical Organization (GPO), Rangsit Pharmaceutical Production Plant 1

##### **Location**

Thunyaburi, Pathumthani, Thailand

##### **Project Mission**

Produce tablets and capsules to meet patient demand in Thailand and abroad

## JUDGES' PANEL CONCLUSION

*Success in applying quality-by-design principals and international best practices, and compliments GPO's new facility, its deployment of a modern quality management system, and honors its success in providing affordable HIV medicines to the people of Thailand.*

The company's desire to boost capacity at its 50-year-old production site in Bangkok led to a major construction project: a new medicine manufacturing facility north of the capital in Rangsit. The plant, which follows Association of South East Asian Nations (ASEAN) alignment to PIC/s international good manufacturing practices (GMP), has become a key part of the Thai government's efforts to control and treat HIV infections. The plant produces antiretroviral (ARV) medicines, in addition to other drug products.

While the existing Bangkok facility still uses paper-based processes, the Rangsit facility has integrated IT systems that allow an entirely paperless and compliant operation. "When we created the new facility, we looked at how we could reduce the paperwork and how to easily track every batch of every medicine we produce," explains Dr. Mukdavan Prakobvaitayakit, Deputy Managing Director of GPO. "We integrated key systems, including MES (manufacturing execution system) for managing the process, eQMS (electronic quality management system) for managing documents and training, and LIMS (laboratory information management system) for managing the laboratory, in addition to the legacy ERP (enterprise planning system)."

*"This is the first plant in the ASEAN region built specially to supply critical HIV medicines affordably"*

"GPO produces more than 5,000 batches per year, and we wanted to gain more efficiency out of the system," says Mr. Teerapong Cheepchol, Deputy Managing Director of Factorytalk Co., Ltd., the IT solutions supplier on the Rangsit project. "We looked into systems like MES batch recording and LIMS systems to make sure that all information is highly integrated, and we are able to transfer back to the originator. No one else in the region has this high integration of their systems; this is a case study for the industry here in Thailand to see the benefit using IT systems."

Its alignment with PIC/s GMP, coupled with GAMP® best practices, has made the Rangsit facility able to supply local HIV medicines at a price 20 times lower than imported medicines, while still achieving global quality standards. In 2017, the facility's production capability was 1.5 billion tablets/capsules. According to Dr. Prakobvaitayakit, expansion of the facility is imminent, which will increase annual production capacity to 4.5 billion tablets/capsules by 2020.

*"Our project can be shared with the other nearby countries; that makes us very proud"*

"The technology is very important because it helps us to reduce our costs," she says. "We serve many patients at the public hospitals, and this means that we can serve more people in Thailand for this price. It makes us proud because this project is for the patients who gain access to specialty medicines. We worked so hard to have this factory and now our hard work has been fruitful."

The Rangsit facility has been inspected by the World Health Organization (WHO) and found satisfactory,





since GPO submitted the HIV dossier for HIV drugs to the WHO Prequalification Program—the first plant in Thailand to achieve such status. “We love that we can supply medicines to our Thai patients, and now elsewhere in the region, like Myanmar and Cambodia,” says Dr. Prakobvaitayakit. “The government pharmaceutical factory in Myanmar also want us to do a technology transfer, so we are happy that our project can be shared with the other nearby countries; that makes us very proud.”

## IN THEIR OWN WORDS

This is the first plant in the ASEAN region built specially to supply critical HIV medicines affordably to the local population. It is linked to WHO’s program for regional supply of medicines for HIV and is the first plant in Thailand to achieve WHO inspection report status. It is now able to supply local HIV medicines for a price 20 times lower than imported medicines and still achieve a global quality standard.

The plant is designed to supply the capacity requirements of the whole country, and to meet PIC/S GMP and WHO prequalification programs. This is the first plant in the region with an integrated IT system to control the process with paperless operation following GAMP best practice. This is the first time an emerging economy in our region decided to invest in state-of-the-art systems to manage the processes and the product quality, rather than use low-cost manual labor, with the well-known associated impact to quality aspects.

## Key Project Participants

### **Manufacturer/Owner, Engineer/Architect (A&E)**

The Government Pharmaceutical Organization (GPO), Pathumthani, Thailand

### **Construction Manager, Main/General Contractor, Piping Subcontractor**

M+W Thailand Co., Ltd., A Company of the M+W Group, Bangkok, Thailand

### **Piping Subcontractor**

Kinetic Systems, Frederick, MD

### **IT Solutions Supplier/Compliance Consultant**

Factorytalk Co., Ltd., Bangkok, Thailand

### **HVAC Subcontractor**

AIRPLUS APPLY Co., Ltd., Pathumthani, Thailand

### **Automation and Control Supplier**

The Auto-Info Co., Ltd., Bangkok, Thailand

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

Unitech Co., Ltd., Bangkok, Thailand

SCHNEIDER Thailand Co., Ltd., Bangkok, Thailand





“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



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**Congratulations to  
Shire for winning  
the 2018 FOYA  
for Facility Integration.**

We are proud to have been a part of this project that successfully introduced a new facility to an already operating site! We are excited for what the future holds for our client and their expanding facilities and capabilities.

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# Congratulations

to all the 2018 FOYA winners!



CRB is honored to be part of the following FOYA teams:



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Facility of the Year Awards

CATEGORY WINNER  
Project Execution • Supplier

## ISPE FOYA for Project Execution

Client: BioMarin Pharmaceutical, Inc.  
Project: Gene Therapy Manufacturing Facility



**FOYA** | 2018

Facility of the Year Awards

CATEGORY WINNER  
Facility Integration • Supplier

## ISPE FOYA for Facility Integration

Client: Shire  
Project: LA Building 8



**FOYA** | 2018

Facility of the Year Awards

CATEGORY WINNER  
Operational Excellence • Supplier

## ISPE FOYA for Operational Excellence

Client: Shire  
Project: LA QC Lab



**FOYA** | 2018

Facility of the Year Awards

Honorable Mention • Supplier

## ISPE FOYA for Honorable Mention

Client: Emergent BioSolutions, Inc.  
Project: BARDA Facility Expansion



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