

Facility of the Year Special Edition

PHARMACEUTICAL ENGINEERING

THE OFFICIAL
MAGAZINE OF
ISPE

A Supplement to MARCH/APRIL 2006

2006



Facility of the Year

WINNER

**Baxter
BioPharma
Solutions**

**Phase IV
Vial and Syringe
Filling Facility**

FINALISTS

**AstraZeneca
Daiichi Asubio Pharma
Janssen Pharmaceutica
Wyeth Pharmaceuticals**

**Special Recognition
Biorex Therapeutics**



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GEA Process Technologies Ireland Ltd.
Ash House, Lime Tree Avenue • Millenium Park, Naas • Co. Kildare • Ireland
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Contact: Sue Shufflebotham-Devereaux

Telephone: +44 (0) 161 254 1700

Facsimile: +44 (0) 161 254 1701

Email: sue.shufflebotham-devereaux@eu.bovislendlease.com

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Photo courtesy of Baxter BioPharma Solutions

SPECIAL EDITION STAFF

Business Initiatives

Director of Business Initiatives
Scott Ludlum
Business Initiatives Coordinator
Lauren Blankley

Marketing/Communications

Director of Marketing/Communications
Susan Pazera
Marketing/Communications Associate
Heather Fortson

Publications

Editor and Director of Publications
Gloria N. Hall
Publications Manager
Lynda D. Goldbach

Sales

Director of International Sales
David J. Hall

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ISPE HEADQUARTERS

3109 W. Dr. Martin Luther King Jr. Blvd.
Suite 250
Tampa, Florida 33607 USA
Tel +1-813-960-2105
Fax +1-813-264-2816

ISPE EUROPEAN OFFICE

Avenue de Tervueren, 300
1150 Brussels, Belgium
Tel +32-2-743-4422
Fax +32-2-743-1550

ISPE ASIA PACIFIC OFFICE

73 Bukit Timah Road
#03-01 Rex House
Singapore 229832
Tel +65-6330-6755
Fax +65-6336-2263

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Baxter BioPharma Solutions A New Shot at Contract Services

A state-of-the-art response to an under-served market... groundbreaking use of modular design... effective use of the latest and most advanced high-speed syringe filling technology. Any one of these attributes is noteworthy, but taken in combination, they spell one thing: pharmaceutical manufacturing excellence. As the winner of the 2006 Facility of the Year Award, Baxter Pharmaceutical Solutions (BPS) has demonstrated world-class quality with its Phase IV Vial and Syringe Filling Project in Bloomington, Indiana, US. Commissioned in mid-2005, the Phase IV facility is the company's response to a market opportunity to provide large-scale syringe filling, aseptic formulation, vial filling, lyophilization, terminal sterilization, and flexible formulation capacity for a variety of challenging products such as insoluble solutions and vaccines.

"With its new Phase IV operation, Baxter, in conjunction with design/build partner Pharmadule AB, has demonstrated true leadership in the rapidly growing contract manufacturing sector," said Peter Bigelow, Senior Vice President of Consumer Healthcare Manufacturing for Wyeth and Chairman of the 2006 Facility of the Year Award Judging Panel. "It is rare to find such an impressive array of cutting-edge filling technologies all within one facility. We were also very impressed with Baxter's use of bolt-on removable components,

PROJECT: Phase IV Vial and Syringe Filling Facility
LOCATION: Bloomington, Indiana, United States
DESIGN-BUILD PARTNER: Pharmadule AB



Facility modules built in a workshop environment.

3-D design throughout, and the combination of innovative technology and practical functionality – a difficult balance for an aseptic environment. These are among the many qualities that make this a truly world-class facility."



Exterior view.

The Phase IV Project consisted of partial demolition and renovation of an existing building as well as new construction, and was completed in only 22 months from start of detailed design to US FDA approval. The project combines conventional construction for administrative areas with state-of-the-art modular construction for manufacturing areas. Additionally, another off-site building was renovated for expansion of packaging operations,

Continued on page 8.

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Congratulations Baxter Healthcare Corporation for reaching the final of the Facility of the Year Award





Staging area for new packaging line.



New packaging line.

and Baxter added large-scale cold storage capacity for temperature sensitive products.

Filling a Need

As pharmaceutical companies become increasingly focused on the R&D pipeline and its impact on sales and marketing, contract manufacturing is becoming a cost-effective alternative to large capital projects - especially if production volumes don't warrant the investment. BPS, a full-service contract manufacturing organization serving the pharmaceutical and biopharmaceutical industries, recognized a need to provide these services all "under one roof," a need that had previously been unmet by other contract manufacturers.

The Bloomington facility is a full service contract manufacturing plant providing form, fill, and finish services to the pharmaceutical industry for a variety of sterile product dosage forms. These products include solutions, suspensions, and freeze-dried powders encompassing human and veterinary small molecule, biologic, biotech, vaccine, and protein pharmaceuticals. BPS wanted to ensure its facility's capabilities could meet client production needs with the growing market preference for prefilled syringes.

For consumers, pre-filled syringes have advantages over traditional packaging in vials, including reduced microbial contamination risk due to less manipulation and exact dosing for greater patient safety and compliance. From a manufacturing perspective, pre-filled syringes improve a client's bottom line as less overfill is required than with vials. Plus, a variety of customized features can be used to meet end users' needs, potentially resulting in product differentiation and market share expansion.

Technologies Leading the Way

The Baxter facility is the first to use a new high-speed syringe-filling system, which can fill 500 syringes per minute, and is a considerable improvement over the 300 syringes per minute capacity of existing technologies. One of the key

attributes of the machine that has increased throughput is the tube handling system, which now handles tubes in parallel instead of serially. The increased throughput of the filler has saved considerable capital costs on the project by alleviating the need for two machines and additional clean space and gowning room.

Another focus of the facility was to provide a new formulation

and filling service for manufacturers of insoluble and unstable drugs. The new technology revolves around Baxter's Nanoedge process, which increases solubility and reduces excipient side effects in formulation. Drug particles are reduced to 100 nanometers in diameter, and then coated with a thin layer of proprietary excipient, creating drug particles that dissolve more rapidly when injected or infused.

Nanoedge has allowed Baxter to solve seemingly intractable formulation problems. This is based on the dilemma of current formulation situations that would ordinarily take one part drug to 10,000 parts of water to dissolve. Instead of requiring a patient to endure a 10 L infusion, Nanoedge would allow for formulations in 10 ml doses. The flexible formulation space included as part of this facility enabled Baxter to commercialize this technology.

"Farming Out" Process Design

The manufacturing portion of the facility expansion was a design/build project provided and qualified by Pharmadule AB, a provider of modular facilities for the pharmaceutical and biopharmaceutical industry. Baxter pursued modular technology because it provided the quickest return on investment with minimal risk and demand on internal resources.



High speed syringe filling line.

Concludes on page 10.

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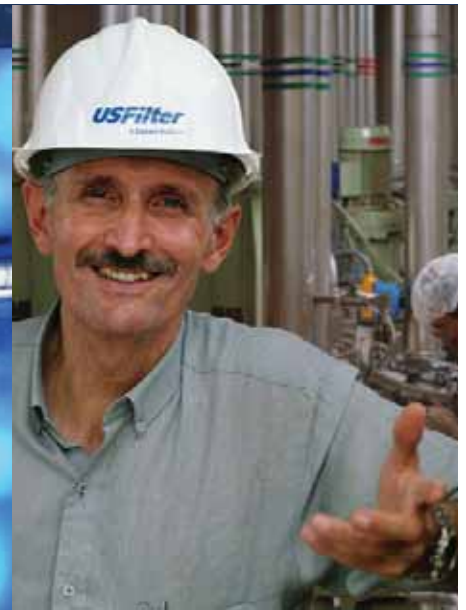
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Rear view of the modular manufacturing area.

The benefits included: shaving 12 months off the delivery schedule; reduced demand on client resources; integrated validation in the basic design phase; elimination of a large portion of installation, commissioning and qualification at the site; and a reduction in local resources and disruption at worksite and to the existing operation.

Offsite Facility Testing and 3-D Design

Modular technology and delivery used for design and construction involved the offsite fabrication of the entire manufacturing process facility, inclusive of structural steel, poured concrete floors, internal finishes, process and utility piping, electrical, automation, HVAC and process and utility equipment, and systems. The modular facility was fabricated in a factory in Sweden, pre-assembled, tested, pre-qualified, disassembled, packed, and shipped across the Atlantic Ocean, then reassembled, and commissioned and validated at the site.

Three-dimensional design was used throughout the facility, which facilitates any later remodelling or expansion of the facility. Airflow patterns in critical areas such as the filling suites were stimulated before finalizing the 3-D design. This allowed for the design to change before start of construction to optimize airflow patterns.

Modularization in combination with the use of 3-D design assured a high level of accuracy in the placement and access to equipment and services. Time and efficiency gains of modularizing the manufacturing areas were realized in Phase II and III expansion projects, which drove the decision to again pursue modularization for the Phase IV project.

The Phase IV facility was designed with foresight to minimize any impact for expansion of the vial filling and lyophilization capacity related to the market demands. The facility modules are designed with 12' x 14' removeable panels that are bolted with gaskets to allow for clean and quick access to the building. Equipment can be added or

removed easily, as well as the quick addition or manufacturing modules for a fast response to market demand without disturbing the ongoing production.

The facility is designed to add a mirror manufacturing suite on the opposite side of the building, which will then utilize the personnel and material corridors as a central spine. Wide, open rooms allow for ample working space and flexibility within the facility.

Tracking and Quality Control


The facility uses a new ERP/MRP enterprise planning system from Oracle to facilitate the tracking and management of material throughout the manufacturing process, providing 100 percent accountability of product tracking from raw materials through packaging. The platform features a production-scheduling program that will monitor constraints and anticipate potential problems, which is a task that previously required six full-time managers.

Environmental Considerations

By constructing the modular manufacturing facility off-site in a dedicated manufacturing facility, Pharmadule was able to greatly reduce the project's impact on the local environment.

Site work logistics were established to assure that no waste or debris entered a creek that runs through the campus. Silt fences and other erosion control measures were employed. Electric and gas utilities were tunnelled under the creek to not disturb fish and wildlife.

Leading the Way in Parenteral Contract Services

As the winner of the 2006 Facility of the Year Award, the Phase IV Project is the realization of BPS's vision to provide contract manufacturing services for pre-filled syringes and lyophilized vials. Through a creative and innovative mix of conventional construction for support areas combined with state-of-the-art modular construction of the manufacturing areas, the project has propelled BPS to become the world's largest supplier of pre-filled syringes - with a greatly expanded capacity for delivering the unit dosage forms that are critical for vaccines being re-developed without preservatives. As a result, Baxter is now the parenteral contract services leader of pre-filled syringes in North America with a total capability of filling up to 300 million 1- to 3-mL syringes each year including automated inspection, labelling, and packaging. For pharmaceutical companies choosing to outsource these operations, the BPS Phase IV Project provides a state-of-the-art, award-winning solution. 

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AstraZeneca

Delivering a Multi-Purpose API Plant

In response to an increased number of development projects, more complex manufacturing processes and due to increased drug substance potency, AstraZeneca is investing in upgrading, replacing, and building new key facilities. The Large Scale Laboratory (LSL) at Macclesfield, UK represents a significant element of this program. As a unique brown-field development, the project utilizes a holistic approach to the venture – from conceptual analysis through establishment of routine operation.

The LSL facility manufactures emerging compounds from AstraZeneca's therapy areas, including gastrointestinal, cardiovascular, respiratory, oncol-



Exterior view.

| | |
|------------------------------|---------------------------------------|
| PROJECT: | Large-Scale Laboratory (LSL) Facility |
| LOCATION: | Macclesfield, United Kingdom |
| DESIGN-BUILD PARTNER: | Jacobs Engineering Group, Inc. |

ogy, and neuroscience. It consists of one large, three-story building comprising three processing areas containing 16 reactors and ancillary equipment. In addition, there are separate chromatography and hydrogenation suites. Significantly, it is an API manufacturing facility capable of a range of different operating scales with a scope of containment solutions capable of a wide variety of chemical and physical transformations and rapidly configurable to deliver any combination thereof.

Creativity, Ingenuity, and Teamwork

In conjunction with Jacobs Engineering, AstraZeneca made an extraordinary effort during the conceptual stage of the project to ensure the requirements of such an asset were relevant for future needs of the company. This resulted in key features, including:

- a diverse range and combination of processing equipment and technologies
- a modular layout concept
- an innovative combination of containment approaches that allows handling of substances with an OEL down to 30ngm^{-3}

- state-of-the-art chromatography technologies
- novel project delivery through "alliancing"

The modular layout concept was not only cost effective but allowed the facility to be doubled in scale on a reserved footprint using the existing design. The entire infrastructure delivered by the original project was sized for the larger plan.

State-of-the-art chromatography technologies were used to increase the flexibility of the facility. For rapid delivery of critical path clinical supplies, the LSL includes a large-scale chromatography facility for separation of intermediates and final APIs. When key steps are made with optimal chemistry and chromatography as a part of the process, strategic route selection decisions can be made. Thus, otherwise non-viable chemical routes can become a commercial reality faster and earlier than anticipated.

A significant component of the chromatography investment is the Simulated Moving Bed (SMB), an innovative continuous manufacturing technique which allows separation of bi-



nary mixtures with far lower use of stationary phases and solvents. Particularly for chiral chromatography, this reduces costs significantly and can make otherwise uneconomic separations viable.

The project was delivered via a novel concept developed within AstraZeneca known as "alliancing." The keys to successful alliancing were in developing a single, integrated multi-disciplinary and multi-skilled project team from a small range of partner companies and AstraZeneca personnel. This was accomplished by forming mutually-beneficial relationships based on open, honest, and trusting relationships in which AstraZeneca's need to obtain value for money, superior safety, schedule, and regulatory compliance adherence was equal to the partners' need to make a fair return.



Interior view.

The Result

The Large Scale Laboratory has been a highly successful venture between

AstraZeneca and its Alliance Partners to deliver a state-of-the-art facility. The

Concludes on page 14.

Thermal Transfer are acknowledged as key members of Astra Zeneca's 'Large Scale Lab' Alliance Team



We are delighted ISPE judges have determined that together in Alliance with Astra Zeneca, we have designed and delivered a world class facility worthy of the Finalist in the 2006 'Manufacturing Facility of the Year Award'.

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Thermal Transfer are specialists in the Design & Build of Cleanrooms & Laboratories


“The LSL project has demonstrated its ability to shorten production time through innovation, processing efficiencies, and well understood and dependable equipment.”



Interior view.

LSL project has demonstrated its ability to shorten production time through innovation, processing efficiencies, and well understood and dependable equipment. As a result, the facility has enabled Campaign 2 (C2) manufacture of drug substance for volunteer studies to

be taken off the critical path. In addition to a significant business advantage, the facility provides an optimum range of manufacturing scales with rapidly configurable containment options to suit the compound being processed, without compromising operabil-

ity. The LSL project is unique in that it represents a complete solution to AstraZeneca's C2 manufacturing needs, delivering flexibility and adaptability, yet achieving these goals through a novel project approach in a highly cost effective manner. 

Meet the 2006 Facility of the Year Award Judging Panel

Peter Bigelow, *Judging Panel Chair*

Senior VP Consumer Healthcare Manufacturing, Wyeth

Tony Felicia

VP R&D Administration, AstraZeneca

Christian Ilsoe

Vice President, Quality and Validation Assurance, NNE A/S

Brian H. Lange, PE

Director – Sterile and Packaging Operations Engineering, Merck & Co., Inc.

Ulrich Rudow

VP Worldwide Engineering and Real Estate, Johnson & Johnson

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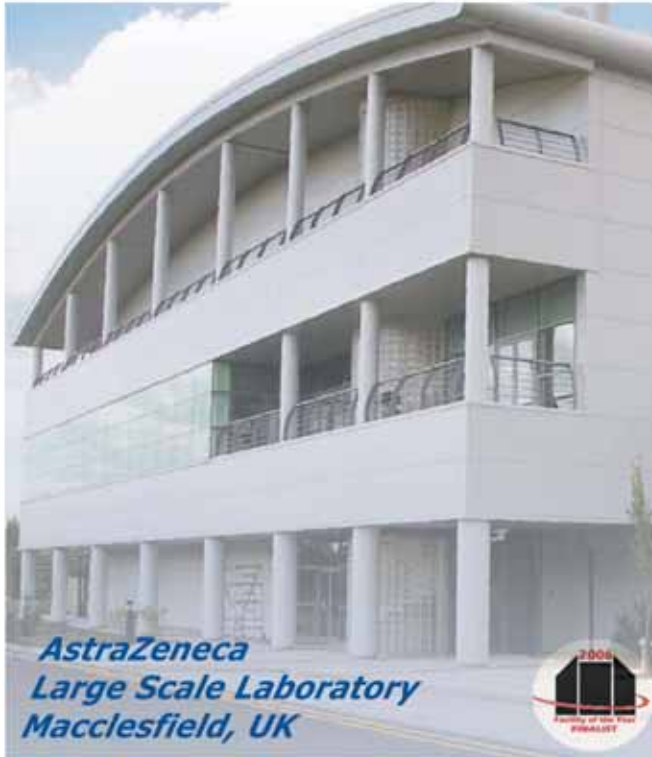
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*AstraZeneca
Large Scale Laboratory
Macclesfield, UK*



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*Wyeth
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Biolex Therapeutics

Simplicity in Approach Leads to Facility Excellence

In an industry in which each new facility or facility renovation project is bigger, more elaborate, and more complex than the last, simplicity is sometimes the best strategy. In expanding the production capabilities of its Pittsboro, North Carolina, US, manufacturing facility, Biolex Therapeutics adopted the “simple and practical” approach for all aspects of the facility expansion and the operation of the completed facility. As recipient of the 2006 Facility of the Year Special Recognition, Biolex has demonstrated how “simple is better” can yield the following benefits:

1. additional manufacturing capacity, which conforms to U.S. and European GMPs
2. flexible manufacturing space, which can be used for production of research grade, pre-clinical and clinical phase materials
3. exceedingly quick and economical facility delivery



Exterior view.

Biolex engaged O’Neal, Inc. to provide integrated design, engineering and construction services on a design/build basis for the facility expansion project. The expansion allowed Biolex to convert an additional 7,500 square feet of a 50-year-old, brick textile mill located in the historic district of Pittsboro into manufacturing space for the production of several complex recombinant proteins, including bulk material for Locteron™, the company’s novel, controlled release formulation of interferon. Locteron just completed Phase 1 clinical trials and this additional capacity has allowed Biolex Therapeutics to immediately ramp up material for Phase 2 clinical trials.

| | |
|------------------------------|--|
| PROJECT: | Phase II GMP Facility Expansion |
| LOCATION: | Pittsboro, North Carolina, United States |
| DESIGN-BUILD PARTNER: | O’Neal, Inc. |

Process Innovation

The Biolex Phase II expansion showcases key innovative technologies in the company’s manufacturing process. Rather than using traditional cell culture methods, the Biolex process employs the small, free-floating aquatic plant, Lemna. Lemna is a clonal plant known to be genetically stable. The method involves introducing a specific gene sequence into the cells of the plant which serve as the template for constructing a target therapeutic protein. By using a whole, intact organism, the environmental requirements for clonal replication and therapeutic expression are minimized. The plant grows in a wide range of conditions in its natural environment, and requires a simple aqueous media of basal salts, a light source, and CO₂ to produce human therapeutics.

By using this expression system, the upstream production process equipment and utility systems required were minimized. The need for stainless steel tanks with CIP and SIP capabilities, WFI, and clean steam systems were eliminated – as were the capital expense and long lead times associated with such equipment.

Fast-Track Project Delivery

The strategy to use a transgenic plant to produce human therapeutics resulted in a facility project involving mostly architectural, HVAC, and electrical design and construction elements rather than the often complex equipment and



Interior view.

utility requirements typically associated with biological manufacturing facilities. The project team was able to further capitalize on these advantages by using off-the-shelf, packaged utility systems to capture capital savings and shorten delivery times over custom designed utility equipment.

Additionally, Biolex used modular-constructed environmental chambers for bioproduction suites within the new expansion area. These suites were slightly customized versions of chambers that have traditionally been used in the agricultural industry and in academic institutions for plant growth and research applications. The suites provide Biolex optimal environment growth conditions in a controlled, contained environment. The modular design of the units allowed site construction to commence while the suites were being constructed in parallel. Once the suites arrived, they were simply erected in place and tied into the installed utility systems. Further time savings were captured by using an enhanced commissioning approach in the validation of the suites.

By emphasizing simplicity of design, construction, and operation, Biolex's expansion project was completed from the beginning of design through the completion of OQ validation in five months, from March to August 2005. The project was completed under budget with no safety incidents and with superior quality.

"The technology employed by Biolex Therapeutics is an excellent example of manufacturing innovation," said Peter Bigelow, Senior Vice President of Consumer Healthcare Manufacturing for Wyeth and Chairman of the 2006 Facility of the Year judging panel. "Instead of using traditional cell culture methods, the Biolex manufacturing process employs a unique expression system. We found that to be a very intriguing new innovation in biotechnology."

2006
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Congratulations Biolex Therapeutics

**From O'Neal, Inc
on receiving a
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Recognition for
The 2006 Facility
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O'Neal is honored to have partnered with you by providing the **engineering, construction and validation** of the world-class Biolex Therapeutics Pittsboro Phase II facility expansion.

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THE BUSINESS OF PROJECT DELIVERY

Daiichi Asubio Pharma Co., Ltd.

Multi-Products and Multi-Scale "Launch Plant"

For patients suffering from cardiovascular disease, central nervous system, and immune systems disorders, effective treatments cannot come too soon. To shorten the product delivery cycle for new drugs in these therapeutic areas, Daiichi Asubio Pharma Co., Ltd. (ASB), a subsidiary of the Daiichi Pharmaceutical Group,

PROJECT: New Bio Plant (NBP)
LOCATION: Gunma Prefecture, Japan
DESIGN-BUILD PARTNER: JGC Corporation



Exterior views.



constructed a new multi-product and multi-scale plant in Gunma Prefecture, Japan. As a multi-product and multi-scale "launch plant" for bulk biopharmaceutical products, the New Bio Plant (NBP) provides small-scale manufacturing for Phase 2 clinical trials as well as large-scale commercial manufacturing. Leading Japanese engineering and construction company JGC Corporation was selected to execute engineering, procurement, con-

struction, and commissioning and qualification.

A unique combination of cutting-edge production processes makes the NBP unique among pharmaceutical facilities in Japan, and perhaps, the entire world. The \$30 million plant is equipped with two fermenters (300 liter and 4,500 liter), separation, reaction, purification and lyophilization systems, and was completed in a remarkable 26

months from start of conceptual study to readiness for Performance Qualification (PQ).

State-of-the-Art Peptide Production

A unique feature of the NBP is a peptide production process by which peptides are produced on a commercial scale from recombinant microorganisms. In the NBP, enzymatic reactions apply a unique, self-developed

Concludes on page 20.

Guaranteeing performance and ensuring trust



JGC congratulates Daiichi Asubio Pharma Co., Ltd. on being selected as a finalist in this year's remarkable Facility of the Year Award competition

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enzyme to achieve high productivity and high purity. The hybrid process for peptide production utilizes both bio and chemical synthesis. Lyophilization is applied for the bio production process.

A Closed System to Prevent Cross-Contamination

Flexible processing and prevention of cross-contamination are essential requirements for a multi-product and multi-scale plant such as the NBP. As a result, the plant features such innovations as closed disposable trays for lyophilization, a closed purification process, a closed continuous solid-liquid separation system, and a unique powder feed system.

“Flexible processing and prevention of cross-contamination are essential requirements for a multi-product and multi-scale plant such as the NBP.”



Interior view.


For flexible processing, mobile equipment has been adapted to meet the requirements of different products and production scales. Common utility stations that can be conveniently connected to variously sized equipment are made available to each production room. Elongated body fermenters and other vessels enable wide-ranging volumes of culture and products to be manufactured. All of these contribute to cost reductions through the minimization of space, piping, cable, valves, and instruments.

Manufacturing Execution Systems (MES) and Digital Control Systems (DCS) offer easily configurable tools for operation and product changes, meeting the multi-product and multi-scale requirements. The DCS was developed based on ISAS88 for changes of recipe and control operations. By

communicating with the DCS, the MES controls the manufacturing step and adopts a bar-code system to prevent cross-connection of piping and erroneous feed of raw material.

Reliability and Compliance

For improved reliability, the NBP is equipped with uninterruptible co-generative electric power, e-mail warning transfer system to mobile phones, an automatic emergency stop system for earthquakes, Web cam monitoring, and IC card access control.

Plus, this world-class and critically important plant is distinguished by full cGMP compliance (Impact Assessment, Risk Assessment and Design Qualification {DQ}), ultra fast track project execution, and in its design phase, 3-D CAD engineering as well as Computational Fluid Dynamics (CFD). Significant contributions to the pharmaceutical manufacturing industry are highly anticipated to result in a stable supply of bio bulk products while shortening the period required for new drug development. 



Exterior view.

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Janssen Pharmaceutica Small Volume Area Produces Big Results

In 2003, the Janssen Pharmaceutica chemical production site in Geel, Belgium installed a new powder-handling installation aptly named the Small Volume Area (SVA) – Powder Unit. This Small Volume Area (SVA), the first of its kind within Janssen's parent company, Johnson & Johnson, is a unique combination of state-of-the-art micronizing equipment and high-tech separation of the working environment using isolators (glove boxes).



Exterior view.

enhanced worker safety, and a boost in production efficiency for 30 different chemical products.

The Need for Increased Production

Janssen's Geel chemical production plant plays a crucial role in producing Active Pharmaceutical Ingredients (APIs) for life-changing medicines to treat mental illness, allergies, women's health issues, and gastrointestinal disorders. Significantly, the SVA process increases production to more than a dozen tons of product each year - equivalent to hundreds of millions of patient treatments annually.

Fully-Contained Process

The SVA is part of a high-containment production chain, which consists of four separate state-of-the-art production installations for weighing, production, powder handling, and material-cleaning. Consistent with the containment technology, these installations are fully enclosed, which substantially enhances quality and safety.

The installation is to be used to obtain the correct particle size distribution for the most potent drugs manufactured at the site. It now allows for greater protection of product,

enhanced worker safety, and a boost in production efficiency for 30 different chemical products.

PROJECT: Small Volume Area (SVA) – Powder Unit

LOCATION: Geel, Belgium

DESIGN-BUILD PARTNER: Janssen Pharmaceutica Chemical Production Engineering

Together, these installations constitute an isolated processing chain. Transport between the various installations is performed by means of special sealed drums which can be opened only after they are coupled to an isolator.

Every stage is executed in a fully closed way through specially designed equipment integrated in isolator technology (glove boxes). New design standards were employed due to ergonomic considerations, equipment size, and pres-



Aerial view.

Continued on page 24.

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sure safety of placing a pneumatic transport system into the isolators.

Testing of mock-up isolators was essential to project success due to the many operations that need to be performed with the equipment such as assembly and dismantling for cleaning. A single, unworkable operation would render the entire installation unusable.

Janssen Pharmaceutica Chemical Production Engineering, the lead design firm on the project, championed the build of the detailed mock-ups, using 3-D software with walk-through mode, and involved operators, technicians, engineers and management from the start of the project, allowing for the creation of an ergonomically-designed installation that saved \$300,000 with initial process flow reviews.

"New design standards were employed due to ergonomic considerations, equipment size, and pressure safety of placing a pneumatic transport system into the isolators."

Installations and Technology Platforms

Spray Dryer

During the spray drying process, a suspension is sprayed at high pressure in a drying chamber with a warm nitrogen stream. Rapid evaporation of the solvent results in a powder-particle form, making uptake in the human body easier for some products. This installation was built with patient friendliness in mind and resulted in enabling patients taking AIDS inhibitors to cut their dose from 16 pills per day down to only two pills per day.

Bromination and Hydrogenation

Two separate installations are available for these processes, and both have processes in place to meet safety standards. Geel is the only site within J&J with such a combination of installations.

Preparative Separations Techniques (PST)

In some cases, chromatography is the only way to separate two highly similar substances, and at the facility in Geel, this is accomplished on a production scale with the PST installation. This is capable of separating 2,100 kg of material in 2.5 days.

Meeting Goals for Product Quality and Safety

Overall, the facility results in a positive impact on product quality and safety.

Quality: Protection of the Product

The SVA installation complies with EU Grade C (ISO 14644-1 Class 7 (particles > 0.5 µm) + microbial requirements), which allows for the handling of intermediate products for parenteral use. It must remain completely sanitizable through Clean-In-Place (CIP) after each campaign. Sterility is not required.

Safety: Protection of the Operator


For the first time, Personal Protective Equipment (PPE) is no longer necessary to protect operators from exposure to high potent APIs. The SVA itself is shielded. The installation has a Design Exposure Limit (DEL) of 50 nanogram/m³. The eight hour average ambient concentration of the product does not exceed this value.



Interior view.

A Heritage of Innovation

For more than 30 years, the Janssen Pharmaceutica site in Geel has played a crucial role within Johnson & Johnson in producing APIs for medicines – and the plant now supplies about two-thirds of worldwide chemical production for

Johnson & Johnson's pharmaceutical sector. The SVA installation is the latest example of the company's ongoing commitment to invest in new technological innovations to ensure efficient, safe, and cost-effective delivery of high-quality medicines. 

| | |
|-------------------|--|
| • Master Planning |  |
| • Concept Design | |
| • Basic Design | |
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BnS Engineering and Foster Wheeler congratulate Janssen Pharmaceutica. Having worked closely with Janssen, we are proud to be associated with the innovative small volume powder unit.



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Wyeth Pharmaceuticals

Biotechnology Excellence in a King-Sized Package

Which comes first, the manufacturing processes or the infrastructure to house and operate the processes? In planning construction for its new biopharmaceutical campus in Grange Castle, Ireland, Wyeth Pharmaceuticals considered both from the start. The result is the largest fully-integrated facility ever built in a single phase.

PROJECT: Wyeth BioPharma Campus at Grange Castle

LOCATION: Grange Castle, Ireland

DESIGN-BUILD PARTNER: Jacobs Lend Lease - JLL (a joint venture between Jacobs and Bovis Lend Lease)



Exterior view.

One of a Kind Campus

Wyeth's new state-of-the-art BioPharma Campus at Grange Castle is not just another biotechnology facility. The campus is an innovative approach to industrial facility design. Rather than introduce another biotechnology plant, Wyeth focused on developing a homogenous campus environment where core functions drive manufacturing and material handling. Also, the dramatic use of curved stone facades and generous glass offer a building to the local community that many would be proud to live beside, in direct contrast to a normal low-key industrial complex.

The integrated campus includes three separate facilities: a Drug Development Facility to coordinate and validate the technologies and procedures required to migrate products and processes from the laboratory to the commercial production stage; a multi-product Drug Substance Facility for media preparation, fermentation, and purification stages of manufacture; and a Finished Product Facility for formulation, vial preparation, filling, capping, and inspection.

Concludes on page 28.

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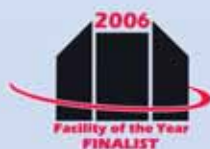
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“Equally significant were the tremendously high project safety standards which resulted in Wyeth posting an overall injury rate notably lower than the national manufacturing average both in construction and operations.”



Interior view.

Achieving Through Partnering

In late 1999, Wyeth had a need to quickly expand production capacity for Enbrel®, a drug used to treat rheumatoid arthritis, and Prevnar®, a vaccine that helps prevent meningitis and bacteremia in children. Motivated by patient need - and the little time patients have to wait for these life-saving drugs - Wyeth envisioned the construction of a fully-integrated biopharmaceutical facility that would allow for flexibility in processing and expandability for future products.

The big question was, “How do you design and build a new 90 acre, 1,000,000 sq. ft., facility that will house more than 1,100 employees and deliver product on schedule?”

Partnering was the answer. Wyeth fostered close relationships with government agencies, design companies, and vendors to implement an alliance contractor framework for construction activities. This allowed Wyeth to easily direct delivery speed and construction quality. The company also mobilized an Integrated Commissioning and Vali-


ation (ICV) organization, to unite all stakeholders under one organization with the sole purpose of qualifying the facility. Equally significant were the tremendously high project safety standards which resulted in Wyeth posting an overall injury rate notably lower than the national manufacturing average both in construction and operations.

Focused on project delivery, design teams conducted interactive sessions that included operators, technologists, designers, equipment suppliers, and construction organizations. Project teams targeted solutions to ensure successful operational start. For example, at an early stage in the drug substance facility design, the team decided to implement a closed process system to permit sanitization of equipment and piping without the need to re-open the system. This allowed for the protection of product quality and a lowered room classification.

For effective start-up, the operations team, engineers, construction teams, and contractors were co-located on the site. Support functions and facilities

were co-located as much as possible. The ICV team was initially co-located with construction, and when the operations' staff took up residence in the buildings, ICV was co-located with operations and site engineering staff to allow for a continuous flow of knowledge transfer and for new staff to become quickly immersed in the project. Material flow was enhanced both from area to area by use of wide enclosed corridors and in manufacturing by the use of closed loop piping and transfer systems.

A Facility for the Long Haul

With its new BioPharma Campus engineered by Jacobs Lend Lease (JLL), Wyeth has achieved much more than the distinction of owning and operating one of the world's largest biotechnology facilities. By combining established industry best practices that optimize manufacturing with team-oriented project delivery methods that drive collaboration and overall speed to market, Wyeth has delivered a true world-class facility that will serve the company well into the coming decades. 

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An Interview with Peter Bigelow

Facility of the Year Judging Panel Chair



Peter Bigelow, Senior Vice President, Consumer Healthcare Manufacturing for Wyeth, has served as the Judging Panel Chair of the Facility of the Year Award (FOYA) for the past two years. This year's competition marks his last year as Chair.

In this interview, Peter gives us a behind-the-scenes look at the judging process and shares his views on how the award plays an

important role in advancing the pharmaceutical manufacturing industry.

Q Tell us about your experiences and what significant contributions the competition has made to the pharmaceutical manufacturing industry.

A The Facility of the Year Award competition has allowed us to showcase exceptional work that's being done by the engineering community in our industry. Typically, many of these projects would be completed without a forum for people to find out about them. This competition has enabled us – at least for some of the major and significant projects in our industry – to provide a broader forum for individuals to see and understand the innovations taking place in facility design and engineering.

Before FOYA, this type of information would be obtained through less timely and less objective methods, such as word of mouth, presentations from service providers, magazine articles, or through facility tours conducted by some of the local ISPE Chapters and Affiliates.

It's important to note that this competition not only highlights how a certain facility was designed or built on time and under budget, it allows us to identify and showcase some of the best practices utilized in the industry today. We've found that some of these best practices come from some of the smaller projects and not only by "Big Pharma."

Q Can you tell us about the judging process?

A Although it sounds like it would be grueling, and there is a lot of work and negotiating involved, the judging process is a wonderful and rewarding experience.

I think that you always want to seek more information than you have. So, being limited to the information in each entry can be a stumbling block to some extent. There were

very few questions as to whether some facilities were qualified, because the companies that submitted facilities did an excellent job showcasing their projects within the award criteria. *The integrity of the entries really reflects the integrity in this industry.*

Because of the high quality of all the presentations and facilities, we had to make some very difficult decisions, although I think we reached consensus pretty efficiently. In most cases, the differentiation between who's a finalist versus who isn't, and who's the overall winner, versus who isn't, is fairly small. When it came to making the final decisions, the tie-breaker was innovation, whether in the form of a new and important process, or in the design or construction, or in the approach of one of the major objectives of the project. Another key factor was overall execution of the project.

Q What are some of the notable technological and innovative advances you are seeing in facility design and construction and how are these advances changing the way facilities are built and pharmaceuticals are produced?

A We are seeing a lot of modularization. That is probably the single most significant technological advance that comes through. The advantages of modularization are the flexibility and the ability to move quickly.

We're seeing a lot of very interesting and innovative processing changes that are more efficient, have higher yields, and are more compliant in respect to Good Manufacturing Practices (GMP). The industry is becoming more highly automated, and with that increased level of efficiency, brings a higher level of compliance.

An example of innovation would be the technology employed by Biorex Therapeutics. Instead of using traditional cell culture methods, the Biorex manufacturing process employs a unique expression system. We found that to be a very intriguing new innovation in biotechnology.

In regard to the use of new technology in the entries, we did see some examples of islands of Process Analytical Technology (PAT), but none of the facilities have implemented PAT to the extent that is anticipated in the future. However, I think that in the next few years, PAT will yield a new kind of era in our industry.

Q Why is it so important for the benefit of the industry for companies with eligible facilities to submit an entry?

A Let me emphasize that in the past two years, each and every facility that was entered into the competition was exceptional and worthy of some kind of an award. This



competition is not about winners and losers. All entries were winners and we selected the best from a group of winners. Therefore, no one should feel embarrassment or any kind of negativity if they are not selected as a finalist.

As I noted earlier, it was very difficult and a little frustrating for the judges because sometimes there was not a lot of differentiation between entries and finalists.

Entering this competition is a tough decision for each individual company. Coming from one of those companies myself, I understand that it is a tough balance between protecting science, investment, and good ideas from competitors, and showcasing new and innovative technologies. But entering this competition accelerates the ability for all companies to employ some of the good work, best practices, and facility and process innovation that is out there. We can make improvements in quality and costs quicker and more effectively. These improvements are a benefit to all of us.

Q Understanding the submission criteria were not ranked or weighted, which of the criteria did the judges seem to be most impressed with?

A The judges seemed to be most impressed with project uniqueness and innovation. Advances in facility design technology and excellence in execution were also important. The ability to bring the project in on time, execute it well, and follow good methodology to get it done also seemed to be important criteria.

Q What messages, best practices, and lessons learned can the pharmaceutical manufacturing industry take away from the competition?

A One message or lesson learned is that good project execution can be done in any part of the world. Innovative and complex technologies can be employed in any part of the world. The industry is truly global. We are producing facilities of similar quality. The way we employ technologies and techniques, and the way we carry out project execution is very similar in every part of the world. The global nature of the pharmaceutical industry is truly reflected in this competition.

Another message is that our industry is a complicated business and there is a lot of competition. Therefore, processes and facilities are getting more complicated, investments are huge at times, and the demands of the business are very significant around facility and process design.

Certainly, another message is that at the forefront of every project is the impact and improvement of quality. Everybody is talking about quality and everybody is trying to make quantum leap improvements in quality.

Q It's possible that state-of-the-art facilities could be associated with large, grandiose, and expensive. Is this

accurate based on your experiences reviewing submissions for the competition?

A There was a mix of large-, small- and medium-sized projects. I think the committee did a good job of not being overly enamored with a project because it was large, and tried to look at a project's innovation, technology, and overall contributions to the industry.

State-of-the-art does not necessarily mean that it has to be big, expensive, and grandiose. And, we're seeing state-of-the-art in every project, regardless of size.

I think "Big Pharma" is stuck in a paradigm when it comes to facility design and has trouble being creative, innovative, and flexible. In "Big Pharma," we tend to design something the way the last project was designed and try to make incremental improvements. Some of the smaller facilities and companies – because they have a small budget and fewer resources – take a totally different approach. Sometimes that approach, which is more agile and creative, can yield excellent results.

I think that "Big Pharma" could learn from some of these smaller projects how to be more flexible and to be more focused on the real needs of the business.

Q What final comments do you have about the Facility of the Year Award competition and its impact on the industry?

A Personally, I think ISPE has made phenomenal contributions to the industry. ISPE brings people together from around the world – from large to small countries, from suppliers to equipment sellers – for an open, honest, and useful forum for exchanging information, for becoming educated, and for finding out about new products. ISPE has helped accelerate a lot of good engineering in our industry. These facilities are real concrete examples of what ISPE talks about all the time in its guides and courses.

It's important for everyone in the industry to learn from each other, to understand what works and what doesn't, and to employ innovation and good solid technologies. It's a very good way to showcase important things that are taking place in our industry. All the competition sponsors, ISPE, Pharmaceutical Processing magazine and Interphex, have similar goals, and this competition is a real complement to what they're trying to accomplish.

The judges we've been able to assemble have done a great job. They've been committed to this competition, had great thoughts, and used their many years of experience to collaborate and make good decisions. So, I really appreciate the committee's efforts.

From a personal point of view, this has been a very rewarding experience for me. It's given me an insightful glimpse of the industry. And, it's made me feel really good about where we're headed as an industry. ☺

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