



FOYA | 20
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2023 CATEGORY WINNERS

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2023 FACILITY OF THE YEAR AWARDS

Category Winners
Spotlight on Excellence



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ABOUT FOYA

- 03** Message from the 2023 FOYA Judges Committee Chair
- 05** Thank You to the 2023 FOYA Judges Committee
- 07** Message from the 2023 FOYA Planning Committee

CATEGORY WINNER PROFILES

- 11** Innovation: Chugai Pharma Manufacturing Co., Ltd.
- 15** Operations: WuXi Biologics Ireland Limited
- 19** Supply Chain & Social Impact: Serum Institute of India Pvt. Ltd.
- 25** Pharma 4.0™: Genentech
- 29** Social Impact: Takeda SA
- 33** Honorable Mention: Nexus Pharmaceuticals, LLC.

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WELCOME & THANK YOU

On behalf of ISPE, I am once again honored to recognize the Facility of the Year Awards (FOYA) Winners. FOYA has been recognizing innovations in the pharmaceutical industry since 2004. Each year presents new and unique challenges for all of us in the project delivery space. Even in this post-pandemic year, supply chain challenges and resource scarcity are still impactful. FOYA projects continue to represent the “best of the best”, informing our industry about truly exceptional projects, and provides winners a forum to present them. We are proud to have recognized projects supporting the international industry pandemic response, leaps in Pharma 4.0™ technology and overcoming supply chain challenges, all while continuing to deliver step innovations for the patients we serve.

WHO SUBMITS AND JUDGES FOYA PROJECTS?

Submissions are reviewed by recognized industry leaders – from all regions of the world and both small and large pharmaceutical and medical device companies. These leaders have extensive global experience in their fields – engineering, manufacturing, supply chain, and quality. They are experienced, knowledgeable, and understand the global landscape. They have had the privilege of personally working on and delivering many innovative projects themselves.

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

HOW ARE THE SUBMISSIONS REVIEWED?

The judging panel meet each year in January to review and discuss merits of submissions. This year was the first in-person meeting in two years due to pandemic travel restrictions. Judges start by assessing the novel character of each project and discuss industry trends and how it is reflected in the submissions. While a template is used to help catalog analyses, judges have the freedom to use their expert judgement in reviewing each project. If a project does not demonstrate excellence in any one category, that category will not be awarded.

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

Judges then select an overall winner from among the category winners. The process involves several rounds of discussions, often very passionately, followed by a series of secret ballots. Once winners have been selected, judges are sworn to secrecy until ISPE announces the category winners.

WHAT MAKES A WINNING SUBMISSION?

Innovation, novelty and patient impact. A myth to dispel is that only large complex projects win awards. However, most are smaller projects that improve quality and efficiency, reduce costs, improve transfer of new products, or implement new information technology solutions. Judges understand that these projects are critical to the success at each facility, so they focus on and award projects that demonstrate these innovations. FOYA receives numerous successful and innovative projects, but in the end, there can only be so many winners. Keeping with our mission to recognize and demonstrate innovation efforts of other projects, this year ISPE announced the FOYA Submission Finalists to showcase the projects that met the qualifications and requirements of submitting a pharmaceutical facility for one of the FOYA named Category Awards.

I would like to thank my Co-Chair Parag Sane, Executive Director Engineering Projects at Amgen and all my fellow FOYA judges for volunteering their time as well as all the companies that submitted projects. Selecting awards gets more difficult each year as the quality and quantity of submissions continues to increase. We are privileged to work in an industry that improves the lives of patients. We strive to continue this mission, and improve our performance in every way, and FOYA allows us to recognize the efforts of those that have.



Antonio C. Crincoli, PE
Chair, FOYA Judges Committee
Vice President, Global Engineering & Technology
Catalent Pharma Solutions



FOYA has been recognizing innovations in the pharmaceutical industry since 2004.

// FOYA projects continue to represent the best of the best... //

ISPE THANKS THE 2023 FOYA JUDGES COMMITTEE

for their continued support
of the FOYA program.



Antonio C. Crincoli, PE
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Biomanufacturing
WuXi Biologics

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Chief Sustainability Officer
Gilead Sciences, Inc.

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Senior Vice President,
Global Head of Engineering
& Maintenance
Sanofi

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Senior Vice President,
Global Engineering
CSL Behring

Lou W. Kennedy
CEO & Owner
Nephron Pharmaceuticals

Brian H. Lange
Associate Vice President,
ERMD Lead
Merck

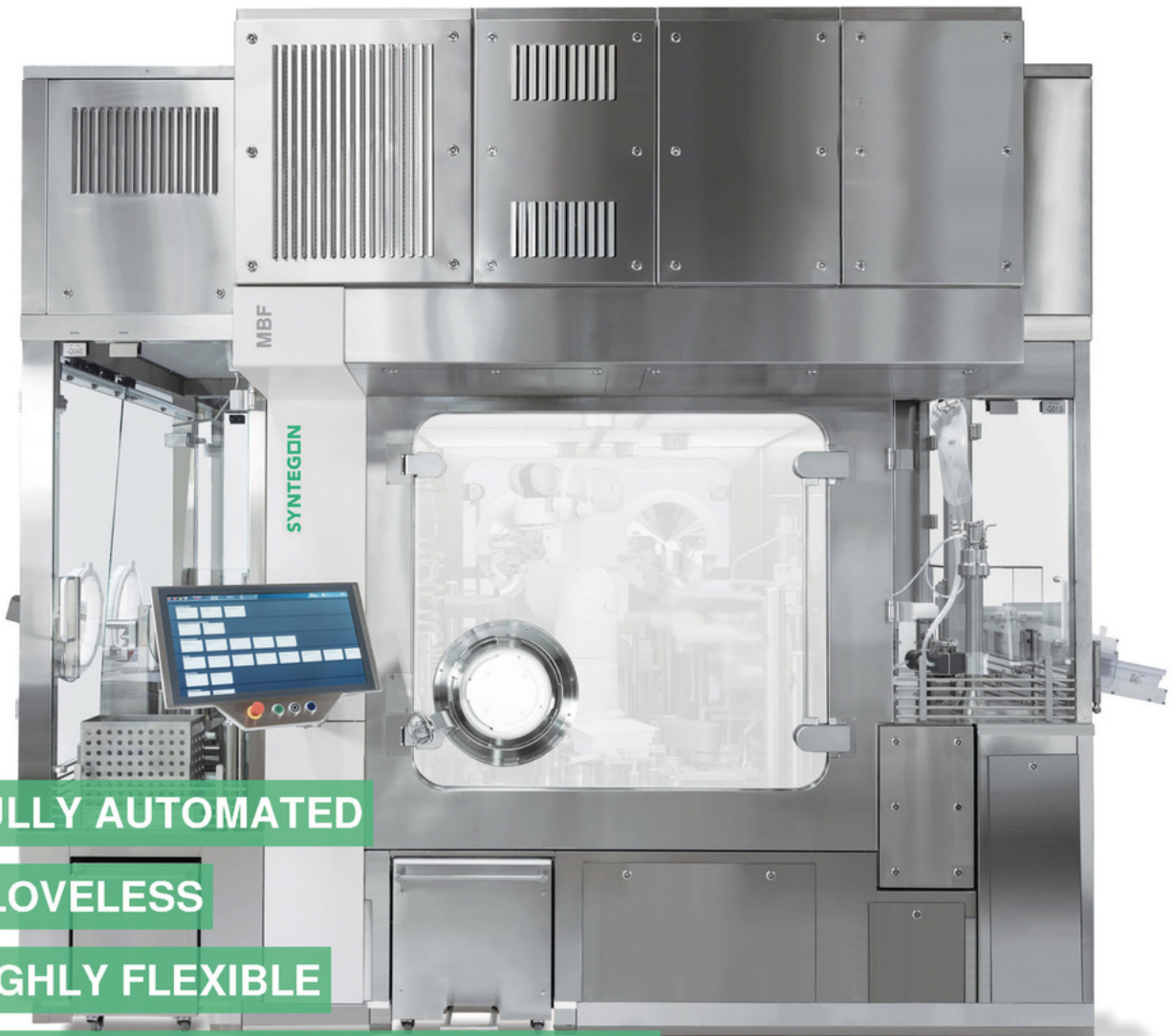
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Technology and
Sustainability
Roche / Genentech

Boyun Son
Vice President / Team Leader,
Corporate Engineering Team
Samsung Biologics Co, Ltd.

Frank Vanermen
Vice President, Head of
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Project Delivery
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2023 FOYA AWARDS PLANNING COMMITTEE

**Welcome to Las Vegas, NV, USA as we celebrate
the 2023 ISPE Facility of the Year Awards!**

The Facility of the Year Awards (FOYA) is one of the most prestigious awards in the pharmaceutical industry, recognizing excellence in facility design, construction, and operation. The awards are a testament to the diligence and innovation of the people who make our industry possible.

The FOYA Program provides a platform to highlight your achievements to help shape the future of pharmaceutical engineering. By acknowledging those who make an impact, we can help to raise the bar for excellence in the pharmaceutical industry.

During this spectacular evening, you will be treated to a wide array of winners' unique stories in each category including Innovation, Operations, Supply Chain, Pharma 4.0™, and Social Impact. New this year, we will announce the 2023 FOYA Overall Winner capturing the essence of the evening.

These inspiring projects are truly your stories, your personal experiences. The stories that are shared are those of dedication and diligence and are the foundation of the FOYA program.

The stories of focus, commitment and faith in science and engineering. These stories embody the rigor required to continuously improve by small steps, to make global leaps forward. This is how we develop, scale, and ultimately manufacture drugs capable of improving the lives of patients, their families and society overall. It is because of that resilience and expertise that your facilities are recognized as leaders in innovation, safety, quality, and operational excellence. To the selected 2023 FOYA Category Winners, thank you for sharing your story, for being a part of the FOYA program, ISPE International, your Affiliate/Chapter, and for your efforts in impacting the future of pharmaceutical engineering.



It is an honor to celebrate your impressive accomplishments.

As the 2023 FOYA Planning Committee Chair, I'd like to thank all the planning committee members and judges for their role in supporting and improving the FOYA program. I've truly enjoyed being a contributor to this great program supported by a wonderful group of committee members, judges, sponsoring companies and ISPE staff. Your commitment to industry advancement and dedication to the FOYA program is greatly appreciated. Thank you for all your hard work in making this event possible.

Finally, we need your stories. I encourage you to submit your projects for consideration in the 2024 Facility of the Year Awards. Please consider your unique project for submission. It is your stories that inspire others and help aid in driving the pharmaceutical industry forward. For information on submitting your project for consideration in 2024, visit ispe.org/FOYA for submission requirements.

Thank you again for being part of this special evening. I look forward to celebrating with you all.

Cheers!

Jim P. Grunwald
Chair, FOYA Planning Committee
Senior Vice President, Business Development
Arcadis | DPS Group





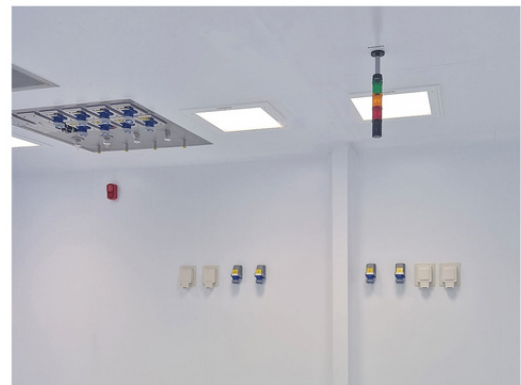
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2023 CATEGORY AWARD INNOVATION

CHUGAI PHARMA MANUFACTURING CO., LTD.

Quick Facts

Project: FJ2 Project

Location: Shizuoka Pref, Japan

Total Facility Size: 65,400 square feet

Project Mission: To create an API manufacturing facility that sets the standard for patient and worker safety through innovative solutions.

Innovation

Winners in the Innovation category exemplify the novel application of process manufacturing techniques, innovative design concepts, innovative technologies, and unique solutions. This includes the implementation of top-of-the-line and custom-developed equipment that yield superior results, improved competitive position, and/or demonstrates imaginative collaboration with vendors, suppliers, and manufacturers. Innovation winners represent the next generation of agile, flexible, efficient, and effective pharmaceutical and biotechnology facilities.

Why Chugai Pharma Manufacturing Co. Ltd. Won

The Chugai FJ2 project focused on safety throughout the entire project design and employed innovative methods to achieve this goal. The FJ2 facility incorporates various cutting-edge building design and equipment concepts to ensure the protection of both the product and workers. These measures include the utilization of smart isolator containment technology, world-class high-potency containment technology, and careful design considerations for worst-case scenarios. It is for these reasons that Chugai Pharma Manufacturing was awarded the 2023 FOYA Category Award for Innovation.



Raising Standards in API Production

The production of Active Pharmaceutical Ingredients (APIs) brings life-saving medications to patients worldwide. To implement cutting-edge technology in this global mission, Chugai Pharma Manufacturing established its state-of-the-art API facility FJ2.

The production of mid-size molecule pharmaceuticals, known for their unique ability to target areas that have been difficult to reach with conventional technologies such as small molecule drugs, presents distinct synthesis challenges. Embracing these complexities head-on, Chugai Pharma Manufacturing has dedicated FJ2 to advanced problem-solving for accelerated API manufacturing.

As a company committed to pioneering breakthroughs, Chugai focuses on developing innovative APIs with maximal potential for patients by prioritizing FJ2's production of drugs with complex molecular structures and exceptional biological activities.

FJ2 comprises of three cutting-edge production lines: "Line A" specializes in producing mid-size molecule APIs, including peptides. "Line B" focuses on small-molecule synthetic APIs, and the "common series" ensures flexibility and versatility in the manufacturing process. These production lines adhere to rigorous global Good Manufacturing Practices (GMPs) and are equipped to manufacture high-potency pharmaceutical ingredients.

Setting an industry benchmark, FJ2 has achieved extraordinary containment performance with Occupational Exposure Limit (OEL) of 0.05 µg/m³. This exceptional level of containment provides enhanced safety for workers and reinforces Chugai's commitment to maintaining the highest standards in pharmaceutical manufacturing.



Innovation From Start to Finish

Attention to detail has set FJ2 apart, beginning with its operational design. Through rigorous assessment, Chugai selected optimal containment equipment and verified its performance with prototypes. The company then made refinements on the basis of mock-ups, resulting in equipment that surpassed expectations during post-installation verification and commissioning.

World-class high-potency containment technology is a core feature of FJ2, ensuring maximum safety for operators. Advanced room pressure control systems and smart containment technology in isolators offer superior flexibility and robustness. Adding to their flexibility, isolators can be easily moved along ceiling-mounted rails, connecting to any production reactor while maintaining high containment levels.

Additional facility features enhancing flexibility and cleanability include a hydraulically-operated filter-dryer units for precise material control and the selection of piping design and components that emphasize smoothness, appropriate gradients, and the prevention of liquid accumulation. The introduction of a spray ring has enabled targeted cleaning in challenging areas.

The advanced technology within the FJ2 facility, paired with efficiency and ease of operation minimizes the likelihood of mistakes and user errors. These improvements streamline operations and contribute to the overall quality of the APIs, ensuring enhanced patient safety.

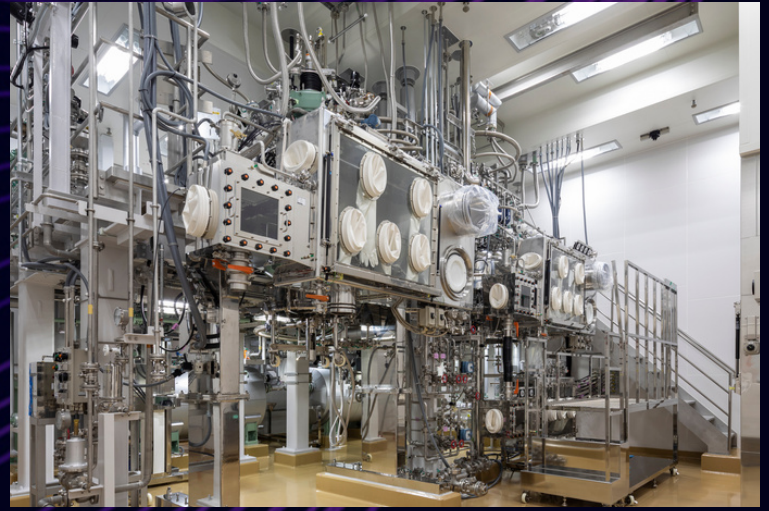
Safety Across the Board

Chugai Pharma Manufacturing's FJ2 is a purpose-built facility with a strong focus on safety measures, benefiting the facility workers and the surrounding community. Environmentally friendly CFC-free natural refrigerants are used in the manufacturing and HVAC systems. The facility ensures proper treatment of exhaust gases through dedicated equipment installed on the roof. Moreover, the facility's high walls not only provide shielding for the surrounding landscape but also mitigate noise pollution.

Recognizing the potential risks of API production, FJ2 incorporates various safety measures to protect against fire hazards and other worst-case scenarios. Foam fire extinguishing systems are strategically installed in areas with hazardous substances, while indoor fire hydrants are positioned throughout the facility. In the event of a hazardous material ignition and explosion, blast pressure is directed upwards to the specially designed folded-plate roof, dissipating the force, and preventing extensive damage to the building. Blast shafts positioned on the facility's north, east, and west sides would further mitigate blast pressure and protect the surrounding area. Facility designers have also incorporated seismic isolation devices, safeguarding employees and preventing equipment-related accidents in the event of an earthquake.

Chugai Pharma Manufacturing's unwavering commitment to safety and innovation is evident in the careful planning, attention to detail, and execution of FJ2. By prioritizing safety measures, enhancing operational efficiency, and addressing worst-case scenarios, the FJ2 facility has demonstrated API manufacturing excellence.





About Chugai Pharmaceutical Co. Ltd.

Chugai Pharmaceutical Co. Ltd., the parent company to Chugai Pharma Manufacturing, was founded in 1925. In the 1980s, in addition to small molecule drug discovery, the company began to engage in biotechnological drug discovery. In 2002, it entered into a strategic alliance with Roche and became a member of the Roche Group. Chugai Pharma Manufacturing Co., Ltd, the awardee for Innovation, was founded in 2006. The Chugai group of companies currently focuses on mid-size molecule discovery as the third drug discovery modality.

Supply Partners and Key Participants

Manufacturer/Owner Name:
Chugai Pharma Manufacturing Co., Ltd.
Engineer/Architect (A&E): JGC Japan Corporation
Construction Manager: JGC Japan Corporation
Main/General Contractor: Kajima Corporation
Electrical Subcontractor: KANDENKO CO., Ltd.
HVAC Subcontractor: Dai-Dan Co. LTD
Automation and Control Supplier:
Emerson Japan, Ltd.

Major Equipment Suppliers:
Kobleco Eco-Solutions Co., Ltd.
GL Hakko Co., Ltd.
YMC CO., Ltd.
Manzen Machinery CO., Ltd.
Nara Machinery Co., Ltd.
ULVAC, Inc.

2023 CATEGORY AWARD OPERATIONS

WUXI BIOLOGICS, IRELAND LIMITED

Quick Facts

Project: WuXi Biologics's Drug Substance Manufacturing Facility in Ireland

Location: County Louth, Ireland

Total Facility Size: 467,500 square feet

Project Mission: To deliver a state-of-the-art drug substance manufacturing facility, as part of the global operations of WuXi Biologics (a leading global Contract Research, Development, and Manufacturing Organization (CRDMO)), while upholding the highest standards of worker safety, engaging with the local community, and upholding an accelerated schedule.

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. These principles, systems, and tools also ensure business continuity through a stable supply environment, health and safety, and customer satisfaction from existing or new facilities, processes, and manufacturing operations.

Why WuXi Biologics Ireland Limited Won

This inspiring project proves that facilities can be developed on a highly accelerated schedule, using innovative solutions while complying with regulatory requirements, overcoming unknown barriers, cooperating with the community, and upholding project success and product safety. The WuXi Biologics Ireland Facility Project is recognized with the 2023 ISPE FOYA Operations Category Award for these reasons.



A Culture of Safety on an Aggressive Timeline

WuXi Biologics is driven by a mission to empower its partners to meet critical patient therapeutic needs, and its Ireland facility is an extension of this mission. Designed to be a multi-product manufacturing site specializing in monoclonal antibodies (mAb) and recombinant proteins, construction was fast-tracked on the facility, a feat complicated by COVID-19 pandemic-related supply difficulties. The rapid construction of the Ireland facility showcased the organization's ability to expedite the project without compromising quality.

In addition to the state-of-the-art technologies and extensive cooperation, rigorous safety protocols were used to ensure the safety and wellness of the project team, particularly amid COVID-19 pandemic risks. This commitment led to impressive results: a Total Recordable Incidence Rate (TRIR) of 0.35 during 6.2 million person-hours and no recordable injuries over the last 13 months in 3 million hours worked.

The team credits its well-established safety culture to effective communication. Print materials, electronic applications, visual aids, and in-person interactions enhanced understanding and protocol adherence, ensuring shared respect for workplace safety. These collaborative efforts enabled the timely completion of the Dundalk facility without compromising the workforce's well-being.

// WuXi Biologics is driven by a mission to empower its partners to meet critical patient therapeutic needs, and its Ireland facility is an extension of this mission. //

The CRDMO Next Door

The WuXi Biologics team agrees that Dundalk, part-way between Dublin and Belfast, was the perfect spot for the facility. Ireland's business environment, regulatory compliance, research facilities, and supply chain ecosystem foster innovation and growth. Dundalk's locality presented an economic advantage and an opportunity for the CRDMO to foster meaningful and symbiotic relationships within nearby communities.

Recognizing the interplay between its success and the well-being of its surroundings, WuXi Biologics prioritizes community engagement as a core value and adheres to environmental, social, and governance (ESG) principles. Sustainable concepts are adopted in the site construction and operations, including reducing energy use and recycling resources. Currently, 100% of power supply comes from renewable energy at Ireland site. During the construction phase, significant efforts were also made to minimize impacts on neighboring communities, including an extensive pre-fabrication plan to reduce disruptive on-site work and the construction of new roads to mitigate visual and noise impacts from construction vehicles. To keep neighbors informed, the company hand-delivered newsletters detailing construction activities, manufacturing products, and the expected effect on the local economy and employment.

The project not only brought about infrastructural development in the local area but also had a positive impact on the local job market creating over 450 full-time positions. WuXi Biologics demonstrated its commitment to preserving the area's historical significance when archaeological remains dating back to the Neolithic period were discovered on the site. Jacobs Engineering worked alongside experts to ensure the protection and preservation of these artifacts and carry out a full archeological evaluation of the site while still adhering to the overall construction schedule.



Advanced and Applied Technology

Now that construction is complete, the 467,500-square-foot facility represents a monumental leap in biomanufacturing capabilities. Equipped with cutting-edge technology, including 6x1KL single-use (SU) bioreactors for perfusion and 12x4KL SU bioreactors for fed-batch, it stands as one of Europe's largest facilities of its kind.

Implementing single-use bioreactor technology brings numerous advantages that elevate productivity and production, such as reduced cross-contamination risk, increased operational efficiency, and enhanced flexibility for multi-product manufacturing. In addition to its hybrid, single-use, scale-out production paradigm, the facility also houses innovative Manufacturing Science & Technology labs, which support manufacturing capacity, product research, and optimization.

Technological advancements within the facility enable highly configurable and flexible manufacturing processes, catering to various perfusion or batch-fed requirements at any scale. These breakthroughs set new industry standards for efficiency and adaptability.

Choosing Dundalk testifies to the organization's dedication to community engagement and responsible growth. The Dundalk facility sits at the forefront of the new generation of biological therapies. It distinguishes itself through its advanced technology, industry-leading project timelines, and steadfast safety dedication. WuXi Biologics models a high standard of corporate citizenship and sets the stage for a mutually beneficial partnership between the company and its surroundings.

About WuXi Biologics

WuXi Biologics is a leading global Contract Research, Development, and Manufacturing Organization (CRDMO) committed to accelerating and transforming the biologics discovery, development, and manufacturing processes. Their comprehensive, integrated platform spans the entire biologics value chain from idea to commercial production, thereby empowering global partners to bring life-saving treatments to patients around the world faster and more efficiently.

Supply Partners and Key Participants

Manufacturer/Owner Name:
WuXi Biologics Ireland
Engineer/Architect (A&E):
Integrated Project Services, LLC (IPS)
Permitting/Fitout: Scott Tallon Walker Architects
Client Side Project Controls/Cost Management: Linesight
Construction Manager: Jacobs Engineering Ireland Ltd.
Main/General Contractor:
PJ Hegarty & Sons
Wills Bros. Ltd
Collen Construction
Piping Subcontractor:
Dornan Engineering
Jones Engineering
HVAC Subcontractor:
Dornan Engineering
Jones Engineering
Automation and Control Supplier: ACal
Commissioning, Qualification Validation:
KPC International Ltd.

Major Equipment Suppliers/Contractors:
ABEC
Brian A. Flynn Ltd.
Ardmac
Ward & Burke Construction Limited
Suir Engineering Ltd
Mercury Engineering



2023 CATEGORY AWARD SUPPLY CHAIN & SOCIAL IMPACT

SERUM INSTITUTE OF INDIA PVT. LTD. (SERUM)

Quick Facts

Project: "NISHWAS" The Breath of Relief

Location: Maharashtra, India

Total Facility Size: 66,488 square feet

Project Mission: To provide millions of doses of the COVID-19 vaccine by adapting a state-of-the-art facility in record time.

Supply Chain & Social Impact

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

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

Why SERUM Institute of India Pvt. Ltd. Won

SERUM achieved the exceptional feat of producing COVID-19 vaccines at a commercial scale in just six months. They began design modification on 1 October 2020, and rolled out the first batch of vaccines on 31 March 2021, despite the challenging work environment created by the ongoing COVID-19 pandemic. By employing real-time project risk management coupled with close multi-disciplinary coordination, SERUM met the urgent demand and advanced its public health mission. Ultimately, SERUM supplied 1,472,010,980 and 276,835,540 doses of Oxford-AstraZeneca's COVISHIELD™ vaccine in 2021 and 2022 respectively. During the same period, SERUM manufactured and supplied 9,008,000 and 129,355,650 doses of Novavax's COVOVAX™/Nuvaxovid™ COVID-19 vaccine and supplied COVID-19 vaccines to over 90 countries worldwide.

By delivering the much-needed COVID vaccine to a populous country like India, this project was an invaluable asset to India's resilient fight against COVID and helped keep its cities open for business. These efforts impacted not only India but also the many other developing countries that administered SERUM vaccines. SERUM's project "NISHWAS" exemplifies how to deliver in record time a robust pharmaceutical manufacturing response to serve humanity's unmet needs in conditions of crisis. For these reasons, SERUM's NISHWAS project is recognized for two FOYA 2023 awards in the categories of "Social Impact" and "Supply Chain."

The Right of Every Human

The SERUM Institute of India (SERUM) was founded in 1966 on the belief that good health is a fundamental right of every human being. What began as a goal to manufacture life-saving immunobiologics has become India's number

one biotechnology company. SERUM is the world's largest vaccine manufacturer in doses produced and sold, bringing 2.5 billion vaccine doses annually to 170 countries.

The Poonwalla Bio-tech Park is an essential part of SERUM's operation, serving as a state-of-the-art manufacturing facility with the necessary technology to manufacture products like vaccines for tuberculosis, human papillomavirus (HPV), Tetanus, Diphtheria, Pertussis (Tdap), and rotavirus. The NISHWAS project took its first breaths at this facility in 2020, when a select SERUM facility was rapidly adapted to produce millions of crucial doses of the COVID-19 vaccine.

A Large Risk for Public Health

The Poonwalla Bio-tech Park was under construction when the COVID-19 pandemic began. As researchers engineered the COVID-19 vaccine formulas capable of saving millions of lives, the decision was made to dedicate a portion of the SERUM facility to COVID vaccine production, dubbed the NISHWAS Project. The decision was a pivot away from their original business plans and an extensive undertaking in planning and cooperation, all risks undertaken in the name of a vaccine that hadn't existed a year before. "Nobody was aware whether this vaccine would be successful or not," said Kedar Gokhale, who served as the Director of the NISHWAS project.

// SERUM's project "NISHWAS" exemplifies how to deliver in record time a robust pharmaceutical manufacturing response to serve humanity's unmet needs in conditions of crisis. //



While Poonwalla Bio-tech Park was initially built to develop an array of known vaccines, the COVID-19 vaccine was still largely a mystery to the SERUM team when they began their facility conversion in October 2020. The COVID-19 vaccine had never been produced at a commercial scale before, and even decisions about which raw materials and packing materials to place on order tested the team.

Adjustments to the facility spanned two months when the world was at a standstill. India allowed extremely limited travel domestically and internationally. For work to proceed, special permissions were given by the Indian government to allow the 600 essential domestic employees permission to travel to work. Those capable of performing their work from home were allowed to do so. Special visas and flights were arranged for approximately 100 technicians not local to India so they could deliver and install the machinery needed for the facility.

Despite working amid a global health emergency, SERUM placed its workers' safety at the forefront. The personal protection equipment typically required to create a sterile facility helped workers stay safe, as well as their compliance with the strict government COVID-19 protocols. Teams of medical personnel remained on-site, recording possible symptoms and maintaining the well-being of workers. For those that fell ill, SERUM stepped in to assist with isolating and caring for the individuals' families.

Leaders guiding the NISHAWS project chalk up their success in such turbulent working conditions to the diligence and collaboration of their teams, along with SERUM's innate care and synergy. They performed much of the NISHAWS work in-house, from engineering design to project execution and qualification. This compact network allowed for efficient collaboration across teams, ultimately executing the facility adaptations with no errors.

Not only was the facility converted successfully in six months, but they successfully navigated the complex regulatory requirements involved in producing a new vaccine that would be shipped and administered worldwide. The facility rose to meet the standards of a wide array of international regulatory agencies, completing multiple rounds of audits before approvals were granted.



Providing a Breath of Relief

The NISHAWS project gets its name from Sanskrit; the English translates roughly to “sigh” or “breath of relief.” This name resonates with the intent of the project SERUM to supply millions with the hope and safety that is shared in each dose of vaccine.

To accomplish this mission, the NISHAWS efforts to perform extended beyond reorganizing existing SERUM facilities. For example, SERUM scientists worked closely with the team at Oxford-AstraZeneca to further develop the COVISHIELD™ vaccine. Ultimately, SERUM scientists were

able to raise the maximum storage temperature of the drug substance and drug product from -60°C to $2-8^{\circ}\text{C}$. Not only was this work advantageous for the facility, but it also directly impacted access to the vaccine, benefiting countries that did not have adequate cold chain storage or transportation capabilities to deliver the vaccine at lower temperatures.

Additionally, SERUM scientists upscaled COVISHIELD™ and Novavax's COVOVAX™/Nuvaxovid™ vaccine production. A 50L batch was scaled to 2,000L in three months. Two months after that, a 4,000L batch was successfully developed. These advances dramatically increased the rate and quantity at which the vaccine was produced.

Ultimately, SERUM's NISHWAS facility produced vast quantities of vaccines, supplying over 1.47 billion doses of Oxford-AstraZeneca's Covishield vaccine in 2021 and 276 million doses in 2022. During the same period, SERUM manufactured and supplied more than 9 million doses of Novavax's Covovax/Nuvaxovid COVID-19 vaccine in 2021 and 129 million doses in 2022. By the end of 2022, SERUM had supplied COVID-19 vaccines to over 90 countries.

An Eye to the Future

Though the World Health Organization has officially declared an end to the COVID-19 crisis, SERUM has decided to keep an eye on the future. While still actively producing COVID-19 vaccines, demand has dropped such that some NISHWAS facilities have been returned to their originally planned configurations. While this new facility conversion

presents other challenges, the SERUM team knows it is necessary to maximize the production of other vaccines in demand.

The COVID-19 pandemic has left an indelible mark on SERUM and the world. As the pandemic waned, the decision was made to create a new Pandemic Preparedness Facility. This building has its own infrastructure, designed to be highly adaptable to produce a vaccine from formulation to dispatch. In addition to its rapid flexibility, the Pandemic Preparedness Facility can also be adapted to produce vaccines with different vectors, including viral and mRNA formulations. SERUM hopes this facility will enable them to respond to future global health crises with even more speed than NISHWAS.

Despite trying and unpredictable circumstances, NISHWAS showcased how to deliver a robust pharmaceutical manufacturing capability and capacity in record time. At the peak of a global crisis, the team behind the NISHWAS project came together to display unprecedented cooperation and agility, delivering a positive impact on public health and a breath of relief for millions.



About SERUM Institute of India Pvt. Ltd.

SERUM is ranked as India's No.1 biotechnology company and the world's largest vaccine manufacturer by the number of doses produced and sold globally (more than 2.5 billion doses annually) which includes Polio, Diphtheria, Tetanus, Pertussis, Hib, BCG, r-Hepatitis B, Measles, Mumps, Rubella, and Pneumococcal vaccines. SERUM exports vaccines to 170 countries. Today, it is estimated that about 65% of the children in the world across 170 countries receive at least one vaccine manufactured by SERUM. SERUM operates with the lifelong mission of "Protection from Birth Onwards" by way of protecting infants by offering human vaccines at reasonable and affordable prices. The welfare of the community is the mantra SERUM exists by.



Supply Partners and Key Participants

Manufacturer/Owner Name:

SERUM Institute of India Private Limited

Engineer/Architect (A&E):

SERUM Institute of India Private Limited

Construction Manager:

SERUM Institute of India Private Limited

Automation and Control Suppliers:

Shree Venkateshwara Controls

Cotmac Electronics Private Limited

Analogic Automation Private Limited

HVAC Subcontractor:

Elm Enterprises Pvt. Ltd.

Shinro Suvidha India Pvt. Ltd

Piping Subcontractor:

Sanpure Systems Private Limited

Fluidline Engineers & Fabricators Pvt. Ltd

Electrical Subcontractor:

Integrated Project Management Services

Powerline Electricals

Clean Room Contractor:

Nicomactaikisha Clean Room Private Limited

Integrated Cleanroom Technologies Pvt. Ltd.



Major Equipment Suppliers/Contractors:

Alfa Laval India Private Limited – Downstream Processing – Cell Separator

Cytiva Life Sciences – Downstream Processing – CROM System

Cytiva – Single Use Bioreactors – 200L, 2000L

Merck KGAA – Downstream Processing – Nano Filtration System

Comecer – Process Isolator

Azbil Telstar – Steam Sterilizers – STER + DECON

Pall India Private Limited – Single Use Mixers – 50L, 200L, 650L, 2000L

Pall India Private Limited – Single Use Bioreactors – 200L, 500L

GEA Westphalia – Downstream Processing – Cell Separator

Sartorius Stedim Biotech GMHB – Single Use Mixers – 50L, 200L, 650L

ABEC INC – Single Use Bioreactors – 4000L

ATEC Pharmatechnik GMBH – Component Processing System – Stoppers & Caps

Steelco Spa – cGMP Parts Washer

Fedegari – Steam Sterilizers – STER

Getinge AB – Steam Sterilizers – DECON

Skan AG – Filling Line Isolator

Groninger & Co. GMBH – Filling Line

Brevetti CEA Spa – Automatic Inspection Machine

2023 CATEGORY AWARD PHARMA 4.0™

GENENTECH

Quick Facts

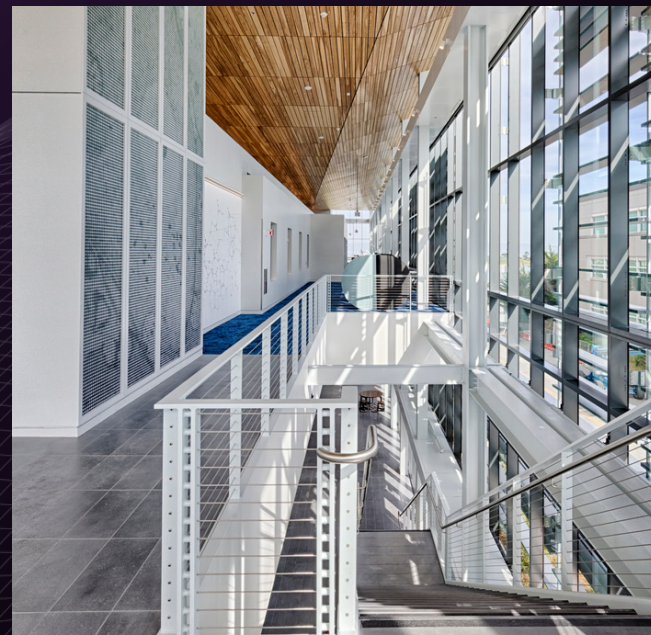
Project: Genentech South San Francisco Clinical Supply Center
Location: San Francisco, CA, USA
Total Facility Size: 78,000 square feet
Project Mission: To create an innovative facility that sets a new paradigm for future projects through the incorporation of new technologies and a team culture of bold collaboration.

Pharma 4.0™

Winners in the Pharma 4.0™ category embody the Pharma 4.0 concept. This includes not only implementing at least one technological innovation but also demonstrating the ability to change the company's culture, processes, and people orienting them towards a 4.0 future. Significant contributions include the 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 Genentech Won

The Genentech Clinical Supply Center (CSC) project is recognized as the 2023 FOYA Pharma 4.0™ Category Winner for being a role model on how the application of bold objectives and end-to-end planning, innovation in applying digital technologies, deep team alignment and integration, and challenging paradigms all lead to a facility that delivers improved outcomes in terms of construction, safety, facility productivity, and patient access to innovative medicines.



Built Boldly

For Genentech, the Clinical Supply Center was an opportunity to do something bold. Leadership within Genentech and its parent company, Roche, knew that the evolution of clinical therapies and the advancement of AI, automation, single-use technologies, and digitization had updated the requirements for optimal operation of pharmaceutical manufacturing facilities. With this in mind, the Genentech team took an ambitious look at the future, aiming to create a facility that could deliver on the promise of medical innovation and usher in a new era of manufacturing for the biotech company.

"The new CSC incorporates the next generation of innovative technology. It's taking the 40-year-old process that we've been using to this new frontier of single-use, fully automated, connected technology," said Dante Lee, a senior leader on the CSC project team.

To achieve their goal, the CSC prioritized innovation and bold thinking, supported by a team culture of trust and collaboration. This approach allowed the team to make decisions quickly, think big, and keep work moving, all while piloting new technologies and navigating COVID-19 protocols.

Embodying Pharma 4.0™

Completed in November 2022 after 19 months of development, the CSC in South San Francisco, CA is a 78,000sf / 2,000L scale small-volume clinical biologics facility. The CSC team evaluated every opportunity to push the envelope in constructing the facility, examining how the facility layout, equipment, digitization tools, and team organization could be improved along the way. The result is surprisingly simple in its design. Particularly notable is the ballroom layout made possible by the shift to single-use technologies. The ballroom, or open floor plan, eliminated the need for separate rooms and teams, allowing for the creation of a product-agnostic layout with downstream flexibility. "There are simplistic elements to the design of the facility that have all these advantages down the road," said Christian Randecker, the Senior Director of Operations, Process Support, Process Engineering for the CSC.

The ballroom design, combined with the incorporation of single-use technologies, means the facility can quickly adapt to producing different therapies while simplifying utility lines and reducing the need for specific equipment. True to the culture of the CSC project, it was a proactive change that strayed from conventional facility design. "[Being bold] was the goal of the project. Ultimately, we found a way to incorporate new technologies, and therefore eliminated the clean steam generator and autoclave," said Mike Greening, the US Head of Project Delivery (and Project Manager for the CSC project).

// **The new CSC incorporates the next generation of innovative technology.** //



The design also enables a central team to run the facility, empowered by incorporating fully integrated automation, robotics, and operations management systems. Paired with fully digital validation and a paperless manufacturing operation, the CSC is built for agility and speed while maintaining high-quality standards for the safety of patients.

A Template for the Next 20 Years

Built to be a template for future Genentech facilities, the CSC facility mixes technical and operational innovations with a straightforward, strategic approach to facility design. However, planning for the future went beyond integrating the latest and greatest technologies.

Sustainability was an objective the team kept front of mind, particularly due to the incorporation of single-use technologies. "It wasn't an afterthought," confirmed Mr. Lee, "It was at the very beginning with an investment into a lifecycle assessment. We really did the ground up, full review of the environmental impact that our facility would have." The team's efforts earned the facility a LEED Gold certification, with notable sustainable features, such as renewable energy generation, significant reductions in energy and water use, and extensive efforts to minimize waste.

The project team values the culture and dedication that have developed as a byproduct and will use the CSC to inform future projects. The team, they agree, is what made this build possible. "We spent a lot of time trying to get a team and culture that can operate a facility like this...The design of the facility allows us to have a team that functions very differently from how we have traditionally. And I just love seeing how that allows us to operate faster, more efficiently, and more sustainably to continue delivering innovative new medicines for the patients we serve."





About Genentech

A member of the Roche group since 2009, Genentech discovers, develops, manufactures, and commercializes medicines for people with serious or life-threatening diseases. With over 13,000 employees in the U.S. and headquartered in South San Francisco, California, Genentech has provided innovative medicines for patients around the world for more than 45 years.

Supply Partners and Key Participants

Manufacturer/Owner Name: Genentech

Engineer/Architect (A&E):

Fluor Enterprise Inc.

Perkins & Will Inc.

Southland Industries

Commissioning and Qualification:

Project Delivery Partners Inc

Valspec

Construction Manager: XL Construction Corporation

Main/General Contractor: XL Construction Corporation

Piping Subcontractor: Murray Company

HVAC Subcontractor: Southland Industries

Electrical Subcontractor: Redwood Electric

Automation and Control Suppliers:

Emerson Process Management LLLP

Major Equipment Suppliers/Contractors:

Global Life Sciences Solutions / Cytiva

Sartorius Stedim North America

Repligen Corporation

Redwood Electric

AES

2023 CATEGORY AWARD SOCIAL IMPACT

TAKEDA SA

Quick Facts

Project: Alpha-1 Antitrypsin Manufacturing Building

Location: Lessines, Belgium

Total Facility Size: 121,949 square feet

Project Mission: To establish a manufacturing facility that would provide reliable in-house manufacturing capacity for the supply of plasma-derived therapies while minimizing the environmental impact and promoting the local community.

Social Impact - Sustainability

Winners in this category honor projects that exemplify the application of novel approaches, standards, and practices that 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.

Why Takeda Won

Takeda has successfully implemented a sustainable facility design aimed at optimizing energy utilization, minimizing waste generation, lowering its carbon footprint, and lessening its ecological influence. The Takeda Manufacturing initiative has been honored with the 2023 Facility of the Year Award (FOYA) in the Social Impact - Sustainability category. This recognition highlights how the project showcases the integration of innovative methods, industry standards, and best practices, combined with ambitious sustainability objectives. The outcome is a substantial reduction in environmental impact within a pharmaceutical manufacturing setting.



The Life Blood of Social Impact

Takeda places significant importance on social responsibility and its impact, a commitment that is evident in the Manufacturing Project situated in Lessines, Belgium. Chosen for its highly skilled workforce and highly developed biotech ecosystem, Lessines served as a perfect spot for the facility, designed with care for the planet and setting an example for the pharmaceutical manufacturing industry in mind.

The facility's proximity to the city of Lessines is an opportunity for the team to form a close relationship with the community, particularly with local representatives and associations. As a large employer in the area, this relationship proved essential during site development and continues to work to benefit both Takeda employees and the community. Notably, the Takeda Lessines employees enjoy engaging with social and sustainability efforts, a feature of Takeda culture. Recent efforts include road clean-up days and ongoing volunteering opportunities, including the delivery of items to Ukraine.

No Sustainable Stone Unturned

The facility is currently one of eight sites in the Takeda Manufacturing network that produces plasma-derived therapies. The facility produces the ready-to-use, liquid preparation of purified human Alpha-1 Antitrypsin (AAT) protein. Patients with a deficiency in AAT suffer from breathing problems. As diagnoses related to this deficiency have expanded, demand for AAT has increased.

The manufacturing process is particularly energy- and water-intensive. To achieve their aim of creating a sustainable facility, Takeda analyzed the entire value chain to reduce the environmental footprint wherever possible.



For example, Takeda Lessines pioneered a wastewater treatment facility on-site in partnership with a Belgian start-up to recycle its wastewater. Thanks to this technology, the facility is the first pharmaceutical manufacturing site in the world to recycle its wastewater to drinking water standards and reuse it in the production process. This system is helping the site reduce up to 60% of its freshwater withdrawal or IML per day. The site also manages its other waste through either recycling or incineration. During incineration, energy recovery is performed, helping to reduce the carbon impact of the facility.

Diversifying energy sources constitutes another pivotal facet of sustainability. In contrast to certain facilities that might adopt a solitary renewable energy solution, such as solar panels, to counterbalance energy requirements, the Takeda Lessines team recognized the potential vulnerabilities tied to relying solely on one renewable source. Consequently, they instituted a strategy of diversification and redundancy to ensure a consistent supply of electricity derived from renewable sources. This approach involves the integration of diverse renewables like wind turbines, photovoltaic panels, and geothermal energy, enhancing the system's resilience against fluctuations in energy availability. By 2026, the objective is to generate 80% of the facility's electricity demand, with a broader ambition to attain complete carbon neutrality by 2030.

Waste management and renewable energy sources are only two of the many sustainable features of the facility. The facility also operates entirely paperless; the team predicts this reduction saves approximately 500 kilograms annually. Where possible, the transportation mode of finished products has shifted from air to sea, reducing carbon emissions even further. A new state-of-the-art carbon net-zero emissions warehouse, fully operational by the beginning of 2024, will make it possible to

centralize all the storage capacity on-site representing a reduction of 1,700 tons of CO2 per year.

Sustainability as a Must-Have

Many of the efforts and technologies implemented at the site are the first of their kind, creating regulatory and process hurdles the team had to overcome. "When you are the first to decide to use these technologies, you're facing the first approvals," notes Thierry Pestiaux, the Head of Site Engineering for Takeda Lessines. That said, the Takeda Lessines team feels strongly that their efforts are an investment for the industry: "The planet is important...these efforts are must-haves."

In addition to the emission reduction initiatives implemented on the facility premises, Takeda envisions that this endeavor will serve as a blueprint for other companies seeking to adopt similar technology. Takeda actively participates in knowledge-sharing initiatives with other companies, fostering the propagation of its sustainability endeavors throughout the entire organization. The Takeda Lessines team has taken proactive steps in engaging with other companies to discuss their facility's technological advancements, including arranging guided tours. Internally, the Takeda culture of social responsibility affirms that their work isn't done. An employee sustainability subcommittee actively collaborates with Takeda leadership, exploring new opportunities to update processes and improve the sustainability of the facility at large.

The facility is a unique example of how new sustainable practices applied within a singular facility can result in a state-of-the-art operation featuring the latest environmentally friendly technologies. Between the facility's technological advancements and the Takeda culture of social responsibility, the facility represents the gold standard of sustainability within pharmaceutical manufacturing.



About Takeda

Takeda is a global values-based, R&D-driven biopharmaceutical leader committed to creating better health for people and a brighter future for the world. For more than 240 years, Takeda has focused on delivering transformative treatments and significantly increasing the value that we bring to society. The work we do transforms lives, helping patients with limited or no treatment options in our core therapeutic and business areas of gastrointestinal and inflammation, rare diseases, plasma-derived therapies, oncology, neuroscience and vaccines.

Supply Partners and Key Participants:

Manufacturer/Owner Name: Takeda Lessines

Commissioning Qualifications & Validation Services: Group-IPS

Piping Subcontractor: ETECH Sprl

HVAC Subcontractor: AXIMA Belgium (Exans)

Automation and Control Suppliers: Siemens

Major Equipment Suppliers/Contractors:

Chaudronnerie Pierre Guérin

Pall Life Science

EATON - Bergerow E. GmbH

2023 CATEGORY AWARD HONORABLE MENTION

NEXUS PHARMACEUTICALS LLC

Quick Facts

Project: Project Tomorrow –
Aseptic Manufacturing Facility
Manufacturing Facility Location:
Pleasant Prairie, Wisconsin USA
Total Facility Size: 84,000 square feet
Project Mission: To build a state-of-the-art
facility to produce critical-need and hard-
to-formulate generics while focusing on
patient safety and future expansion.

About the Category

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

Why Nexus Pharmaceuticals LLC Won

Project Tomorrow showcases Nexus Pharmaceuticals consistent focus on meeting patient needs for the long term. While establishing an impressive design and technology aligned with current industry standards, Project Tomorrow also includes thoughtful plans for maintaining quality standards while facility capacity and capability expand. Delivering these capabilities as a small, family-owned generic company showcases their commitment to patients and their company mission.



// Nexus is committed to transforming the generics industry, specializing in producing priority generics, such as critical-need and difficult to formulate products often in short supply. //

Generics in Short Supply

Nexus Pharmaceuticals is on a mission to address the shortage of generic medications in the market. Founded in 2003 by chemists Mariam S. Darsot and Shahid Ahmed, Nexus is a uniquely American company built on dreams of developing better products at a lower cost for customers. With a strong focus on innovation and process improvement, Nexus is committed to transforming the generics industry, specializing in producing priority generics, such as critical-need and difficult-to-formulate products often in short supply.

Under its ambitious Project Tomorrow, Nexus invested \$85.3 million to construct an 84,000-square-foot facility, with a large portion of construction occurring during the COVID-19 pandemic. During peak shutdowns, various restrictions forced Nexus to adopt a lean approach and overcome challenges, such as keeping teams small and working with long lead times for equipment procurement. Completed in 2022, the facility houses a high-speed manufacturing line and state-of-the-art technology for producing aseptic, terminally sterilized, and lyophilized products.

The production of these products requires extensive attention to detail and planning, all of which are reflected in Project Tomorrow. In particular, Nexus prioritized safety, for patients and workers alike, by implementing intentional automation, isolation technologies, single-use disposable technologies, and thorough operator training to reduce contamination risks. The meticulous validation of automated processes was of utmost importance to the Nexus team, particularly in areas with multi-use equipment where maintaining safety and quality standards are critical. By combining automated inspection systems, at various points in the capping and final vial inspection processes, Nexus's processes and procedures help to ensure product integrity and efficient drug production. These examples of process enhancements within the facility reinforce Nexus's commitment to excellence.



Expansion Guaranteed

Project Tomorrow was constructed with a visionary approach to prioritize future needs. This state-of-the-art establishment was designed to maximize production output, benefiting patients and supply chains alike. From the inception of this project, expansion plans were integrated into its very foundation.

The three-story facility was designed to accommodate up to six fill lines in the years to come. To accomplish this, architects considered every detail, including the placement of support columns and roofing design, allowing for efficient equipment placement and optimized space. Moreover, rigorous planning of utility piping runs maximizes expansion potential while providing significant long-term cost savings.

In addition to its physical infrastructure, Project Tomorrow implements cutting-edge processes that streamline the creation of life-saving drugs. The facility boasts the remarkable capability to produce multiple products simultaneously, ensuring a versatile and efficient production line. Should the need arise, it can swiftly decontaminate a line in just three hours, exemplifying its adaptability and commitment to maintaining the highest quality and safety standards. Furthermore, the facility's flexible nature enables it to accommodate different product configurations, catering to various pharmaceutical requirements as needs arise.

Project Tomorrow stands at the forefront of pharmaceutical manufacturing, setting new standards for efficiency, scalability, and innovation. By combining forward-thinking design with streamlined processes, this

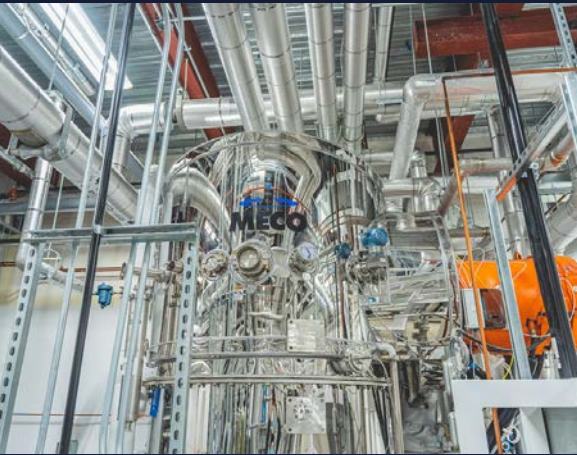
facility is primed to modernize the production of vital medications and meet the ever-growing demand for healthcare advancements.

Made in the USA, for the USA

The story behind the groundbreaking facility's construction is one of American determination. While acknowledging the importance of international contract manufacturers, Nexus Pharmaceuticals also recognizes the pressing need for expanded access to affordable generics within the USA and hopes Project Tomorrow will be just one example of the capabilities of American pharmaceutical manufacturing.

Throughout the development of Project Tomorrow, Nexus fostered genuine relationships with its vendor partners, working with as many local vendors as possible to create and maintain the facility. This collaborative approach allowed the Nexus team to work efficiently during facility development while supporting local businesses. This thoughtful sentiment can also be seen in their plans to focus the facility on developing drugs in low supply or with high demand in American hospital systems, including their ephedrine sulfate ready-to-use injectable, EMERPHED®.

The combination of patient focus and drive to improve the status quo encapsulates the spirit of Nexus Pharmaceuticals. This close-knit, family-owned company is unafraid to take bold risks. With purposeful construction and an unwavering commitment to the well-being of patients across the country, Project Tomorrow exemplifies how industry-shaping accomplishments follow when passion, determination, and a sense of purpose converge.



About Nexus Pharmaceuticals LLC

Nexus Pharmaceuticals LLC is a woman-led, minority-owned, and family-owned healthcare company and certified diverse supplier based in Lincolnshire, Illinois, USA. Nexus is a uniquely American family company, built on the dreams of its founder, Mariam S. Darsot, to fill a gap in the market to develop better products at lower costs for consumers. Nexus specializes in developing priority generics, such as hard-to-formulate, critical-need molecules routinely in short supply.

Supply Partners and Key Participants

Manufacturer/Owner Name: Nexus Pharmaceuticals

Engineer/Architect (A&E):

Integrated Project Services, LLC (IPS)

Pierce Engineers, Inc.

Pinnacle Engineering Group

Construction Manager: Turner Construction Company

Main/General Contractor: Turner Construction Company

Commissioning Qualifications & Validation Services:

SAVIS, Inc.

cGMP Consulting, Inc.

Project Manager: RLSmith LLC

Piping Subcontractor: J.M. Brennan, Inc.

HVAC Subcontractor: J.M. Brennan, Inc.

Automation and Control Suppliers:

Siemens Life Sciences

Rockwell Automation

Major Equipment Suppliers / Contractors:

Franz Ziel GmbH

Bausch + Stroebel + Co. KG

Fedegari Technologies, Inc.

IMA Life

MECO

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for receiving an ISPE Facility of the Year Award

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Operations Category



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