



THE SUPERIOR CONTROLLER

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Massachusetts Biological Awards Automation Contract to Superior Controls

Massachusetts Biological Laboratories (MBL), a Jamaica Plains, Massachusetts-based FDA-licensed developer and manufacturer of biologic products, has signed a contract with Superior Controls to automate its new manufacturing facility being built in

Mattapan, MA. Superior Controls will design and implement MBL's Process Control System (PCS) to monitor and control the manufacturing of monoclonal antibodies as well as other biological products.

Superior Controls has chosen Elan's XFP Product to provide computer-based Electronic Work Instructions for operators and Intellution's iFIX, iHistorian, and infoAgent as their operator inter-

face, data collection, and web-based data analysis tools respectively. More than 20 networked Allen-Bradley PLCs will control and monitor equipment to perform cell culture and purification of monoclonal antibodies as well as filling and packaging of licensed and R&D stage liquid parenteral (injectable) products. In addition, wireless technology (802.11)

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"Superior Controls and their vendors are providing us with a flexible and powerful architecture to build on today and in the future as we move to paperless manufacturing in the years to come," said Weiner.



The Superior Controller is published by Superior Controls, Inc. of Plaistow, NH—the leading controls system integrator specializing in the design and implementation of industrial automation and information systems.

The purpose of this newsletter is to present project examples to our customers. Your comments are welcome. Write or Fax:

Superior Controls, Inc.

P.O. Box 977 ■ Plaistow, NH 03865
(603) 382-2000 ■ Fax (603) 382-0122

e-mail: eng@superiorcontrols.com

www.superiorcontrols.com

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Xcellerex and Superior Collaborate on Paperless Manufacturing

Xcellerex LLC in Marlborough, MA, a fast-growing contract manufacturer of Biologics, is improving the way business is done in contract manufacturing. In collaboration with Superior Controls, Xcellerex is designing automation and information systems for its manufacturing processes and business that will make critical information available to its customers through web interfaces. Superior Controls is providing consulting and technical resources to develop this paperless EFactory™ initiative.

Typically, a pharmaceutical or biotech company (the customer) that develops a potential drug therapy must test the drug in clinical trials as part of an FDA-required approval process. The customer often outsources the manufacture of this clinical drug supply to a contract manufacturing organization (CMO). The CMO implements the various process steps, such as media prep, buffer prep, seeding, cell culture production, harvesting, purification, and chromatography in strict accordance with the customer's instructions. But until now, there has been no easy way for customers to continuously monitor the process online to make sure that the CMO is following their detailed batch procedures and meeting their production requirements.

This communication gap with the CMOs has motivated several experienced manufacturing

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Excellerex and Superior Collaborate on Paperless Manufacturing

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scientists and engineers at Xcellerex to redesign the entire customer interface. Xcellerex has used these innovative manufacturing technologies to manufacture GMP products.

Xcellerex's proprietary manufacturing platform, called Flexmax™, is designed to rapidly produce biotherapeutics products for the clinical trial market. The process can also be used for biogenerics, personalized medicines, and vaccines. By using a unique combination of single-use manufacturing equipment and modular systems, Xcellerex is able to eliminate CIP, SIP, autoclaves, washers, and the other support equipment found in traditional, capital-intensive pharmaceutical facilities.

Phase I automation of the Xcellerex FlexMax™ platform, implemented partly by Superior Controls, used a PLC-based automation system to collect temperature, flows, and other critical process data from the seeding, production, harvesting, concentration, and chromatography steps and saved these electronic records to a SCADA system.

"We're collaborating with Superior Controls because of their focus and broad experience with automation projects for the BioPharm Industry. Their staff of 30+ engineers and ability to implement large automation projects with validation and GAMP4 documentation is a critical factor," says Galliher.

Phase II automation will make these electronic batch records available to customers through a web interface. Additionally, all documentation normally provided on

paper will become an electronic record. All critical manufacturing and business records, such as standard operating procedures, operator training status, validation, metrology reports, and work instructions will be placed on glass (the monitors), so they are transparent and easily available to the customers via a wide area network, in real time.

Parrish Galliher, President/CEO for Xcellerex, says, "We're collaborating with Superior Controls because of their focus and broad experience with automation projects for the BioPharm Industry. Their staff of 30+ engineers and ability to implement large automation projects with validation and GAMP4 documentation is a critical factor."

Xcellerex, although not yet a household name, is poised to revolutionize the way contract manufacturers service the BioPharm Industry.

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will be used to provide batch reports and work instructions to operators on the plant floor.

MBL, the fourth oldest biologic manufacturer in the U.S. today (established 1895), has a long history of developing and manufacturing biological products to reduce morbidity and mortality. These products include Smallpox Vaccine (1904), Typhoid Vaccine (1912), Scarlet Fever Antitoxin (1925), Tetanus Vaccine (1941), and in 1950 the first "combination vaccine," Diphtheria-Pertussis-Tetanus Vaccine. In the past 50 years, MBL pioneered a number of immune globulins including Hepatitis B (1972) and Cytomegalovirus (1990). In the past 20 years, MBL has

developed and produced "Orphan Products"—those products intended for limited populations (less than 200,000 patients per year).

The new manufacturing facility in Mattapan is the largest single expansion in MBL's history. "We have chosen a great team to implement the control system for our new manufacturing facility," said Larry Weiner, MBL Director of Engineering, continuing, "Superior Controls and their vendors are providing us with a flexible and powerful architecture to build on today and in the future as we move to paperless manufacturing in the years to come."

Superior Controls – First in Nation on Quality Audit

Superior Controls proudly announces that it is the first Level 1 System Integrator in the nation to pass the very rigorous "Best Practices and Benchmarks" quality audit performed through the Controls System Integration Association (CSIA) twice. Three years ago, Superior Controls was one of only 20 engineering firms to pass this audit (performed every three years). The audit focuses on six areas deemed critical by CSIA:

- General Management
- Human Resource Management
- Project Management
- Quality Management
- Financial Management
- Business Development

Customers consider these areas most important in their selection of a control system integrator for a long-term partnership.

Superior Controls was also the first Level 1, Registered Member (based on minimum sales and staff requirements) to pass this audit in New England. We are very proud to be the very first system integration firm in the country to pass this stringent audit again.

THE PEOPLE WHO ARE SUPERIOR CONTROLS

Six Professionals Join Superior Controls



Randy Olsson is a veteran automation engineer with more than 20 years of experience designing and implementing factory automation and process control solutions. While at the Foxboro Company,

Randy provided project engineering services implementing DCS systems; at Polaroid, he provided project engineering/project management services focused on batch and factory automation applications; and at Fidelity Investments, he developed mission critical financial applications. Randy has a MBA from Worcester Polytechnic Institute, a BS in Chemical Engineering from University of Lowell, and has completed additional graduate level studies in Computer Sciences.

Vivek Puthazath, a talented chemical engineer, holds an MS from the University of Mass-Lowell and a BS from Bangalore University. Vivek acquired extensive project design experience at CDI



Engineering in Boston; and plant support, maintenance, and installation experience at Seabrook Station in Seabrook, N.H. Vivek also worked as a process engineer at Sunshine Chemicals, where he developed manufacturing processes for adhesives. In addition, Vivek has done extensive research on pH control using neural networks.



Andrew Pineo is a seasoned professional with 22 years of hands-on experience designing and building automation systems. Andrew has spent time assembling and programming automated

assembly machines and ovens at Gould, Inc. He also led a team of technicians building control

panels and later provided engineering design support at Beckwood Services. Andrew served four years as a U.S. Army Squad Leader and for the past nine years, has consistently been one of the top runners on the Superior Controls' running team.

Wenyuan Wang is a talented electrical engineer with an MS and BS from the University of Mass-Lowell. His 10 years of experience include manufacturing improvement work at Teradyne, Inc., and International Power Devices. Wenyuan also acquired HPLC and polymer chemistry experience at Whalen Biomedical in Somerville, MA. Wenyuan joins Superior Controls on his brother Wentao's recommendation. He joined Superior Controls back in '00.



Weiwei Li (pronounced Wayway Lee) is a very knowledgeable controls engineer who this year is completing an MS in mechanical engineering from the University of Mass-Lowell. He holds an MS in telecommunications engineering from Shanghai, China, and a BS in automatic control engineering from Northwestern Polytech

in Xian, China. Weiwei worked for nine years in research and project management including a NASA project, a software project to analyze train operation in China, the development of computer-controlled safety software, and computer-controlled hydraulic systems. Weiwei has written and published six papers and one book (two chapters) on his research.

Prasad Joshi is a talented Electronics Engineer with 10 years of hands-on automation experience. Prasad recently automated the newspaper printing press at Heidelberg Web Systems in Dover, NH. He also has worked at Siemens and Integral Strategies, Inc. where he designed and started up PLC-based automation systems for: Steel Cold Rolling Mills (Bethlehem Steel); Bloom and Tube Furnaces (US Steel); Cement Plants (Portland Cement); Walking Beam Furnaces (China); and Bell Less Top Blast Furnaces (India), amongst other projects.



Team Superior Races for Ninth Year



For the ninth year in a row, Team Superior competed in the Cigna Corporate 5K (3.1 miles) Road Race in Manchester, NH, to benefit the Special Olympics.

On a beautiful August day, along with 6,400 other runners, Team Superior raced against its traditional competitor, Horizon Electric—and lost. Many running analysts are attributing this unusual loss to the two dozen Dunkin' Donuts sent by Horizon to Superior Controls disguised as “energy biscuits,” on the morning of the race. Regardless, all had a great time and Superior Controls is already in training for next year’s race.