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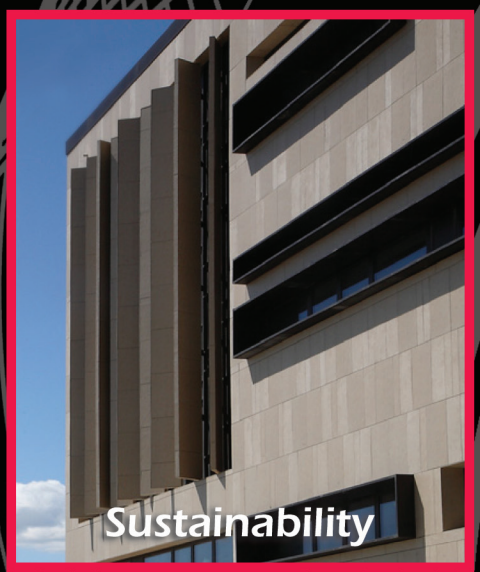
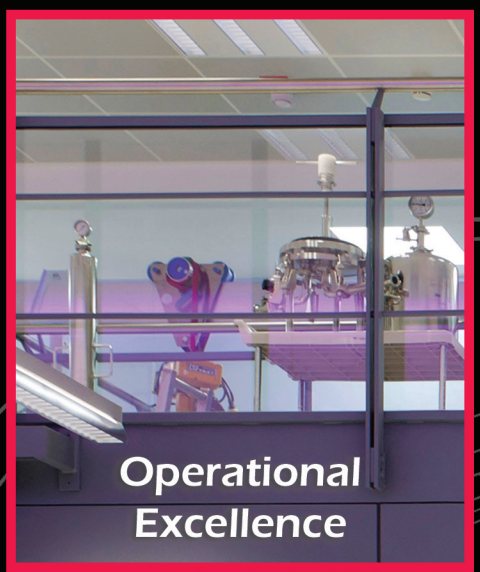
2012
Facility of the Year Awards
CATEGORY WINNERS

Facility of the Year Awards

CATEGORY WINNERS





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Cover Photographs

Photos courtesy of Chiesi Farmaceutici S.p.A., Eisai Pharmatechnology & Manufacturing Pvt. Ltd., Merck & Co., Inc., Rentschler Biotechnologie GmbH, and Roche Diagnostics GmbH

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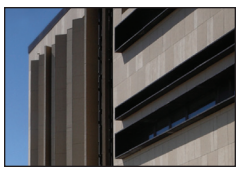
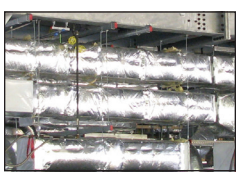
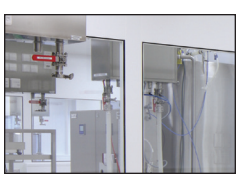
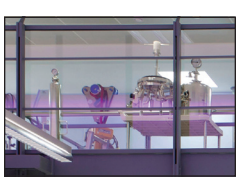
2012 Facility of the Year Awards
CATEGORY WINNERS

Articles









2012 Facility of the Year Awards Program:
Winning to Benefit Patients Worldwide

The Facility of the Year Awards (FOYA) program is the industry's premier awards program dedicated to celebrating innovation and accomplishments in facility design, construction, and operation.

The FOYA program recognizes state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies to enhance the delivery of a quality project, as well as reduce the cost of producing high-quality medicines. Now entering its ninth year, the awards program effectively spotlights the accomplishments, shared commitment, and dedication of individuals in companies worldwide to innovate and advance pharmaceutical manufacturing technology for the benefit of patients worldwide. The FOYA program is sponsored by ISPE, INTERPHEX, and *Pharmaceutical Processing* magazine.

"Our 2012 Category Winners reflect the true spirit of the Facility of the Year Awards program," said FOYA Judging Panel Chair, Chaz Calitri. "The winning projects exemplify innovation in pharmaceutical manufacturing for the benefit of patients all over the world, who depend on us for medications that are high quality, available, and affordable."

"Our winners come from five different countries and include novel, low cost biologics facilities, creative and visionary industry-academia-government collaborations, and hyper-fast track investments made to ensure vaccines get to patients in need. We are also proud this year to recognize facilities that seek to speed up drug development as well as facilities that greatly reduce the environmental "footprint" of manufacturing in the communities in which they reside," said Calitri.

Chiesi Farmaceutici S.p.A.: building façade.

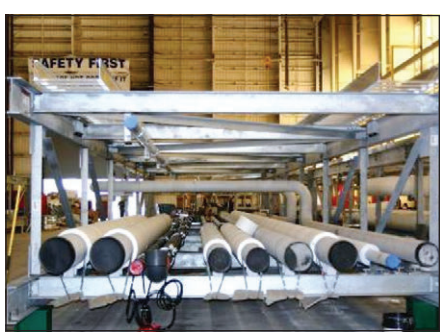
Eisai Pharmatechnology & Manufacturing Pvt. Ltd.: water pretreatment.

The FOYA Judging Panel named five Category Award Winners and selected one project for Special Recognition. The winning companies and respective award categories are:

- **Chiesi Farmaceutici S.p.A.,** winner of the Facility of the Year Award for *Sustainability* for its Research and Development Centre in Parma, Italy
- **Eisai Pharmatechnology & Manufacturing Pvt. Ltd.,** winner of the Facility of the Year Award for *Project Execution* for its Eisai Knowledge Centre in Visakhapatnam, Andhra Pradesh, India
- **Merck & Co., Inc.,** winner of the Facility of the Year Award for *Facility Integration* for its Vaccine Bulk Manufacturing Facility (VBF) Program of Projects in Durham, North Carolina, USA
- **Rentschler Biotechnologie GmbH,** winner of the Facility of the Year Award for *Equipment Innovation* for its REX III project in Laupheim, Germany
- **Roche Diagnostics GmbH,** winner of the Facility of the Year Award for *Operational Excellence* for its TP Expand project in Penzberg, Germany
- **National Institute for Bioprocessing Research and Training (NIBRT),** winner of the Facility of the Year Award *Special Recognition for Novel Collaboration* for its New Greenfield facility in Dublin, Ireland

The Facility of the Year Awards program is truly global, as submissions over the past eight years have been received from more than 25 different countries and territories. Each of the submissions was reviewed by an independent, blue-ribbon judging panel consisting of global senior-level executives from all aspects of the industry. These industry professionals included:

- **Chaz Calitri, Judging Panel Chair**
  Vice President, Global Engineering, Pfizer, Inc.
- **Jim Breen**
  Vice President, Project Management Worldwide Engineering and Real Estate, Johnson and Johnson
- **Steve Dreamer**
  Head of Global Pharma Engineering and Operational Excellence, Novartis Pharma AG



Merck & Co., Inc.: interior pipe rack module.

Rentschler Biotechnologie GmbH: supply area.

- **Brian H. Lange, P.E.**
  Director, Quality Services, West Point Quality Operations, Merck & Co. Inc.
- **Shinichi Osada**
  General Manager Biopharm, Industrial and Logistics Systems Division, Hitachi Ltd.
- **Andy Skibo**
  Senior Vice President, Global Engineering and Facilities, MedImmune
- **Ron Trudeau**
  Vice President, Facilities Engineering Services, Baxter Healthcare
- **Jon Reed**
  Vice President, Global Engineering, Genentech
- **Georgia Keresty**
  President, Janssen Alzheimer Immunotherapy, Johnson and Johnson
- **Karen Kinney**
  Director, Sustainable Facilities, LEED AP/Project Management and Engineering, BD

2012 Facility of the Year Events

The Overall Winner – selected from the Category Winners – will be revealed at ISPE's Annual Meeting in November. There will be several other opportunities to learn first-hand about the facilities being honored as "best in their class." These events include:

- **INTERPHEX*2012*** – Meet the Category Award Winners from 1 to 3 May at the Facility of the Year Awards Display Area near the front of the exhibit hall of the Jacob K. Javits Convention Center in New York City, New York, USA. This is your opportunity to meet personally with representatives from winning teams to discuss the success stories associated with these pharmaceutical manufacturing facilities. To register or for more information, visit www.interphex.com.
- **ISPE 2012 Annual Meeting** – Learn first-hand who will win the coveted Overall Facility of the Year Award during ISPE's 2012 Annual Meeting and hear presentations from the winning teams, 11 to 14 November in San Francisco, California, USA. For more information, visit www.ISPE.org.
- **Feature Articles** – Comprehensive coverage will appear in *Pharmaceutical Engineering* magazine and *Pharmaceutical Processing* magazine.

Visit www.facilityoftheyear.org for more information about the awards program and comprehensive details about each of this year's award-winning projects and their support teams.

About ISPE

ISPE, the International Society for Pharmaceutical Engineering, is a not-for-profit Society of 22,000 pharmaceutical professionals in 90 countries who use expert knowledge to create high-quality, cost-effective GMP solutions. ISPE is "Connecting a World of Pharmaceutical Knowledge" by providing Members with opportunities to develop their technical knowledge, exchange practical experience within their community, enhance their professional skills, and collaborate with global regulatory agencies and industry leaders. Founded in 1980, ISPE offers online learning opportunities for a global audience and has its worldwide headquarters in Tampa, Florida, USA; its European office in Brussels, Belgium; an Asia Pacific office in Singapore; and its newest office in Shanghai, China. Visit www.ISPE.org for additional Society news and information.

Roche Diagnostics GmbH: open plan lab.

About INTERPHEX

Now in its 33rd year, INTERPHEX is the largest gathering for FDA regulated drug and drug delivery products for technical professionals in development & manufacturing for pharmaceutical, biologic, generic, contract manufacturing and supporting services. ISPE is the exclusive official association sponsor of this industry-leading annual event. Scheduled for 1 to 3 May 2012 at the Jacob K. Javits Convention Center in New York City, New York, USA, the event hosts more than 650 suppliers on the show floor along with an expanded conference program, featuring a high-profile roster of subject matter experts. For information, visit www.interphex.com.

About *Pharmaceutical Processing*

Pharmaceutical Processing magazine is the pharmaceutical industry's leading information provider, reporting on a full range of innovative new products, equipment, technology, and trends for 28,000 engineers and managers responsible for the development, manufacture, validation and packaging of pharmaceuticals. An official sponsor of INTERPHEX, *Pharmaceutical Processing* distributes critical information to these professionals in a timely manner through a full range of print, electronic and online media. For information, visit www.pharmpro.com.

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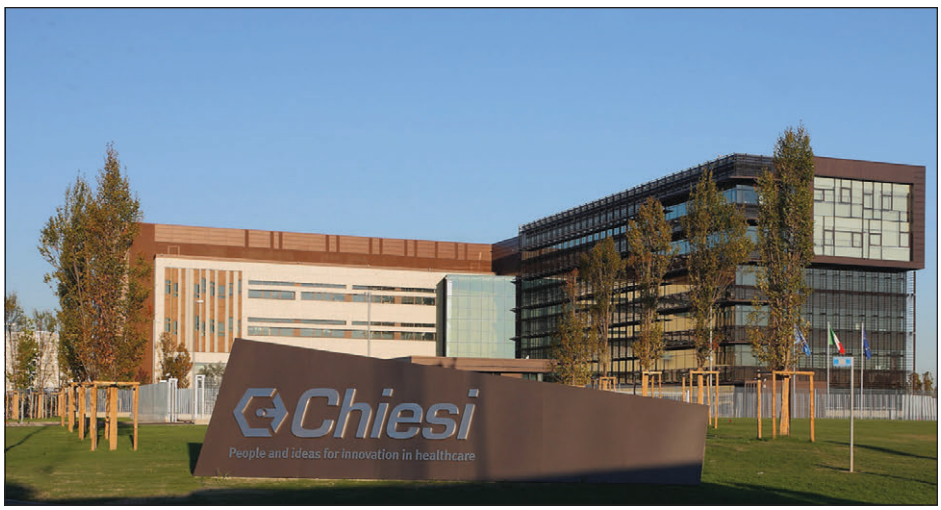
Chiesi Farmaceutici S.p.A.

Building Commitment to Sustainability

Introduction

Chiesi Farmaceutici's Research and Development Centre in Parma (Italy) was built to represent Chiesi's "corporate headquarters of R&D," hosting all of the company's skills and technologies for the identification of lead compounds, preclinical and clinical development, and the management of regulatory activities and its R&D portfolio.

Not only does the center confirm the company's commitment to R&D; it represents Chiesi's commitment to sustainability. The judging panel was impressed with the center's realization of a comprehensive sustainability strategy, garnering the project the **2012 Facility of the Year Award for Sustainability.**



Front view.

Project Overview

Pride in Research

A family-owned company, Chiesi engages in the research, development, production, and sale of pharmaceutical products for therapeutic areas, such as respiratory, central nervous system, neonatology, muscular-skeletal, and cardiovascular diseases. Chiesi also provides solutions for the treatment of asthma, chronic obstructive pulmonary, respiratory distress syndrome, and hypertension, among others. In 2010, the company's investment in R&D reached a total of $198.2 million, representing 15% of their total revenue. In addition to the new Research and Development Centre in Parma, Italy, Chiesi operates three other research centers located in Paris, France, Chippenham, UK, and Rockville, Maryland, USA.

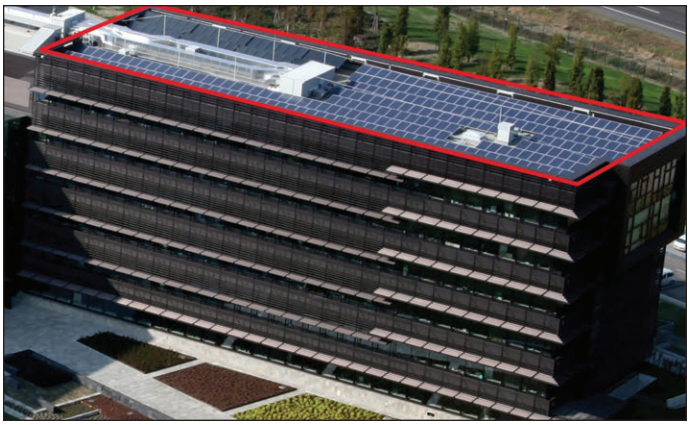
The new 236,806-square-foot center in Parma coordinates and integrates the activities of all research sites, making it possible to complete the entire cycle of drug research and development: studies of molecular synthesis aimed at selecting the most promising molecules; preclinical and formulation studies which evaluate the efficacy and tolerability of candidate drugs; clinical trials; and finally, registration for the authorization of the release for marketing of new drugs.

Chiesi Farmaceutici S.p.A.

Category Winner – Sustainability

Project: Research and Development Centre
Location: Parma, Italy
Project Mission: The new Research Centre in Parma represents further evidence of Chiesi's commitment to enhance and cultivate the capacity to create value through innovation.
Size: 236,806 sq. ft. (22,000 sq. m.)
Total Project Cost: $117,480,000
Duration of Construction: 29 months


Solar shadings on the built façade.



Photovoltaic array and solar panels on roof.

Pride in Sustainability

In addition to projecting to the world that Chiesi takes pride in its research, particular attention was paid to incorporate tangible, sustainable systems and processes into the new center to minimize energy consumption and waste production and improve the overall conditions for the occupants.

The project team realized their comprehensive vision of a four dimensional sustainability strategy with features such as: extensive use of atriums and glass walls to maximize lighting; "smart system" lighting that gradually adjusts to external conditions; an Energy Hub Scheme that integrates renewable and traditional energy sources; a highly energy efficient building envelope with a ventilated façade, thermal insulation, and solar shading; and waste recovery systems designed into the facility to include the transfer of thermal energy of exhaust air and water use.

Both a Challenge and a Win: Designing a Sustainable Lab

Laboratory facilities present a unique challenge for energy efficient and sustainable design because of their inherent complexity of laboratory systems, health and safety requirements, long-term flexibility and adaptability needs, energy use intensity, and environmental impacts. The typical laboratory is anywhere from three to eight times as energy intensive as a typical office building and costs about three times as much per unit area.

Chiesi asked its project team to concentrate their effort on designing a very innovative facility with low energy consump-

Why Our Project Should Win

The following is an excerpt from Chiesi Farmaceutici's submission, stating in their own words, the top reasons why their project should win the 2012 Facility of the Year Award:

- **Integrated sustainable design.** The latest energy-saving strategies were implemented without compromising the functionality of the laboratories or impacting negatively on the environment. Laboratory buildings are an exceptional consumer of natural resources, especially for heating and cooling requirements associated with conditioning ventilation air. Energy saving and recovery by design was the innovative approach to substantially reduce the amount of energy associated with labs' needs.

- **State-of-the-art and innovative realization.** Thanks to Chiesi's commitment to innovation, Jacobs' first class international experiences in laboratories, and EFA's local knowledge and architectural judgment, the project team was able to design and execute a state-of-the-art facility for Chiesi's Research. Innovative solutions were sought since planning, when specialists verified the latest and emerging trends and techniques for laboratories. Innovative design enhances the "Flexi Labs Concept" and the choice of modularity and flexibility to meet future needs (expansions, reconfigurations, usage changes). Research lives out of innovation and it is motivated by it.

- **"The person at the centre" in a high quality work environment.** The facility is inspired by the idea of making "the person," with his/her ideas and activities, the focal point. The open plan, multifunctional and flexible rooms, help cultures and competencies get in touch and create opportunities for the exchange of ideas and collaboration. All occupants can find a comfortable and productive work environment, adjustable to their personal needs in terms of ergonomics, comfort and flexibility, and encouraging a "sustainable" attitude toward energy saving.

- **Project complexity and lean approach in multidisciplinary execution.** The project complexity required an organization capable of supporting a large number of different requirements from very different fields. Throughout the project, different issues were faced, from primary urbanization through architectural, space planning, modern laboratories design, specific equipment knowledge, chemical synthesis, state-of-the-art HVAC and mechanical plants, instrumentation, and other technical or regulatory issues. Only a committed and strongly technically prepared project team was capable of incorporating all necessary solutions in a sound design, resulting in the winning card for successful project execution. Lean approach helped in eliminating "waste," allowing the important achievements in the execution of time schedule and cost reduction.

- **An outstanding safety performance.** More than 700,000 hours were worked without any incident on site. A strong and solid Health, Safety, Environmental (HSE) program was implemented throughout the project and outstanding results were achieved. The construction site was used as a "case history" by Parma University as an excellent example of cooperation and alignment between teams (construction, HSE, Chiesi's).

Continued on page 8.

Notes from the Judging Panel – What Impressed Them

- *The design team did an excellent job of realizing their comprehensive vision for designing and building a sustainable facility from the outset by developing and implementing strategies to enable the energy-efficient R&D Centre. These strategies optimized energy consumption by reducing demand, harvesting free energy, increasing efficiency, and recovering waste.*
- *The extensive use of atriums and glass walls that maximize natural lighting throughout the facility combined with the "smart system" lighting that gradually adjusts to external conditions*
- *The ability of an Energy Hub Scheme, which was the result of a comprehensive energy demand study, to cleverly integrate renewable and traditional energy sources.*
- *The building envelope is highly energy efficient with a ventilated façade, thermal insulation, and solar shading.*

Award Category – Sustainability

Winners in this category exemplify the application of novel approaches, tools, and techniques intended to improve effective use of energy, minimize waste, reduce carbon footprint, incorporate green manufacturing techniques, reduce environmental impact, and result in more efficient processing, utilities support, and business advantage.

tion. The centerpiece of that effort was a four dimensional sustainability strategy:

- reduce demand
- harvest free energy
- increase efficiency
- recover waste

Reduce Demand

The reduction of energy demand is attained by reducing internal loads and concentrating the most energy consuming equipment in dedicated rooms where it is possible to balance the heat loads by dedicated units. The lighting system, an important energy demand, is managed by a centralized system that controls the light on/off of the lamps, which are installed at low energy consumption (Type 5). The orientation of the facility was defined to optimize daylight impact on the building; the heat transmission and radiance was reduced to a minimum by providing several trees around the facility.

Laboratory benches are equipped with overhead service: the utility services run above the ceiling and all have quick connect and disconnect features for easy hook-ups.

Natural lighting reaches the labs at the core of the building through glass curtains.

Harvest Free Energy

A comprehensive energy demand study was conducted, resulting in a clever integration of renewable and traditional energy sources called the "Energy Hub Scheme." The facility harvests free energy by using site resources, such as daylight, and solar heating to power conditioning, service water heating, and power generation. Daylight is improved by increasing the glazing surface of the offices (located along the perimeter of the laboratories) and by installing glass walls internally to permit laboratories (located in the core of the building), to be reached by daylight. Solar energy, which partially covers the demand of the building, produces the required energy for sanitary water demand and part of the required electrical energy. The solar energy is captured through the installation of more than 100 kWpeak of polycrystalline photovoltaic array and solar panels on the roof of the building.

Increase Efficiency

Energy efficiency is increased through its lighting system, a building envelope with a ventilated façade, thermal insulation, and solar shading, and by using an appropriately sized HVAC system that reduces energy demand and use.

Fume hoods, the most critical component of laboratories, were equipped with a proximity sensor that automatically closes the sash if after a settable time, the sensor does not detect any operator presence, reducing the amount of exhaust air and limiting the overall energy demand of the facility. The ventilation rate of the laboratories is optimized by a control system that selects the adequate supply airflow rate, depending on: the number of fume hoods in operation, internal heat load related to the lab equipment, and minimum air changes. The supply and exhaust air are controlled by motor fans controlled by a Variable Frequency Driver system, minimizing energy consumption.

Recover Waste

A peculiar challenge of a recovery system for a laboratory facility, where different types of chemicals are managed, is recovering as much energy as possible from the exhaust air while avoiding risk of cross contamination. The engineering team met this challenge by installing a dedicated and properly sized chiller that transfers the thermal energy of the exhaust air to the hot water circuits of the HVAC heating system. This system results in twice as much energy recovery compared with a traditional system.

Conclusion

In its quest to build a state-of-the-art research center, Chiesi also showed its innovation in sustainability. Chiesi's comprehensive sustainability strategy overcame complexities inherent in laboratory systems, health and safety requirements, long-term flexibility and adaptability needs, energy use intensity, and environmental impacts. The strategy resulted in the design and build of innovative systems and processes that maximize the use of natural resources and minimize the energy consumption and environmental impact of the facility.

Key Project Participants

Designer/Architect: Jacobs® (NYSE:JEC), Pasadena, California (with Emilio Faroldi Associati as Local Architect) *(See ad on page 19)*

Engineer/Construction Manager: Jacobs® (NYSE:JEC), Pasadena, California *(See ad on page 19)*

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Excellence in Project Execution Enhances Efficiency and Productivity

Introduction

The **Eisai Knowledge Centre,** winner of the **2012 Facility of the Year Award for Project Execution,** is hailed as the first large production facility in India by a major Japanese pharmaceutical company.

Located on a greenfield site in Visakhapatnam, Andhra Pradesh, India, this contemporary Active Pharmaceutical Ingredients (API) Research and Production and Oral Solid Dosage (OSD) Manufacturing complex spans 50 acres and comprises 14 independent buildings. The center was built in just 17 months for an investment of under $50 million. Also remarkable was the project team's ability to overcome the challenges of delivering a project of this size, given the complexities of doing so in India.

Response to a Business Plan

To more effectively respond to a rapidly changing market, meet the needs of patients worldwide, and ultimately transform itself into a top-tier, high-performing company, Eisai developed a strategic plan to further enhance efficiency and productivity in its global operations. Key to Eisai's supply chain and growth plan was the need for a flexible, multi-purpose facility capable of manufacturing API in a variety of formats.

The Eisai Knowledge Centre is designed to be a global comprehensive pharmaceutical complex for the manufacturing of drug substances (API) and drug products (OSD), as well as research of API. The center covers the complete production cycle from research to product development, to pilot plant, to clinical manufacturing and manufacturing of drug substances, and ultimately, the final drug product in solid dosage form.

The center meets Eisai's strategic plan objectives of generating higher efficiency and productivity by integrating drug discovery, research, production, global procurement, and administrative functions into one site.

View of complex from drug substance facility.

Project Overview

Supporting the production of current products and meeting the needs of a growing product development pipeline was critical. The center manufactures Aricept®, an Alzheimer's disease drug, Myonal®, for the treatment of spastic paralysis

Purified water system.

Eisai Pharmatechnology & Mfg Pvt. Ltd.

Category Winner – Project Execution

Project: Eisai Knowledge Centre
Location: Visakhapatnam, Andhra Pradesh, India
Project Mission: To design and build a state-of-the-art manufacturing and process research complex to ensure a stable supply of high quality pharmaceutical products. To support Eisai's global logistic infrastructure and support API manufacturing operations in Japan.
Size: 2,180,189 sq. ft. (202,546 sq. m.)
Total Project Cost: $41,000,000
Duration of Construction: 17 months

Continued on page 12.

Notes from the Judging Panel – What Impressed Them

- *Outstanding safety record of no reportable safety incidents with more than five million man-hours worked.*
- *The completion of the entire complex that includes construction activities for all 14 facilities was accomplished in just 17 months.*
- *The ability of the project team to overcome the challenges of delivering a project of this size given the complexities of doing so in India.*
- *Good Japanese style and quality with a high degree of automation.*
- *The capital efficiency of the project is commendable given such a high quality, fully integrated R&D and manufacturing complex was delivered for an investment of under US $50 million.*

Award Category – Project Execution

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.

caused by disease, and Pariet®, a proton pump inhibitor. The center will supply products to the US, Europe, Japan, and other global markets.

The complex comprises 14 buildings. The drug product facility has an annual capacity to produce approximately two billion tablets. The drug substance facility has an annual capacity of 30 tons. R&D and manufacturing are supported by 12 other facilities located within the complex, including warehousing (raw materials, packaging materials, and finished goods), engineering services, quality assurance (validation, stability, etc.), quality control, information technology, process development, regulatory, and administration.

All technical buildings are integrated from a business and production standpoint. The drug substance facility is designed

Pilot plant drug substance (API) building.

to produce all the API requirements for the drug product facility. The production capacities, operating schedules, storage capacities, etc., of the drug substance facility are matched and integrated with the production capacities of the drug product facility.

The site integrates API research, support, and manufacturing facilities into one flexible, state-of-the-art complex, increasing Eisai's capacity and capability to research, scale-up, and manufacture multiple API products simultaneously.

Robust Project Management

The entire facility was constructed in 17 months. To achieve such an aggressive deadline, construction activities for all 14 facilities began simultaneously and in parallel. The center's innovative design and project size demanded a well-organized and coordinated effort to deliver a successful project. The project team attributes its success to robust project management practices, including upfront planning, continuous monitoring and communication, and resource management.

The entire project was handled by one project team and at its peak 2,000 personnel were working at the site. Remarkably, despite five million man-hours worked, there were no reportable safety incidents.

Upfront Planning

According to Eisai, early planning was key to coordinating a project of this magnitude. Project parameters were defined early in the pre-planning stage. An integrated project team was established at project inception and continually collaborated with all stakeholders. Lessons learned from several Eisai projects located in the US, UK, and Japan were incorporated and implemented.

Process research lab in R&D building.

Continuous Monitoring and Communication

Project implementation, planning, and execution were tracked via MS Project and S-curve. The project team worked together to continuously monitor and forecast deliverables and address potential issues. Daily planning meetings offered tight coordination and addressed critical issues in a timely and proactive manner. Schedules were continuously monitored to avoid any unnecessary delays. There was excellent communication among the entire project team.

Why Our Project Should Win

The following is an excerpt from Eisai's submission, stating in their own words, the top reasons why their project should win the 2012 Facility of the Year Award:

- The Eisai Knowledge Centre is a unique, completely integrated complex that offers state-of-the-art flexibility, capability, and capacity, mitigating risk of global supply chain interruption and meeting current and future strategic drug development/manufacturing needs.
- Integration of API research, API manufacturing and OSD manufacturing platform, and critical utilities into one, 50-acre complex.
- Unique complex, which covers the "full product cycle" from research to formulation, where all technical buildings are integrated from a business and production standpoint. Drug substance facility is designed to produce the entire API requirement for the drug product facility. The production capacities, operating schedules, storage capacities, etc., of the drug substance facility are matched and integrated with the production capacities of the drug product facility.
- Entire complex was completed in 17 months and was under budget. Construction for all 14 facilities started simultaneously and in parallel. The entire project was handled by one project team.
- Highest quality level to meet Japanese, European, and US standards.
- Lessons learned from project-launching global manufacturing facilities in the US and UK, along with design concepts from existing formulation facilities in Japan, were optimized and implemented into the Knowledge Centre complex.
- Awarded the "Best Facility" in the Eisai Worldwide Network.

Concludes on page 14.

Courtyard/mezzanine of R&D/Laboratories/QA building.

Key Project Participants

Architect, Engineer, and Construction Manager: B. Mehtalia Consultants Pvt. Ltd. (Mumbai, India)
Main/General Contractor: JMC Projects (India) Ltd. (Ahmadabad, Gujarat, India)

Drug product access corridor.

To control the budget, cost review meetings were held. Unnecessary expenditures were identified and removed. Eisai attributes speed in decision-making as key to keeping the project on schedule, which resulted in the project being delivered under budget.

Resource Management

Depth of the team's experience, along with industry knowledge and multiple facility construction know how were success factors, according to Eisai. So were a collaborative design process and manufacturing-centric team. Outstanding teamwork, cohesive relationships, communications and commitment to safety and quality resulted in increased efficiency and productivity by the project team.

Conclusion

By employing robust project management practices, Eisai was able to deliver a capital efficient, state-of-the-art complex under an aggressive timeline. The Eisai Knowledge Centre offers the flexibility, capability, and capacity to mitigate the risk of global supply chain interruption and meet the company's current and future strategic drug development and manufacturing needs.

Congratulations,

Eisai Pharmatechnology & Manufacturing Pvt. Ltd.

Facility of the Year, Project Execution

2012 Facility of the Year

Eisai Knowledge Centre

Visakhapatnam, Andhra Pradesh, India

2012 Facility of the Year Awards
CATEGORY WINNER
Project Execution • Supplier












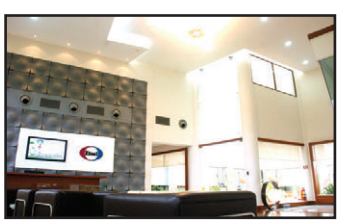

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Merck & Co., Inc.

Focus on Integration Doubles Vaccine Output

Introduction

Faced with a projected production shortfall for the Varicella product franchise, Merck responded by delivering the **Vaccine Bulk Manufacturing Facility (VBF) Program of Projects** in Durham, North Carolina, USA. Through an integration-focused design, build, deliver approach, the facility was built in record time and doubled the output of the vaccine used for chicken pox and shingles, earning it the **2012 Facility of the Year Award for Facility Integration.**

Exterior view.

The Merck team used an innovative hybrid modular construction strategy that maximized off-site fabrication and equipment testing. The team was organized as "One Team" with all members co-located in an integrated partnership. Lean Six Sigma principles were used throughout the project and resulted in accelerated transfer of systems to operations. Integrating more than 200 lessons learned from the existing facility and process, the facility was delivered 40% faster than industry benchmarks.

Project Overview

In early 2008, Merck was realizing new indications and new markets for the Varicella product franchise that were resulting in a projected production shortfall to market demand. Millions of people a year would suffer from chicken pox and shingles if Merck didn't increase production capacity.

Merck & Co., Inc.

Category Winner – Facility Integration

Project: Vaccine Bulk Manufacturing Facility (VBF) Program of Projects
Location: Durham, North Carolina, USA
Project Mission: To deliver a Varicella bulk manufacturing facility in a phased approach that is aligned with the Merck Manufacturing Division (MMD) Manufacturing Strategy and supports the business objectives of MMD and MVID for Varicella bulk containing products.
Size: 214,000 sq. ft. (19,881 sq. m.)
Total Project Cost: $315,000,000
Duration of Construction: 31 months

The challenge was that in less than four years, patients would need more than double the Varicella manufacturing output. This meant the team had to design, build, and license a new production facility that was larger than the existing manufacturing – and do it in less than four years. Merck had never constructed and licensed a sterile vaccine manufacturing facility that large or that fast before; in fact, the initial Monte Carlo analysis conducted by an industry benchmarking group indicated a less than 3% chance for delivering the facility on time.

The existing Merck site located in Durham, NC, was chosen for the Varicella Bulk Manufacturing Facility (VBF) Program of Projects. The VBF project comprises four integrated and simultaneously designed and constructed buildings: the Virus Vaccine Bulk Facility Building, the Energy Center Expansion, the Material Management Support Facility Expansion, and the Operational Support Facility Expansion.

The Merck team's rapid design, build, deliver approach was supported by three main strategies:

- Innovative (Hybrid) Modular Execution
- "One Team" Project Delivery
- Lean Six Sigma Approach to Commissioning, Qualification, Validation (CQV)

Innovative (Hybrid) Modular Execution

The project schedule demanded a significant amount of overlap between what would typically be sequential activities such as Basis of Design (BOD) and Detailed Design. For example, the floor layout development would need to continue (not be fixed) until well into the detailed design phase. The innovative

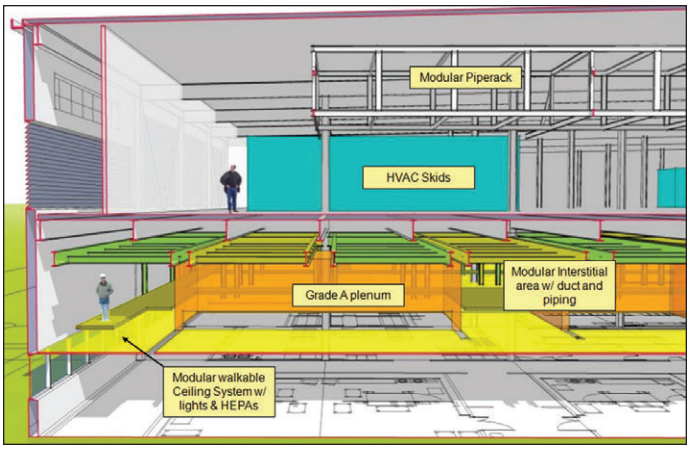


Diagram showing the four module types that were inserted into the pre-fabricated building shell.

strategy developed by the team was to decouple the design and construction of the building envelope and shell from the interior process components and to design and construct the envelope and shell independently. This meant the design and construction of the interior process components was separated from the envelope and shell until much later in the project timeline. The result was that changes to the building layout during BOD could be accommodated and would not impact the design and construction of the other elements of the project.

This decoupling to allow parallel activities was taken a step further in the interior process components. The team ultimately selected an innovative modular approach that included off-site modular construction for the interstitial/mechanical space, the AHUs, the duct risers, and the piperacks interior to the building, as well as the cleanroom space.

Essentially, the building shell was stick-built using an economical pre-engineered building, and modular construction

Ductwork riser skid.

Continued on page 18.

Notes from the Judging Panel – What Impressed Them

- *Delivery of a new 214,000-square-foot production facility that doubled vaccine output for Chicken Pox and Shingles that was delivered 40% quicker than industry standards.*
- *Effective use of an innovative hybrid modular construction strategy that maximized off-site fabrication and equipment testing.*
- *Organization of the team as "One Team" with all members being co-located in an integrated partnership*
- *Utilization of Lean Six Sigma principles throughout the project that resulted in an accelerated transfer of systems to operations.*
- *Interesting for this application was the utilization of the integrated construction execution strategy which decoupled the design and construction of the building envelope and shell from interior process components, and independent design and construction of the envelope and shell.*

Award Category – Facility Integration

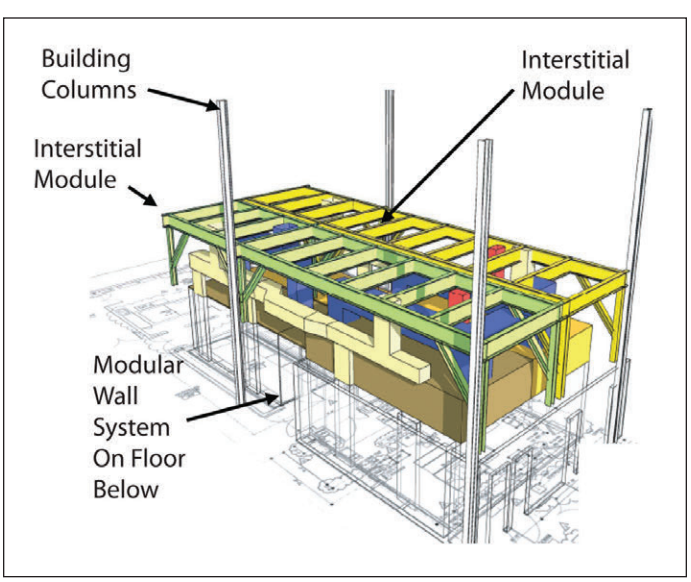
Winners in this category exemplify the application of good design practices and superior conceptual planning which led to excellent integration of facility and process, yielding efficient, clean, pleasant environments promoting business advantages for staff and enterprise, encouraging excellent processing outcomes. Synergistic merging of process and building to create environment of form and functional excellence.

was used for all the interior components listed above. As soon as the building shell was dried in and the elevated slab poured, modules were installed simultaneously above the slab (AHU and duct riser skids) and below the slab (interstitial modules). This strategy resulted in the ability to establish two independent work zones (above and below the slab).

"One Team" Project Delivery

The project team was organized into "One Team" that included all members – owners, engineers, contractors, and vendors. This was a critical aspect of delivering a hyper track project because a lot of information needed to flow quickly, requiring a single, integrated project team. This was no small challenge given the 50 equipment suppliers and 46 subcontractors required to execute the project.

Given the scheduling and coordination complexities, it was decided to align the project organization around the principles of Lean project delivery. The team would need to utilize Lean Six Sigma tools and find partners that were both amenable to it and willing to take on a significant challenge. In this approach, the team utilized collaborative relationships with suppliers and subcontractors, facilitated Kaizan brain storming sessions, used A3 decision making, and construction "pull" leadership to minimize engineering deliverables to only the absolute minimum design details necessary to obtain building permits and construction quality drawings. This approach



Concept of interstitial module.

Interstitial module.

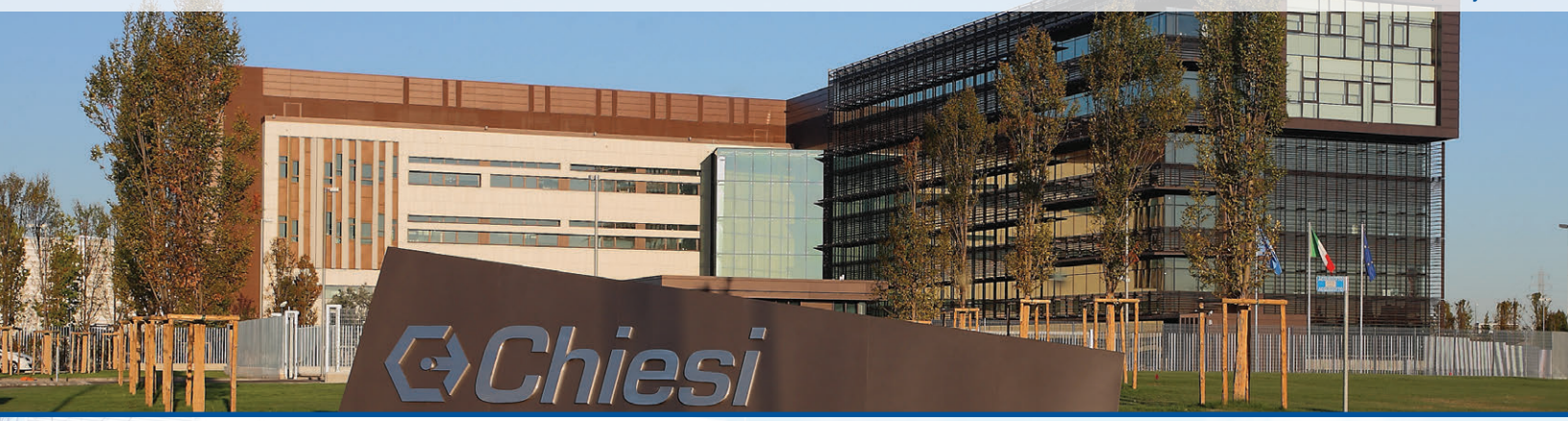
Continued on page 20.

A proud partner

Jacobs congratulates Chiesi Farmaceutici, Merck, and the National Institute for Bioprocessing Research and Training on winning 2012 Facility of the Year Awards. We appreciate the trust you place in us to execute your award–winning projects.

ISPE Category Winner for Sustainability

Chiesi Farmaceutici
Parma, Italy



ISPE Category Winner for Facility Integration

Merck VBF
Durham, N.C., USA

ISPE Special Recognition for Novel Collaboration

National Institute of Bioprocessing Research and Training
Dublin, Ireland

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HVAC skid.

resulted in a streamlined design process that optimized both constructability input and fabrication details.

Lean Six Sigma Approach to CQV

The team again reached into their Lean Six Sigma tool box and formed several teams to address each of the main operational areas or production suites of the manufacturing facility. These "Suite Teams" were made up of representatives from Technical Operations, Production, and support from Maintenance, Quality, Process Engineering, Automation, Validation, and/or Commissioning and Construction. The collaborative approach allowed the teams to discover system deficiencies during start-up, determine and address root causes, and continue testing with minimal schedule disruption. The result was an accelerated transfer of system ownership from Construction to Commissioning to Qualification to Operations.

Why Our Project Should Win

The following is an excerpt from Merck's submission, stating in their own words, the top reasons why their project should win the 2012 Facility of the Year Award:

- Reduced the suffering of millions of patients by delivering a facility that meets Merck's manufacturing needs, providing high quality vaccine much faster than industry norms.

- Implemented a first-of-a-kind hybrid modular approach that maximized off-site fabrication and equipment testing such that those activities could be done in parallel with on-site construction to deliver the facility on schedule and within budget. The building shell and enclosure were stick-built using a pre-engineered building approach. The interstitial area, AHUs, duct risers, interior pipe racks, and cleanroom panels were done using modular construction. One hundred twenty eight (128) modular units, representing 270,000 craft hours, were moved off-site and executed in parallel with the on-site construction. This approach achieved a schedule the IPA's risk assessment identified as having less than 3% chance of success while reducing the schedule by five months and saving over $43.3 million.

- Organized the project team into "One Team" where all team members – Merck, Jacobs, subcontractors, and vendors were co-located in an integrated partnership. This team worked collaboratively with key design build contractors, modular providers, equipment suppliers, and other service providers. This single team organization allowed the use of a construction "PULL" approach such that design efforts and documentation were the minimal needed to support construction and validation. The team was critical to making the people machinery work effectively by minimizing the amount of non value-delivering activities. This was critical in being able to deliver the hyper track project. There was just too much information that needed to flow quickly for people not to be seated together.

- Lean Six Sigma principles were used in the organization and execution of commissioning, qualification, and validation. This approach resulted in very smooth and efficient transition from construction execution to operations. The Suite Teams allowed the qualification of separate areas to be executed in parallel and Suite Team leadership remained consistent as the activities progress from engineering through validation. The result was an accelerated transfer of system ownership from construction to commissioning to qualification to operations. This approach allowed Merck to complete CQV faster than any other project.

- The design team incorporated more than 200 lessons learned and forward looking regulatory attributes from the existing Varicella manufacturing operations. Splitting the building shell and interior process components allowed those design concepts and decisions to be incorporated much later – well into the construction phase with minimal impact to the aggressive timeline.

- By moving 270,000 craft work hours off-site and decoupling significant critical path activities, the modular construction strategy proved to be a paradigm shift; the project could not have been completed with traditional methods in the established timeframe and budget. This approach opened multiple simultaneous work fronts that normally would not have been available; a traditional approach would have required many more sequential activities.

Concludes on page 22.

VACCINE BULK MANUFACTURING FACILITY PROGRAM OF PROJECTS

2012 Facility of the Year Award for Facility Integration

- Completed 40% faster than industry benchmarks.
- Executed more than 1.45 million man hours with zero lost time incidents.
- Used a Lean Six Sigma approach to Commissioning, Qualification, Validation (CQV) to accelerate the transition from project execution to operation.
- Awarded *Engineering News–Record's* 2011 "Best of the Best" Award for Industrial/Manufacturing.
- Granted LEED Silver status for the Office Support Facility.

Congratulations and thank you to our project team for a job well done.

MERCK

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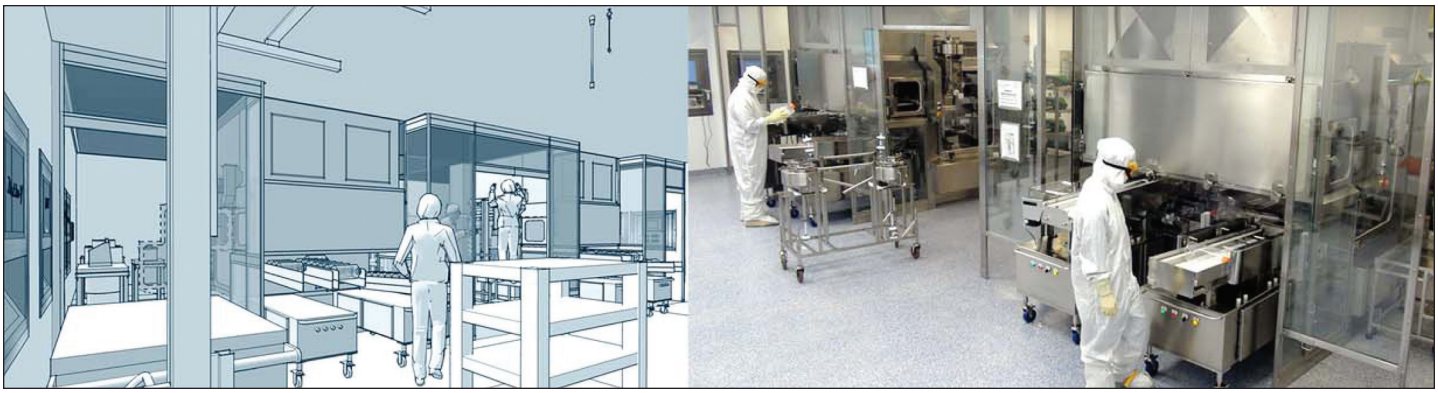

Graphic depiction of room space and finished room.

Key Project Participants

Designer/Architect: Jacobs® (NYSE:JEC), Pasadena, California *(See ad on page 19)*

Engineer: John R. McAdams Company, Inc. (Durham, North Carolina, USA)

Construction Manager and Main/General Contractor: Jacobs® (NYSE:JEC), Pasadena, California *(See ad on page 19)*

Conclusion

Despite the industry experts' odds, the VBF project team was able to meet Merck's goal of providing Varicella to more patients. Through an integration-focused design, build, deliver approach, the team completed the project in record time (Charter to OQ completion in roughly 24 months) with a savings of $43,000,000. Millions of patients will now be able to receive preventative vaccinations from a world class facility that is part of Merck's global supply chain.

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Answers for infrastructure.

Rentschler Biotechnologie GmbH

Innovation and Teamwork in Single Use Technology

Introduction

Rentschler, a global full-service contract manufacturer, needed an additional facility to host multiple products and achieve maximum flexibility. The solution was found in the design and construction of a new facility in Laupheim, Germany, which received the **2012 Facility of the Year Award for Equipment Innovation.**

The project team realized flexibility and rapid process changeover through the consistent implementation of single use and ready-to-use technology throughout the facility. To overcome current limitations of single use technologies and to increase manufacturing capability, Rentschler partnered with several suppliers to create a customized single use preassembled manufacturing kit that increases reliability while reducing preparation and contamination risk. Also jointly developed was a highly automated skid for virus filtration that can accommodate a wide variety of manufacturing protocols.

Upstream manufacturing.

Project Overview

The new manufacturing facility was implemented in the former lab area of an existing building. Construction included a complete remodeling of cleanrooms and utilities.

At the beginning of the design process, Rentschler made the decision to follow the conventional segregation concept with separate cleanrooms for upstream manufacturing and pre- and post-virus reduction downstream manufacturing, respectively, to ensure cGMP compliance and customer acceptance.

Rentschler Biotechnologie GmbH

Category Winner – Equipment Innovation

Project: REX III (Rentschler EXpands III)
Location: Laupheim, Germany
Project Mission: Design and build a clinical manufacturing facility with the capability to host multiple products and to achieve maximum flexibility for process design and manufacturing. Optimize the facility with regard to manufacturing costs and product cycle time while maintaining Rentschler's high quality and customer satisfaction standards.
Size: 9,800 sq. ft. (910 sq. m.)
Total Project Cost: $9,900,000
Duration of Construction: 7 months

Empty suite with utilily columns.

Notes from the Judging Panel – What Impressed Them

- *Creation of a customized single use preassembled manufacturing kit that included bags, assemblies, and tubing, which increases process reliability while reducing both preparation time and contamination risks.*
- *The Rentschler facility was constructed for only $9.9 million and features full configurable, multi-purpose cleanroom suites.*
- *Development of a highly automated skid for virus filtration that can accommodate a wide variety of manufacturing protocols.*
- *Operation of the facility, with a significant reduction of fixed costs and only slightly higher variable raw material costs – contributes to a highly favorable cost structure for custom biologics manufacturing.*

Award Category – Equipment Innovation

Winners in this category exemplify the novel application of commercially available and custom developed process manufacturing and facility management tools, which yielded superior results, advanced processing understanding, and improved competitive position. Includes imaginative collaboration with vendors, suppliers, and manufacturers.

However, to maximize flexibility and to speed up product turnaround, the project team developed a flexible space concept featuring four similar, multipurpose cleanrooms and one inoculum suite. The team also implemented 100% mobile, single use and ready-to-use manufacturing equipment for upstream and downstream processing. The 9,800-square-foot facility has an annual capacity of 10 manufacturing projects with up to 24 batches at 1,000 L scale.

Configurable, Multi-Purpose Cleanrooms

A series of four completely independent, connectable, and configurable all-purpose cleanrooms were constructed. The cleanrooms include connections to the facility-wide Data Logging System (DLS), which is preconfigured for plug and play setup of mobile manufacturing equipment.

The cleanrooms are equipped with utility columns that support all manufacturing operations. They are standardized to provide electricity, pressurized air, process gases, and cooling water for diverse manufacturing skids in flexible plug and play setups. Due to the consistent use of mobile single use manufacturing equipment, steam-in-place, and clean-in-place operations were not required, excluding the need for steam and water supplies, as well as drains from the cleanrooms. This resulted in considerable cost benefits during construction and qualification. Since there are only two points of use for highly purified water implemented in the supply areas outside the cleanrooms, QC monitoring costs also are reduced significantly.

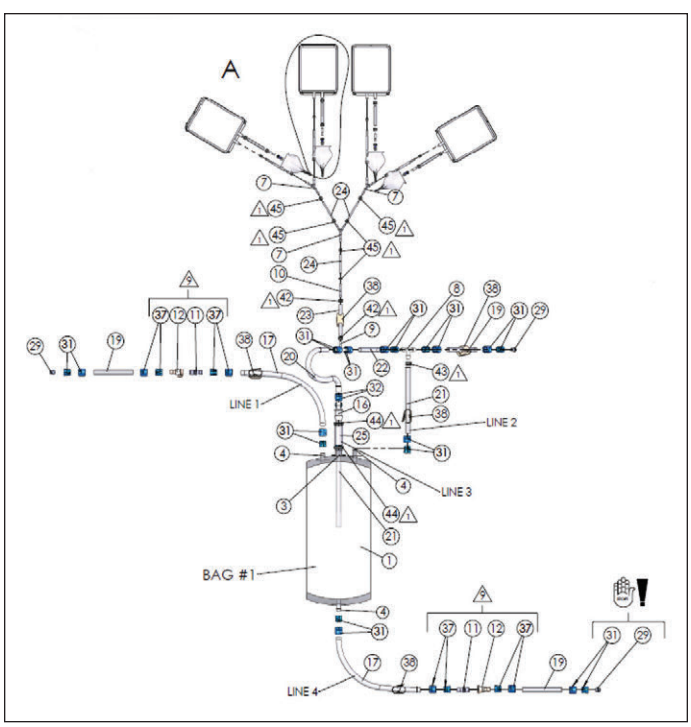
Collaboration with Suppliers

To overcome current limitations of single use technologies associated with standardization, functionality, and scale, Rentschler customized and improved several systems in collaboration with various suppliers.

Single Use Preassembled Manufacturing Kit

Although product changeover time is often minimized in single use manufacturing suites, actual labor for product changeover usually is not. The setup of standard disposable materials for manufacturing requires extensive manual work and preparation time. The connection of bags with filter capsules, sampling bag assemblies, and tubing can take more than 40 man hours for a 1,000 L scale fed-batch process, according to Rentschler representatives.

Furthermore, single use components are not yet standardized across suppliers – with serious impact on process reliability:



Customized single use bag assembly.

Continued on page 26.

Virus filtration skid.

- While bag sizes are comparable, inlets and outlets are attached in different locations. Thus, containers usually need modifications to accommodate bags from different suppliers.

- All suppliers offer their propriety connector systems only, and tube diameters differ. Connecting parts from different suppliers (e.g., a bag from one supplier with a sampling assembly from another) while maintaining sterility is only feasible under a laminar flow hood.

- Suppliers usually do not support tube welding with their standard configurations.

In collaboration with Pall and Millipore, Rentschler developed a standardized single use kit including bags, assemblies, and tubing. Preassembled components are delivered gamma irradiated, and can be connected via tube welding. Since manipulations after gamma irradiation are minimized, and most connections are made by tube welding, contamination risks are minimized and process reliability is significantly increased.

Parts from both suppliers can be utilized interchangeably, thus supply safety is increased. In order to minimize tie-up of capital and on site storage space, a kanban system was implemented with both suppliers.

Rentschler is willing to share its single use kit design standards with other users and suppliers for the advancement

Why Our Project Should Win

The following is an excerpt from Rentschler's submission, stating in their own words, the top reasons why their project should win the 2012 Facility of the Year Award:

The overall goal was to meet aggressive cost targets for clinical manufacturing services to the biopharmaceutical community, while maintaining Rentschler's high quality and customer satisfaction standards. In order to reach this goal, the project team addressed and accomplished multiple developmental, engineering, and operational tasks.

Developmental tasks include:

- Implementation of a novel mAb platform technology into manufacturing by direct scale-up from 20 mL shake flask to 1,000 L.
- Co-development of a single use equipment and equipment automation.
- Design of a standardized single use preconfigured manufacturing kit provided by two different suppliers.

Engineering tasks include:

- The design of independent, fully configurable, multipurpose cleanrooms.
- 100% implementation of single use technology to render CIP/SIP obsolete and to significantly reduce utility needs.
- Design and implementation of mobile stand-alone single use equipment skids and controls, in combination with plug and play utilities and DLS.

Operational tasks include:

- Debottlenecking of the facility for mAb fed-batch-processes.
- Optimization of material flow outside manufacturing areas.
- Implementation of a 5s/visual factory concept.

The outcome is a unique state-of-the-art facility that fully taps the potential of single use technology.

Furthermore, this clinical manufacturing facility paves the way toward the factory of the future for commercial biologics manufacturing since it addresses many of its essential needs:

- Utilization of multi-product facilities due to high titer processes, high efficacy drugs, and niche products
- Standardization and further development of single use equipment
- Application of 100% single use technology – a prerequisite for the manufacturing of novel products in the areas of cell therapy and gene therapy

Downstream processing viewed from buffer/media supply area.

of industry wide standards and for the development of more reliable and cost-effective solutions.

Virus Filtration

Since there are no virus filtration systems commercially available at 1,000 L scale at this time, Pall and Rentschler co-designed a system based upon a tangential flow filtration system. The fully automated skid can hold up to four virus filtration modules from any supplier. Virus filtration modules are connected to the gamma sterilized flow path assembly via sterile connectors. The assembly is customized and already includes prefilter capsules.

The system offers the following features:

- constant pressure or constant flowrate operation
- built-in integrity testing
- all types of virus filters can be mounted (1 to 16 m2 of membrane area)
- easy, fast, and robust assembly of manifolds and filters through sterile connectors
- also applicable for depth filtration and 0.2 µm filtration
- Siemens S7 control system with Win CC visualization

Key Project Participants

Designer/Architect: Gerold Kohler (Laupheim, Germany)
Engineer/Construction Manager: PhC PharmaConsult GmbH (Heidelberg, Germany)

Conclusion

The Rentschler manufacturing facility was designed with the capability to host multiple products and to achieve maximum flexibility for process design and manufacturing. While maintaining Rentschler's high quality standards, the facility was optimized with regard to manufacturing costs and product cycle times. Project goals were achieved by implementing a flexible space concept and single use and ready-to-use technology. Current limitations of single use technologies were overcome through collaboration with suppliers on innovative, customized solutions.

The project was carried out with an aggressive cost target of $9.9 million, which compares to about 60% of the investment needed for the implementation of a comparable conventional clinical manufacturing facility.

This novel facility has a significant reduction of fixed costs and only slightly higher variable raw material costs, thus contributing to a highly favorable cost structure for custom biologics manufacturing.

Roche Diagnostics GmbH

Optimizing Existing Resources to Realize Operational Excellence

Introduction

Roche set out to double its capacity for early research and technical development of therapeutic proteins at its biotechnology site in Penzberg, Germany. They accomplished this goal without constructing a new building.

The so called **"TP Expand"** project, winner of the **2012 Facility of the Year Award for Operational Excellence,** was the result of an innovative and well-engineered master plan featuring several independent projects and a GMP IT system known as Data Acquisition Management Analysis System (DAMAS). The DAMAS system is the key component that enabled a high level of operational excellence at the Penzberg site.

Aerial view.

The TP Expand project encompassed the renovation of 15,000 square meters of floor space in five different facilities, the relocation of 2,600 assets, and the successful execution of the entire project without any shutdowns.

Completing the R&D Value Chain

Roche's Penzberg site is the largest research, development, and production location within the Roche corporation, and one of the largest technology centers in Europe. As Roche's European Center of Excellence for therapeutic protein research, Penzberg's core tasks include the global supply of protein therapeutics for clinical trials.

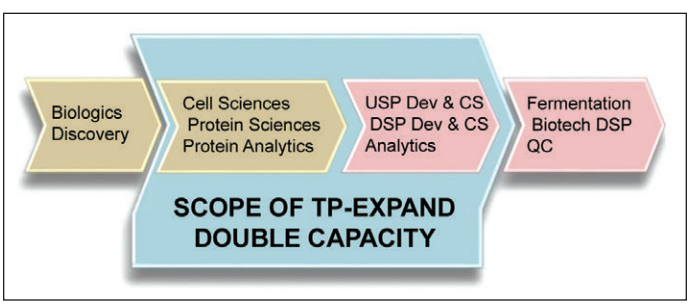
Increased R&D capacity supports expanded and more rapid development of biopharmaceuticals. The TP Expand project completes the value chain for discovery and technical development of biologics through reduced cycle times, increased supply efficiency, and improved quality/process risks.

"This investment adds the missing links to the added-value chain in Germany," said Thomas Schmid, Executive Committee Spokesman, Roche Diagnostics GmbH. "We can now cover every stage from the early investigation of protein therapeutic candidates through to the production of market-ready biopharmaceuticals. Our scientists will now be able to develop twice as many protein therapeutic candidates through to Phase I clinical trial readiness every year than they used to."

Roche Diagnostics GmbH

Category Winner – Operational Excellence

Project: TP Expand
Location: Penzberg, Germany
Project Mission: The project is part of the site master plan. It converted existing facilities to state of the art R&D labs.
Size: 161,458 sq. ft. (15,000 sq. m.)
Total Project Cost: $209,871,400
Duration of Construction: 29 months



TP Expand completes the value chain for discovery and technical development of biologics.

Notes from the Judging Panel – What Impressed Them

- *Roche accomplished its mission of doubling biologics R&D production capacity without new construction by developing an innovative and well engineering master plan featuring six independent projects involving five different facilities and a state-wide GMP IT system (DAMAS) that penetrates every aspect of the R&D operation for data acquisition, management, and analysis.*
- *The DAMAS system realized the site's vision of implementing a site-wide data management system that enabled a high level of Operational Excellence at the Penzberg site.*
- *The Roche program encompassed the renovation of 15,000 square meters of floor space in five different facilities, the relocation of 2,600 assets, and the successful execution of the entire project without any shutdowns. Yet it was completed in just 36 months.*

Project Overview

The TP Expand project goal was to double R&D capacity at its Penzberg site. The strategy for achieving this goal centered on integrating and optimizing existing facilities. The challenge was to upgrade and reconfigure unused building space and provide a seamless network among R&D facilities at the Penzberg site.

The project encompassed the consolidation and optimization of operations, including major upgrades to five buildings and the relocation of Roche's Munich R&D operations to Penzberg. In addition to physical infrastructure enhancements, TP Expand implemented DAMAS, a site-wide, GMP-validated IT system. The paperless system connects every aspect of R&D operations in upstream processing (USP) and downstream (DSP) processing labs, pilot plants, and analytic labs. DAMAS links

Common Data Problems and How DAMAS Solves Them	
Problem	**Solution**
Manual data entry is slow and unreliable.	DAMAS captures and completes data electronically and automatically.
Data are scattered and incomplete; some reports are missing.	DAMAS guides the workflow documentation. Data is complete, accurate, and in a single database.
Cannot find all related data; waste time searching.	Data is linked in a searchable context – so it is easy to find data and trace it to its source.
Organizational silos impede collaboration.	DAMAS provides access to a common data pool and opens new frontiers for collaboration.

Continued on page 30.

Why Our Project Should Win

The following is an excerpt from Roche's submission, stating in their own words, the top reasons why their project should win the 2012 Facility of the Year Award:

Outstanding Project Execution

- The team got it right the first time: DAMAS was up and running, construction was completed as specified, and all equipment was operational – including commissioning and qualification, where required.
- Achieved the goal of doubling capacity for R&D and integrated more than 260 R&D staff – using existing buildings.
- The project was completed 15% under budget and was significantly ahead of schedule – most subprojects, two to eight weeks early.
- TP Expand set a new standard for team collaboration and cooperation between project and user teams.
- At the subproject level, every team was highly skilled and handled challenges with finesse.
- With no accidents, the project achieved a perfect safety record.

Excellent Facility Integration

- Integrated DAMAS with all R&D processes. As a single, standardized platform, it helps promote broader collaboration and eliminate silos.
- Integrated 260 additional staff to accommodate R&D capacity expansion.
- Relocated Munich development operations to Penzberg, integrating staff and equipment.
- Integrated 250L SUBs in R&D pilot plants in Building 221, and in GMP facilities in Building 352. Compared to conventional bioreactors, SUBs cost less, occupy less space, and reduce cycle time.
- Repurposed defunct manufacturing space as an open-plan lab equipped with the latest technologies for R&D.

Exceptional Project Management

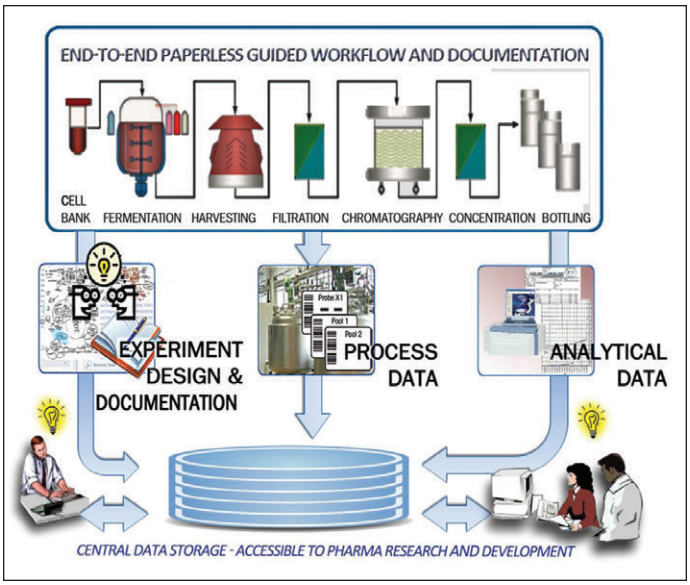
- Identified space in existing buildings to accommodate expansion. This saved more than €200 million over alternative greenfield project options.
- Master plan, procedures, and protocols were developed and put in place at the project inception.
- At the highest level, the Master Project Team managed the entire project and its six subprojects with precision.
- Six subprojects were designed around major project objectives for flexibility and more efficient delegation.
- Decision-making occurred quickly, at the lowest levels possible, eliminating potential bottlenecks.
- The Master Project Team centrally managed commissioning, qualification, validation, and overall project compliance.
- Effective communication ensured coordination between subproject teams and between project teams and user teams.
- Because overarching functions (procurement, contracts, controlling, scheduling, etc.) were handled by the Master Project Team, Project Managers could focus on project goals and respond to challenges with agility.

Outstanding Program of Operational Excellence

- Implemented DAMAS, a cross-functional, GMP validated automation and IT platform for R&D.
  - End-to-end electronic workflows and integration with automation improve operating efficiency.
  - Automated data acquisition, central storage, and accessibility promote excellent quality, consistency, and accuracy.
  - Mobile device support (Toughbook) and compatibility with global standard databases and lab information management systems enable integration with existing technologies.
- Established a common technical platform for USP and DSP pilot plants for Research and Development.
- Installed 250 L SUBs in R&D pilot plants and GMP facilities. SUBs cost less, install quickly, occupy less space, and reduce process and cycle time than conventional bioreactors.

Unique Project Challenges Overcome

- OPC is the universal standard for data interchange in automated equipment. In practice, about half of the equipment had problems interfacing with DAMAS. Implementation engineers resolved all and rolled out DAMAS on schedule.
- Connecting of different types of analytic devices for automated data acquisition in DAMAS.
- Successfully accommodated expansion by optimizing the use of existing buildings.
- For continuous operations of Building 221, the team used temporary flexible hoses as a connection solution and methodically replaced the entire old plant- and process utilities piping and equipment.
- To minimize impact of the shutdown of Building 352, the project team coordinated a 90-day construction window, scheduled hour-to-hour, around the clock and completed 75% of the construction and commissioning in that time.
- Starting with only an empty shell of a building, converted former production space in Building 363 in a cutting-edge, open-space lab facility with three lab floors and a pilot plant.
- With a test series in progress at the site, successfully disassembled, transported, installed, re-commissioned, and re-qualified $26.4 million worth of equipment, lab by lab, without disturbing the test series.



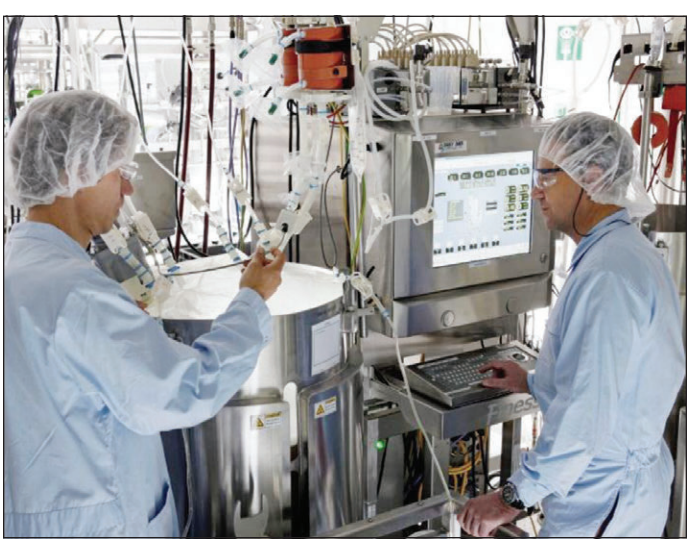
common technical platforms, lab information and management systems, mobile computers, and diverse databases.

Operational Excellence through DAMAS

Not only did the primary goal of doubling R&D capacity require optimizing facilities and equipment, but it also required optimization of human resources. The project steering committee identified a strategy that would optimize current staff in two ways: relieve them of mundane repetitive tasks and make the most of the intellectual development resources of the enterprise at large.

Typically, traditional approaches to data acquisition, storage, and accessibility are problematic because they include multiple software applications and some degree of manual data entry.

The project team's unconventional strategy: implement a site-wide data management system that interfaced with all data points in both research and development, eliminating



Therapeutic protein research in progress.

Concludes on page 32.

ISPE would like to thank the following companies for their generous advertising support which made this Supplement possible.

Advertiser's Index

The Facility of the Year Award is sponsored by:

ISPE
Connecting a World of Pharmaceutical Knowledge

INNOVATION + INTELLIGENCE + PASSION
INTERPHEX 2012

Pharmaceutical Processing

On the ground floor, Building 363 contains a fully equipped 900 m^2 pilot plant, which includes a mezzanine floor of 300 m^2 for 12 people.

Award Category – Operational Excellence

Winners in this category exemplify the application of modern management techniques aimed to improve operating efficiencies, promote excellent quality, consistency, and yield competitive cost of goods from existing and new facilities, processes, and manufacturing operations.

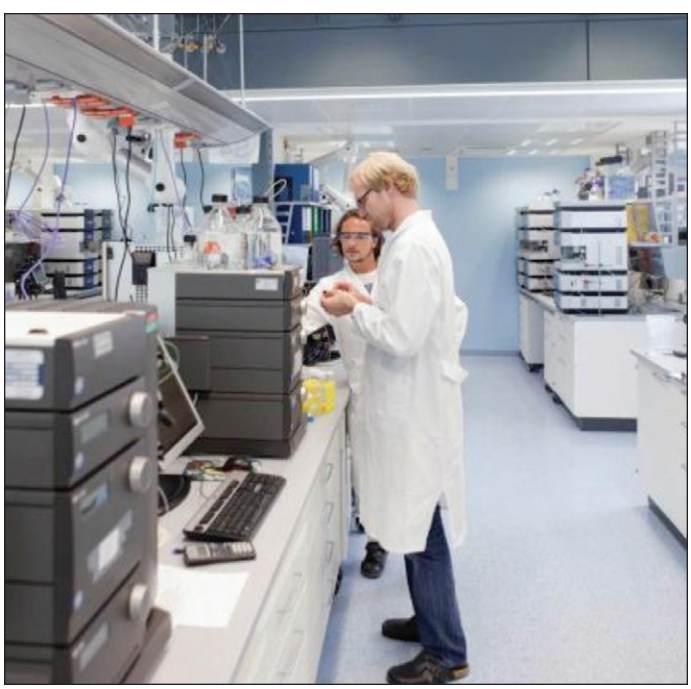
manual entry, and providing a central shared knowledge base. The strategy was realized with DAMAS, a new GMP-validated data acquisition, management, and analysis system.

DAMAS interfaces with all data acquisition points in all labs as well as USP/DSP pilot plants for research and development. Previously, this data was collected and stored according to various methods and standards, at various production stages. DAMAS provides a single database, a universal standard, a common technical platform.

Research and development generates product and process knowledge from experiments. In DAMAS, data is electronically collected and then stored in contextual association with its origin (e.g., an experiment) with clear historical hierarchy. "This coupled accessibility across workgroups and divisions means that research, analysis, and discovery are supercharged," said Roche representatives. Collaboration and easy comparisons of data from different projects makes analyzed experimental data and the associated findings available for new projects. DAMAS can handle more than 700,000 samples per year and run parallel discovery projects for more than 260 users.

Conclusion

The primary project goal of TP Expand was to double R&D production capacity at the Roche Penzberg site. Instead of spending hundreds of millions of Euros on a greenfield expansion strategy, the project team reconfigured and integrated existing buildings and optimized facilities, equipment, and human resources. By implementing an innovative site-wide data management system, the project team enabled increased efficiency and flexibility, resulting in a high level of Operational Excellence at the Roche Penzberg site.



Coworker synergy in the lab.

Key Project Participants

Designer/Architect/Engineer: M+W Group GmbH (Stuttgart, Germany) *(See ad on page 29)*
Construction Manager: CCM GmbH (Höhenrain, Germany)

Building a brand new facility is never easy. But it can be easier.

Building a new, state-of-the-art pharmaceutical or biotechnology facility is no mean feat. But when you can rely on an international team of highly experienced and totally committed specialists, it all becomes a lot easier.

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National Institute for Bioprocessing Research and Training (NIBRT)

Unique Collaboration to Advance Ireland's Biopharmaceutical Industry

Advancements in pharmaceutical manufacturing sometimes come through innovative collaborations that can ultimately lead to "game changing" outcomes.

From its regular consultations with industry, in the early 2000s, the Irish Government determined that the manufacture of biologics clearly would have a significant impact on the existing pharmaceutical industry and require a highly skilled workforce. To support the development of the biopharmaceutical industry in Ireland, stakeholders in government, industry, and academia joined forces and built the National Institute for Bioprocessing Research and Training (NIBRT) **New Greenfield Facility,** winner of the **2012 Facility of the Year Special Recognition for Novel Collaboration.**

The New Greenfield Facility project arose from a real need: biopharma clients in Ireland had a strong requirement for a facility to train personnel and conduct applied research in advanced manufacturing techniques. The new facility would help industry optimize the process of getting their product to market without being gated by issues such as personnel training, laboratory validation, and process de-bottlenecking. Conventional construction and project management procedures need to allocate almost a year into a new build schedule for these activities, common to every pharmaceutical site.

The complexity inherent in manufacturing biologics would require employees to be fully competent working in a highly controlled cleanroom; familiar and skilled in bioreactor control, the harvesting of delicate complex components, purification using chromatography and ultra-filtration techniques; and confident with a complex array of bioanalytical techniques.

The above requirements were immediate and would continue to increase for at least a decade. The Irish Government convened a team of key stakeholders from government, industry, and academia which concluded that only a dedicated prototype manufacturing facility integrated within an academic community would satisfy the need.

The NIBRT facility at dusk.

That facility is the New Greenfield Facility, a medium scale bioprocessing plant located on the perimeter of the University College Dublin, which is Ireland's largest university. Standing on what was an early 18th century walled kitchen garden (that in recent years was the location of the University soccer fields and facilities) is a building that replicates the most modern industrial bioprocessing facility.

The total building area is approximately 6,500 square meters over two floors. At the heart of the building is the bioprocessing pilot plant, consisting of extensive upstream, downstream, fill-finish, and associated analytical facilities. These facilities are all operated in a realistic GMP simulated operational manufacturing environment. The facility also provides extensive research laboratory areas with ample capacity for NIBRT research teams and client companies.

The upstream facility is based on a modern biopharmaceutical production plant and is operated under simulated GMP conditions. The plant was designed to the highest industrial standards and specifications and provides hands-on competency based training. The upstream plant (with one 30 liter and two 150 liter bioreactors)

Trainee in the process control room.

NIBRT

Special Recognition for Novel Collaboration

Project: New Greenfield Facility
Location: Dublin, Ireland
Project Mission: To build a state of the art manufacturing training and research facility
Size: 69,965 sq. ft. (6,500 sq. m.)
Total Project Cost: $46,400,000
Duration of Construction: 16 months

Trainees in the upstream pilot plant.

can facilitate batch, fed batch, and perfusion technology for cell culture. Harvesting of cells can be achieved by either centrifugation or filtration technologies, followed by culture clarification to remove any cell residues. The plant also is capable of supporting single use bioreactors up to 1,000 liters and is used for training staff on the latest disposable technology.

The downstream plant is designed to operate at current industrial levels of monoclonal antibody production, and is particularly suited for scale up and development purposes. In addition to two chromatography skids, an industrial sized column packing and integrity testing capability also is provided. Two separate ultra-filtration, micro-filtration skids support column operations for concentration of product and buffer exchange.

The fill finish suite comprises a clinical trials size vial filling machine located in a Class A LAF with RABS ports in a simulated Class B area. This equipment is used to expose trainees to all aspects of a sterile media trial. Trainees are expected to prepare their own sterile media and perform all necessary line checks/connections and cleaning prior to completing individual sterile media fill trials. Viable and non-viable particle and environmental monitoring is undertaken during training, along with rapid microbial and objectionable organism testing. The ability to perform a successful sterile media fill under simulated GMP conditions is assessed at the end of each course. Trainee's performance is also checked against the latest quality compliance and quality assurance standards to establish full GMP compliance procedures are met.

The purpose built research laboratories are fully equipped to perform academic and industry focused research and to develop cutting edge analytical technologies. The analytical labs are home to NIBRT's Centre for Complete Process and Product Characterisation which is fully equipped with a comprehensive array of bioanalytical equipment featuring state-of-the-art mass spectrometry and chromatography equipment. This enables NIBRT to provide a wide range of bioanalytical research, training and services to industry.

Industry has access to the facility for a wide range of uses, including:

- training and education programs on manufacturing technology, operational excellence, and best practices
- process optimization, applied research and development programs
- test bed for new technologies and processes
- showcase for latest technologies and products

The NIBRT New Greenfield Facility project is the realization of a novel idea through a unique collaboration by a diverse group of stakeholders. The world class facility provides training and applied research for the bioprocessing industry, giving Ireland a competitive advantage in the advancement of its biopharmaceutical industry.

Key Project Participants

Designer/Architect: Jacobs Engineering (Dublin, Ireland) *(See ad on page 19)*

Engineer: Jacobs Engineering (Dublin, Ireland) and Project Management Group (Dublin, Ireland) *(See ad on page 33)*

Construction Manager: DPS Engineering and Construction (Dublin, Ireland)

Notes from the Judging Panel – What Impressed Them

- *The ability of government, industry, and academia to effectively join together and realize a vision of a biologics facility that provides research and training facilities to industry.*
- *Having the vision of such a novel idea realized through innovative collaborations that ultimately resulted in having a significant impact on the existing pharmaceutical industry in Ireland.*

The FOYA Judging Process: An Interview with Scott Ludlum, ISPE's Project Manager for the Facility of the Year Awards Program

Q Describe the Facility of the Year Awards and the role you play in the program.

A The Facility of the Year Awards program has really evolved into what the three sponsors – ISPE, INTERPHEX, and Pharmaceutical Processing magazine – had envisioned it to be. It is truly the premiere global awards program that recognizes state-of-the-art pharmaceutical manufacturing projects that utilize new and innovative technologies both to improve the quality of their projects and reduce the costs of producing high quality medicines. Over the years, there have been dozens of Category Winners recognized from about 15 different countries.

I am fortunate to have been involved in managing the program since its inception eight years ago. I cannot emphasize enough that the recognition and success the awards program has achieved since its implementation is due largely in part to the tireless support and dedication of senior level industry executives who serve as volunteers on the Judging Panel and the Facility of the Year Committee.

Q How are the Category Awards Winners and the Overall Winner for the annual Facility of the Year Awards Program chosen?

"I can attest there has never been an instance when even just one of the judges disagreed with the selection of the Category Winners and Overall Winner. I attribute this to the judges' unprecedented level of professionalism and passion for making this industry a better one."

A Once submissions are received by the deadline at ISPE, they are carefully reviewed to ensure each submission meets all eligibility requirements. It is not uncommon for ISPE to request additional information or clarification on information received, to ensure that each submission is eligible and will be assessed equally by the judges. Actually, this is my responsibility and it can sometimes be a grueling task.

One of the requirements of serving on the Judging Panel is that they must be willing to carefully review each submission. Typically, the judges have about four weeks to review as many as 30 submissions. During the all-day judges meeting, they discuss each and every submission in alphabetical order to determine which projects deserve to be recognized as Category Winners. Once the Category Winners are chosen, the judges vote again to choose the Overall Winner.

We developed a very detailed process for selecting the Overall Winner to ensure transparency that entails voting for the top three projects by allocating a total of 6 points. Each judge allocates 3 points for the project deemed best, 2 points for the project deemed second best, and 1 point for the project deemed third best. The project with the highest number of votes is deemed Overall Winner of the Facility of the Year Awards program.

Q What is the role of the sponsoring organizations in the judging process?

A ISPE, INTERPHEX, and Pharmaceutical Processing magazine have an extremely important role in the awards program, and specifically in overseeing the judging process. Our role is to always remain neutral and we do not vote in the judging process. We do, however, participate by assisting to identify and address judging process questions. Sometimes it becomes necessary to make a process decision about how to resolve a question or issue related to the judging process. In those instances, we as neutral participants representing the owners of the program, provide ideas and guidance from purely an administrative perspective.

Q What is the process for addressing submitted projects that judges were involved with, had knowledge of, or pertain to the same company and/or subsidiary company?

A Good question. Due to the number of judges, typically 10 to 12, and the global reach of the organizations the judges are employed with, it is inevitable for there to be a conflict of interest. However, addressing the issue of conflicts of interest is a very important component of maintaining a credible judging process. And it is something current Judging Panel Chair Chaz Calitri, of Pfizer, takes very seriously.

We address potential conflicts of interest at the onset of the judges meeting by asking each judge to identify projects they worked on directly, are aware of, or are associated with through their companies or a subsidiary company. We compile a list of all conflicts of interest and the judges who are associated with them. Then, when the judges discuss and ultimately choose the Category Awards Winners, judges identified with a conflict of interest are not able to discuss the project or vote for it to be selected as a Category Award Winner. If other judges have questions or require purely factual information, the judge with the conflict of interest may respond to their questions. But, the judge with the conflict of interest may not talk about the project or vote for it to be a winner. However, once the Category Winners have been chosen the judge with the conflict is able to vote for the overall winner. I remember during the judges meeting in 2011, there were so many submissions from Pfizer that Chaz Calitri left the room completely. I think it was about 30 minutes before he came back in to the room.

I think it is safe to say we developed a very comprehensive process that ensures all submissions are judged equally and that it is impossible for any one of the judges to unduly influence the outcome of the voting.

Q What specific criteria is the judging based on? Are the criteria weighted?

A The criteria judging is based on have not changed much since the inception of the program and it is not weighted at all. One of the primary components of the criteria is the executive summary, which includes:

- General information about the company
- Key technological engineering and innovative features of the facility
- Information about the products that are manufactured
- What makes the project or facility unique
- The results they achieve
- And information about site selection including the number of buildings and the opportunities for expansion

The other primary component of the criteria is focused on significant contributions to:

- The Pharmaceutical Manufacturing Industry
- Project Uniqueness and Innovation
- Quality
- Operational Excellence
- Project Execution
- Sustainability

The Facility of the Year Committee also significantly enhanced the awards

Continued on page 38.

"The program recognizes and awards technological innovation and unique aspects of projects, regardless of whether they are new or renovation projects or whether they are a billion dollar project or a 2 million dollar project."

program and made the judging process much easier and more precise with the addition of categories. This is why the judges now select Category Awards Winners. Detailed information for each Category is available at www.facilityoftheyear.org.

Q Has there ever been an instance when the judges did not reach consensus and were not able to choose the Category Awards Winners and Overall Facility of the Year Award Winner?

A We have been extremely lucky that there has never been a time when the judges were not able to choose an Overall Winner. I can remember one or two years when the discussions and decision process took much longer than expected and the decision was not made until the end of the day. Each year we are reminded how difficult it is for the judges to choose the Category Winners and Overall Winners, because there are so many outstanding projects being constructed. But, due to the tremendous level of global expertise in all facets of facility design and construction, as well as the tremendously diverse experiences of the judges, the judges are able to conduct amazingly insightful discussions and analyses. I can attest there has never been an instance when even just one of the judges disagreed with the selection of the Category Winners and Overall Winner. I attribute this to the judges' unprecedented level of professionalism and passion for making this industry a better one.

Q Should only "big Pharma" companies submit an entry and do small projects have a legitimate chance of winning?

A This is another excellent question and an issue I would like to clarify and elaborate on. I can personally attest that every member of the Facility of the Year Committee and Judging Panel is conscious of doing everything possible to encourage all companies, including those with small projects, to submit an entry. We have spent countless hours over the years discussing how we could be more effective with the Facility of the Year Awards marketing and promotional campaign to make it more enticing for smaller companies, companies building small projects, or contract manufacturers.

We realize the perception could be (from the outside looking in) that big Pharma projects are the ones named Category Awards Winners and Overall Awards Winners. But that really is not true. There may be an assumption that the larger, shiny new projects are the ones winning the awards. But, it is not the size, the cost, or how beautiful a project looks on the outside. The program recognizes and awards technological innovation and unique aspects of projects, regardless of whether they are new or renovation projects or whether they are a billion dollar project or a 2 million dollar project. There have been several small projects named as Category Awards Winners over the years. For example, one of the Category Awards Winners for 2012 is Eisai Pharmatechnology and Manufacturing Pvt. Ltd.'s Knowledge Centre project, which won the 2012 Facility of the Year Award for Project Execution. One reason the project is being recognized is because such a high quality, fully integrated R&D manufacturing complex was delivered for under US $50 million.

Another 2012 Facility of the Year Award Winner is the German contract manufacturer Rentschler Biotechnologie GmbH, which won the Facility of the Year Award for Equipment Innovation.

Facility of the Year Awards website, **www.facilityoftheyear.org**.

And then there was Baxter Biopharma Solutions, which won the 2006 Overall Facility of the Year Award.

These are real world examples that show that you have to enter in order to win!

Q What advice do you have about how to compile a submission that will impress the judges?

A Follow the submission instructions and contact me if you have any questions. The submission form is very detailed and specific regarding what and how information must be provided. It is important to follow these instructions exactly because the judges have requested this information. If we receive submissions that don't include the required information, we cannot submit the entries to the judges until it is provided.

It is also very important to focus on providing as much specific information and data as possible that demonstrates how your project is unique and what the innovative qualities of the project are. As I stated earlier, projects will not win the Facility of the Year Award because they are the most expensive or because they look good. Winning projects should be exemplified in submissions that provide concise, relevant information that distinguishes or differentiates the innovative features of a project. Don't simply tell the judges that it is a technologically advanced state-of-the-art new facility; provide specific examples about the equipment, technology, people, and processes employed to make it a truly remarkable project. The judges base their decisions on the relevance of the content provided and not on the quantity of information included in the submission.

In recent years I also have seen the judges placing a strong emphasis on safety in the working environment and this is consistent with the submission guidelines.

The most important advice I can offer is to plan for submitting an entry as carefully and thoroughly as you would project plan a new or renovated facility. Don't wait until the last minute so that you are rushed to finish the entry and submit it on time. Expect that developing an entry will take longer than anticipated and try to give your team at least a month to compile the submission. In other words, start thinking about submitting an entry today and project plan your entry submission process the same way you project plan the construction of your facilities.

With that in mind, let me encourage any company that has constructed a new facility or renovated an existed one between 1 November 2010 and 30 November 2012 to submit an entry for the 2013 Facility of the year Awards Program. We are now accepting submissions and complete details are available at www.facilityoftheyear.org. You can also contact me at sludlum@ispe.org.

Submit an Entry to the 2013 Facility of the Year Awards Program

2013
Facility of the Year Awards
Awarded by ISPE, INTERPHEX, Pharmaceutical Processing

Your efforts to construct new or renovate existing manufacturing facilities that enhance patient health and safety deserve to be recognized.

The 2013 Facility of the Year Awards (FOYA) Program is your chance to spotlight your company's commitment to innovation and excellence in pharmaceutical manufacturing.

FOYA Category Winners are acknowledged by global regulators, industry colleagues and business leaders alike as the driving forces in the future of the pharmaceutical industry. Don't miss your opportunity to participate in this premiere awards program – start assembling your submission today!

All Submissions Due by 19 October 2012

For more information on eligibility requirements, submission procedures, and past winners, visit www.FacilityoftheYear.org

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Pharmaceutical Processing

Claim Your Spot Among the World's Leading Pharmaceutical Manufacturing Innovators

"For the entire team, winning the Facility of the Year Award is confirmation of the fact that we have genuinely made a great achievement over the last two years."

– FOYA Category Winner in Operational Excellence

Attend the 2012 ISPE Annual Meeting in San Francisco, California USA 11-14 November to hear the 2012 Facility of the Year Awards Overall Winner announced LIVE!