

**Xcellerex** 

INDUSTRY
Life Sciences

# Goals

- Address the growing demands in the biomedical market space for more effective biopharmaceutical manufacturing processes
- Develop a solution that would define a model for improving how biopharmaceuticals, vaccines and other therapeutics are developed, manufactured and commercialised

# Challenges

 Integrating complex technology with ultra-high levels of functionality was considered the greatest challenge in creating a biomanufacturing platform that employs a single-use technology, controlled environment modules, process automation and electronic batch records

## **AVEVA Solution**

- System Platform
- InTouch HMI
- Batch Management
- Historian

## Results

- Xcellerex's FlexFactory enabled companies to achieve significant cost savings in several areas, including a capital investment reduction that can exceed 60 percent
- The solution decreased the facility space required by 40 percent, lessened water usage and waste by 85 percent, and lowered the overall cost of finished products by 32 percent
- FlexFactory reduced deployment time from 3-5 years to 12-18 months, which enabled the production of high value products 2 to 4 years sooner than traditional technology
- The solution achieved an overall reduction in development time of nearly 60 percent, with an estimated 80 percent saving in rework time, which reduced costs and shortened time-to-market



MARLBOROUGH, Massachusetts - Xcellerex is revolutionising the way biopharmaceuticals and vaccines are developed, manufactured and commercialised with the development of FlexFactory, a manufacturing platform designed to enhance production of these critical biopharmaceutical products. During the development stages of this pharmaceutical production solution, Xcellerex quickly identified the need to integrate single-use technology, controlled environment modules, process automation and electronic batch records into its FlexFactory platform.

Xcellerex identified Wonderware by AVEVA software as ideal for integrating with this new, innovative manufacturing technology platform. Xcellerex selected System Platform powered by Wonderware as the backbone of the complete biopharmaceutical automation software application.

Other AVEVA solutions included InTouch HMI powered by Wonderware, Batch Management to provide effective batching operations and Historian powered by Wonderware to serve as the system's powerful application to maintain historical production data.

The integration of AVEVA software components has enabled Xcellerex to offer customers significant improvements in production processes, including 70 percent faster deployment, 75 percent reduced capital investment and an unmatched level of flexibility. Years of single-use biomanufacturing experience enabled Xcellerex to design and integrate a solution offering an efficient, highly functional biomanufacturing technology platform.

"FlexFactory from Xcellerex enables customers to reduce capital investment by more than 60 percent," said John A. Chickosky, Chief Commercial Officer and President of Biosystems at Xcellerex. "FlexFactory is able to decrease the actual space needed to build a manufacturing facility by 40 percent, lessen water usage and waste by 85 percent and lowers the cost of goods sold by 32 percent."

"With the integration of AVEVA's software, Xcellerex has been able to deploy FlexFactory® manufacturing capacity, very quickly, resulting in an overall reduction in development time of nearly 60%. This directly impacts customers with reduced costs and shorter time-to-market. In fact, we've been able to reduce deployment time from 3-5 years to an amazing 12-18 months. This results in huge implementation savings and the ability to begin producing high value product 2 to 4 years sooner than traditional technology."

John A. Chickosky Chief Commercial Officer and President of Biosystems Xcellerex

#### **Examining a Changing Market**

The biomanufacturing market is currently undergoing enormous growth and change. Previous manufacturing models can no longer address the expectations and standards of this evolving industry. Instead, companies such as Xcellerex chose to reevaluate the biomanufacturing process and develop strategies designed to greatly improve overall efficiencies.

In the old business model, much of the cost came from the need to maintain clean, sterile conditions in process vessels as well as to preserve air quality in large-scale manufacturing suites. This required a manufacturing facility to invest \$100 to \$300 million and spend three to five years in the validation process before a single product could be developed for commercial sale.

With the single-use technology from AVEVA, deployment time has been reduced to a remarkable eight to twelve months. This results in significant implementation savings and the





ability to begin producing high-value products two to four years sooner than what was achievable using conventional technology.

"Xcellerex advances in developing innovative manufacturing solutions has revolutionised the way companies are starting to manufacture the drugs that we use," said Darren Kline, Director of Marketing and Business Development at Wonderware North. "FlexFactory has tremendously accelerated the time of building a plant, reducing on average from several years to only several months."

### **Excelling Toward a More Efficient Future**

Xcellerex utilises patented process equipment in conjunction with the Wonderware by AVEVA software to achieve a highly productive and profitable manufacturing process to bring pharmaceutical products to market. The Wonderware by AVEVA software provides reusable object oriented technology, which enables a reduction in time to test, validate and debug the system throughout a customer's facility.

The software gives Xcellerex a more efficient technology framework, while ensuring the highest quality in biomanufacturing. In 2010, Xcellerex was awarded the Grand Pinnacle Award during the AVEVA Operations Management Open contest, in a field of 40 competing entries. Xcellerex has proven to be a leader in operational excellence while remaining both efficient and innovative.

#### The Solution for Winning - Wonderware by AVEVA

To achieve significant implementation savings and accelerated production, FlexFactory is strategically integrated with Wonderware software, resulting in a system designed to provide a business benefit in the shortest period possible.

With System Platform powered by Wonderware, FlexFactory provides a single, scalable software solution for all the SCADA, supervisory HMI and MES needs of biomedical industry automation and information personnel. By featuring an industrialised application server, a powerful historian server and an

easy-to-use Historian Clients, System Platform offers unparalleled connectivity for demanding, precisiondriven real-time biomanufacturing environments.

"The biggest benefit for Xcellerex is Wonderware's comprehensive object architecture functionality," said David Mills, Senior Director of MES and Automation at Xcellerex. "This feature adds tremendous value to Xcellerex and its customers by providing a unified architecture across all different types of process designs."

Users of FlexFactory are able to create application standards via System Platform with the development of templates for re-use in any application with similar functionality. System Platform enables the creation of standardised templates resulting in reduced training time and lower costs while driving consistency and quality across the enterprise.

It also features Historian powered by Wonderware, a high-performance real-time database for historical information. This software component enables process and performance decisions to be evaluated and made by management in real-time.

Xellerex's application also features InTouch HMI powered by Wonderware, which provides advanced graphic visualisation. InTouch HMI is designed to maximise productivity, optimise user effectiveness, increase quality and lower development, maintenance and operational costs by featuring custom graphical views of real-time industrial processes.

The software solution also includes Batch Management, which enables users to deploy batch functions that adhere to the ISA S88 flexible batching standard. Batch Management offers comprehensive batch execution and equipment history, material genealogy, stringent security, web-based reporting and the ability to facilitate the design and implementation of systems that are compliant with FDA 21 CFR Part 11 regulations.

"The Wonderware by AVEVA system is an excellent, comprehensive solution for Xcellerex and its FlexFactory technology," said Mills. "To make any system changes, operators simply



modify the object template once, and related objects are fixed across all instances saving us an additional 80 percent in rework time."

## Operational Excellence at its Finest

With the innovative strategies implemented by Xcellerex in its FlexFactory platform, the company has developed a solution that revolutionises the way pharmaceutical companies manufacture products vital to the health and well-being of the world's population.

This type of forward thinking is the cornerstone of operations excellence. The Wonderware by AVEVA software used in Flex factory from Xellerex have enabled biomanufacturing companies to achieve a significant overall reduction in development time of nearly 60 percent. This achievement directly impacts the customer's bottom line with substantially lower manufacturing costs and shorter time-to-market.

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#### **About AVEVA**

AVEVA is a global leader in engineering and industrial software driving digital transformation across the entire asset and operational life cycle of capital-intensive industries. The company's engineering, planning and operations, asset performance, and monitoring and control solutions deliver proven results to over 16,000 customers across the globe. Its customers are supported by the largest industrial software ecosystem, including 4,200 partners and 5,700 certified developers. AVEVA is headquartered in Cambridge, UK, with over 4,400 employees at 80 locations in over 40 countries.

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