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June 2015

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RECOGNIZING INNOVATION. BY DESIGN.

FOYA 2015
CATEGORY WINNERS

2015
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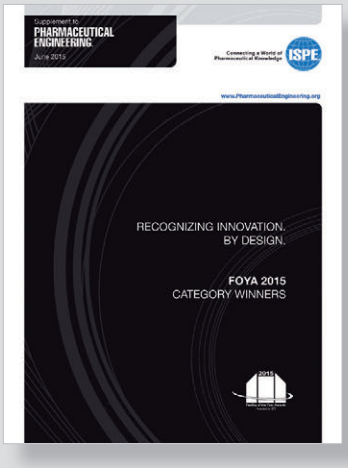
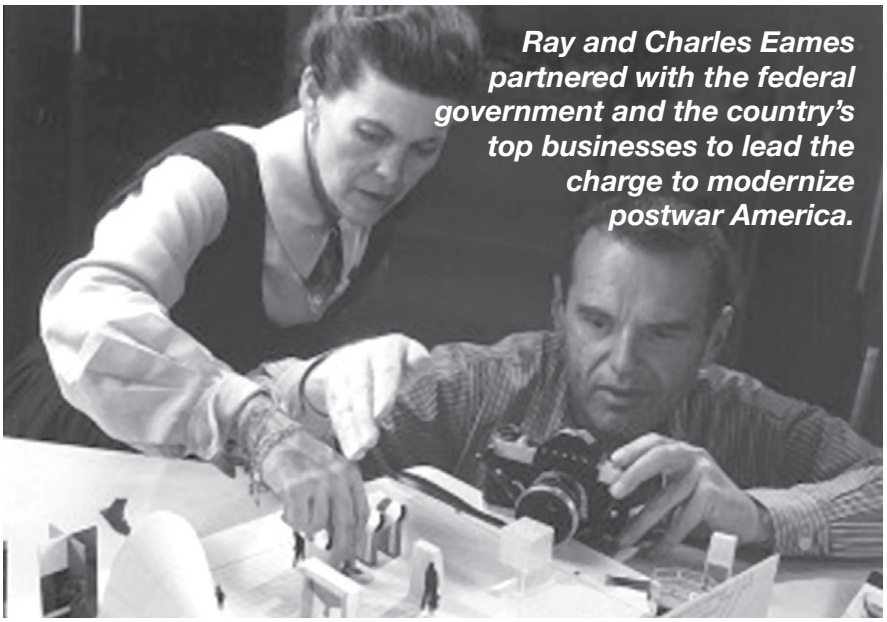


Category Winners

RECOGNIZING INNOVATION. BY DESIGN.

It's a spark, a fleeting thought, an 'aha': the moment when you recognize potential, that makes you want to create something new, or improve something familiar. It's the moment you see value in innovation.

With an idea comes the responsibility of expression: encouragement, careful planning and successful execution. And recognition, the responsibility ISPE assumes on behalf of its members around the world. Because we need leaders and mentors to ensure that quality medicine reaches the people who need it, when they need it, anywhere in the world.



Ray and Charles Eames partnered with the federal government and the country's top businesses to lead the charge to modernize postwar America.

Photo courtesy: Library of Congress (A-22a)

Celebrating purpose, intent and innovation

Innovation can come in many forms. And you never know when a particular breakthrough will change the world. Indeed, history is replete with the legacies of innovators who have reinvented the rules using science and the power of their imaginations. As Eliel Saarinen said, "Always design a thing by considering it in its next larger context – a chair in a room, a room in a house, a house in an environment, an environment in a city plan".

Just think of the areas of manufacturing, design and engineering; individuals with a vision and a passion to effect change have shaped the world we know today. People like Ray and Charles Eames, designers who influenced the way we make chairs. Like Henry Ford, who perfected the concept for an assembly line and manufactured the first affordable car. Or architects like Zaha Hadid and Oscar Niemeyer, who have designed and erected buildings that defy gravity, as well as convention.

Regardless of the industry, these individuals share a common trait. Each of them took matter that would not bend to established standards—whether it was plywood, metal, concrete or light—and shaped it to suit their respective visions. Their clarity of intention fuelled their resolve and ultimately, their success. They redefined what was possible.

In many ways, our FOYA winners share that trait as well. Perhaps they have not yet reached the dizzying heights of the innovators I mentioned above. But who is to say that one day, one won't? Or, perhaps, not enough time has passed for us to truly appreciate the greatness of their innovative processes, projects and products.

Vision begets innovation. At ISPE, we want to see our vision of a world without drug shortages inspire engineers around the world to find solutions. And why shouldn't we?

ADVERTISERS' INDEX

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ISPE's members work in an industry where ideas lead to the creation of medicines; an industry that manufactures medicines to create possibilities; and an industry that can positively impact people's lives. That is its essential purpose and it is achieved through collaboration with a broad spectrum of stakeholders from the pharmaceutical industry, regulatory agencies, health organizations and patients.

ISPE's FOYA program, too, fosters collaboration. The FOYA winners represent the collaborative efforts of engineers, architects, designers, contractors and suppliers. On the surface, their efforts had positive impact on their organizations by increasing manufacturing efficiency, reducing costs and lead times, or helping reach new clientele. However, from ISPE'S perspective, the fruit of their efforts runs deeper than that. Their efforts support an underlying purpose that all ISPE members share—to ensure quality medicines reach the people who need it, when they need it, anywhere in the world.

FOYA was created just over a decade ago to celebrate six facets of manufacturing excellence: *Project Execution, Facility Integration, Equipment Innovation, Sustainability, Process Innovation and Operational Excellence*. Each of the FOYA categories stands on its merit, yet each embodies a form of innovation. It is that common purpose, intent and innovation that we celebrate through FOYA.

John E. Bournas
President and CEO
ISPE

CONGRATULATIONS!

The category winners of the 11th Annual FOYA program join the ranks of 57 winners from 15 countries, who have been recognized by their peers for their extraordinary achievements and innovative and forward-looking contributions in advancing pharmaceutical manufacturing.

Astellas Pharma Inc. (Equipment Innovation), **AstraZeneca China** (Project Execution), **IDT Biologika** (Facility Integration) and **Pharmalucence** (Honorable Mention) have each captured the spark of innovation and transformed it into processes, projects and products.

The facilities honored as the 2015 ISPE FOYA Category Winners exemplify the ideals of the FOYA program and ISPE's dedication to enhancing patient health through advancements in pharmaceutical manufacturing.

We have one more winner to announce, the 2015 FOYA Overall Winner, and that will happen during the plenary session at the **2015 ISPE Annual Meeting** in Philadelphia, Pennsylvania from 8-11 November. We look forward to seeing you there.

FOYA 2016

Facility of the Year Awards

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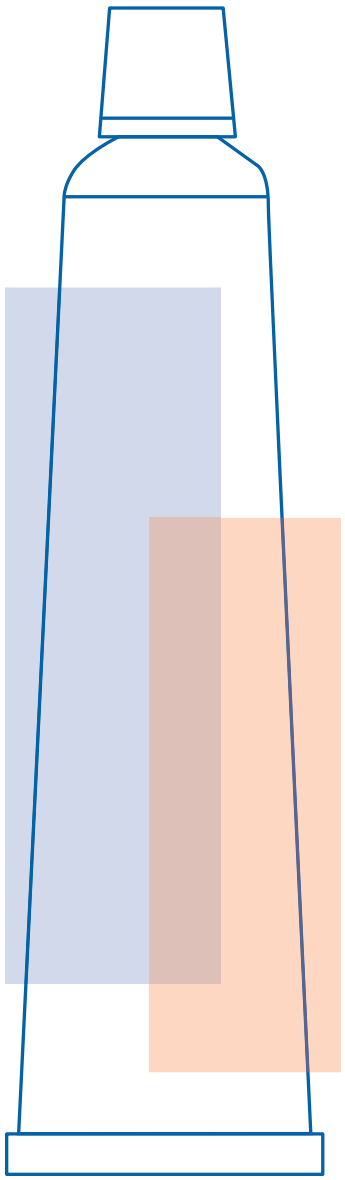
Astellas Pharma Inc.
Innovative equipment for a global supply chain



Faced with the need to supply language-specific products to multiple European countries while dealing with long lead times and high stock levels, the Astellas Pharma team took an innovative approach to product labeling that has radically improved their global supply chain.

Astellas Ireland Co., Ltd., Kerry plant (Kerry) provides distribution of filled ointment tubes to affiliates across Europe. For this project's target product, PROTOPIC® Ointment, the plant was importing pre-printed, pre-filled tubes in 72 presentations (3 sizes, 2 strengths and 26 areas in Europe) from Astellas Pharma Tech Toyama Technical Center (Toyama TC) in Japan. The Kerry plant would then pack and deliver the products to sales affiliates in Europe.

Lead times were very long, typically taking more than 6 months from order placement to receipt of the product. "From a production point of view, our Toyama TC facility had to carry 72 different tubes, which was very cost consuming and not very effective," said Takeshi Furukawa, Director of Engineering Group at Astellas Pharma Inc.

"We began to look at the concept of a tube labeling process that could take pre-filled tubes printed with only common information and label them with country specific information," said Furukawa, who led the project from the conceptual stage through to deployment.

The Astellas team, with trusted vendor Harro Höfliger, succeeded in developing and producing a unique packaging equipment design that applies soft transparent labels on the entire surface of both sides of pre-filled laminated tubes.

Their innovation dramatically improved plant flexibility, simplified the supply chain by reducing presentations from 72 to 6, significantly reduced acceptance testing, halved product stock levels from 6 months to 3 and improved overall delivery times.

Astellas Pharma Inc.

Category Winner – Equipment Innovation

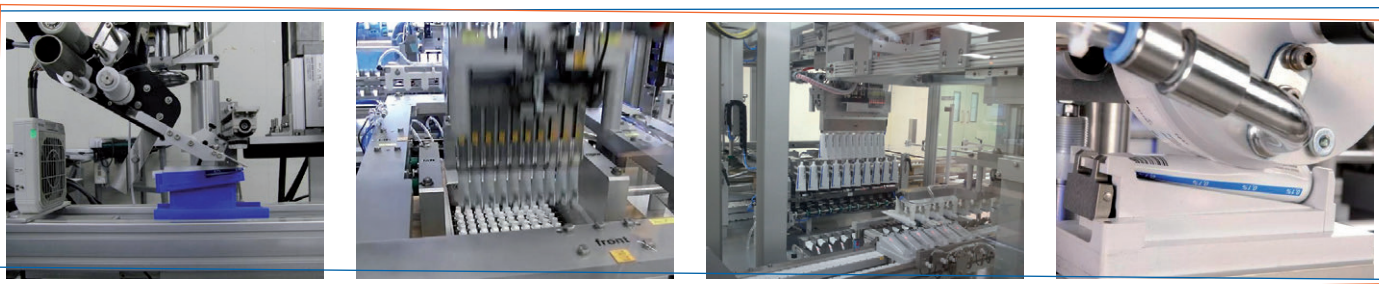
Project:
Tube Labeling Project

Location:
Killorglin, Co. Kerry, Ireland

Project Mission:
Develop and introduce a tube labeling machine to innovate the tube products global supply chain

Site area:
146,000 m^2

Floor space:
14,400 m^2



Project Overview

Astellas Ireland Co., Ltd Kerry plant, a subsidiary of Astellas Pharma Inc. (API), was established in 1992 in County Kerry in the southwest of Ireland. With a total site area of approximately 146,000 m^2 with a floor space of 14,400 m^2, the Kerry plant produces capsule and ampoule products shipping all over the world and packs tube, vial and sachet products imported from Astellas subsidiary plant in Japan to ship to European countries. Thus, the Kerry plant produces and ships Astellas products globally.

The target products of this project, PROTOPIC® Ointment Tube 10g, 30g and 60g, are produced by Astellas Pharma Tech Toyama Technical Center (Toyama TC) shipping all over the world. For European markets, Kerry plant would import bulk tube products from Toyama TC, pack them into cartons and ship to European countries.

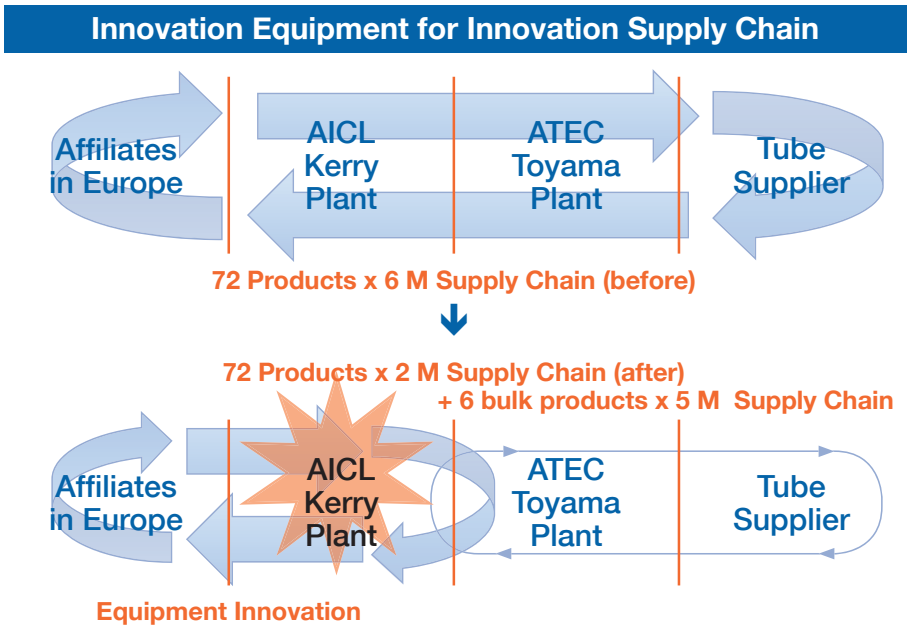
The artwork of tube products are designed by the artwork development group of Astellas Pharma Europe B.V. (APEB) in the Netherlands, working together with regulatory affairs groups and sales affiliates for each country in Europe.

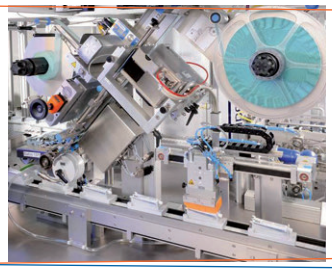
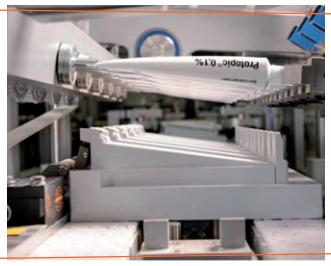
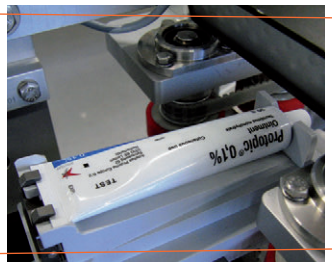
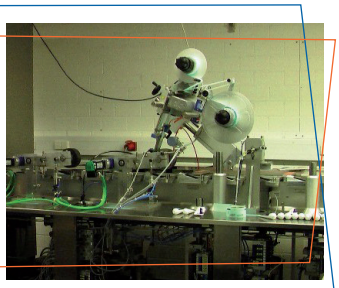
As many countries in Europe use their own language, there were 72 presentation laminated tubes (2 strengths; 3 configurations for each strength) for 26 areas in which Toyama TC filled ointment product. The Kerry plant received orders from each sales affiliate in Europe and ordered Toyama TC filled tubes country-by-country.

The Toyama TC ordered pre-printed country-specific empty tubes from a supplier in Japan, taking account the number of tubes stocked in the warehouse and orders by Kerry plant. Since the delivery time for an empty tube is 4 months, it took more than 6 months from order placement to receipt of product at sales affiliates in Europe, taking account production of Toyama TC and delivery from Japan to Ireland and packaging in Kerry plant (see FIG-1). In addition, typical lead time for new introductions or changes to the tube artwork was 10-12 months. This resulted in the following issues for Astellas:

- 6-months of stock was required in the market due to the long product delivery time;
- Typical lead times for new introductions or changes to the tube artwork were 10-12 months from artwork being available to shipment of the finished product to the affiliate;

Figure 1: Tube supply chain



- At Toyama TC, tube production had many losses due to the many small batch change-overs (change-over time loss, product loss, QC sample time and sample loss);
- At Toyama TC, warehouse space loss for country specific empty tubes;
- At Kerry Plant, QC acceptance test sample loss and time loss.

To address these issues, Astellas groups initiated a study to assess whether Toyama TC could fill product into common tubes printed with only common information for all markets in Europe and Kerry Plant could introduce a process to add country specific information on common tubes.

A global project team led by API members was set up as this project dealt with issues both in Japan and Europe. After some trials in 2008, API engineers succeeded in producing samples which applied two soft transparent labels on the entire surface of both sides of laminated tubes. European affiliates and regulatory affairs members confirmed that samples were acceptable.

In the next stage, API engineers started to develop a Basic Concept machine to automate the process of applying a label. Labels must be applied to the whole surface of the filled tube, on both sides, with no bubbles and wrinkles and in the correct position. The team looked for this technology in the market but couldn't find it; they then decided to develop it internally. In 2009 they succeeded in developing a

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Daniel Drossel
Mechanical Engineering Technician
(Design department)

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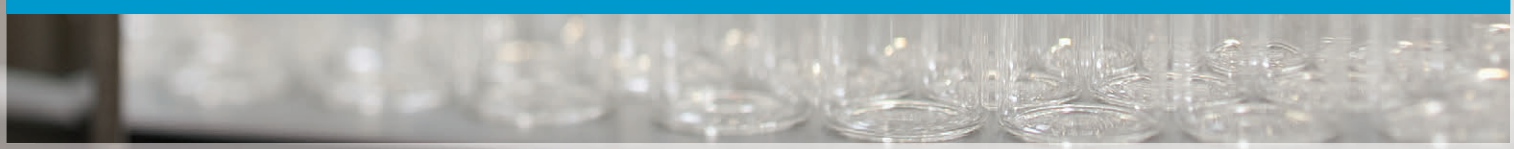

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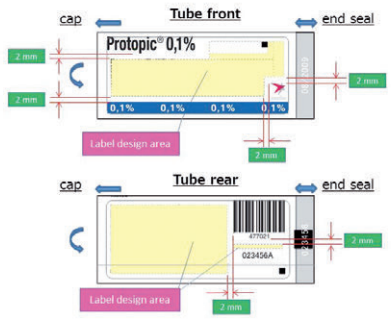
basic technology of this application after several investigations.

Kerry plant engineers were given the responsibility to introduce a production machine and selected an innovative vendor, Harro Höfliger Verpackungsmaschinen GmbH (HH) in Germany. In 2010, the concept of a labelling machine that could label filled tubes was designed together with HH based on the basic technology. Trials and FAT were successfully carried out at HH in 2012, after which the machine was transported to Kerry in February 2013. Installation and qualification were all scheduled in a specific time slot and completed as planned with minimal impact on other production lines at Kerry plant in April 2013.



"Supervisors, technicians and safety personnel were involved during trials and FAT, so the transition to the production environment was very smooth," said Furukawa.

Meanwhile, a kick-off meeting was held at APEB head office in Netherlands in March 2012 with members from regulatory affairs, artwork development, operational planning groups, Kerry plant and API to discuss regulatory issues, new artwork and stock controls. Project members completed the preparation to introduce common tubes with very precise time lines. At Toyama TC, in December 2012, validation to introduce common tubes was completed and production of common tubes was started in January 2013. First common tube batches arrived in Kerry in March 2013.

First production at Kerry plant in May 2013 as planned and labeled tubes have been introduced country-by-country since then. Production has been very stable and no quality issue has occurred. The objectives of this project were therefore achieved as follows:

- In the market, product stocks reduced dramatically from 6 months to 3 months.
- New products launches and artwork changes are quicker, 6-8 months vs. 10-12 months previously and more flexible than before.
- At Toyama TC, number of batches per year was significantly reduced from 200 to 100 and the number of tube presentations from 72 to 6.
- At Toyama TC, warehouse space for empty tubes stocked by countries was reduced.
- At Kerry plant, QC acceptance sample tests reduced from 200 batches to 100 batches.
- The project has successfully transformed the Astellas supply chain through machine innovation.

"Normally pre-print tubes are used for tube packaging products in the pharmaceutical industry. We took the time required to introduce a very unique and stable machine at Kerry. I think the Kerry team is quite proud of this new process," concluded Furukawa.

FOYA Judges Panel Conclusion

"This is an example of a project team challenging the standard and making imaginative and effective use of equipment innovation as a way to improve the way products are efficiently packaged and supplied to global markets."

In Their Own Words

The following is an excerpt from Astellas Pharma Inc.'s submission, stating the top reasons why their project should win the ISPE 2015 Facility of the Year Award:

Innovation of tube packaging products

- Successfully developed brand new and unique tube packaging products (filled tubes applied with labels).
- Designed new packaging products from patient, regulatory, packaging material design, bulk production and packaging production point of view from the early stage of this project.
- The packaging design was maintained and optimized through the project's later steps and led to introduce a successful production process.

Innovation of tube packaging machine

- Successfully developed a brand new and unique machine that applies labels on filled tubes. Normally, in the pharmaceutical industry, pre-printed tubes are used or labels are applied to empty cylindrical tubes before filling.
- Took 3 development steps as Basic concept machine (Japan), Proof of Principle machine (Germany) and Production machine (Germany) and technical knowledge was transferred between each step and improved during each step.
- Examined bulk tube qualities and process very carefully from the early stage of this project. Necessary changes to the bulk production process were added and necessary functions of the production machine were included. This led to a stable production performance of the production machine at Kerry Plant from the beginning.
- Introduced a full automation system, such as carrier tube handling with RFID system, barcode checking and camera system to prevent wrong products from contaminating good products.

Innovation of tube products supply chain

- Successfully developed a brand new and unique tube products packaging supply chain, which starts from applying labels on filled tubes by developing new tube packaging products and a new Tube Labeling machine.
- The tube supply chain was dramatically simplified and made more flexible to reduce delivery times and product stock levels. Product description on a tube is now informed to patients more quickly.
- Bulk tube production in Toyama TC became very simple; handling reduced from 72 to only 6 packaging product presentations.

Manufacturer/Owner	Astellas Ireland Co. Ltd., Kerry Plant Philip Gammell
Designer/Architect	Harro Höfliger Verpackungsmaschinen GmbH Michael Kronmueller
Engineer	Astellas Ireland Co. Ltd., Kerry Plant Rory Mc Shane
Main/General Contractor	Astellas Ireland Co. Ltd., Kerry Plant John Mc Keon
Automation and Control Supplier	Harro Höfliger Verpackungsmaschinen GmbH Michael Kronmueller
Major Equipment Supplier/Contractor	Harro Höfliger Verpackungsmaschinen GmbH Michael Kronmueller

AstraZeneca

TAIZHOU SUPPLY SITE PROJECT

Farmers' Fields to Pharmaceuticals

2015

Facility of the Year Awards

CATEGORY WINNER

Project Execution

AstraZeneca China

Detailed planning allows AstraZeneca to go from farmer's field to production in under two years

When the Chinese government launched its "Healthy China 2020" program to provide universal healthcare access to all of China by 2020, it was seen by many to be radical and ambitious. When AstraZeneca set out to turn a farmer's field into a fully-functional pharmaceutical facility capable of manufacturing five billion tablets of high-quality, affordable medicines within two years, it may have seemed next to impossible.

However, the AstraZeneca China team was up to the challenge. With backing from the company's Board of Director and Senior Management, and an initial budget allocation of US$217 million, the project team used both best-practice and innovative project management techniques to complete the facility 18% under budget, three months ahead of schedule, all while maintaining an exemplary safety record.

"The team worked very hard and very smart from the beginning," said Martin Teo, Project Director, Taizhou Project. "This was a large project, with 80 management, designer and engineering staff in addition to 1000+ workers on the site. We managed the project and all its resources by developing a one team, one goal approach from Day 1. Throughout the execution, we used planning tools extensively along with innovative supplier procurement and cost saving strategies."

China is recognized as an exciting and challenging market to execute any project. It presents an operating environment that is both new and unpredictable. In launching what, at the time, was the company's largest ever investment in a lesser known but ambitious "third tier" city like Taizhou, AstraZeneca knew the project might face challenges.

"The major contributor to this project's success has been good planning," said Alan Osborne, AstraZeneca's Regional Head of Global Engineering, Asia-Pacific. "Setting up expectations, defining requirements, working through what really could be done and then blending that with the right cultural strategy and a good understanding of the local environment and the people we had here."

AstraZeneca China

Category Winner – Project Execution

Project:
Taizhou Supply Site Project, Phase 1

Location:
Taizhou, Jiangsu Province, China

Project Mission:
Deliver a high-volume, cost-effective manufacturing facility to supply 5 billion tablets of modern medicine per year to the China market.

Site area:
90,000 m^2

Floor space:
49,600 m^2

Project Overview

The Chinese government's action plan was launched in 2009 to deliver quality and affordable medicines to China's burgeoning population, particularly in less affluent rural areas were the need was largely unmet. Already one of the leading pharmaceutical companies in China with a large portfolio of innovative medicines, AstraZeneca was in good position to meet these needs when, in late 2011, the AstraZeneca Board of Directors and Senior Executive Team approved a five-year investment program to establish a high-throughput, cost-effective site that would support China's health initiative.

Seeing the opportunity to develop a close working relationship with the regional China Food and Drug Administration (CFDA) as well as the commitment of local government, the decision was made to locate the site in China Medical City (CMC), Taizhou, Jiangsu Province. An initial budget of US$217 million was allocated for Phase I of the project to build a site to accommodate formulation, packing, laboratories, warehousing, an administrative wing and site utilities in a 49,600 m^2 facility. AstraZeneca's cardiovascular product Betaloc and its asthma medicine Bambec were to be supplied from Taizhou for this first phase of the project.

One Team. One Goal.

A highly-integrated and multinational team from China, Sweden, Denmark, the UK and the Americas was built. The team included an AstraZeneca engineering team, engineering and construction management consultants, local trade contractors, equipment suppliers and cross-functional AstraZeneca end-users. From the beginning, the AstraZeneca mantra "One Team, One Goal" was embraced.

"Everyone's roles and responsibilities were clearly defined. We made sure everyone knew what they needed to do and how they could contribute to the project. We had clear communications and meeting plans; whether we would meet by teleconference or videoconference or have everyone come to China every two or three months for a face-to-face discussion. It was all in the project plan," said Martin Teo.

Recruiting and retaining a high-performance work crew also played an important role in meeting the project's objectives. In China, employee turnover rates are routinely in the 15-20% range; for this project, the turnover rate was only 6%. "We made sure our people worked in a healthy and safe environment every day and we frequently used small but appropriate recognitions for teams that performed well or reached certain milestones. I think these things helped our people realize that AstraZeneca is a place they wanted to be," said Osborne.

To meet the project's fast-track schedule, Teo and his team used an innovative "Plan-Do-Review" interactive visual planning method throughout the construction stage. The process results in the production of a clear and concise visual tool for the sequencing of project works and their interfaces. For this project, it allowed teams to condense a 3,000 line schedule into one visible board. All contractors were trained on the use of the tool and it was used at each stage of the project.

The detailed planning and visual tools used by the project team helped shortened an already tight project schedule from 23 to 20 month and also resulted in impressive Health & Safety results. Thanks to careful selection of manufacturing partners along with an emphasis on employee training and engagement, the project delivered an outstanding safety performance of zero OSHA (Occupational Safety and Health Association) recordable accidents and only two first-aid incidents in 3.26 million man hours.

To further reduce lead times and generate cost savings, the project team endeavored to source locally as much as possible. A total of 32 out of 37 manufacturing equipment packages were manufactured locally, including granulators, fluid bed dryers, tablet presses, coaters and blenders. Quality was maintained through an aggressive program of vendor support, including in-factory engineering monitoring and training. Benefits included the anticipated reduction in lead times, proximity to after-sales support and over $10 million in cost savings.

Design and sustainability

Lean design principles were applied throughout the design phase to eliminate operational inefficiencies and deliver optimum manufacturing performance from the start of operation. From design to the first three months of manufacture, overall lead time was reduced by 10%, or one working week though continuous improvement.

In addition, the project focused on having a minimal impact on the environment. Using a novel electro-oxidation process in addition to conventional biological treatment, the AstraZeneca Taizhou facility has achieved over 99% Active Pharmaceutical Ingredient (API) removal rate from API containing waste water. This not only far exceeded local regulations, but also surpassed AstraZeneca's own stringent standards.

With two additional phases expected, the Taizhou site has the potential to expand to nine billion tablets per year, placing AstraZeneca in a position to supply China with affordable, safe, efficacious medicine in support of the government's healthcare reform plans for over 1 billion people.

In addition to the FOYA category award, the Taizhou facility project has received both internal and external recognition, including an "Excellent Site" award from Taizhou City regulators and a "Safe and Orderly Construction Site" award from the Jiangsu provincial government.

FOYA Judges Panel Conclusion

"This facility was one of the earliest large pharmaceutical facilities developed in partnership with the CFDA and local authorities, to establish the city of Taizhou as a new pharmaceutical hub. Programs including a fully integrated project execution team including all key internal and external stakeholders, and a Plan-to-Do Review process helped drive this project to success."

When change is the only constant, are your facilities up to speed?

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In Their Own Words

The following is an excerpt from AstraZeneca China's submission, stating the top reasons why their project should win the ISPE 2015 Facility of the Year Award:

Project Execution

- **We went from 'Farmers Fields to Pharma GMP Sample' in less than two years.** The team implemented existing project execution tools into parallel work streams which allowed them to go from farmers' fields to pharma GMP sample in a mere 22 months and to supply medicines to Chinese patients three months early. This would be considered a remarkable feat in the US or Europe. However, given the added complications of construction in China, this was truly a remarkable achievement. The facility was held to the same design and construction standards as every other facility built by AstraZeneca. In addition, the project was delivered 18% under budget with zero OSHA recordable accidents after 3.26 million safe man hours.
- **We implemented a business first in working with Taizhou authorities for contractor permitting.** Close cooperation with the local Taizhou authorities in the early planning phases and then throughout the project allowed us to contract individual construction packages, rather than a main contract as is the standard in China. This gave us greater control over quality and schedule and reduced the construction schedule by four months.
- **We set a new standard in China for sourcing strategy.** Of the 37 manufacturing equipment packages purchased, 32 were manufactured in China, leading to over US$10 million in savings. All packages purchased have been tested and validated and are 100% operational. This was facilitated by an extremely thorough assessment of local suppliers, including ensuring that we procured responsibly and avoided intellectual property infringement. We also invested efforts in improving suppliers' fabrication and mentoring them through the AstraZeneca GMP validation documentation requirements.

Sustainability

- **We installed an industry first in innovative waste water treatment.** Using an innovative electro-oxidation process as a pre-treatment step to treat waste water containing Betaloc, the site is able to convert toxic API into smaller non-toxic molecules. This has exceeded the already stringent AstraZeneca waste water treatment standard and achieved over 99% API removal.
- **We exploited our automated HVAC system to dramatically reduce energy consumption.** In addition to extraordinarily low air change rates, we introduced an automated system that further reduced air changes by 45% during non-operational hours such as nights and weekends, resulting in considerable energy and carbon savings.

Key project participants	
Engineer	NNE Pharmaplan (Tianjin) Co., Ltd. Shanghai Branch Company / Xin Ning (Matthew) Zhang (XNZ)
Construction Manager	Cockram Projects (Shanghai) Construction & Enginering Co.,Ltd / David Mazou
Civil and Structural Contractor 1	Shanghai Yangzijiang Construction (Group) Company Ltd / Zeng Xianfu
Civil and Structural Contractor 2	Jiangsu Huaxin Engineering Project Management Co.,Ltd./ Zhou Ke
Piling Contractor	Jiangsu Province Rock-soil Engineering Ltd / Deng Zhi Song
Interior Decoration Contractor	Shenzhen Overseas Decoration Engineering Co.,Ltd / Dai Bo
HVAC / Cleanroom Contractor	China Electronica System Engineering No.2 Construction Co./ Chen Ming Rong
MEP(MEch&Elec&Plumb) Contractor	Yixing Industrial Equipment Installation Co.,Ltd. / Huang You Kang
Fire Fighting Contractor	China Fire Engineering Co., Ltd / Wang Zhixin
BMS Contractor	Siemens Building Technologies (Tianjin) Ltd / Ye Guo Quan
Security/IT/ISTS System Contractor	Wuxi Anji Electrical Engineering Co.,Ltd / Xin Nuo Ping
AHUs supplier	Shanghai Bennovest Energy Saving Technology Co., Ltd. / Xie Zhiming
Fluid Bed Dryer supplier	GEA PROCESS ENGINEERING CHINA LIMITED / Kathy Lam
Packing Line supplier	MARCHESINI GROUP S.p.A./ Leonardo Ercolani
Tablet Press	FETTE (Nanjing) COMPACTING MACHINERY CO., LTD / Jiang Jiyun
Coater	Zhejiang Xiao Lun Pharmaceutical Machinery Co., Ltd. / Su Changhua
Purified Water System	BWT WATER TECHNOLOGY (SHANGHAI) CO., LTD / Janson zhu
Business Process Management	Tibco Software Ltd.
Software Provider	Susanne Palmehag

Category Winner

2015
Facility of the Year Awards
CATEGORY WINNER
Project Execution • Supplier

2015 Facility of the Year for Project Execution

AstraZeneca Supply Site Project Taizhou, China

Cockram Projects China would like to thank AstraZeneca and other project consultants for their support during the Construction Management of the AstraZeneca Supply Site Project.

Through our combined efforts, the 533,000ft² Manufacturing Facility was constructed within 20 months with zero OSHA recordable incidents in 3.26M working hours.

CATEGORY
Project Execution

LOCATION
Taizhou, China

CONSTRUCTION MANAGER
Cockram Projects China

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Winner 2015 Facility of the Year category "Project Execution"

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Facility of the Year Awards

2015

Astellas Pharma, Inc.
Equipment Innovation
Tube Packaging and Labeling Equipment Project
Kerry, Ireland

AstraZeneca China
Project Execution
Market Supply Solid Dose Facility
Taizhou, China

IDT Biologika GMbH
Facility Integration
Biologics and Vaccines Production Facility
Dessau, Germany

Pharmalucence Pharmaceuticals
Honorable Mention:
Execution and Entrepreneurial Spirit Construction of New Aseptic Filling Facility
Billerica, Massachusetts, US

2014

Boehringer Ingelheim Pharma GmbH & Co. KG
Equipment Innovation
Aseptic Area 5 and Combi Line Facility
Biberach, Germany

F. Hoffmann – La Roche Ltd.
Sustainability
B250-Q2K Facility
Kaiseraugst, Switzerland

Grifols Therapeutics Inc.,
Project Execution
Grifols North Fractionation Facility
Clayton, North Carolina, US

Patheon Pharma Services (formerly DSM Biologics)
Process Innovation
Biologics Plant of the Future
Brisbane, Australia

Penn Pharmaceutical Services Ltd.
Facility Integration
Project PennDragon- Contained Manufacturing Facility
Tredegar, South Wales, UK

Pfizer Ireland Pharmaceuticals
Operational Excellence
NSI Capacity Expansion
Grange Castle, Dublin, Ireland

WuXi Apptec Pharmaceutical of China
Honorable Mention:
Process Innovation
Fully Single Use mAB Production Facility
Wuxi City, China

2013

Biogen Idec
Facility Integration
Flexible Volume Manufacturing Project RTP
North Carolina, US

F. Hoffmann – La Roche Ltd.
Project Execution
TR&D – Building
Basel, Switzerland

MedImmune
Equipment Innovation
UK Automation Upgrade Project
Speke, Liverpool, UK

Merck & Co., Ltd.
Operational Excellence
Vaccine and Biologics Sterile (VBSF) Project
County Carlow, Ireland

Morphotek, Inc.
Sustainability
Pilot Plant
Ambler, PA, US

Novartis Vaccines and Diagnostics
(Overall Winner)
Process Innovation
Flu Cell Culture Facility
Holly Springs, North Carolina, US

2012

Chiesi Farmaceutici S.p.A.,
Sustainability
Chiesi Farmaceutici Research and Development Centre Facility
Parma, Italy

Eisai Pharmatechnology & Manufacturing Pvt. Ltd.
Project Execution
Eisai Knowledge Centre Facility
Andhra Pradesh, India

Merck & Co., Inc.
(Overall Winner)
Facility Integration
Merck Vaccine Bulk Manufacturing Facility (VBF) Program of Projects
Durham, North Carolina, US

Rentschler Biotechnologie GmbH
Equipment Innovation
REX III Manufacturing Facility
Laupheim, Germany

Roche Diagnostics GmbH,
Operational Excellence
TP Expand Project
Penzberg, Germany

National Institute for Bioprocessing Research and Training (NIBRT)
Special Recognition:
Novel Collaboration for its New Greenfield Facility
Dublin, Ireland

2011

F. Hoffmann – La Roche Ltd.
Process Innovation
"MyDose" Clinical Supply Facility
Kaiseraugst, Switzerland

MedImmune, LLC
(Overall Winner)
Project Execution
Frederick Manufacturing Center (FMC) Expansion Facility
Frederick, Maryland, US

Merck and Co., Inc.
Facility Integration
Global Clinica Supplies Manufacturing, Packaging and Warehouse Expansion Project
Summit, New Jersey, US

Novartis Vaccines and Diagnostics GmbH
Equipment Innovation
"MARS Project" (Marburg Site) Facility
Marburg, Germany

Pfizer Health AB
Operational Excellence
Project Pegasus – Bio 7 Manufacturing Facility
Strängnäs, Sweden

Pfizer Manufacturing Deutschland GmbH
Sustainability
SPRING and E-MAP (Strategic Plant Restructuring and Energy Master Plan) Project
Freiburg, Germany

Shire HGT
Honorable Mention
Project Atlas, Building 400 Facility
Lexington, Massachusetts, US

11 Years of Innovation

2010

Biogen Idec
Operational Excellence
North Carolina, US

Genentech
(Overall Winner)
Project Execution
Tuas, Singapore

MannKind Corporation
Equipment Innovation and Process Innovation
Connecticut, US

Pfizer Biotechnology Ireland
Sustainability
County Cork, Ireland

Pfizer Ireland Pharmaceuticals
Facility Integration
Dublin, Ireland

2009

Aseptic Technologies
Equipment Innovation
Gembloux, Belgium

Centocor Biologics Ireland
Sustainability
Ringaskiddy, Cork, Ireland

Centocor R&D Schaffhausen
Facility Integration
Schaffhausen, Switzerland

hameln pharma
Operational Excellence
Hameln, Germany

Orchid Chemicals & Pharmaceuticals
Regional Excellence
Aurangabad, India

Roche Pharma Biotech Production Basel
(Overall Winner)
Project Execution
Basel, Switzerland

2008

Boehringer Ingelheim Pharma GmbH & Co. KG
Facility Integration
Biberach, Germany

Bristol-Myers Squibb
Equipment Innovation
New Brunswick, New Jersey, US

IDT Biologika GmbH
Operational Excellence
Dessau-Rosslau, Germany

Pfizer Manufacturing Deutschland GmbH
(Overall Winner)
Process Innovation
Illertissen, Germany

F. Hoffmann La Roche AG
Project Execution
Basel, Switzerland

2007

Cook Pharmica, LLC
Facility Integration
Bloomington, Indiana, US

Genentech
(Overall Winner)
Project Execution
Oceanside, California, US

Shanghai Roche Pharmaceuticals, Limited
Project Execution
Regional Excellence
Shanghai, China

Taiyo Pharmaceutical Industry Co., Ltd.
Equipment Innovation
Takayama City, Japan

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

2006

AstraZeneca
Large Scale Laboratory (LSL) Project
Macclesfield, UK

Baxter BioPharma Solutions
(Overall Winner)
Phase IV Vial and Syringe Filling Project
Bloomington, Indiana, US

Daiichi Asubio Pharma Co., Ltd.
NBP (New Bio Plant) Project
Tokyo, Japan

Janssen Pharmaceutica
Small Volume Area Facility
Geel, Belgium

Wyeth Pharmaceuticals
The Wyeth BioPharma Campus at Grange Castle Project
Dublin, Ireland

Biolex Therapeutics
Special Merit Recognition:
Pittsboro Phase II Facility Expansion Project
Pittsboro, North Carolina, US

2005

Alkermes, Inc.
Brickyard Square Manufacturing Site
Cambridge, Massachusetts, US

Apotex, Inc.
Expansion to its Etobicoke, Ontario Manufacturing Facility
Winnipeg, Manitoba, Canada

KOWA Company Ltd.
New addition to its Manufacturing Plant for Oral Solid Dosage Products
Nagoya, Japan

Lundbeck Pharmaceuticals Ltd.
New Manufacturing Facility at Seal Sands, Middlesborough, UK
Copenhagen, Denmark

Novo Nordisk A/S
(Overall Winner)
New Manufacturing Plant
Hillerød, Denmark

New capacities and globally recognized competencies

Advance Vaccines and Biotherapeutic Projects with IDT Biologika

2015
Facility of the Year Awards
CATEGORY WINNER
Facility Integration

IDT Biologika, a major manufacturer of human vaccines, completed and certified the construction of a large-scale production facility dedicated to filling and lyophilization of biologics and vaccine products. With this new infrastructure IDT Biologika provides capacities for large scale commercial filling and freeze-drying of new recombinant and modified live human vaccines.

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Am Pharmapark
06861 Dessau-Rosslau
Germany

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fax: +49 (0) 349 01 88 55 323
www.idt-biologika.com

IDT Biologika

Using state-of-the-art technology to achieve business growth while promoting patient safety

IDT Biologika is an innovative privately-held company with more than 90 years of experience in research, development, manufacture and distribution of biologics for the global protection of human and animal health. For almost 20 years, the company has been manufacturing live vaccines for phase 1 and phase 2 clinical trials. In 2014, IDT Biologika completed a project that now allows them to manufacture for both late stage clinical trials and contract manufacturing for commercial supply.

The company had developed expertise through its focus on recombinant and non-recombinant live vaccines for early stage clinical trials designed to address some of the world's most dangerous infectious diseases. These vaccines require advanced technology to manufacture as well as specific environmental conditions to prevent cross-contamination. As their expertise grew, IDT Biologika was able to develop some of its products for Phase 3 clinical trials as well.

"The question we got from some of our customers was how far we would be able to manufacture these products for commercial supply as well," said Dr. Andreas Neubert, Vice President of Vaccines at IDT Biologika.

Seeing the opportunity to grow the business in a new way, company management took the decision to construct a new large-scale production facility dedicated to filling and lyophilization of biologics and vaccine products. A mere three years from ground-breaking, the facility is certified to biosafety levels (BSL) 1 and 2 for live vaccines. It was inspected for GMP certification in July 2014, qualified (for IQ, OQ and PQ) in September 2014, and authorized for manufacturing in October 2014; it is now fully operational.

Built with future expansion in mind

The 40 million Euro building equipped with a 12 million Euro isolator filling unit expanded the company site in Dessau, Germany from two to three buildings and provided the capacity for large scale commercial filling and freeze-drying of new recombinant and modified live human vaccines. The

IDT Biologika

Category Winner – Facility Integration

Project:
Multipurpose Biologics and Vaccines Production Facility (Isolator Vaccine Filling Unit)

Location:
Dessau-Rosslau, Germany

Project Mission:
Live human viral vaccine filling facility

Site information:
25,000 m^3 building volume; 1,600 m^2 cleanroom area

facility was designed with future expansion in mind. Two additional freeze dryers can be added to the existing filling line and a second filling line with two freeze dryers is also expected.

“This will enable us to produce two products at the same time and to have the necessary scale for future commercial products,” said Dr. Neubert. “The good news is that we already have customers who need that capacity.”

In terms of patient care, Dr. Neubert says that it all about safety. A system with multiple process control tools has been implemented. Continuous particle and microbiological tests, repeated camera inspections, 100% fill volume controls, vial coding and washing of capped vials assure the highest quality filled vaccines. “These are all parameters that improve the safety for the patient,” concluded Dr. Neubert.

Project Overview

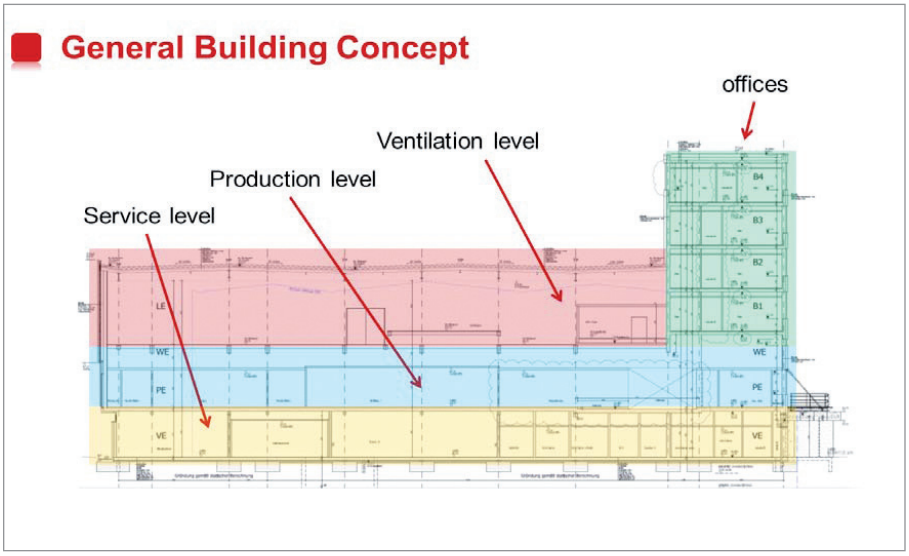
The new multipurpose biologics and vaccines production facility building was constructed at the IDT Biologika BioPharmaPark, located in Dessau-Rosslau in Saxony-Anhalt, taking advantage of existing site infrastructure. The BioPharmaPark company network minimizes business risks and builds on expertise, know-how and long-term market experience with the goal of strengthening the existing company network for further development of biotech and pharmaceutical businesses. The newly constructed and purposely-designed facility represents a best-in-class and innovative facility. It utilizes purpose-built “state-of-the-art” production and processing equipment, housed within an optimized building for the unique application and process flow for the company’s current and future products.

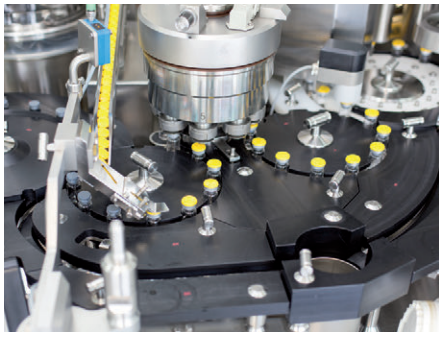
From the 100% process control vial transport system, state-of-the-art freeze-drying components featuring innovative loading and unloading systems, and industry leading aseptic BSL 2 isolator technology, coupled with unique strategy devised to guarantee the shortest supply and disposal routes, this new multipurpose biologics and vaccines production facility achieves maximum benefit from the innovative equipment utilized in the project for biomedical products manufacturing.

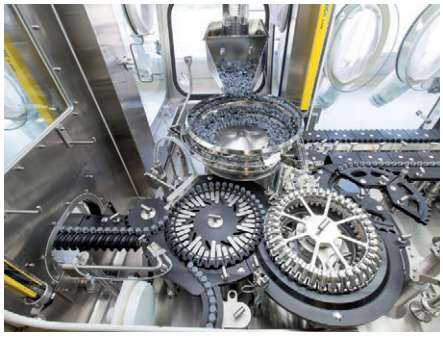
Designed for efficiency

The unique building concept is based on three physical levels. The purposed concept behind the multipurpose facility consists of strict horizontal division of the service areas and the serviced areas. A unique strategy was devised to guarantee the shortest supply and disposal routes: the production area is located at the building’s center with a maintenance level and air conditioning systems located above and the media supply for the productions area below. All operations are contained to the extent possible in cleanrooms and in closed technical systems.

Design of the integrated equipment suite represents significant contributions in operational excellence, including three isolator segments for high flexibility and fast product changes, resulting in efficient product change over and increased efficiency. Utilizing industry leading aseptic isolator technology, high level safety is achieved for product change over and eliminates risk of cross contamination. IDT’s use of isolator technology achieves reduced costs associated with environmental monitoring for reduced cost of goods, reduced working capital, and reduced cycle time.







Ambitious timeline

Key to achieving the aggressive project timeline represents significant contributions in excellence in project execution, as the project management principal that brought together experts from the operating company, quality assurance, general contractor, architect, and technical planning firm (designer) into a joint project team and proved decisive in the project's success. The group project discussions were held as regular meetings. Tasks regarding technical issues were dealt with in separate discussions and then announced and presented in the meetings. The contract giver's management was informed of the project's status (budget, deadlines, and decisions) in monthly reports. Budget control was conducted by the general contractor according to the principles of German norm DIN 267, confirmed by the contract giver's controlling department, and evaluated at the meetings.

"Our target was to streamline all processes," said Dr. Neubert. "We had a project plan with a matrix for all different types of equipment and activities to organize our team. We also had teams follow-up on technical challenges in areas where we expected risks and others where we did not expect risk. It was all done with a good project management approach."

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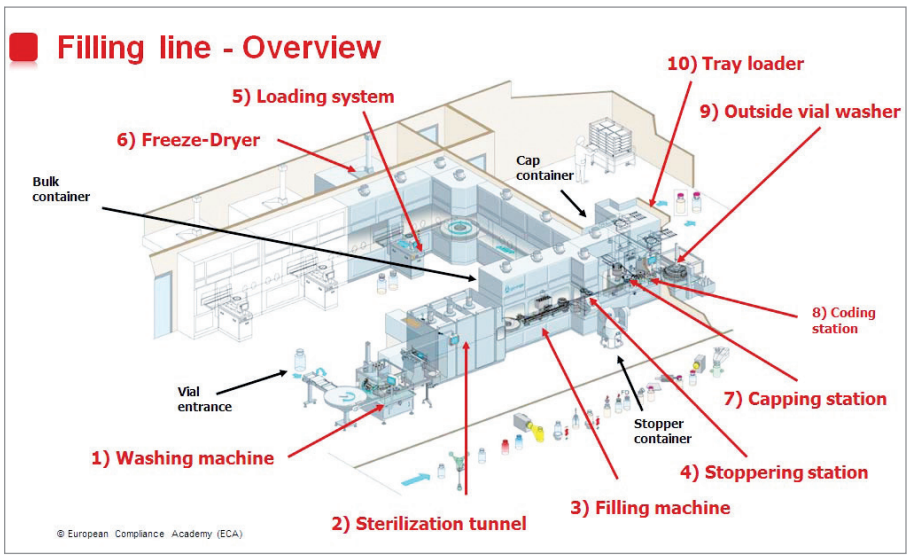
The construction timeline for the project initiated with ground-breaking on 14 April 2011, and proceeded through the mechanical completion date of 1 September 2013, resulting in a fully integrated facility. The facility was designed and commissioned for use in a range of advanced biomedical technologies required in medium to large clinical stage and commercial stage volumes, including a sterile liquid filling line engineered to handle up to 24,000 vials per hour, and certified to biosafety levels (BSL) 1 and 2 for live vaccines, featuring a 1,600 m^2 cleanroom area. Inspected for GMP certification in July 2014, qualified (for IQ, QQ and PQ) in September 2014 and authorized for manufacturing in October 2014, the new facility is now fully operational.

To support growth and expansion, BioPharmaPark offers on-site resources that include health and safety protection, personnel services, finance and accounting services, and support for legal and regulatory requirements compliance services among others. Technical resources include on-site water supply and waste water conditioning facility, energy and media supplier, waste management services and maintenance of facilities such as planning and implementation of complex investment projects.

IDT Biologika now offers one of the most dynamic facilities designed for biomedical products manufacturing. Its vaccine development team are experts in live viral vectors increasingly utilized in the development of novel vaccines, making the company a fully integrated development and production operation at one site, an essential requirement of time sensitive projects. Accordingly, the company is able to accommodate the development, testing and manufacture of vital vaccines and other biological products for the world's leading biopharmaceutical industries.

FOYA Judges Panel Conclusion

"The highly automated manufacturing facility for filling and freeze-drying is designed to be modular, efficient and expandable. The site's layout was devised to guarantee the shortest supply and disposal routes. Design of the integrated equipment suite represents significant contributions in operational excellence resulting in efficient product change over and increased efficiency."



In Their Own Words

The following is an excerpt from IDT Biologika's submission, stating the top reasons why their project should win the ISPE 2015 Facility of the Year Award:

Project Execution

New scalable multi-product facility for manufacturing of future biopharmaceuticals and vaccines

The new scalable multi-product facility for manufacturing of future bio-pharmaceuticals and vaccines was built to extend and provide capacities for large scale commercial filling and freeze-drying of live human vaccines, with the objectives of flexibility, use of state-of-the-art technology, and comprehensive regulatory compliance. With the completion of this facility, IDT Biologika is equipped to manufacture up to 100 million vials per year of freeze-dried and liquid presentations for growth well into the future.

Highly automated manufacturing facility for filling and freeze-drying

The highly automated manufacturing facility for filling and freeze-drying is designed to be modular, efficient and expandable. The purposed concept behind the multipurpose facility consists of strict horizontal division of the service areas and the serviced areas. A unique strategy was devised to guarantee the shortest supply and disposal routes. All operations are contained to the extent possible in cleanrooms and in closed technical systems.

Certified for operations with live recombinant or non-recombinant vaccines up to biosafety level 2

The new facility is certified for operations with live recombinant or non-recombinant vaccines up to BSL 2. Designed as a multi-product facility, certification for assurance of aseptic processing and containment with control of cross-contamination was a design cornerstone.

High speed filling line with integrated real time process control and quality assurance technologies for up to 24,000 vials per hour

Designed to meet the future growth potential in vaccine production volumes, driven by increasing health-care market demands, current and future regulatory requirements, and the need to operate efficient state-of-the-art facilities, the new facility integrates a state-of-the-art high speed filling line with integrated real time process control and quality assurance technologies for up to 24,000 vials per hour.

A fully automated loading and unloading freeze-dryers

Key to the efficiency of the new facility is a fully automated loading and unloading freeze- dryer at shelf capacity of 40m^2 each, equal to at maximum 178,000 vials per batch that is fully integrated into the isolator. The fully automated system for loading and unloading is fully automatic, allowing for transfer line by line. The unloading system is segmental with separation possible, allowing for tracing of all segments.

Key project participants	
Manufacturer / Owner	IDT Biologika GmbH Am Pharmapark 06861 Dessau-Rosslau Germany
Designer/Architect	HEENE + PRÖBST GMBH Berthold-Schwarz-Straße 26 D-67063 Ludwigshafen / Rhein Germany
Engineer	BIDECO Bio- und Pharmasysteme GmbH Jarekstrasse 7 D-88400 Biberach (Riss) Germany
Construction Manager	HEENE + PRÖBST GMBH Berthold-Schwarz-Straße 26 D-67063 Ludwigshafen / Rhein Germany
Main/General Contractor	TEW Servicegesellschaft mbH Am Pharmapark D-06861 Dessau-Rosslau Germany
HVAC Subcontractor	Daldrop + Dr.Ing.Huber GmbH + Co. KG Daldropstraße 1 D-72666 Neckartailfingen Germany
Automation and Control Supplier	Neuberger Gebäudeautomation GmbH Oberer Kaiserweg 6 D-91541 Rothenburg Germany
Major Equipment Supplier(s)/ Contractor(s)	groninger Pharma groninger & co. gmbh Hofäckerstraße 9 D-74564 Crailsheim Germany
Major Equipment Supplier(s)/ Contractor(s)	HOF Sonderanlagenbau GmbH Ludwig-Rinn-Str. 1-3 D-35102 Lohra Germany
Major Equipment Supplier(s)/ Contractor(s)	SKAN AG Binningerstrasse 116 Allschwil 4123 Switzerland

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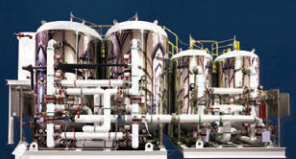
Carbon Filters & Softeners


Vapor Compression


Ultra Filtration


Reverse Osmosis


MASTERpak™

Pharmalucence

Navigating through a perfect financial storm with entrepreneurial spirit

For many, the summer of 2007 was the dawn of difficult times; financial markets were on the verge of collapse and the world would soon be drawn into a long recession. For Pharmalucence, however, the financial crisis in many ways represented a perfect storm; an opportunity for the company to capitalize on its management's entrepreneurial spirit and transform the way it does business.

Pharmalucence was created in 2007 through a management buyout of CIS-US, Inc. by three long-term employees who shared the vision to become both an advanced contract manufacturing organization (CMO) and a leading manufacturer of radiopharmaceuticals.

The assets acquired from the buyout included a legacy manufacturing operation at one of four separate leased facilities. This presented a challenge on two fronts. First, the facilities were in critical need of modernization and second, the four-facility scenario created numerous operational inefficiencies. For example, warehousing, primary manufacturing, packaging, quality and administration were spread between various buildings.

Pharmalucence Inc., a Sun Pharma Company

Honorable mention

Project:
Aseptic Fill-Finish Facility

Location:
Billerica, MA, USA

Project Mission:
To replace the existing manufacturing facility and consolidate all operations into a single-owned building to secure the current product line and allow for future business growth. Design of the new manufacturing facility to provide a minimum ten-year worldwide compliant design.

Site information:
70,000 sq. ft (6,500 m^2)

Significant change was needed to ensure the long term availability of the company's product supply and the viability of their business. Given limited financial resources their challenge was to effectively plan, prioritize and implement the upgrades needed for full regulatory compliance and product supply integrity all within a competitive business model.

"We saw the need for a new infrastructure, the need to secure the jobs of our colleagues and find a way to make it all happen," said Ed Connolly, Vice President of Operations at Pharmalucence, when asked about the entrepreneurial approach taken by the company. "Throughout this project, our mantra was that patient safety is number one; and by keeping that as the focus, everything else would work out."

Pharmalucence partnered with IPS (Integrated Project Services, Inc.), a full service engineering company, to develop a strategic business model and execution plan. Weighing options, they took the bold financial and technical step to consolidate their four existing operations into a single modern facility. They identified an existing facility large enough for their objectives and near enough to retain existing staff.

When the time had come to acquire the facility, the company benefitted from what could be seen a perfect storm of circumstances arising from the ongoing financial crisis. "We had some fortunate timing in that we were able to secure a low interest bond from the state and because the economy was doing so poorly, the pricing on some of the equipment was very favorable," said Connolly. "Also, the pricing of the building we acquired was significantly less than when we initially looked at it."

Nonetheless, financial capital was limited and new revenue generation would have to come from the investments. Expansion into the CMO business was seen as a solid basis for projecting the revenue by leveraging a state-of-the-art operation.

"We had the luxury of having a profitable core product line, which provided us cash flow during the build-out," said Connolly. "We saw the growth of contract manufacturing as very compatible with maintaining our existing products and adding revenue through the CMO business."

▸When the time had come to acquire the facility, the company benefitted from what could be seen a perfect storm of circumstances arising from the ongoing financial crisis.◂

Project Overview

To build and integrate their facility with limited resources, Pharmalucence developed a strategy that leveraged a turnkey Guaranteed Maximum Price ($GMP) project delivery systems with cutting edge advanced aseptic process technology, facility design based on new Quality by Design (QbD) principles, validation using risk assessment principles, and innovative financing leveraging the government's stimulus program. This project's success relied on all five of these approaches came together in an integrated approach to create a fully compliant state-of-the-art facility.

The five part facility integration program was initiated in the second quarter of 2010 and successfully implemented in the fourth quarter of 2014.

The company identified an existing vacant 70,000 square foot building shell in nearby Billerica, Massachusetts that met the required financial criteria and geographic proximity to the existing facility for employee retention. It was large enough for the complete integration of the operations from the four existing buildings into this one building. Upon build-out, it would also contain space for future growth considerations. The project resulted in a state-of-the-art facility with improved operating efficiency, reduced operational risks, reduced operating costs, increased manufacturing capacity, greatly reduced regulatory compliance risk, flexibility for growth and a sustainable business model.

The strategic plan was successfully completed by:

Project Delivery
Contracting with IPS (IPS-Integrated Project Services, Inc.) for a full EPCMV (Engineering, Procurement, Construction Management and Validation) contract based on Guaranteed Maximum Price ($GMP) allowed Pharmalucence to meet their initial cost limitations by implementing a target cost approach during the design phase while controlling project spending on the extremely tight capital budget during the execution of the project.

Process Technology
Pharmalucence implemented a fully integrated aseptic filling line for both liquid and freeze dried vials based on isolation technology. A detailed concept phase analysis of isolator verses RABS technology showed that in this case, project level costs were $5 milion less for isolator technology; the RABS option actually exceeded the project budget. The projected operational savings provided by isolation technology also allowed the project to meet the financial objectives for a legacy product manufacturer.

QbD Based Facility Design
The facility design integrated a unique and cutting-edge design process that is based on newly defined ICH QbD principles starting with the end in mind, which proved to minimize any design changes throughout the project implementation. This process begins integrating the business strategies with the project operating and engineering objectives, followed by detailed definition of all operating philosophies and procedures prior to commencing with any engineering design.

Risk Based CQV
A risk based CQV (Continuous Quality Validation) approach was fully implemented on this project resulting in a lean process along with the reduced validation costs required by the project budget.

Innovative Business Plan
The Pharmalucence management team successfully obtained a Stimulus Program backed loan, local tax incentives and a favorable real estate market associated with the economic market conditions that existed in 2010 to generate an innovative financial package. The management team then integrated the cutting-edge lean QbD design and validation processes with the GMP project delivery system for an integrated design to cost control program.

"For me, this is the best project I've ever been involved with," said designer/architect Sterling Kline of IPS. "They used recently-proven technology on the cutting edge, so for the next 20 years, they know that they'll be sound. I have other clients who are now looking at Pharmalucence as a role model."

The project has indeed been a resounding success, in pure business terms and in workforce expansion. "During such trying financial times, when everyone else was laying people off, we grew from 70 employees to 100," concluded Connolly.

Initial marketing of CMO services was enthusiastically received by the pharmaceutical industry. So much so that during this promotional period, the business and facility came to the attention of Sun Pharmaceutical, who moved to purchase the company. The transaction closed on 15 July 2014.

Going forward, this project can serve as an industry business model for the replacement of legacy facilities with legacy products that are at risk of stock outages or at risk of losing market opportunities.

▸ Our mantra was that patient safety is number one; and by keeping that as the focus, everything else would work out. ◂

FOYA Judges Panel Conclusion

"Pharmalucence is honored for accepting risk and succeeding in building a new facility that effectively addressed the market shortage for low margin legacy and generic radio-pharmaceutical products. Through good planning and prioritization they met the challenge of balancing investment, appropriate compliance, efficient operations and business viability."

In their own words

The following is an excerpt from Pharmalucence's submission, stating the top reasons why their project should win the ISPE 2015 Facility of the Year Award:

The Pharmalucence Business and Facility Integration Project provides a business case to solve the legacy facility, legacy product, drug shortage problem: This project will have a major impact on the pharmaceutical industry by providing an economically viable approach to delivering cost sensitive drugs by manufacturing in a state-of-the-art facility utilizing cutting edge processes while meeting internationally harmonized regulatory compliance expectations. This project team was able to define and implement this low cost, compliant and reliable supply model solution for drug shortage prevention while the rest of the industry was just defining the root cause and prevention program.

The first project to use an innovative integrated facility ICH QRM design approach to QbD: This project utilized risk based analysis for all key design decisions from the point of inception. Facility integration based design decisions for technology and facility layout were all evaluated and documented against business, operational, technological and financial risk throughout the entire design process eliminating design changes and forming the basis for an integrated CQV process. This project design process is likely the first practical model of the QbD design process alluded to in the ICH Q8, 9, and 10 documents.

Synergistically merged facility and process technologies to meet the regulatory requirements for integration, separation and automation: This project has utilized a fully integrated filling line that incorporates isolation technology, single-use product contact parts, automated lyophilizer loading and unloading, and 100% check-weighing. The design integrates the facility with the equipment with a modular panel system that allowed for accelerated installation, walkable ceiling to access the integrated isolator and the flexibility for the addition of a second future lyophilizer without disruption to the new lines' production schedule.

Developed and implemented a new superior conceptual planning process based on predefined operating philosophies and processes: This project utilized a cutting edge design process that is based on an ICH Q9 risk based approach. The process defines and documents, in order, the business mission; project mission; business, operational and engineering objectives; all operational philosophies; products and product parameters; the manufacturing processes and then the traditional engineering design process begins. This process ensures you begin with the end in mind and results in fewer design changes and a significantly shorter design process.

Utilized a fully integrated, $GMP based turnkey project delivery approach that prioritized schedule, outsourced capital risk and secured regulatory compliance: An integrated design-build-validate package was awarded to IPS. The lean, integrated approach allowed for an accelerated schedule that was required to meet rapidly ending leases. The $GMP contract limited Pharmalucence's budget risk, and the design firm's portfolio of regulatory approved barrier technology driven designs ensured minimal compliance risk.

Key project participants	
Manufacturer / Owner	Pharmalucence Inc., a Sun Pharma Company Edward Connolly
Designer/Architect	IPS-Integrated Project Services, Inc. Sterling Kline
Engineer	IPS-Integrated Project Services, Inc. Andy Haines
Construction Manager / Commissioning and Validation	IPS-Integrated Project Services, Inc. John Costalas

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