



THE SUPERIOR CONTROLLER

VOLUME 11 ISSUE 1

Alkermes' New Facility: A Process Automation Success

Superior Controls engineers recently completed the design and installation of a major process automation system for Alkermes' new \$40 million pharmaceutical manufacturing facility (90,000 sq. ft.) located in Chelsea, MA. One of the first products to be produced at the new facility is an inhaled formulation of insulin for the treatment of diabetes.

"Superior Controls designed and implemented the entire GMP, validated automation system to control and monitor more than 2500 production process values . . ."

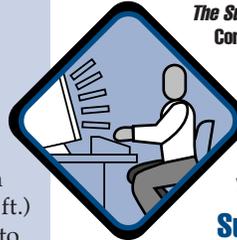
Alkermes, a Cambridge-based pharmaceutical company, is a world leader in the development of products based on sophisticated drug delivery technologies. One of these proprietary technologies involves the delivery of drugs to the lungs using pharmaceutical products based on Alkermes' inhaled Advanced Inhalation Research ("AIR") pulmonary delivery system. This technology produces particles with a low density, porous structure for efficient delivery to the lungs using a simple, convenient, breath-actuated inhaler.

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**1 of the 4 Operator Interfaces
for the Chelsea Facility**



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:

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University Targets Validation

When the University of MA-Lowell, Chemical Engineering Department decided to develop and teach a course on FDA BioPharma Validation requirements they turned to their Board of Advisors.

Bob Konopacz, Senior Director of Manufacturing at Wyeth, Joe Musiak, Associate Director of Process Engineering at Biogen IDEC, and Rick Pierro, President of Superior Controls volunteered to form a Validation Subcommittee and, with Professor Carl Lawton, the team developed an outline for the Validation Course. In addition,



Bob Konopacz
(Senior Director of Manufacturing, Wyeth)

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In collaboration with Eli Lilly, Alkermes is using the AIR system to develop an inhaled formulation of insulin for the treatment of diabetes and is also developing other partnered and proprietary products. This effort required the renovation of a 100-year-old building in Chelsea, MA and the creation of a 90,000 square foot, fully validated production facility.

The manufacturing process involves a sophisticated spray drying operation along with specialized formulation, handling, and filling processes for the low density and easily aerosolizable inhalation product. Capsule filling operations are also performed at the Chelsea facility.

Superior Controls designed and implemented the entire GMP, validated automation system to control and monitor more than 2500 production process values with Alkermes' and PFI personnel. The networked system is based on Allen Bradley PLCs and RSView SE software technology and includes six Superior Controls' designed control enclosures and four industrial operator interfaces. Redundant servers collect and store GMP data in compliance with 21CFR Part 11 (FDA Electronic Record Requirements) from 12 separate skids and support systems. The system is Web enabled allowing real-time graphics, reports, and alarms to be monitored from Alkermes' Cambridge, Chelsea, and Ohio sites through their wide area network. The entire project was implemented by Superior Controls, Alkermes, and PFI personnel in less than *ten* months. Superior Controls engineers also assisted with the IQ and OQ validation tasks.



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Alkermes' 90,000 sq. ft. refurbished Pharmaceutical facility in Chelsea, MA.



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Lower portion of the 2 story spray dryer.

University Targets Validation *(Continued from Page 1)*

each of the three board members developed and presented a lecture for fifty students in Professor Lawton's "Biotech Regulation" course. Not one student fell asleep.

Rick Pierro and Patty Ascanio of Superior Controls presented "Validation Requirements and Procedures for Automation and Information Systems." Joe Musiak focused on "Validation Requirements for Skids and Purchased Equipment" and presented Biogen's North Carolina expansion as an example. Bob Konopacz wrapped it up with a fascinating talk on "Validating the Process." Interesting, real life stories, shared by all three speakers, helped keep students awake. Professor Carl Lawton pointed out, "the students' feedback was incredible—they were amazed and impressed that FDA validation requirements can be so wide ranging and complex." All three speakers agreed to lecture again at next year's course.



**FDA Validation Team (from left to right)
Professor Carl Lawton, Rick Pierro (Superior Controls),
Joe Musiak (Biogen IDEC) and Bob Konopacz (shown on page 1)**

THE PEOPLE WHO ARE SUPERIOR CONTROLS

Five Professionals Join Superior Controls



Peter Fox has joined Superior Controls as our Southern Region Business Development Manager. As such, Peter is focused on customer development for southern

Massachusetts, Connecticut, Rhode Island, New Jersey, and New York projects.

Peter is an experienced automation engineer with a BS in Electrical Engineering Technology from Connecticut State University, an MBA from Sacred Heart, and more than 20 years experience in automation. Peter's experience includes implementing GE and AB based PLC and servos at Bridgeport Machines Company, Producto Machine Company, and MAN Roland Corp. He also served as Operations Manager for Eagle Electric's, Norwich, CT, branch and recently spent three years in sales development for a small systems integrator focused on the energy production automation market.

Peter lives with his wife, Lorry, and two children in Westerly, RI.

Dana Briere is a talented Electrical and Computer Engineer with a BS from the University of New Hampshire. Dana's work experience includes designing and programming OPTO22 and



Intellution-based systems, panel design, as well as the implementation and start up of automation projects for a Massachusetts-based distributor. Dana gained his networking experience while working as a test engineer on Ethernet switches and routers at Enterasys Networks in North Andover, MA. During his undergraduate years, Dana maintained over 50 networked computers as a Computer Consultant and Lab Instructor at UNH.

Raman Bharatula recently received a BS in Systems and Control Engineering from Case Western Reserve University in Cleveland, OH, where he was a member of the Dean's Honor List.

Originally from Salem, NH, Raman held internship positions at Sanmina Corporation, where he used UniCam and AutoCAD software to help design circuit boards; Johnston & Johnston Associates, where he designed parts using AutoCAD; and QC Drilling and Routing, where he assisted with CNC programming for machinery.



Zachary Gendron received his BS in Electrical Engineering Technology from Northeastern University. As an undergraduate, he taught students to use variable frequency drives, Siemens S-7 PLCs, and other automation equipment as a Teaching Assistant in the ICS Lab. Zack also spent four years at Hill-Rom Corporation where he developed a

prototype for an electrically powered patient transport device using a DC power.

Anthony Whitesell is an experienced Electrical Engineer with an MS and BS from the University of New Hampshire. Anthony's career includes work at Integrated Robotics, Portsmouth, NH, where he designed automatic welding and machining systems using ABB Robotics and Allen Bradley PLCs; Sunrise Labs, Auburn, NH, where he designed automatic voting machines, engraving machines, and smart communication networks for valves; Allegro MicroSystems, Concord, NH, where he designed and implemented various machinery and automation systems; and Smith and Norrington, Windham, NH, where he helped design gas pipeline metering and SCADA systems.



University Lab Named for Superior Controls

Superior Controls is pleased to announce that the University of Mass–Lowell Engineering Department has named their refurbished and modernized computer laboratory the: **Superior Controls, Inc. Chemical Engineering Computer Laboratory**

At the April 29th dedication ceremony, Rick Pierro, president of Superior Controls, cut the red ribbon with Professor Donatelli (left), Chemical Engineering Department Chairman, and Dean Ting (right).



Students utilize some of the 20 new computers at the Superior Controls, Inc. Lab.

Superior Controls has hired many engineering students—presently we have eight such staff members—from the university during the past 12 years and has supported the Chemical Engineering Department through tours, presentations, donations, technical assistance, and hardware donations. We are very proud to be associated with the new Computer Lab.