FOYA 2026

ISPE Facility of the Year Awards

2026 CATEGORY WINNERS

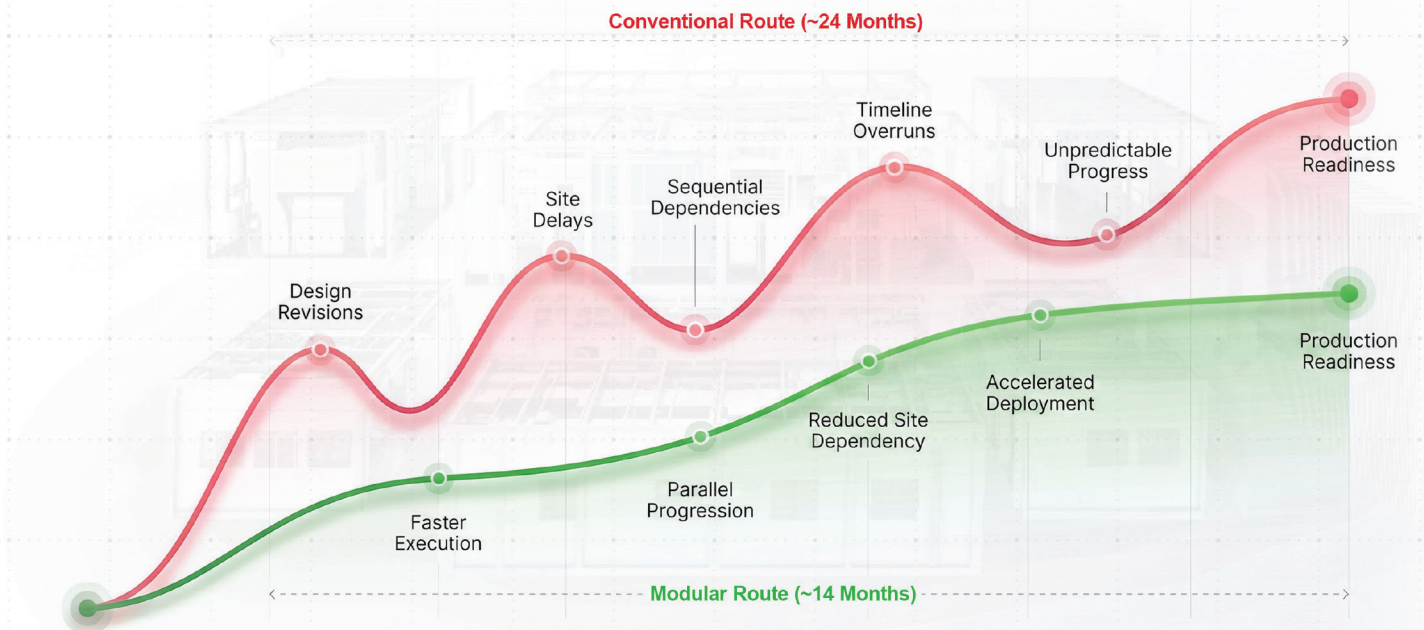
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Welcome and Thank You

On behalf of ISPE, I am excited to recognize the winners of the 2026 ISPE Facility of the Year Awards (FOYA). For 21 years, the FOYA program has showcased consistent improvement in mindset and technological innovation. While the award categories and criteria remain the same, what's different this year is the ambition of the submissions. The 2026 FOYA winners do more than demonstrate excellence—they reflect the future of pharmaceutical facilities, where advanced therapies, speed, and integrated design are the benchmark.

We on the FOYA Judging Committee are pleased to recognize transformational projects that have had a profound impact on humanity. We also celebrate exceptional accomplishments that are driving paradigm shifts in Pharma 4.0™ technology and sustainability, improving the supply and availability of medications to underprivileged populations, and continuing to innovate and deliver advanced therapies to patients.

FOYA projects consistently showcase the best of the best in pharmaceutical manufacturing, each year bringing new and unique solutions to project delivery challenges. While the awards continue to recognize facilities that incorporate innovative technologies, enhance product quality, and improve process and cost efficiency, there is a greater focus on how these aspects are integrated into a cohesive whole.

Can my company's project be submitted?

FOYA is a globally recognized award program that annually receives project submissions from around the world. These submissions come from a range of organizations, including large global corporations in pharma, biopharma, and medical devices, regional companies, government-backed organizations, and innovative cell and gene therapy enterprises. FOYA recognizes these projects across multiple categories, including an overall FOYA winner.

Who are the judges?

The submissions are reviewed by the FOYA Judging Committee, composed of a diverse mix of recognized life sciences industry leaders from various geographies and organization sizes. These judges have demonstrated extensive experience in various fields, such as engineering, supply chain, manufacturing operations, and quality. Committee members have firsthand experience leading and delivering complex, successful projects, many of which have been recognized with FOYAs in the past.

What is the submission review process?

The FOYA Judging Committee meets in person each January to review and discuss the relative merits of each submission. Each judge reviews all submissions and volunteers to present a summary of one project to the judging panel.

Judges use a process of elimination that typically lasts multiple rounds. First, each project is rated for the quality of the submission, its merits against FOYA categories, innovative approaches, and social impact. Projects that meet the criteria and compare strongly with other projects advance. In the second round, projects are compared within the various FOYA categories, with shortlisted submissions advancing to the third round.

In the third round, each category winner is chosen and assessed. (If no submissions meet the criteria, that category award is not given.) Judges assess all the category winners for holistic execution approach, innovation, social impact, digital innovation, and other factors to determine the project that stands out as the overall FOYA winner. All voting for every round is anonymous.

All FOYA judges sign a confidentiality agreement. If a FOYA judge's organization has submitted a project, that judge abstains from any discussions concerning that submission.

What does a winning submission look like?

Key differentiators like patient impact, execution, safety, innovation, and unique approaches are essential for FOYA category winner consideration; these factors are not limited to large and complex projects. Judges understand that smaller projects often enhance production capacities, expedite product transfers, improve supply chain robustness, and deploy new transformational digital technologies, all crucial for resilient supply chains and efficient operations. Therefore, the overall impact of a project is more significant than its size in determining award winners.

Every year we receive numerous submissions, and our judges work diligently to identify the distinguishing factors that set projects apart. Keeping with that goal, ISPE announced the 2026 FOYA Submission Finalists at the 2026 ISPE Facilities of the Future Conference in February to showcase projects that met all qualification requirements for their respective FOYA category winning recognition.

Thank you to all the judges for their dedication in support of these important industry awards. Their thoughtfulness and diligence have strengthened the ISPE FOYA program over the years. The quality of submissions, level of innovation, and excellence in execution make the judging process increasingly challenging. Thanks to all the organizations and their service provider partners who put tremendous effort into preparing this year's high-quality submissions.



Parag Sane
Chair, FOYA Judging Committee
Associate Vice President, Global Capital Projects
Amgen Inc.

FOYA 2026
ISPE Facility of the Year Awards

Thank You to the 2026 FOYA Judging Committee for their Continued Support of the FOYA Program

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Scott W. Billman
Solventum

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Johnson & Johnson

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Eli Lilly & Company

Jian Dong
WuXi Biologics

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Frank Vanermen
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Felix A. Velez
Johnson & Johnson

Rong Zhang
Bristol Myers Squibb

Jörg Zimmermann
Vetter Pharma Fertigung GmbH & Co. KG

Message from the 2026 FOYA Planning Committee Chair

On behalf of the planning committee, I'm pleased and honored to celebrate this year's winners of the Facility of the Year Awards and congratulate them on their remarkable achievements in our industry. I'm proud and full of admiration for the 2026 winners, as well as all who share in the commitment and dedication to innovate and advance pharmaceutical manufacturing technology for the benefit of patients around the world.

Last year, FOYA celebrated its 20th anniversary, but it's obvious from this year's winners that our industry is not resting on its laurels. The winners reflect a continued desire of industry leaders to stay ahead of innovation and manufacturing needs while focusing on what's next—not looking back at what we've already achieved.

The Importance of Collaboration

Building a pharmaceutical facility is complex, requiring the expertise of a diverse group of professionals. A FOYA recognizes much more than a single company. It celebrates the collective achievement of a diverse range of professionals, including the vital contributions of the architects, engineers, constructors, and equipment partners whose collaboration makes success possible.

As a Vice President for a global integrated design, construction, and operational readiness firm specializing in the life sciences industry, I know the challenges and triumphs of partnering with pharmaceutical manufacturers who have built winning projects. As this year's Chair of the FOYA Planning Committee, I've had the privilege to see the dedication, not only to technical expertise and innovation, but collaboration and trust between all the teams that work together to build these winning projects.

Each step requires planning, coordination, and precise execution, and winning an award is a source of pride for the entire team, from the visionary leaders who set the goals to the skilled workers who bring their vision to life.

Continued Focus on the Future

While the FOYA program has always recognized innovation, the 2026 FOYA Category Winners exemplify our industry's evolution toward the success of advanced therapies (e.g., CAR-T therapies), modularity, enhanced safety, and the incorporation of aspects of Pharma 4.0™—digitalization, automation, and 5G smart manufacturing—that are essential to propel our industry forward.

Innovation, Safety, and Sustainability

Whether it is consolidation of process steps for making antibody-drug conjugates (ADCs) to secure the supply chain, production of steam using renewable energy, improved operational efficiency, use of 5G computing architecture, or incorporation of automation and digital tools that are an evolution toward lights-out manufacturing, winning projects were designed and built with efficiency, safety, and sustainability at the forefront.

The projects we honor today reflect a commitment to making a difference to workers and patients worldwide.

The Human Element

Innovations, operational improvements, and integration of Pharma 4.0™ all lead to more efficient manufacturing. In the end, though, our industry exists to serve people, and awards were given for a resilient facility designed with a requirement of complete operational uptime for CAR-T cell therapies for late-stage oncology trials, raising the bar on exposure limits for high-potency APIs and earthquake protection, and accelerating execution of a parenteral manufacturing facility from greenfield to validation in record time. The projects we honor today reflect a commitment to making a difference to workers and patients worldwide.

I extend heartfelt congratulations to all the FOYA recipients. Thank you to the members of the FOYA committees for their hard work and commitment to recognizing the best in our industry. As we celebrate these achievements, let us also look to the future with optimism and determination. The challenges we face are great, but so are the opportunities. By working together, we can achieve even greater heights and continue to make a lasting impact on the world.



Paula Casalino
Chair, FOYA Planning Committee
Vice President Operations Canada
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The Voice of the FOYA Awards: Dave DiProspero's Lasting Impact on the Facility of the Year Awards

By Scott Fotheringham

This will be the first year that Dave DiProspero attends the ISPE FOYA Banquet and Awards Celebration as a retired professional engineer. DiProspero, who has been the emcee for every awards ceremony since the first banquet in 2014, is set to retire in September from his role as Senior Fellow, Pharmaceutical Process Technology at CRB. He's been in the pharma industry for more than four decades and a member of ISPE for more than 30 years.

"I was a young engineer when I first joined ISPE in the early 1990s," he said. "After several years of limited member participation and attending a few meetings and conferences, I decided to raise my hand and volunteer for involvement on my first committee. Since then I have been involved in and have chaired several committees. My involvement with ISPE has been key to my career success and professional growth."

DiProspero has extensive experience in drug product process technology, equipment, facility layout and design, and process engineering. As a subject matter expert in oral solid dosage forms, he has plenty of volunteer experience with ISPE, including authoring many technical articles in *Pharmaceutical Engineering®* magazine and speaking on tablet and capsule manufacturing and regulations. He also was the co-team leader of the *ISPE Baseline® Guide: Oral Solid Dosage Forms (Third Edition)* [1] and the *ISPE Good Practice Guide: Continuous Manufacturing of Oral Solid Dosage Forms* [2] and reviewer of other guides.

"These require a heavy time commitment," DiProspero said about the guides, which can take years to complete. "You don't just put it down on paper and let it go."

For the OSD Baseline Guide, which included industry review, peer reviews, and approval by the Guidance Documents Committee, they had to address more than 500 comments. The benefits of this work are threefold. He finds he has extensive opportunities to work alongside colleagues in the industry and get to know his clients since all the major pharmaceutical companies are involved. Along with networking, there's valuable education and experience. Finally, the work gives DiProspero international recognition within the industry, largely related to his role at CRB and ISPE.



The Only FOYA Awards Emcee

DiProspero joined the planning committee for the FOYA program around 2010, about five years after the FOYA program inception. He chaired the committee for three years. He recalls that first banquet in Baltimore, MD.

"We had 50 people in the room that night," he said. "The next year we came to Philly and we added some music and a DJ and dressed up the affair. It's crazy how it's taken off since those early years and is now an industry must-attend black-tie affair. Last year at the 20th anniversary of the FOYA program in Charlotte, NC, more than 500 people attended, with a sit down dinner, guest speakers, and industry-leader award presenters."

DiProspero comes by being a performer honestly—he's been a musician for more than 25 years, currently managing and singing in a semi-professional classic rock band called Right Turn at 40 (est. 2006) [3]. The band is mainly a spring and summer festival band that performs in and around southern New Jersey and covers classic rock songs from the '60s through the '90s. The band will actually be performing at the Tuesday Night Celebration gala for this year's 2026 ISPE Annual Meeting & Expo in Washington, D.C.

"Being on stage with a microphone comes naturally to me," DiProspero said. "I'm a bit of a ham, I think I can speak pretty well, and I like people. The Awards Banquet is a fun night, a little looser than the many technical talks

I've done for ISPE. We try to make it like the Grammys or the Oscars, interjecting a bit of humor and lots of fun."

While the guests already know the Category Winners—they were announced at the 2026 ISPE Europe Annual Conference—the Banquet allows a formal presentation of each award and gives the winners a chance for a formal acceptance and speech, in a roomful of peers. The overall winner is also announced at the Banquet.

"In the past few years, winning a FOYA comes with a lot of prestige," DiProspero said. "There's an enormous amount of pride and bragging rights for the companies who walk away with an award. It's also a big deal for the architecture and engineering firms, constructors, and contractors who worked on the facilities. It is quite common for the architecture and engineering firms to write the submissions for the company."

The Awards Banquet also gives winners the opportunity to share pride in their accomplishments with their entire team, who often come up on stage for the acceptance. Beyond that, DiProspero believes that a FOYA submission has other benefits, even for those who don't win.

"I've been involved in writing submissions that did not win," he said. "It gives you a chance to document your project after completion, a record that can be applied to your next project. There's a lot of blood, sweat, and tears going into these capital projects and it's a nice chronicle of those efforts."

With his retirement, Dave DiProspero leaves a legacy extending far beyond his technical expertise. His always positive attitude, infectious smile, and get-it-done volunteer leadership and longstanding role with the FOYA program has helped strengthen ISPE's role within the pharmaceutical industry. While retirement gives him more time to spend with his three grandchildren, pursue his passion for photography, and certainly continue his music career, FOYA Banquet attendees can take comfort knowing that the voice of the Awards Banquet isn't stepping away just yet.

"This is just too much fun for me," he said. "I agreed I'll probably do it in 2027, as well. And then we'll figure it out from there and let someone new step into the role.

"On a personal note, I'd like to thank Jeff Biskup—the B in CRB—and the firm in general for their commitment to ISPE and to the many incredible ISPE members I've met over the years. CRB and ISPE will always hold a fond place in my heart."

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1. https://ispe.org/publications/guidance-documents/oral-solid-dosage
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3. https://rightturnat40.com/





2026 ISPE FOYA Category Award

INNOVATION – Novel Technology

Hepalink Pharmaceutical Group Co., Ltd.

QUICK FACTS

Project: Shenzhen Hepalink Pingshan New Pre-filled Syringe Manufacturing Facility

Location: Shenzhen, China

Total Facility Size: 297,715 square feet

Mission: Secure global supply of critical anticoagulant therapies through innovative, high-viscosity pre-filled syringe manufacturing, leveraging 5G-enabled digitalization, AI-driven process intensification, zero-touch logistics, and vertically integrated facility design to maximize quality, sterility, efficiency, resilience, sustainability, and patient safety worldwide.

ABOUT THE CATEGORY

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

Why Hepalink Won

Hepalink used a combination of innovative technologies and an inventive design to build a next-generation manufacturing facility for high-viscosity drug products in Shenzhen, China. The innovations of this project allow an annual capacity of 330 million units of enoxaparin sodium injection, fostering global supply security of this critical anticoagulant. Combined with 99.99 percent logistics stability from its 5G multi-access edge computing (MEC) architecture and a dual-site (Pingshan–Nanshan) digital collaboration model that enables plug-and-play recipe transfer, the facility delivers both volume and resilience to prevent supply disruption.

The design, which rises vertically instead of relying on a traditional sprawling layout, makes the most of its shrunken footprint in a city where land is exceedingly scarce. This vertical integration of its physical layout means Pingshan has a greater than 50 percent increase in space utilization when compared with traditional layouts.

Physical isolation of production processes within the EU GMP-certified facility, along with a 5G-powered “electronic fence,” improves safety and sterility. Beyond the ongoing safety built into the production process, construction of the facility resulted in no lost-time injuries during 703 days of construction and operations.

These advancements comprise six unique innovative features that earned the facility recognition as a lighthouse project, securing its place on the Chinese government’s prestigious list of pioneered 5G-enabled pharmaceutical manufacturing sites.

5G-Enabled Ecosystem

The facility achieves network latency of less than 10 milliseconds and closed-loop data control to maintain data sovereignty. This has significant value for pharmaceutical manufacturing in terms of safety, speed, and efficiency.

- **Safety:** The 5G network ensures stable online connectivity and high-speed communication for all autonomous guided vehicle (AGV) terminals and personal digital assistant mobile data terminals in the factory, securing safe material transfer and efficient data operations. Furthermore, the



5G-powered “electronic fence” combined with AI vision detects unsafe behaviors in real time, cutting negligence-related risk in half, as well as millisecond-level AGV collision avoidance to minimize crash risk, while a local data closed-loop ensures data sovereignty.

- **Speed:** The fully sunken 5G MEC architecture achieves network latency of less than 10 milliseconds for real-time equipment interconnection. This enables AI visual inspection 13 times greater than manual inspection and 99.99 percent logistics delivery stability.
- **Efficiency:** 5G enables one-operator multi-machine control. It also supports coordinated scheduling of the environmental monitoring system, building management system, and water-cooling storage system, which combined deliver an annual electricity cost reduction of US$560,000 (~15 percent). The 5G system also replaces a traditional wired network and Wi-Fi infrastructure, significantly reducing cabling and maintenance costs.

Zero-Touch Logistics

The facility’s seamless integration of 5G AGVs with vaporized hydrogen peroxide transfer chambers is an industry-first—achieving a fully unmanned material flow from the warehouse to Grade A isolators. This eliminates human intervention as the primary contamination source, directly leading to a 100 percent success rate in the site’s first media-fill simulation and process validation. It also removes flammable isopropyl alcohol spraying from production areas, reduces warehouse-logistics headcount from 50 to 18, and sets a new benchmark for sterility assurance.

AI Process Intensification

The facility features an all-in-one nest removal and inspection machine, powered by deep learning-based AI, which eliminates glass-to-glass contact and boosts inspection throughput to 24,000 units/hour with 100 percent defect detection.

Digital Twin Synergy

The facility established a digital twin collaborative model between the Pingshan and Nanshan sites, allowing for rapid transfer of technical resources and production recipes. Through integrated containment and traceability (H3/B1) systems and unified warehouse management system data, both sites share real-time inventory, production plans, quality data, and best practices, allowing plug-and-play recipe transfer, and cross-site material and personnel deployment. The digital integration also led to a unified cross-site sales and operational planning rhythm.

“The digital twin model is not limited to design and construction,” said Caixue Wei, Vice President of Manufacturing and Operations, Global Industrial Affairs at Hepalink. “It remains a live operational backbone for ongoing dual-site collaboration between the two sites. This significantly enhances operational resilience.”

Technical Problem-Solving

The production of pre-filled syringes containing high-viscosity drug products is prone to pump seizing during filling and glass breakage during high-speed inspection. Pingshan successfully addresses these industry challenges through three solutions:

- **Nest removal and inspection machine:** By combining two unit operations in this single machine, the risk of glass breakage is minimized.
- **5G-enabled AI:** An AI deep learning model is trained to distinguish



About Hepalink

Hepalink Pharmaceutical Group Co., Ltd. is a global leader in the heparin industrial chain. Currently, the company operates seven industrial parks, owns more than 50 subsidiaries, and employs over 2,000 people. Its products are registered in 81 countries and sold in more than 50 countries worldwide. Its core business covers the investment, development, and commercialization of the entire heparin chain, large molecule contract development and manufacturing organization (CDMO) services, and innovative drugs. These three business segments work in synergy, driven by a mission to explore, develop, and provide high-quality, safe, and effective medications and services to protect patient health.

Supply Partners and Key Participants

Engineer/Architect: Tianju Shi Engineering Technology Group Co., Ltd.

Commissioning, Qualifications, and Validation Services: Tianju Shi Engineering Technology Group Co., Ltd.

Construction Manager: Tianju Shi Engineering Technology Group Co., Ltd.

Main/General Contractor: Tianju Shi Engineering Technology Group Co., Ltd.

Piping Subcontractor: Shanghai Austar Pharmaceutical Technology Equipment Co., Ltd.

HVAC Subcontractor: Hangzhou Airkey Technology Co., Ltd.

Automation and Control Supplier: Tianju Shi Engineering Technology Group Co., Ltd.

Major Equipment Supplier or Contractor: Shanghai Swisslog Technology Co., Ltd.; Syntegon Packaging Technology (Hangzhou) Co., Ltd.

Additional Suppliers: Shanghai C&S Engineering & Equipment Co.; Marchesini Group (Shanghai) Trading Co., Ltd.; MAQUET (Shanghai) Medical Equipment Co.; Zhong Xing Li Lian International Trading (Shanghai) Co., Ltd.



air bubbles from particulate contamination, as well as detect scratches and cracks in the syringes.

- **Engineering innovations:** Along with equipment suppliers, the company developed specially coated plungers and created precise ceramic pump clearance tolerance to resolve both pump seizing and glass breakage.

Vertical Integration

To overcome extreme land scarcity, the project embedded a 24-meter-high automated stereoscopic warehouse into the facility's core, increasing space utilization by 52 percent compared to traditional layouts. Raw materials and packaging flow vertically instead of horizontally using spiral conveyors.

Securing Supply of a Critical Drug Product

The Shenzhen Hepalink Pingshan pre-filled syringe manufacturing facility exemplifies how innovation is redefining the future of pharmaceutical manufacturing. More than a capacity expansion project, it demonstrates a novel engineering model that successfully overcomes the challenges of limited urban space while meeting the highest international quality and regulatory standards. By integrating a robust 5G digital foundation with a vertically optimized manufacturing layout, Hepalink has created a facility that maximizes efficiency, enhances operational control, and supports long-term sustainability without compromising product quality or patient safety. Its innovative approach illustrates how digitalization and advanced engineering can transform manufacturing performance in constrained environments.

"Hepalink Pingshan project's achievement of EU GMP certification further validates its world-class design and operational excellence," said Caixue Wei. "The facility sets a new benchmark for the manufacture of high-viscosity pharmaceutical products and serves as a lighthouse for the global pharmaceutical industry and a model for future manufacturing excellence."

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2026 ISPE FOYA Category Award

INNOVATION – Facility of the Future

Sanofi S.A.

QUICK FACTS

Project: Modulus

Location: Neuville-sur-Saône, France and Tuas, Singapore

Total Facility Size: Each facility is 258,000 square feet

Mission: Design and scale replicable, AI-enabled modular biomanufacturing facilities capable of rapidly switching between therapies, accelerate deployment and changeovers between products, maintain quality, and deliver essential medicines faster worldwide.

ABOUT THE CATEGORY

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

Why Sanofi S.A. Won

The rise of monoclonal antibody therapies transformed the pharmaceutical industry, leading to the construction of large single-product, stainless-steel manufacturing facilities. With the advent of personalized medicine and the development of mRNA vaccines that surged during the COVID-19 pandemic, the limitations of these fixed and inflexible production facilities became apparent.

Modulus was born out of a need to surmount these limitations. Sanofi's twin modular sites—a greenfield facility in Tuas, Singapore and a brownfield facility in Neuville-sur-Saône, France—were conceived and constructed simultaneously using a standardized design that promotes global consistency, regulatory compliance in different regions, and operational integration. Adaptations are possible to meet regional requirements while maintaining the standardized design.

The most significant innovation is that Sanofi designed and delivered two nearly identical facilities simultaneously, on time and within budget, in locations separated by 10,000 kilometers. This standardized modular architecture offers a blueprint for future facilities, reducing project risk, accelerating deployment, and ensuring consistent quality across regions.

"For Sanofi, this award affirms that our investment in manufacturing innovation is not just the right strategic direction, it is being recognized as the new standard for the industry," said Benjamin Chia, Head of Global Engineering and Maintenance, Vaccines and Project Delivery. "The FOYA signals to our partners, regulators, and the broader healthcare community that Modulus is not a concept or a prototype, it is a fully realized, operational platform that is already changing what is possible in biopharmaceutical manufacturing."

Flexible Plug-and-Produce Manufacturing

Traditional vaccine manufacturing facilities rely on fixed equipment built for a single product. At the heart of the Modulus design are modular ballrooms with standardized docking stations to allow for rapid equipment



changes that support diverse products, platforms, or modalities without a need for renovation.

"The most striking capability of Modulus, and one that sets it apart from anything else in the industry, is that a changeover between pre-validated technology platforms, such as from mRNA vaccine production to monoclonal antibody manufacturing, can be completed in as little as seven to 10 days," said Chia. "The industry standard for the same transition in a conventional facility is typically several months."

This flexibility allows Sanofi to rapidly modify production bays to make a range of biologics, including vaccines, mRNA, viral vectors, recombinant proteins, enzymes, and monoclonal antibodies, that ensure long-term operational sustainability without extensive need for additional capital investment. Each of the 34 production pods is equipped with interconnected, standardized equipment that can be reconfigured like a sophisticated plug-and-play system. This includes standardized docking stations for utilities, services, and data interfaces that house both upstream and downstream operations and equipment. Rather than tearing down and rebuilding dedicated infrastructure, the relevant pods are reconfigured, swapping in the appropriate single-use assemblies and re-establishing the validated process parameters for the new platform.

Operational agility is facilitated by modular, mobile partitions that can be moved to create different containment areas. Advanced HVAC zoning can be adapted to each new room configuration to guarantee regulatory and biosafety standards.

The facilities are designed to support six different production platforms in the same manufacturing facility. These range from stainless steel equipment to single-use closed systems, to accommodate six vaccine modalities, as well as enzymes and monoclonal antibodies.

"Single-use technology is one of the key enablers of Modulus's exceptional changeover speed, and its integration throughout the facility was a deliberate and central design choice," Chia said. "In traditional stainless-steel manufacturing, switching from one product to another requires extensive cleaning validation, sterilization cycles, and prolonged downtime to ensure there is no cross-contamination between products. This is time-consuming, resource-intensive, and introduces significant regulatory complexity. With single-use technology, there is no need for cleaning validation between products, which dramatically compresses the time needed to prepare a production space for a new process. Combined with the modular pod architecture, this means a space can be cleared, re-kitted, and re-qualified for a new product in a fraction of the time it would take in a conventional facility."

Single-use technology also reduces the risk of cross-contamination, which is particularly important when manufacturing multiple products simultaneously across different pods. It supports a cleaner, safer, and more reliable manufacturing environment, all of which contribute to the quality and consistency of the medicines and vaccines we produce for patients.

Rapid Changeovers Enabled by Pharma 4.0 Technology

Both sites are buttressed by enterprise-wide digital orchestration using a digital twin platform that allows real-time monitoring, predictive maintenance, and information technology/operational technology convergence.

The Modulus facilities have automated dock-to-shipping material



About Sanofi S.A.

Sanofi is a global biopharmaceutical company dedicated to discovering, developing, and delivering medicines and vaccines to millions worldwide. Guided by the mission to "chase the miracles of science to improve people's lives," Sanofi innovates in R&D and leverages AI at scale to build a healthier, more resilient world. The company transforms the impossible into possible by creating therapeutic solutions that enhance quality of life and address global public health challenges.

Supply Partners and Key Participants

Engineer/Architect: PM Group; Jacobs International Consultants Pte. Ltd.; RSP Architects Planners & Engineers (Pte) Ltd.

Commissioning, Qualifications, and Validation Services: Sanofi S.A.

Construction Manager: Vita PMC SG Pte. Ltd.

Main/General Contractor: Egis Group, Bouygues Construction

Piping Subcontractor: JEL Maintenance Pte. Ltd.

HVAC Subcontractor: Wah Loon Plant & Instrumentation Pte. Ltd., Clauger

Automation and Control Supplier: Schneider Electric IT Singapore Pte. Ltd.

Major Equipment Supplier or Contractor: Shanghai Morimatsu Pharmaceutical Equipment Engineering Co.; Sartorius Stedim Singapore Pte. Ltd., Bilfinger



handling, using autonomous mobile robots, standardized totes, and semi-automatic kitting operations to streamline operations while minimizing manual handling and contamination. There is also robotic UV decontamination to improve biosafety and automated waste handling.

"The digital backbone of Modulus plays a critical role in changeovers," said Chia. "AI-driven systems, real-time sensor data, and connected process analytics mean that our teams have full visibility of the line at every stage of the changeover, enabling faster qualification checks and reducing the risk of errors that could otherwise extend timelines."

Globally Replicable Modular Design

The Modulus concept was born in 2018 from a small group of Sanofi colleagues who asked a bold question. What if we could completely reimagine how a biopharma facility is designed? There was no blueprint to follow, no industry precedent to reference. They started with a blank page and a conviction that manufacturing could be smarter, faster, and more flexible.

The twin Modulus sites represent a major development in Sanofi's global manufacturing network, enhancing rapid and flexible delivery of essential medicines, as well as improving pandemic readiness and ensuring safety, digital operations, and sustainability. These multi-product facilities are modular, scalable, and AI-enabled, allowing multiple vaccines and biologics to be produced simultaneously.

"Receiving this FOYA recognition is a tremendous honor," Chia said. "This recognition belongs foremost to the extraordinary people who dared to imagine Modulus and then had the courage and tenacity to build it. What you see today in Singapore and France is the realization of that vision, and this award is a validation of every late night, every technical challenge overcome, and every boundary pushed along the way.

"Most importantly, this award reminds us why we do what we do, to get life-changing vaccines and treatments to patients faster and more reliably than ever before. That mission is what drives us every day, and it is what Modulus was built to deliver."

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2026 ISPE FOYA Category Award

OPERATIONS – Operational Excellence and Pharma 4.0™

Bayer AG

QUICK FACTS

Project: SOLIDA-1

Location: Leverkusen, Germany

Total facility size: 205,000 square feet

Mission: Accelerate delivery of complex medicines through modular, autonomous, digitally integrated manufacturing that enables rapid scale-up, operational excellence, sustainable performance, and continuous innovation.

ABOUT THE CATEGORY – OPERATIONS

Winners in this category exemplify the application of novel tools and approaches to delivering projects that improved efficiencies, overcame unusual challenges, promoted effectiveness, and organized stakeholders and project team participants in ways that led to successful outcomes such as efficiency, delivery, quality, product yield, consistency, and cost of goods. Projects demonstrate a culture of continuous improvement behaviors which yielded superior results. Additionally, these principles, systems and tools ensure business continuity through stable supply environment, health and safety, and customer satisfaction from existing or new facilities, processes, and manufacturing operations.

ABOUT THE CATEGORY – PHARMA 4.0

Winners in this category embody the Pharma 4.0 concept. This includes not only implementing one or more technological innovations, but also demonstrating the ability to change their culture, processes, and people orienting them towards a Pharma 4.0 focused future. Significant contributions include application of one or more applied science-based solutions or digital innovations like automation, robotics, digital twin, or advanced processing understanding; substantial improvement to operational practices; or technologies widely and strategically implemented across the organization.

Why Bayer AG Won

Winning a FOYA is a significant achievement for the team of any pharmaceutical manufacturing facility. Earning two awards in the same year is even more remarkable. Bayer's SOLIDA-1 site, in Leverkusen, Germany, accomplished this feat by combining operational excellence with a pioneering digital manufacturing model.

SOLIDA-1 is designed to manufacture a range of oral solid dose (OSD) products, including cardiovascular therapies and high-potency oncology drug products. The facility has a modular, adaptable design that speeds up technology transfers, allows scaled production from launch to commercial release, and faster launches of complex medicines, reducing time-to-market by up to one year. All of this while improving equipment effectiveness and cutting workforce needs in half. SOLIDA-1 co-locates clinical and commercial-scale production, reducing time to market for new therapies while supporting seamless scale-up from small launch batches to as many as one billion tablets annually.

SOLIDA-1 sets a new threshold for Pharma 4.0 with end-to-end autonomous operations, advanced robotics, AGVs, integrated manufacturing execution system (MES) and data platforms, electronic batch records (EBRs), and AI-enabled access to manufacturing data. Its connected digital systems, combined with exceptional sustainability performance, positions the site as a model for the future of pharmaceutical manufacturing.

Modular and Adaptable

The judges were impressed by SOLIDA-1's scalable modular design, which includes end-to-end autonomous manufacturing and extends to all levels of operations—technologies, processes, and buildings.

- **Technologies:** This facility has the capability to seamlessly add new equipment, as needed, to support different processes. "The equipment for this type of facility needs to be standardized where possible and adaptable where necessary," said Juergen Wiedemann, Strategic Program Lead, Bayer AG. "Standardized interfaces and platform concepts are essential to enable rapid integration, plug-and-play

capability, and repeatable qualification. At the same time, pharmaceutical processes, containment requirements, product characteristics, and regulatory expectations still require tailored engineering."

SOLIDA-1 demonstrates this balance: proven technologies were combined with custom-developed robotics, process-compatible containers, and a dedicated production flow control layer where no existing market solution could meet the required level of autonomous orchestration.

- **Processes:** At the process level, SOLIDA-1 is designed to accommodate a wide range of manufacturing requirements within a standardized module architecture. By concentrating support functions and utilities in the front section of each module, the facility provides a large, open production space that can be configured for different process technologies and product needs. Combined with an open ballroom manufacturing concept, this enables equipment layouts and process flows to be adapted, upgraded, or repurposed with minimal impact on infrastructure, allowing the facility to efficiently support evolving product portfolios while maintaining operational efficiency and scalability.
- **Buildings:** SOLIDA-1 consists of independent modules connected to a central spine, with copy-and-paste scalability that reduces cost, time, and project risk for future expansions. The administrative and production modules are separated, with each area designed according to its functional, regulatory, and technical requirements.

"This separation prevents unnecessary duplication of complex systems, such as cleanroom infrastructure, HVAC, fire protection, containment features, and GMP utilities in areas where they do not add value," Wiedemann said. "At SOLIDA-1, the modular concept also means protection levels are applied only where required, with the central spine serving as a physical and operational backbone. The result is a leaner, more cost-efficient design with fewer interfaces, reduced complexity, improved maintainability, and full compliance with safety and quality expectations."





Wiedemann believes this type of modularity will become an important blueprint for future greenfield pharmaceutical sites.

"The greatest value lies in combining standardization with adaptability," he said. "Instead of designing each facility as a one-off project, manufacturers can establish repeatable module templates, standardized utility concepts, defined interfaces, and a scalable backbone that allows new capacity or technologies to be added step-by-step."

Wiedemann asserts that this approach supports faster deployment, more resilient supply networks, and better alignment of capital investment with uncertain pipeline demand for the wider industry. It is especially relevant as the industry moves toward more flexible manufacturing platforms, advanced manufacturing technologies, and digitally integrated facilities that can evolve over time rather than being locked into one product or technology configuration.

End-to-End Automation

Complete digitalization and end-to-end automated manufacturing are baked into the entire value chain, progressing into levels 3 and 4 of the Pharma 4.0 automation pyramid with the future intent of achieving a true lights-out manufacturing concept across production and





About Bayer AG

"Health for all, Hunger for none." Bayer is a global enterprise with core competencies in the life science fields of health care and nutrition. Its products and services are designed to help people and the planet thrive by supporting efforts to master the major challenges presented by a growing and aging global population. Bayer is committed to driving sustainable development and generating a positive impact with its businesses. The Bayer brand stands for trust, reliability, and quality throughout the world.

Supply Partners and Key Participants

Engineer/Architect: Bayer AG; Pharmaplan (now part of Exyte); Glatt GmbH

Commissioning, Qualifications, and Validation Services: Bayer AG

Construction Manager: Mainka Bau GmbH & Co. KG

Piping Subcontractor: PORR Industriebau GmbH

HVAC Subcontractor: PORR Industriebau GmbH

Automation and Control Supplier: Glatt GmbH

Major Equipment Supplier or Contractor: Glatt GmbH

Additional Supplier: Siemens AG

logistics. Major process steps—from material handling and automated weighing to formulation, compression, coating, cleaning, intralogistics, and electronic documentation—are automated and digitally connected through an integrated automation ecosystem. This significantly reduces manual intervention, improves process stability, and supports highly repeatable execution.

"SOLIDA-1 is not a people-free facility," said Wiedemann. "Human expertise remains essential for oversight, quality assurance, exception handling, technical support, continuous improvement, and regulatory responsibilities. The key achievement is that operators are shifted away from repetitive manual tasks toward higher-value supervision and decision-making. In this sense, SOLIDA-1 represents a major step toward fully autonomous pharmaceutical manufacturing. Not completely unmanned, but highly automated, paperless, data-driven, and designed for minimal routine human intervention."

The innovative ballroom concept is a first for OSD manufacturing, allowing free movement of robots, AGVs, and materials across the production floor. By removing traditional barriers, it lays the groundwork for seamless automation and an adaptable manufacturing environment that can readily accommodate new technologies.

Towards a Lights-Out Future

The next stage of Pharma 4.0 is the transition from highly automated and digitally connected operations to predictive, adaptive, and self-optimizing manufacturing. This will be enabled by digital twins, AI-supported decision-making, predictive and prescriptive maintenance, real-time quality monitoring, and plug-and-produce architectures that allow seamless integration of equipment and systems.

"SOLIDA-1 already creates the foundation for this evolution through near-real-time data collection, automated EBRs, cloud-based data storage in addition to GMP historization, process analytical technology-enabled process feedback, automated statistical process analysis, and initial AI-enabled use cases," said Wiedemann. "These capabilities move the facility beyond automation alone toward intelligent operations, where data can actively support process optimization, faster root-cause analysis, and more efficient product launches."

"For Bayer, the next frontier is not simply more automation, but greater autonomy with strong governance," Wiedemann said. "This will include validated AI models, trusted data, digital twins for simulation and optimization, predictive quality systems, and human experts increasingly acting as supervisors of intelligent manufacturing ecosystems. Regulatory developments are moving in the same direction, with the US Food and Drug Administration highlighting advanced manufacturing technologies and issuing a risk-based credibility framework for AI used to support regulatory decision-making. The future of Pharma 4.0 will be defined by facilities that are modular in structure, autonomous in execution, intelligent in decision support, and transparent in compliance."

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2026 ISPE FOYA Category Award

OPERATIONS – Project Execution

Eli Lilly & Company

QUICK FACTS

Project: Lilly Concord

Location: Concord, North Carolina, USA

Total facility size: 1,100,000 square feet in 11 buildings spanning a 75-acre site

Mission: Deliver an innovative pharmaceutical manufacturing facility through the rapid design, modular construction, replication of proven platforms, and digital twin validation to optimize production, reduce timelines, and improve patient access to high-demand medicines globally.

ABOUT THE CATEGORY

Winners in this category exemplify application of novel approaches, standards and practices which result in efficient processing, resourceful utilities and business advantage by accelerating a shift to sustainable facility design, intended to ensure the effective use of energy, minimize waste, reduce carbon footprint, incorporate green manufacturing techniques, and reduce environmental impact or increasing patient access and preventing drug shortages through in-country-for-country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment and fast-track drug production; and designs which overcome specific geographical challenges.

Why Eli Lilly & Company Won

From conception to commissioning, building a new pharmaceutical manufacturing facility typically takes years—five to 10 is not unusual. Every phase requires careful planning and coordination, including design, site preparation, construction of the building envelopes, interior fit-outs, installation of utilities and process systems, and procurement and qualification of equipment. Such a long timeline is unacceptable for many drug products on the market today. Complex injectable therapies are one example of medicines with rapidly growing demand, making long manufacturing timelines impractical.

Finding innovative ways to expedite the design and construction of the Concord project has helped Lilly meet the growing demand for incretin therapies and aligns perfectly with the company's strategy to expand manufacturing capacity. The site earned recognition for exceptional project execution by delivering a complex, US Food and Drug Administration-approved parenteral manufacturing site from breaking ground on a 415-acre greenfield site to first validated production runs of assembled devices in a mere 30 months, an execution timeline well below the industry standard.

Success was driven by an innovative execution strategy combining disciplined governance, parallel design-build delivery, replication of other proven Lilly facility platforms, extensive modularization, and advanced digital twin technology. Offsite fabrication and skidded utility systems optimized installation and commissioning, while more than eight months of virtual testing reduced onsite validation effort and improved startup readiness. Together, these approaches enabled faster delivery, reduced risk, maintained quality and compliance, and established a scalable model for future pharmaceutical facilities.

A Parenteral Facility for the Future

The Concord facility is designed to fill and inspect pre-filled syringes, as well as assemble and package auto-injector devices. This project leveraged the successful design of Lilly's Research Triangle Park (RTP) facility, with targeted modifications to address the



unique operational and site-specific needs of the Concord facility.

"Since bringing Lilly Concord online—drawing on proven models from our Lilly Research Triangle Park facility—we have continued to expand its capabilities in step with growing demand for our medicines," said Dan VonDielingen, Senior Vice President, Global Parenteral Network Expansion, Eli Lilly and Company. "Lilly's investment in the Charlotte and Concord region is a long-term commitment to expanding US manufacturing capacity and strengthening the supply chain that gets medicines to people who need them."

The project succeeded in such a short time span because of an innovative delivery strategy that included structured decision-making and oversight, modularization, replication of validated design platforms, and coordination between operations, engineering, construction, and automation teams.

Parallel Design-Build Execution

Key to the project's shortened delivery was a Cold Dark Shell strategy, which allowed construction of building foundations and envelopes, along with major utilities distributions, prior to interior fit-out. This provided time for simultaneous interior design and reduced the timeline by almost six months compared to traditional sequencing while maintaining compliance and quality. A centralized governance model empowered rapid decision-making of each of the project's five autonomous workstreams: site development, logistics, parenteral manufacturing operations, device assembly and packaging, and administrative and lab spaces. This model supported barrier resolution and aligned project execution with operational readiness milestones.

Replicating a Proven Design

Judicious replication of the successful facility and equipment design of the Lilly RTP site, while incorporating targeted improvements, significantly expedited the completion of this project. Reliance on established equipment, standardized layouts, and pre-qualified automation templates minimized engineering effort, eliminated original equipment manufacturing design time, reduced long-lead equipment delays, and streamlined testing, qualification, maintenance, and manufacturing execution systems integration. This approach significantly derisked commissioning and compressed startup, allowing the Concord site to achieve initial device-assembly and syringe-filling operations much faster than Lilly RTP.

Offsite Modularization and Skidded Delivery

Modular, skidded construction advanced installation, improved quality, and reduced complexity. A prime example of this process



About Eli Lilly & Company

We're a medicine company turning science into healing to make life better for people around the world. It all started nearly 150 years ago with a clear vision from founder Colonel Eli Lilly: "Take what you find here and make it better and better." Harnessing the power of biotechnology, chemistry and genetic medicine, our scientists are urgently advancing science to solve some of the world's most significant health challenges.

Supply Partners and Key Participants

Engineer/Architect: Hanbury

Construction Manager: BE&K Building Group

HVAC Subcontractor: McCorvey Sheet Metal

Mechanical Contractor: Kirlin Way

Electrical Contractor: Code Electric, Inc.

Mechanical and Electrical Engineer: HIPP Design & Consulting, Inc.



was the design, fabrication, and partial offsite testing of 25 separate modules of the 14,000 square-foot central utility plant (CUP). The entire CUP was also constructed offsite in South Carolina, then delivered to Concord and reassembled. Modularization allowed parallel construction, optimized utilities commissioning, and reduced onsite labor congestion and serves as a model for future Lilly projects.

Virtual Facility Execution and Validation

The Concord project advanced pharmaceutical facility delivery through extensive use of simulation and digital twin technology before equipment delivery, allowing more efficient project execution. A high-fidelity virtual model replicated the full manufacturing ecosystem, including prefilled syringe filling lines, formulation systems, clean utilities, autoclaves, and part washers. This allowed validation of automation logic, human-machine interface functionality, alarms, interlocks, and startup sequences before equipment arrived onsite. More than 250 days of virtual testing reduced floor-based testing by approximately 50 percent, accelerated commissioning and qualification, and improved safety and compliance. This approach established a scalable model for faster, more reliable facility start-ups across future Lilly projects.

Rapidly Meeting Patient Needs

The Concord manufacturing site shines light on how a paperless, automated, and digitalized parenteral production facility can efficiently deliver high-demand medicines while ensuring quality, safety, and operational resilience. Most notably, the project's unmatched speed from breaking ground to validated production represents a blueprint for future pharmaceutical manufacturing projects and has a significant impact on meeting patient and consumer needs, particularly for drug classes with high demand and ongoing supply shortages.

"Strong partnerships with state and local governments, universities, and economic development organizations remain central to our success here," VonDielingen said. "Both Concord and our RTP site are built to scale with us and we remain committed to growing alongside the communities that have made them possible."

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2026 ISPE FOYA Category Award

SUPPLY CHAIN

BSP Pharmaceuticals SpA

QUICK FACTS

Project: An integrated state-of-the-art site for antibody-drug conjugates (ADC), drug substance (DS), and drug product (DP), from investigational new drug (IND) to commercial supply

Location: Latina, Italy

Total Facility Size: 2,790,000 square feet

Mission: Create a fully integrated ADC manufacturing facility that unites drug substance conjugation and drug product fill-finish under one quality system, strengthening supply chain resilience, accelerating delivery, enhancing safety, and improving patient access to critical oncology drugs.

ABOUT THE CATEGORY

Winners in this category exemplify novel application of principles, systems, and management tools aimed at improving operational speed, robustness, and response. These could be applied to areas in which delivery to market impacts patients, technology amplifies supply chain robustness or security, or candidates exemplify modern approaches to disruption.

Why BSP Pharmaceuticals SpA Won

At its Latina, Italy site, BSP Pharmaceuticals has addressed a significant industry bottleneck in ADC manufacturing: a fragmented supply chain. The site co-locates DS conjugation and DP fill-finish within a single facility under one quality system. This eliminates multiple inter-site transfers, reduces cold chain risks, improves traceability, accelerates batch release and regulatory preparedness, enhances worker safety when handling highly potent compounds, and shortens time to market. The result is a more resilient and efficient supply chain that supports the production of life-saving oncology therapies.

Consolidating Conjugation and Fill-finish at One Site

Founded in 2006, BSP Pharmaceuticals is an Italian CDMO specializing in the production of oncology, cytotoxic, and immunotherapy drugs for pharmaceutical and biotechnology partners. It operates from investigational new drug to commercial supply. The company currently manufactures 13 of the 19 ADCs approved for the commercial market and provides service support for more than one hundred bioconjugated clinical programs.

Traditionally, the critical steps needed to manufacture an ADC are managed in separate, often geographically distant sites, resulting in a highly fragmented supply chain. Monoclonal antibodies are shipped from one facility, the linker-payload complex is shipped from another, and conjugation occurs at a third site. This DS is shipped again to a fill-finish facility to produce the DP. Each handover runs the risk of cold chain interruption, transportation problems, and delays that affect product integrity and delivery to patients.

The Latina facility consolidates conjugation and fill-finish operations within a single facility, which represents a fundamental shift in the structure of ADC supply chains. It is unusual to have a fully integrated supply chain for commercial-scale DPs as complex as ADCs, making the Latina unique in the industry. Monoclonals, cytotoxin-linkers, and intermediates are protected from exposure risks, handling complexity, and extended storage. Cold chain logistics are streamlined,



while on-site storage as low as -80°C eliminates the need to move temperature-sensitive materials between sites. All critical components are received at one site, which means fully packaged DP is produced and shipped through a unified supply chain.

"Inter-site transfers of highly potent, cytotoxic intermediates introduces exposure risk, cold chain challenges, and the potential for quality deviations during transit," said Aldo Braca, Chief Executive Officer and President, BSP Pharmaceuticals. "By housing both steps at Latina, end-to-end integration compresses the overall manufacturing cycle, strengthens batch traceability, and gives us a unified point of accountability for the entire ADC production process."

A Single Quality System for DS and DP

A single quality management system (QMS) across the entire manufacturing process delivers full traceability, improved compliance, and faster batch release, while harmonized documentation reduces complexity and drives higher quality outcomes.

"Co-locating drug substance and drug product operations creates a continuous quality oversight loop that simply isn't achievable when the two steps are separated," Braca said. "Quality control (QC) teams can monitor critical quality attributes—conjugation efficiency, drug-to-antibody ratio, aggregation levels—and immediately apply those insights to the downstream fill-finish process without the delays inherent in inter-site communication."

Any out-of-trend result detected at the DS stage can trigger a real-time review before the material advances, preventing quality risks from propagating. Shared analytical infrastructure also avoids the need to repeat or transfer testing between sites, reducing variability in results.

"Ultimately, the proximity of drug substance and drug product operations fosters a culture of integrated quality ownership, where every team member understands how their work connects to the final product delivered to patients," said Braca.

Accelerated Regulatory Pathway

When DS and DP operations are split across multiple sites, regulatory agencies must inspect and approve each location separately. Each site requires its own set of manufacturing authorizations, standard operating procedures, and QMS. Coordinating across those different regulatory frameworks adds considerable overhead and risk. By integrating DS and DP manufacturing, the Latina facility streamlines regulatory pathways for fast-track approvals, reduces post-approval changes, and speeds commercial readiness.

"At Latina, inspectors can assess the full manufacturing journey in a single visit, from conjugation through final fill-finish," Braca said. "There is one integrated quality system, one unified set of batch records, and one accountable manufacturing team. This transparency simplifies the inspection process for authorities, accelerates responses to queries, and reduces the likelihood of cross-site inconsistencies being flagged. It also streamlines chemistry, manufacturing, and controls dossier preparation and post-approval change management, since changes affecting both drug substance and drug product can be addressed in a single regulatory submission."

Safety by Design

The cytotoxic payloads used in conjugation are among the most hazardous substances handled in pharmaceutical manufacturing, and those handled at the Latina site have an occupational exposure limit below 10 nanograms per cubic meter. Every transfer of these materials between facilities introduces occupational exposure risk, packaging complexity, transport hazards, and emergency response challenges across multiple jurisdictions.

"The design of the Latina plant confines the handling of highly potent active pharmaceutical ingredient-conjugated intermediates to one containment-engineered environment with a highly trained



About BSP Pharmaceuticals SpA

BSP Pharmaceuticals SpA is a contract development and manufacturing organization. The BSP campus hosts two segregated facilities to serve clients with development from preclinical GLP to cGMP manufacturing for clinical and commercial supply of cytotoxic and high-potency oncology drugs and non-cytotoxic, innovative compounds for Immunotherapy and other therapeutics applications. The company has facilities designed to handle small and large molecules, including ADCs (conjugation and fill finish), peptides, proteins, oligonucleotides, and nano medicines. BSP is technologically developed to meet the needs of innovators with its high-containment facility for a full range of integrated services aimed to support the entire lifecycle of a product, from formulation and process development/optimization, through scale-up and scale-down studies.

Supply Partners and Key Participants

Engineer/Architect: Akkodis Italia

Commissioning, Qualifications, and Validation Services: Akkodis Italia

Construction Manager: Rebis Service Srl

Piping Subcontractor: Stilmas S.p.A.

HVAC Subcontractor: OC Srl

Automation and Control Supplier: Tecnoelectric

Major Equipment Supplier or Contractor: IMA Life; Fedegari Autoclavi SpA

Additional Suppliers: Syntegon Telstar; Sartorius Stedim Italy Srl



workforce operating under a unified safety management system," said Braca. "There is one containment strategy, one spill response protocol, one set of engineering controls—all optimized for ADC-specific hazards."

This consolidation dramatically reduces the number of touchpoints where exposure incidents could occur and enables a more proactive, coherent approach to occupational health across the entire production chain.

During project execution, BSP Pharmaceuticals recorded a lost-time injury rate of only 0.14 during 1.4 million work hours and presented 900 safety toolbox talks.

Accelerated Time to Market

One of the most significant timelines in ADC drug development is the period between clinical batch release and first patient dosing, or between regulatory submission and commercial launch. Any inefficiency in manufacturing, such as delays at batch handover, inter-site shipping, redundant QC testing, and misaligned release schedules, directly compounds patient wait times. The resilience of the Latina supply chain reduces these delays and has meaningful impacts on time to market.

"Thanks to Latina's integrated supply chain, we have eliminated many of these points of inefficiency," said Aldo Braca. "Batch release decisions are made with full visibility across both drug product and drug substance, without waiting for material to arrive from a remote site. This allows for a faster, more agile response to demand fluctuations or clinical trial schedule changes. For innovative oncology therapies where urgency is critical, the ability to reduce cycle time without compromising quality is not just a competitive advantage, it is a patient-centered imperative."

BSP Pharmaceuticals has shown that the production of complex ADCs can be dependable and efficient while addressing one of the most critical challenges in oncology manufacturing.

"The expansion of the Latina site establishes a new standard for supply chain resilience and rapid product delivery," said Aldo Braca. "For patients and partners alike, it means a more reliable, predictable supply of complex, life-saving therapies."

WATCH BSP PHARMACEUTICAL'S VIDEO

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2026 ISPE FOYA Category Award

SOCIAL IMPACT – Unmet Medical Needs

AstraZeneca

QUICK FACTS

Project: Commercial Cell Therapy Facility

Location: Rockville, Maryland, USA

Total facility size: 105,000 square feet

Mission: Deliver uninterrupted, autologous T-cell therapies at commercial scale through fully electrified, resilient biomanufacturing, guaranteeing 100 percent uptime, reliability, and net-zero carbon operations while allowing rapid personalized oncology treatments for more than 4,000 patients annually.

ABOUT THE CATEGORY

Winners in this category exemplify application of novel approaches, standards and practices which result in efficient processing, resourceful utilities and business advantage by accelerating a shift to sustainable facility design, intended to ensure the effective use of energy, minimize waste, reduce carbon footprint, incorporate green manufacturing techniques, and reduce environmental impact or increasing patient access and preventing drug shortages through in-country-for-country manufacturing; outbreak, epidemic, or emerging health crisis response via rapid deployment and fast-track drug production; and designs which overcome specific geographical challenges.

Why AstraZeneca Won

This three-story, fully electrified biomanufacturing facility produces autologous T-cell therapies at commercial scale, as well as for late-stage oncology clinical trials. The site can produce therapies for up to 4,000 patients per year. However, because each therapy is derived from a patient's own cells and is intended for that individual alone, the facility cannot maintain an inventory of cells.

The time-sensitive nature of these therapies dictated the essential design requirement of unfailing operational uptime, including no facility-wide maintenance shutdowns or power outages. The design and construction teams have created a facility in which the probability of an unplanned total power loss is reduced to one incident in 10,000 years, while also meeting the company's mandate to support environmental sustainability in the design.

"To achieve this ambitious goal, there was a shift in mindset for this project, reflecting our need to embed sustainability as a core design parameter alongside quality, reliability, and performance from the outset, rather than treating it as an add-on," said Brian Stamper, Manufacturing Excellence Lead at AstraZeneca. "In practice, this meant rethinking utilities, embracing electrification, and aligning infrastructure choices with the needs of the therapy."

For the broader industry, this facility demonstrates that environmentally responsible design can coexist with highly reliable, patient-critical manufacturing when supported by thoughtful engineering, redundancy, and integrated supply chains.

Resolving the Redundancy-Sustainability Trade-off to Save a Day and Save the Planet

Personalized medicine requires speed. Delays in autologous treatment are not an option for oncology patients, for whom even a day can make a difference to their quality of life or chances of survival. And, because their treatment is derived from their own cells, maintaining a viable, uninterrupted supply chain for samples and raw materials is critical. This demands a non-negotiable requirement for 100 percent uptime.

"We believe that each bag of patient-



derived material is analogous to that patient," Stamper said. "This mindset reinforces the patient-centric nature of autologous cell therapy, where continuity is essential. It drove our design philosophy, which was centered on uninterrupted operations, full traceability, and risk mitigation."

This translated into eliminating single points of failure, incorporating redundant utilities and backup systems, and enabling operational flexibility. It also extended beyond manufacturing to the entire supply chain, ensuring that material handling, logistics, and quality controls consistently protect product integrity at every step.

To maximize operational uptime, the design team focused on identifying and mitigating all potential risks to continuous operation. They looked to industries with similar requirements for uninterrupted performance, safety, and resilience, including mission-critical data centers, nuclear power sites, and oil refineries.

Multi-layered resiliency of electrical, mechanical, and manufacturing processes was baked into the design since downtime could mean loss of a single patient batch, contamination, or critical data failures. Layers of protection analysis helped design a facility that could anticipate and avoid such downtime events.

Electrical

Complete electrification supports the facility's net-zero carbon operations and the company's sustainability goals. But it came with a dilemma—it required infrastructure capable of virtually eliminating the risks of relying on a single utility source and potential external grid outages.

The engineers imitated a Tier IV data center to design a reliable power system that relies on two independent power systems. This system has a layered protection architecture and was validated with failure mode analysis. The system features:

- Dual independent power service
- On-site generation
- Uninterruptible power supply
- Centralized monitoring

The facility has two data rooms, each of which can meet the facility's entire IT load, ensuring full digital redundancy.

Mechanical

The mechanical systems were designed with layers of redundancy to support GMP manufacturing. Sustainability and resiliency were included in the design of utility equipment, ductwork, piping, and insulation. Essential HVAC air-handling units (AHUs) are powered through dual electrical sources with transfer switches to maintain operation during maintenance. Two rooftop dedicated outside air systems (DOAS) run in parallel to ensure redundancy if one is offline. The DOAS units also supply individual secondary AHUs dedicated to each cleanroom. Electric boilers provide redundant capacity for the coldest days when the heat recovery chiller and air source heat pumps cannot meet the site's load.

Manufacturing

Resiliency extends into the heart of the site, which is designed with four independent cell processing suites, each equipped with flexible workstations, dedicated utilities, and isolated air handling systems. This means that the suites are not connected and any one of them can be taken offline without affecting the others. Redundancy is further embedded through backup processing areas, duplicated critical infrastructure systems, and extensive process modeling to support high-use operations and maintain production continuity during maintenance or equipment downtime.



About AstraZeneca

AstraZeneca is a global, science-led biopharmaceutical company that focuses on the discovery, development, and commercialization of prescription medicines in oncology, rare diseases, and biopharmaceuticals, including cardiovascular, renal and metabolism, and respiratory and immunology.

Supply Partners and Key Participants

Engineer/Architect: CRB

Commissioning, Qualifications, and Validation Services: Project Farma

Construction Manager: CRB

Piping Subcontractor: Pro-Air

HVAC Subcontractor: Environmental Air Systems

Automation and Control Supplier: RoviSys Building Technologies

Major Equipment Supplier: Hatzel & Buehler, Inc.; Siemens Industry, Inc.; Cummins Inc. (Generators); Trane US Inc (Chillers); Havtech, LLC (Semi-custom air handlers)

Sustainability

The cell therapy facility is completely electrified, has net-zero carbon operations, and is designed for LEED Platinum certification. Its water and energy use are half that of a conventional biopharmaceutical manufacturing facility. In addition to full electrification, the facility relies on smart lighting to reduce unnecessary energy use, elimination of energy draws from unused equipment (e.g., monitors), electric vehicle charging stations, electrical submetering, and preparation for future installation and integration of a solar power system. Electrification, combined with the integration of renewable energy sources eliminates operational carbon emissions, which could have been an estimated six million pounds of carbon annually.

The team used energy modeling and simulations to design the mechanical systems for maximum energy efficiency. This included advanced heat recovery strategies, such as a heat recovery chiller, water reuse, an exhaust ventilation glycol loop, air source heat pumps, and an enthalpy wheel. Systems to reduce simultaneous heating and cooling improved the energy efficiency of heating and cooling systems. The use of low greenhouse gas emissions refrigerants and leak detection minimize unnecessary emissions from the facility.

For the manufacturing processes, the cleanrooms were designed for sustainability and flexibility, accommodating diverse process platforms and technologies so multiple products can be produced without significant changes. Closed processing and optimized air change rates further reduce energy use, utilities, and operating costs while ensuring GMP compliance and resilience.

Redundant, Reliable, and Replicable—A Roadmap for the Future of Cell Therapy Manufacturing

“The combination of purpose, partnership, and respect for every individual on site makes this a good place to work,” Stamper said. “From day one, we made sure each worker understood the transformative impact of the facility they were helping bring to life for patients, which gave the work real meaning. By pairing that shared purpose with a strong focus on physical safety, mental wellbeing, recognition, and open dialogue, we created an environment where people feel valued and empowered to bring their best selves to work every day.”

AstraZeneca’s Rockville site establishes a foundation of patient-first reliability together with environmental sustainability at commercial scale for commercial cell manufacturing.

“The benefits of the site’s design are broadly transferable to other facilities,” Stamper said. “While specific design details may remain proprietary, the underlying principles of early integration of sustainability, designing out single points of failure, and aligning facility design with the therapeutic modality, are transferable and can inform future projects.”

In these ways, the commercial cell therapy facility in Rockville points a way for future biopharmaceutical projects to merge uninterrupted delivery of life-saving patient care with environmental stewardship.

WATCH ASTRAZENECA’S VIDEO



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2026 ISPE FOYA Category Award

SOCIAL IMPACT – Sustainability Efforts

Takeda

QUICK FACTS

Project: AHEAD – (Advanced Heat Pump Demonstrator)

Location: Vienna, Austria

Total Facility Size: 10,760 square feet

Mission: Demonstrate that industrial decarbonization is achievable at scale, transforming waste heat into carbon-free steam to help significantly cut CO_2 emissions. To openly share a replicable model to facilitate sustainable manufacturing globally.

ABOUT THE CATEGORY

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

Why Takeda Won

Climate change is complex, persistent, and difficult to solve. Takeda, which has committed to net-zero greenhouse gas emissions in its operations before 2035, has embraced its responsibility to address climate change with the AHEAD project, the world's first of its kind industrial heat pump capable of producing high-pressure steam at 11 bar(a), ~184°C, and 2.5 tons/hour using only natural refrigerants. Until recently, industrial heat pumps were incapable of generating boiling water. This flagship sustainability project at the company's largest manufacturing facility demonstrates that even one of the most energy-intensive processes in pharmaceutical manufacturing—the production of high-temperature steam for GMP-compliant processes—can be decarbonized. AHEAD produces steam for the facility, which produces more than 20 drug products for patients around the world with rare and complex diseases, highlighting the important role pharmaceutical manufacturers can play in addressing climate change.

"AHEAD produces steam for one facility of our Vienna campus," said Maria Löflund, Takeda Site Head in Vienna. "Producing more than 20 life-transforming therapies for patients around the world with rare and complex diseases, we recognize that a healthy environment supports human health. Ensuring that projects are both environmentally and economically sustainable is fundamental to how we operate."

A Scalable, Replicable, and Transformative Model for the Future

The foundation of the heat capture and steam generation system is a heat pump capable of upgrading waste heat from the existing refrigeration system stepwise to produce high-pressure steam (up to 11 bar(a), ~184°C, and 2.5 tons/hour), meeting GMP requirements. AHEAD reduces CO_2 by as much as 80 percent, equivalent to approximately 1,600 tons of CO_2 saved annually at the largest production site in Vienna. AHEAD produces CO_2-free steam for more than seven months each year, making it a fully functional utility.

From a technical perspective, the project demonstrates how steam generation can be



decarbonized on an industrial scale. AHEAD replaces conventional fossil fuel-based boilers with a system combining a high-temperature heat pump and mechanical vapor recompression, fully powered by renewable electricity and natural refrigerants.

A key focus of the project has been scalability and transferability. Simulation models, operational data, and system design were developed to support replication at other sites and industries. Implementation remains dependent on site-specific factors, particularly waste heat availability and steam demand. In this context, AHEAD provides a validated technical reference that can be adapted to different industrial environments to support process heat decarbonization.

"AHEAD is a first-of-its-kind industrial system for high-temperature steam generation," said Löflund. "We implemented AHEAD from the outset as a fully operational, utility-scale system and it serves as a reference for industrial-scale decarbonization of steam generation."

A Collaborative Knowledge-Sharing Model

The project is a collaborative effort between Takeda, AIT Austrian Institute of Technology, and Sustainable Process Heat (SPH), and is supported by the Austrian Climate and Energy Fund. AIT is expected to provide a final report by early 2027, assessing not only actual operating parameters but also the feasibility of replicating AHEAD at other Takeda manufacturing sites.

"We decided from the start to openly share the knowledge we would gain with this groundbreaking technology," Löflund said. "By doing so, we are hoping to encourage adoption in the pharmaceutical industry and beyond. No single company can address the climate challenges alone, particularly in energy-intensive sectors such as pharmaceuticals."

By making technical insights, operational learnings, and system design transparent, AHEAD is intended to support other organizations in adopting similar solutions. This reflects Takeda's broader conviction that decarbonizing industrial energy systems requires collective action.

Takeda has actively sought to exchange technical details with external stakeholders, opening the Vienna energy center and the AHEAD system to industry representatives from multiple industries who reached out. More than 50 companies have participated in site visits and discussions following commissioning. In addition, AHEAD was featured at the IEA Heat Pump Conference in Vienna in May 2026, attracting more than 100 international participants from research and industry. It also was showcased at COP28 and the World Expo 2025 in Osaka, Japan, and won the Net-Zero Industries Award in Austria.

"The concept is not limited to pharmaceutical manufacturing," said Löflund. "AHEAD applies the principle of upgrading low- to medium-temperature waste heat to high-pressure steam, which is relevant across multiple sectors with comparable energy profiles, including chemicals, food processing and advanced materials."



About Takeda

Takeda is a values-based, R&D-driven biopharmaceutical company headquartered in Japan, focused on creating better health for people and a brighter future for the world. Takeda discovers and delivers life-transforming treatments across key therapeutic areas, including rare diseases, oncology, neuroscience and plasma-derived therapies. Guided by its commitment to patients, its people and the planet, the company works with partners to advance healthcare. The entire pharmaceutical value chain for plasma-derived therapies is located in Vienna. Patients in more than 100 countries are supplied with life-transforming therapies from Vienna.

Supply Partners and Key Participants

Research Partner: AIT

Major Equipment Supplier: SPH

Simulations and Safety

Takeda's research partner, AIT, developed detailed, data-driven models to evaluate more than 160 annual scenarios. These experiments optimized steam production and minimized unnecessary stops and starts of the AHEAD system, predicted energy savings, and revealed integration challenges.

"Simulation was a central enabler in the design and optimization of AHEAD, allowing the team to move from concept to a fully operational industrial system," Löflund said. "Given the complexity of integrating a new energy system into an existing GMP environment, it was essential to understand how the system would behave under real operating conditions, including seasonal variability and partial-load operation. This simulation approach allowed engineers to define system parameters, size components, and optimize control strategies, ensuring a balance between efficiency, reliability, and operational stability. Beyond initial design, simulation also supported risk assessment, integration planning and long-term performance optimization, including alignment with existing utilities and GMP requirements. In this way, AHEAD shows how simulation-based engineering can de-risk complex innovation projects, allowing confident implementation at industrial scale."

The supplier of the heat pump, SPH, modified its high-temperature unit, which normally uses synthetic refrigerants, to work with n-butane, a non-fluorinated refrigerant that doesn't contribute to greenhouse emissions. The use of this flammable refrigerant required construction of a dedicated building to maintain stringent safety and regulatory requirements without disruption of ongoing work at the facility.

A Time Capsule Reminds All of Takeda's Environmental Goals

AHEAD is a milestone for Takeda in its efforts to decarbonize its operations and contributes directly to its target of achieving net-zero greenhouse gas emissions in operations by 2035. As a visual gesture to this commitment, the project team integrated a time capsule into the outer wall of the AHEAD building at the beginning of construction. It contains wishes for a sustainable future, positioning AHEAD as an innovation helping to lead the way.

"The time capsule is made of metal and includes a daily newspaper from the day of sealing, as well as a group photo of the entire project and leadership team," said Löflund. "Rather than being buried underground, it was placed behind a small window, making it visible to employees and visitors. This was a deliberate decision to ensure that the project's sustainability ambition remains visible and accessible over time."

The capsule reflects the broader objective of the AHEAD project, which is to contribute not only a technical solution, but also to support the long-term transformation of industrial energy systems with a lower environmental impact.

WATCH TAKEDA'S VIDEO



2026 ISPE FOYA Category Award

HONORABLE MENTION

Chugai Pharma Manufacturing Co., Ltd.

QUICK FACTS

Project: FJ3 Project

Location: Fujieda City, Japan

Total facility size: 126,271 square feet

Mission: Empower Chugai's integrated API supply network with world-leading, safe, automated manufacturing for cyclic peptides and other innovative small molecules and macrocyclic peptides. Using proprietary dual-production technology, modular design, and scalable operations, FJ3 accelerates access to therapies for global patients with untreated diseases.

ABOUT THE CATEGORY

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

Why Chugai Pharma Manufacturing Won

Completed in November 2024, FJ3 is a multi-product facility that advances dual manufacturing of both conventional small molecules and macrocyclic peptides within a single, integrated equipment platform. The project overcomes the longstanding limitations of solid-phase peptide synthesis with a proprietary liquid-phase process that allows efficient and scaled-up production of macrocyclic peptides. Scale-up challenges were overcome through the use of modular design, full automation and integrated digital systems that reduce manual work, support remote monitoring, and anticipate future innovations, like digital twins.

Worker safety and operational continuity are ensured with industry-leading containment systems capable of a limit of 0.03 $\mu g/m^3$ for highly potent APIs (HPAPIs), as well as seismic isolation to withstand Japan's highest anticipated earthquake activity.

This project excels as an exemplar of socially responsible manufacturing. Significant waste reduction, energy-efficient HVAC, and use of green electricity and low-carbon construction materials demonstrate a sustainable approach to design.

Together, the qualities of this project combine sustainability and operational excellence, enhancing patient impact, protecting workers and the community, and exemplifying the spirit of innovation and excellence that FOYAs are meant to celebrate.

Dedicated to Patients, Community, and the Environment

Chugai Pharma Manufacturing's FJ3 facility is located at the company's Fujieda site in Shizuoka Prefecture. This area is known for its tea plantations, beautiful white-sand beaches, and mountains—the snow-capped peak of Mt. Fuji is visible from the roof of the facility. Chugai was founded in 1925 by Juzo Ueno after a cataclysmic earthquake led to drug shortages. He wanted to create drugs that benefit the world, a vision that the company follows to this day. It entered a strategic alliance with Roche in 2002 and continues to manufacture innovative medicines for the global community.



Today, Chugai's clinical pipeline includes several novel macrocyclic peptides—midsize molecules containing non-natural amino acids—that combine oral delivery with precise target specificity for previously untreatable diseases. These offer specific targeting of difficult-to-reach intracellular and extracellular targets, such as KRAS, an intracellular protein implicated in tumor proliferation.

Traditionally, macrocyclic peptide production has been hampered by the challenges associated with solid-phase synthesis, including excessive reagent use, specialized equipment requirements, limited scalability, and challenges handling low-reactivity non-natural amino acids.

To solve this, Chugai modified classical liquid-phase synthesis to create a proprietary, ultra-efficient platform they call classical solution peptide synthesis (CSPS).

"Conventionally, macrocyclic peptide manufacturing requires specialized equipment based on solid phase synthesis," said Mitsuteru Kohriyama, facility manager of FJ3. "FJ3 demonstrates that both small- and mid-size molecules can be produced within the same equipment configuration, establishing a new benchmark for flexible and efficient facility design across the pharmaceutical industry."

This design leads to capital efficiency and reduced manufacturing costs since both small molecule and macrocyclic peptide APIs can be manufactured with standard equipment, such as stirred-tank reactors and filter dryers.

"Grounded in a deep understanding of the structural characteristics and behavior of each amino acid, CSPS serves as a versatile peptide synthesis platform, providing a foundational technology applicable to future cyclic peptide drug development broadly," said Kohriyama. "We believe it provides significant value to the industry to access previously unreachable therapeutic targets that have traditionally been difficult to reach with biologics or small molecules."

Scale-up Through Modular Design, Automation, and Workforce Efficiency

FJ3 is designed to deliver flexible, scalable, and highly automated manufacturing to enhance operational efficiency and accelerate timelines across multi-product operations. To expand capacity beyond what is possible at facilities that rely on separate production lines, FJ3 uses a single, integrated equipment configuration to produce both conventional small molecules and macrocyclic peptides. The team scaled complex, high-risk processes, including the operation of multiple lines that use large volumes of flammables and HPAPIs. A lean workforce can operate these lines, including non-hazard-rated equipment for HPAPI drying, thanks to the project team's expertise and collaboration.

FJ3 leverages modularized process equipment and control systems to streamline technology transfer and improve cost efficiency and speed across the product development lifecycle. Fully automated and digitalized, the facility integrates distributed control, manufacturing execution, warehouse management, and enterprise resource planning systems to minimize manual handling, reduce operator burden and human error, and support remote monitoring, as well as make room for future digital twin deployment.

Safety, Resilience, and Sustainability—by Design

Risk assessments and simulations of containment of HPAPIs at FJ3 have set an industry benchmark (0.03 µg/m^3) that is a 40 percent

improvement compared to Chugai's existing—and award-winning—FJ2 facility. Other manufacturing facilities are sure to benefit from this isolation technology and design, which ensures containment even in glove-failure scenarios.

In keeping with the company's history responding to the threat of earthquakes in Japan, seismic isolation systems are designed to preserve building integrity and allow continuous operations even for the country's highest anticipated earthquake intensities.

"The seismic isolation system using spherical sliding bearings adopted at FJ3 provides a compact design with increased underfloor space and optimal piping layout," said Kohriyama. "This model will benefit pharmaceutical facilities in seismically active regions throughout the Pacific Rim to preserve building integrity and ensure operational continuity."

The significant waste reduction and energy efficiency at FJ3 are also closely aligned with Chugai's corporate policy and mission, which adheres to the Roche Group's safety, security, health, and environmental protection policy, in which sustainability is a core pillar.

- **Waste Reduction:** The CSPS method reduces waste per kilogram of API to less than 10 percent of conventional methods. Recovery systems for used catalysts and organic solvents are also installed. This represents a major step toward green manufacturing and contributes to the sustainability goals of the entire pharmaceutical industry.
- **Energy-Efficient HVAC System:** With independent control of six manufacturing lines, smart controls based on real-time load, and a coefficient of performance improvement from 3.9 to 4.7, the HVAC system uses 20 percent less energy.
- **Elimination of Fluorocarbons:** All chillers use natural refrigerants, aligning with Chugai's goal of completely eliminating fluorocarbons by 2030.
- **Use of Green Electricity:** FJ3 and the entire Fujieda site sources green electricity, demonstrating a commitment to decarbonization.
- **CO_2 Reduction During Construction:** With a reliance on low-carbon construction materials, the manufacturing process itself was sustainable.

A Future-Ready Pharma Facility

The FJ3 facility sets a new standard for pharmaceutical manufacturing by uniting innovation, operational agility, and sustainability to deliver novel therapies for unmet medical needs, safely and at scale. With dramatic waste reduction, energy efficiency, use of green electricity, and incorporation of low-carbon construction materials, this project also deserves recognition for its socially responsible design and operation.

As the FOYA judges noted, "FJ3 reflects a holistic approach to sustainability by design, where innovation accelerates patient impact, safety protects people and communities, and sustainability safeguards what comes next."

WATCH CHUGAI'S VIDEO



About Chugai Pharma Manufacturing Co., Ltd.

Celebrating its 100th anniversary in 2025, Chugai is a leading Japanese pharmaceutical company known for its strategic alliance with Roche and a strong portfolio of proprietary products. Under the slogan "Innovation all for the patients," Chugai continues to drive breakthroughs in healthcare. Chugai Pharma Manufacturing Co., Ltd. serves as the core manufacturing entity within the group, delivering high-quality medicines to patients around the globe.

Supply Partners and Key Participants

Engineer/Architect: JGC Japan Corporation; Kajima Corporation

Commissioning, Qualifications, and Validation Services: JGC Japan Corporation

Construction Manager: JGC Japan Corporation

General Contractor: JGC Japan Corporation

Piping Subcontractor: Heiwa Fusou Techno Co., Ltd.

HVAC Subcontractor: Daidan Co., Ltd.

Automation and Control Supplier: Emerson Japan, Ltd.

Major Equipment Supplier: Kobelco Eco-Solutions Co. Ltd (Glass lined reactor); MANZEN Machinery Co, Ltd (Containment isolator)



2026 ISPE FOYA Category Award

HONORABLE MENTION
FUJIFILM Biotechnologies

QUICK FACTS

Project: Galaxy

Location: Holly Springs, North Carolina, USA

Total Facility Size: Nearly 1,000,000 square feet

Mission: Create a scalable, resilient, and rapid drug manufacturing hub that could meet global needs with speed and precision. The goal was met when Operations thawed their first vial of cells in fall 2025.

ABOUT THE CATEGORY

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

Why FUJIFILM Biotechnologies Won

The Galaxy project is a large-scale monoclonal antibody manufacturing facility in Holly Springs, North Carolina, USA, designed to be one of the largest end-to-end cell culture manufacturing sites in North America. It is a prime example of a transformative trend in biopharmaceutical manufacturing facility delivery that relies on modularization, replication of proven designs, and integration of Pharma 4.0™ technologies to enhance predictability, improve coordination, and efficiently scale operations. The approach significantly reduced project risk by leveraging lessons learned and embracing data from previous facilities as part of a "design once, build many" strategy for the design and construction of this facility.

Safety risk was also reduced by incorporating accident prevention into the design process. Combined with sustainability initiatives targeting LEED Gold certification, Galaxy has established a scalable, replicable template for future pharmaceutical facilities.

"Design Once, Build Many"

The Galaxy project features two drug substance manufacturing buildings, each equipped with four 20,000 L bioreactors, and standardized upstream and downstream capabilities. It was designed using FUJIFILM Biotechnologies' proprietary kojoX™ modular replication strategy, which incorporates standardized layouts, equipment, and processes. The company used its Denmark facility as a blueprint for Galaxy, while the Galaxy modular design has been replicated five times. Digital replication, bespoke design tools, and digital twins meant the Galaxy project saw engineering costs cut in half, an 80 percent reduction in supplier design time, and a 70 percent efficiency gain.

"Our kojoX approach allows us to build upon proven designs rather than starting from scratch with each new facility," said Jordan Ulrich, Vice President, Project Delivery. "By leveraging a digitally replicated model with harmonized facility layouts, equipment, processes, and operating procedures, we have dramatically reduced design timelines and accelerated project execution. This approach not only shortens timelines but also creates greater consistency across our global



manufacturing network, enabling us to respond more quickly to growing demand for biologics. These replication principles, which secure the supply of medicines to patients, would be expected to continue to be of high interest in other pharmaceutical manufacturing facilities."

This replication design strategy reduces risk by minimizing the number of unknowns typically associated with large-scale capital projects. The ability to start a new project with as-built designs and schedules from previous projects provides significant insights and advantages in planning and forecasting. During execution, teams are able to progressively apply lessons learned from existing facilities that have reduced cost and schedule risk while providing teams with a more efficient means of execution.

"Beyond the building phase, this approach enables our start-up and operational teams across facilities to share expertise and best practices, helping identify and address potential challenges earlier in the project lifecycle," Ulrich said. "Ultimately, this supports greater certainty and speed in our ability to meet patient demand."

Digital Replication Aligned with Pharma 4.0

Leveraging the site's digitalization and alignment with Pharma 4.0 principles, project teams used a suite of advanced execution technologies, including 4D construction simulation, AI-enabled progress tracking, and drone-based site monitoring. For example, a robotic layout system with autonomous inkjet printers marked the floor plan on the foundation's concrete slab. The use of robotic layout technology is still relatively new but is becoming more common across advanced construction projects like the one at Holly Springs.

"With our core strategy of replication, precision in layout was paramount, and we've had great success in pairing robotic layout with our digital design," Ulrich said. "For a project of this scale and complexity, we have heavily relied on technologies like this to support our broader strategy of leveraging innovation, standardization, and harmonization wherever possible."

The kojoX software replicated designs of other facilities to reduce design time of the Galaxy facility by about one year, producing an initial design model that was 75 percent right on the first pass. Along with the use of digital twins, this enables rapid global expansion and is in keeping with Pharma 4.0. It will make design and construction of future replicated facilities more efficient, with fewer errors.

This digital design process also streamlined collaboration between FUJIFILM Biotechnologies and its partners, including architects, engineers, and construction teams.

Advanced Safety and Sustainability Practices

For FUJIFILM Biotechnologies, its strategy of proactive accident prevention has evolved from an activity typically completed in the design phase to a mindset and culture established from the beginning. This meant that many hazards could be avoided before they reached the construction site through modularization and extensive offsite fabrication. This approach eliminated more than 1.7 million hours of high-risk work, including one million hours moved off the construction



About FUJIFILM Biotechnologies

FUJIFILM Biotechnologies, made up of several legal subsidiaries of FUJIFILM Corporation, is a world-leading contract development and manufacturing organization (CDMO) for biologics, vaccines and advanced therapies. With over 30 years of experience, the company specializes in developing and manufacturing biopharmaceuticals using microbial, mammalian, and host/virus systems. With over 5,000 employees, FUJIFILM Biotechnologies operates a fully integrated, kojoX global network with major facilities in the United States, the United Kingdom, and Denmark. FUJIFILM Biotechnologies offers comprehensive services, ranging from proprietary cell line development, to process and analytical development, and through to clinical and commercial manufacturing.

Supply Partners and Key Participants

Engineer/Architect: Jacobs

Commissioning, Qualifications, and Validation Services: FUJIFILM Biotechnologies

Construction Manager: Jacobs

site. In addition, safety training using virtual reality scenarios and an around-the-clock onsite medical center providing continuous medical and mental health care added to this "prevention through design" culture. Together, these strategies resulted in an exceptional safety record: more than 13 million safe work hours and a total recordable incident rate of 0.06, which is 25 times better than the construction industry average.

"We developed a collective vision of safety and consistently embedded it into our decisions as design progressed," said Ulrich. "Importantly, we also used our digital tools to drive a heavy focus on constructability in design so that not only could the facility be operated safely, but it could also be built safely. And it's never static; the same replication principles of lessons learned that have made us more efficient have also made us safer through all project phases. The early focus in design, paired with the foundational culture we've built around it, has yielded a safety record that we are very proud of."

A range of sustainability measures integrated into the facility's design and construction to support FUJIFILM Biotechnologies aim for LEED Gold certification. Water reduction strategies included conservation and the complete replacement of potable water in its cooling tower with reclaimed water. Energy and emissions reductions through optimization of utility systems and use of ultra-low NOx boilers and heat recovery chillers. Onsite renewable energy generation includes a 1.3 megawatt rooftop solar array. These choices result in a reduction of CO_2 emissions by more than 1,700 tons compared to similar conventional large-scale manufacturing facilities.

Digital Replication as a Design Strategy

"Digital replication is fundamentally about influencing the speed and scalability of biopharmaceutical manufacturing facilities," Ulrich said. "Traditionally, the industry would treat each new facility as a unique project, requiring significant design, engineering, and validation efforts."

Modularization and digital replication are gaining traction in pharmaceutical manufacturing, and the Galaxy project provides a template for other facilities to follow, even if they're of a substantially different size.

"While individual facilities may vary based on customer needs, manufacturing technologies, or site-specific requirements, the core principles of kojoX remain highly adaptable as our strategy is built around harmonization of equipment, technologies, and processes," Ulrich said. "Even in projects of different design or size, applying common design philosophies, operating procedures, and digital systems can create efficiencies in execution and connection across a manufacturing ecosystem."

The first application of this replicable template for future facilities will support FUJIFILM Biotechnologies' long-term expansion plan, which ultimately envisions 32 20,000 L bioreactors to help ensure continuous supply of biologics therapies globally.

WATCH FUJIFILM'S VIDEO

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