NAME **James F. Long**

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EXPERIENCE

Position: **PROCESS DEVELOPMENT CONSULTANT, AUTOMATION**

Employer: Automated BioProcess Solutions

Employed: January 1996 to Present, Formal Business Established in 2014

Recent Projects: **JAVA Controlled Fermentor/ Single Use Fermentor**

Originally in **JAVA** and **C++**. Integrated Sensor an pumping systems. Agitation, pH, DO,Temperature, Auto-Sampler, etc. 15L scale. Implementation in **Emerson DELTA V** available.

Biomass to Hydrogen Plant Siemens: **S7-TIA portal**.

Grinder operations, continuous media preparation, anaerobic reactor, Hydrogen Collection System.

Cell Culture Media Plant-wide System: **S7, Allen Bradley PLC**

RODI delivery system, CIP system, Media preparation Tank Farm, Continuous Sterile Filtration Station, Filling Line Interface.

Continuous Tangential Flow Cell Retention System **S7- TIA portal**

TFF unit designed to operate attached to cell culture reactor as a cell retention system. Sterile cleaning Sequence Batch controlled. **Emerson DeltaV** interface and Translation.

Automated reagent Dispense System, **Arm Cortex C++**

Multiple size container capable sterile filling unit for operation in a LAF hood. **Modbus TCP** communication, 5 channel synchronous fill by weight. Containers from **100ml to 1L filled to +/-0.5 grams**. Integral check weigh at each station.

Shake Flask Array Monitoring System**: ARM C++**

Single, Dual or Quad Unit systems designed fabricated and implemented to use **Laser Back-scatter Biomass, Optical or wet pH, and DO**, temperature monitoring during shake flake operations.

Modbus TCP communication to **Maitrikon Data Historian**.

Rotary Low Shear Valve for Tangential Flow Filtration**:C++**

SolidWorks 3D design, Fusion 360 3D design, ABS printed Valve body, C++ ARM processor controlled, MODBUS TCP device for closed loop back pressure control of TFF unit. No holdup or Sanitary Autoclavable design. Bio compatible FDA approved materials. 1 wetted part. Integrated with C++ TFF system.

600L Bio-Reactor Retrofit: **Allen-Bradley Compact Logix**

Replaced microprocessor with **Allen-Bradley Compact Logix** for reactor enviromental control. Hybrid with C++ systems for Mass balance using Multiple Scale Array on Ethernet. Online **Glucose Monitoring** and Sampling. Operational data to Data Historian. Media Pre-heating and feed optimization. control and Data collection.

Ultra-Micro Pump Blending System: **C++ ARM**

Capable of Delivery at 100 microliters per day continuous flow. Four channel blending system for dilutions. Stepper drive micro gear pumps. Batch scheduling/recipe interface.

Job description: This is my consulting company and a company I do consulting and **Process control system design services (hardware and software). Circuit Board Design and 3D Device prototype design and Printing.**
Process development services:

- BIOLOGICAL / ORGANIC SYSTEMS
- COSMETICS/ INDUSTRIAL CHEMICAL / PETROLEUM / MINING
- Biological production (FERMENTATION, CELL CULTURE, PURIFICATION)
- Real Time Microprocessor instrumentation interface development for controls and MES Development
- New Instrument technology development

See my website. And my portfolio at:

www.BioProcessIT.com

- **List of proficiency in Systems and Awards at the end of this document.**
- Current Clients:

Corbion, Coherus, Expression Systems, Marin Scientific, Optimum Processing, Piranha Color Systems, Therma Corporation.

Position: **SENIOR PROCESS CONTROL ENGINEER, AUTOMATION**

Employer: THERMA CORPORATION, INC.

Employed: August 2013, January 2015

Projects: Agilent Fab Solvent Controls

Solazyme Bio-Fuel Fermenter, Centrifuge, Biomass Press Controls

Cobalt Fermenter Controls, HMI and Historian.

Novartis Utilities controls Water Purification

Anaerobe Systems Bio-Hydrogen controls Plant Design

Job description:
Process control system design services (hardware and software). Process development services:

- Process Controls Designs Allen Bradley Logix Processors; Siemens TIA Portal, Factory Talk, Wonderware, OSI PI.
- Instrumentation and electrical Panel Design, Procurement, Panel shop Fab, Installation
- Biological production Systems design Continuo and sequential processes
- Remediation of process equipment and Field troublE-shooting
- New Process systems Design.

Position: **SENIOR PROCESS CONTROL ENGINEER, AUTOMATION**

Employer: K2 PURE

Employed: November 2012 to May 2013

Projects: Plant wide Historian (Factorytalk/OSI PI Historian)

Cooling Tower Upgrade

Process Gas Analyzer Modifications (CL2, H2)

Electrolyzer Cell Control modifi

Plant gas pressure Control Optimization and Interlocks.

Job description:
Process control system design services (hardware and software). Process development services:

- Process Analyzer Specification and procurement
- Pressure control software and interlock development (RSLogix5000)
- Feed stream water filtration and treatment sequences (RSlogix500)
- Plant-wide dashboard and graphic development (FactoryTalk SE)
- Plant-wide Historian remote access implementations (OSI PI/FactoryTalk Historian)

Position: **ASSOCIATE DIRECTOR , AUTOMATION ENGINEERING**

Employer: BioMarin, Inc.

Employed: November 2008 to August 2009

Projects: Engineering Library Inventory and procedures Project

MES Project

Gali Production Expansion Project (**Rockwell FactoryTalk**)

Waste Neutralization Project

Chromatography Upgrade and Validation Project

Production Network Infrastructure Upgrade Project

Position: **PRINCIPAL ENGINEER, AUTOMATION ENGINEERING**

Employer: Genentech, Inc.

Employed: January 1995 to November 2008

Projects: CCP2 Automation Lead

Cell Culture Fermentation Revamp **Emerson DeltaV**

Enbrel™ Automation Lead

Large Scale Final Purification Expansion

TNK Automation/Process Revamp.

Fermentation Control Systems Project

tPA upgrade.

Job description:
Lead and group manager/engineer responsible for the development of novel process equipment, evaluation of new instrumentation technologies, process control improvements, engineering standards development, resource planning, and project program management. Responsible for economic analysis, and feasibility of automation/process development projects.

Manager of automation engineers for a new Cell Culture production and Recovery Bio-processing plant. Responsible for DCS system selection, business system interfaces, and supervision of a staff of automation engineers who were in turn responsible for segments of the plant and utilities. Plant design is of a fully electronic batch, work instruction, and lot release capable design.

Lead automation engineer for a project to revamp fourteen production fermenters and associated CIP/SIP operations. Full automatic batch and electronic batch reporting. Supervisor/Lead for the group of engineers responsible for developing a corporate standard DCS automation library of S88 software modules and the associated

engineered document set.

Manager of automation engineers for the transfer of Enbrel production to Genentech from Immunex/Amgen. Production in two fermenter suites and recovery. Revamp of Automation and development of S88 recipes. Responsible for direction to engineering firms and contractors in support of design implementation startup and validation.

Lead automation engineer for a multi-product capable final purification suite. CIP/SIP, process vessels, Chromatography, and Tangential Flow Filtration (TFF) Operations were automated using state of the art, ISA S88.01 Modular Batch Control concepts. **Allen-Bradley PLC, RSView, RSBatch**, and Windows NT 4.0 were used to create a plant capable of flexible batch production. Software Architecture for Large Scale Final Purification Expansion. This design was awarded ComputerWorld Smithsonian Award 1998, for Manufacturing. Also, the START award for Software Technology in Manufacturing, 1998. This plant currently purifies Rituxan™, Herceptin™, NGF, E-25, rTRY and several clinical products. **Allen-Bradley Control Logix.**

Project Lead Engineer for the production purification train for Tenecteplase™ this effort included the modification of existing single product dedicated Chromatography and TFF equipment to accommodate multiple products. Revamp include retrofit of Existing equipment with Modular Batch Control software, and improved the consistency of validation between manufacturing areas at Genentech.

Supervisor/Lead Engineer for Corporate Batch Programmable Logic Controller (PLC) strategy team. This team of engineers identified methods to optimize the deployment of batch technology for multi-product systems at Genentech. Engineering Design, Testing, Quality Assurance, and Migration strategies and procedures were formulated by this group under my direction.

Automation Infrastructure Team Lead. Prepared Corporate Specifications for Control Panels, Corporate Standards for Instrumentation, standard project execution procedures, and corporate P&ID nomenclature reference sheets for review and approval by Engineering Management.

Supervisor/Group Leader for the Cell Culture Fermentation Control System Revamps (of 22 fermenters). This system required both GMP manufacturing and Clinical experimentation efforts to be carried out on the same set of equipment. Technology developed here was used to produce standard methods for Batch DCS installations at South San Francisco.

Lead Engineer for Corporate DCS Strategy team. This team of engineers developed corporate policy for issues related to DCS system design and documentation methods under my direction. This group also conducted reviews of systems for 21CFR11 compliance evaluations. This group prepared corporate policy documents on 21CFR11 as they relate to Automated process systems.

Position: **LEAD PROCESS CONTROL SYSTEMS ENGINEER**

Employer: Berlex Biosciences, Inc.

Employed: June 1992 to February 1996

Projects: Development/Clinical Manufacturing Pilot Plant

Fermentation Development SCADA Revamp

Mass Spectrometer Multiplexing Panel

Mammalian Fermenter Prototype

Dual Microbial Fermenter Prototype

Automated Media Blending Skid

Portable Continuous Sterilizer Skid

Betaseron™ Fermenter Project

Job description:
Lead Engineer and Supervisor for both Process and Control Systems engineers and Fermentation Systems Development. Responsible for prototype work on MIS information infrastructure associated with the **MES, SCADA and LIMS Ethernet networks**. Developed data mechanisms for plant floor integration with an ORACLE RDBMS backbone. Supervised automation and process engineers and directed contract engineers. Prepared Corporate Automation Policies, and procedures, and standards.

Project Manager directing contractor hardware design of plant automation skids and mechanical equipment. Responsible for all custom software programming of plant Control Systems. Designed custom reactor hardware and software packages for the above systems using SIMATIC PLC hardware, DMACS or TISTAR SCADA software, APT PLC programming software, online dynamic simulation software was programmed using C.

Position:	**PROCESS CONTROL SYSTEMS ENGINEER**
Employer:	Miles/Cutter Biological, Inc./Bayer AG
Employed:	August 1989 to June 1992
Projects:	Multi-purpose Pilot Plant
	Freeze Dryer 'F' Project
	Fermentation Research and Development Lab
	Miles r-FVIII Kogenate™ Production Facility, Project 1866

Job description:
Lead Engineer for Conceptual and detailed automation design for Multi-purpose Pilot

plant Distributed Control Systems. Specified Factory and Site Acceptance Test Procedures for Software and Hardware of Distributed Control Systems. Specified UPS and electrical equipment for plant electrical infrastructures. Responsible for network architecture design of **ABB MOD300 DCS** systems.

Responsible for field evaluation and modifications to control systems and process equipment. Conducted thermal and chemical performance experiments to ensure adequate and reliable system CIP and SIP performance. Developed custom C code for the data acquisition of these experiments. Also programmed high level **sequencing language routines (TCL)** for automatic cleaning and sterilization of process equipment and reactors using the ABB MOD300 DCS. Directed contractors responsible for sequence, interlock, and loop configuration modifications.

Lead project engineer for the fermentation development laboratory, utilizing networked PLC to perform control and data acquisition for an array of development fermenters. Directed contractor resources to fabricate and program control and instrumentation stations for fermenters. Directed electrical and instrumentation contractors for building system and utility modifications.

Lead Engineer for Lyophilization suite modification project. Supervised the electrical design along with the HMI and PLC programming efforts for the packaged unit. Developed integrated Instrument index, datasheets, and P&IDS using AutoCAD, and Paradox Database. Prepared Corporate Standards for instrumentation, control panel design, and other Automation topics.

Position: **PROCESS DEVELOPMENT ENGINEER**

Employer: Bio-Response/Baxter

Employed: October 1987 to August 1989

Projects: Fermenter Instrumentation Package Design

Gas Chromatography Auto-Sample Control System

Automated Liquid Chromatography System

Aseptic Flow Injection Analyzer for Ammonia

Job description:
Responsible for the design and improvement of mammalian cell culture apparatus and processes. **Developed cell culture oxygenation systems leading to two U.S. patents.** Developed an online automated aseptic analyzer for previously unusable (aseptically) ion selective electrodes.

Designed and built a plant wide, gas analysis and mixing system. This system was a set of micro-embedded controllers programmed using **PASCAL, BASIC, and MAS86** programming environments.

Designed and built a computer based online, harvest conditioning system for direct loading of cell free culture fluid onto **HPLC** columns.

Designed and built an online control system package for a standalone mammalian cell culture unit. This unit provided redundant measurement and control of pH, pO2, recycle flow, perfusion flow, media pre-heat, reactor temperature, gas flows, and gas composition. This unit provided monitoring only for NH3.

Received informal machinist training and welding technique instruction on the job. Fabricated nearly all of my own experimental equipment using lathe, mill and TIG/MIG welding. Experienced in the machining of polycarbonate, Teflon, and Stainless Steels.

Position: **PROCESS CONTROL ENGINEER**

Employer: Bechtel Petroleum Inc.

Employed: June 1983 to October 1987

Projects: Kennecott Utah Copper Division Modernization Project

SOHIO Consolidated Engineering Project

ARCO Cherry Point Coke Calciner Project

Union Oil Rodeo Refinery Revamp Project

Job description:
Specified and configured computer based Control and Monitoring systems including: **FOXBORO** Microspec, **HONEYWELL** TDC2000, and **FISHER ProVox** Systems. Developed dynamic simulations for process control at start-up. Assigned as field start-up engineer, responsible for trouble-shooting loops in the field, and for configuration of DCS/SCADA systems. Other responsibilities included the configuration of the DCS/PLC interface and specification of process instrumentation such as control valves, magnetic flowmeters, ultrasonic flowmeters, transmitters, process switches, local annunciators, etc.

Designed loop and logic diagrams using CADD systems such as: **AutoCAD**, PCAD, and MacDraft. Also developed intelligent P&ID software capable of generating various Control Systems documents using DBASE III, ARTEMIS, and LOTUS 123 Systems.

Prepared control strategies for the following units: WASTE HEAT RECOVERY SYSTEM, FLUE GAS DESULFURIZATION UNIT, WET ELECTROSTATIC PRECIPITATOR SYSTEM, and WASTEWATER NEUTRALIZATION SYSTEM. Specified process analyzers for pH, SO2, NOX, and CO. Other responsibilities included review of PLC programming and the design of annunciator systems.

Prepared control strategies for the following units: PRIMARY CRUDE UNIT, SECONDARY CRUDE UNIT, DELAYED COKING UNIT AND COKE DRUMS, DECOKING AND STEAM OUT FACILITIES, and UTILITIES. Responsible for field evaluation of existing instrumentation to modify and interface existing equipment with a computer based Distributed Control System.

EDUCATION

Graduated 1983 from University of California, Santa Barbara with a Bachelor of Science in Chemical Engineering. EIT Certificate. Grade Point Average 3.6/4.0.
University of Minnesota Short course on Fermentation

- Emerson DeltaV System Administrator
- Emerson DeltaV Control and Batch configuration
- ICONICS GENESIS Configuration
- Intellution DMACS Configuration
- Honeywell TDC 2000/3000/PKS Configuration
- Foxboro I/A System Configuration
- Allen-Bradley AI PLC, PLC5 Programming
- Rockwell Software RSView
- Fisher ProVox System Configuration
- General Electric PLC LogicMaster 90/30, 90/70
- Texas Instruments APT 555 PLC Programming
- TISOFT configuration
- Siemens S7, TISTAR, H1 Configuration
- UNIX System Administrator training
- ABB MOD300 System Configuration) TCL, CCF)
- ABB Advant Configuration
- Sequencia OpenBatch Engineering Training

training
- Rockwell Software RS Batch, RSLogix, ControlLogix, RSNetworx, FactoryTalk SE/ME, FT Historian training
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- FieldBus, DeviceNet, ModBus, CANBus

AWARDS Shell Foundation Award

Stauffer Chemical Corporation Award

Computerworld Smithsonian Award for Manufacturing, 1998

Start Magazine Award, Software Technology in Manufacturing 1998

PUBLICATION BioPharm “Automated Media preparation from Liquid concentrates.”

Control/Software Strategies, April 1998 “BioTech Startup Streamlined”

Rockwell International Media Exposition 1999, “Genentech uses RSBatch for FUN and PROFIT”

REFERENCES Furnished upon Request.