Technical Leader & Project Manager

AREAS OF EXPERTISE

- **Operating Systems and Platforms: Microsoft Windows Server 2008, XP, NT, Unix and DOS**
- **Automation, Control Systems Hardware and Instrumentation: Allen Bradley (Controllogix, SLC, PLC 5/40) GE Fanuc, RTP, DeltaV, ProcessLogix**
- **Automation, Control Systems, and Manufacturing IT Software: Allen Bradley ProcessLogix, RSBatch, Suite of RA Products, Emerson DeltaV, Intellution iFix and iBatch, Wonderware, OSI PI, Werum PAS|X MES, RA ProPack PMX MES**
- **Software Packages, Programming Languages and Databases: MS Office, OSI PI, Oracle 8i, 10i, 11i, Visual Basic, Visual C++, SEND (FDA submission software)**
- **Communications and Protocols: DeviceNet, ControlNet, Hart, Modbus, Fieldbus, Profibus**
- **Werum PAS-X**
- **Propack**
- **CNC Programming**
- **Network Administration**
- **Cyber Security**
- **ISO 9000**

INTRODUCTION

Consultant has 17 years in pharmaceutical experience helping Heathcare Organizations – Medical Device, Biotech and Pharmaceutical - meet GMP requirements by implementing QA, IT, Automation Engineering specifications. Some pharma implementations involved installation and commissioning of an entire automation system for a new process. Others required working hand in hand with the FDA as a coach and mentor providing technical and regulatory guidance. Consultant has previously received the President's award for helping a team of QA, IT, CSV, and Process Engineers achieve a FDA pre-audit certification by successfully implementing a MES solution that interfaced with SAP and the factory floor automation system. These successes required intimate experience with Part 11, Data Integrity, Track and Trace, Engineering Standards, and IT / Automation expertise. Consultant's technical know-how coupled with a natural ability to foster sound business relationships will help any organization reach a higher level of overall operational excellence.

WORK EXPERIENCE

2006 – Present
Industry Consultant
Duties:

- Responsible supporting the development of engineering specifications for new and existing packaging lines: EpiPen and atropine (nerve gas antidote) for both military and civilian markets. Perform FEMA risk assessments.
- Provide CAPA resolution and investigation assessments. Proactively supporting the overall improvement of packaging line throughout and productivity by minimizing line variability and human error.

- Client under consent decree. Provide technical and regulatory oversight and guidance for implementing MES for a new plant startup. My role involves mentoring and coaching the engineering, IT, CSV, and QA teams, helping them to achieve sustainable compliance.
- Assure that MES was properly configured, implemented, and validated for client's FG packaging lines. Required understanding of packaging and cleaning MBRs. Prepared for Track and Trace functionality and serialization implementation.
- Given oversight of the multi-vendor implementation of a Rosemount RS3 to Emerson DeltaV migration project performed under a consent decree environment. Helped to guide the validation effort through site QA, Compliance, Regulatory Affairs, and Quantic. Responsible for reviewing all engineering documentation for adherence to quality regulations. Authored DeltaV SOPs for Automation Engineering. Developed the overall Commissioning and Validation strategy document for Mass-Bio leveraging GAMP5 and ASTM E2500 guidelines.
- Responsible for leading the effort to deploy and validate the Werum PAS|X MES MBR implementation of the Viral Vaccine Manufacturing site master formula for Varicella, Rotavirus, and MMR. Mapped Site Master Formula paper batch record to the underlying MES PAS|X software code to demonstrate MBR regulatory compliance for Agency submittal.
- Worked with the global Automation team and authored the PLC and DeltaV based Process Control Systems Programming and Change Management SOP. This SOP also includes procedures for creating and modifying Functional Requirements, Detail Design Specifications, Testing and Reporting Requirements for various types of hardware and software modifications.
- Responsible for leading the effort to develop the vaccine MBR Detailed Design Specification for FDA licensure submission. Mapped paper based production recipe MBR to MES PAS|X software basic and technical function modules of the Varicella vaccine recipe code to demonstrate MBR regulatory compliance for Agency submittal.
- Led effort to design & implement a Johnson Controls Metasys Building Management System (BMS) for client's newly constructed Research Innovation Center's GMP building. Set up a BMS server running MS Windows Server 2008 and interfaced JCI's Metasys FEC and NAE controllers via BACnet using a SCADA engine to feed the MS SQL Server tag database. Iconics Genesis32 application was used to generate the HMI graphics, alarms, trends, and reports.
- Testing the new PMX Version 4.3 release software application modules: EDB, EBR, DISY, EQM and the MRP interface via shop orders to verify production procedures, routings, BOMS, reporting, material consumption and module functionality prior to formal testing. To streamline OQ testing commitments, the requirements were fully tested using high level scripts, which placed greater understanding on the PMX software and its interactions. Any deviations were flagged, recorded, worked out with AB vendor to reolve software issues, and then performed retesting to satisfy requirements and specifications.
- Engineering design, specifications, validation and implementation of a Propack MES solution using a GAMP 4 rsik based approach .Developed the hardware specifications for all the MES equipment and the MES interfaces, which were used for the subsequent issuance of purchase requisitions, redesigned NEMA4X workstations to run cooler by using an electrothermo cooling device, coordinated installation and commissioning of all MES workcenters, developed a Master Validation Protocol (MVP) that can be reused to qualify subsequent MES rollouts, responsible for defining the hardware and software configuration for interfacing scales, balances, document and label printers. Finally, I was responsible for supporting the Thin Client application interface via Citrix servers and I developed the ".htm, .hta, and .ica" files for connecting the user to the application server using WEB pages via a Citrix load balanced server farm. Supported MES training and gained an intimate knowledge of PMX and its interface to SCADA, PLC, and DeltaV systems via an AIA middleware communications package. Configured and qualified the Intermec Barcode readers and associated label printers.
- Project involved implementing a global Weigh & Dispense Manufacturing Execution System (MES). My responsibility was to provide Werum PAS|X support and develop the initial validation

documentation based on Amgen's URS and Risk Analysis. The WD MES currently interfaces to a JD Edwards ERP via a Tibco middleware interface. The WD MES involved installing Oracle 10.2 modules on a central server and distributed clients, and configuring PAS|X components to work with JDE and a variety of scales, balances, scanners, label printers, and PC's. At Amgen's request, I spent two weeks in Germany executing software FAT scripts and developed the overall operational readiness tests, which exercised the MES to ERP interface. In addition, configured and qualified the Symbol barcode reader/ scanners. The Amgen WD MES project was very successful, and has better prepared Amgen to make the transition to SAP when the JDE ERP was eventually replaced.

- Project involved programming a HPLC chromatography column to perform such operations as isocratic fractionation, gradient fractionation, PAT blending, etc., The HPLC program runs on an Allen Bradley ControlLogix processor and allows the user to run multiple methods (recipes) via standard ISA S88 batch operation. Project utilized GAMP 4 methodologies for developing the Detailed Design Specification, Software Test Specification, Test Cases, and the resultant HPLC control program.

03/2005 – 01/2006
Eli Lily
Technical Leader / PM (Speke, England)
Duties:

- Worked with a multi-national team to develop and implement OSI PI with DeltaV. As the Project Leader, my main responsibility was to help delineate the logical and sequential configuration of the PI interfaces, and develop the IQ and OQ test protocols. In addition, I developed the full Validation documentation package with the cooperative efforts of Lilly QA, MIS, and Validation.

07/2004 – 02/2005
Genentech, Inc.
Technical / CSV Lead Engineer
Duties:

- Provided oversight support of Clean Utilities Systems, such as, Clean Steam, Autoclaves, RO Water, Freeze / Thaw, Centrifuge, seed fermenters, etc., for the new Cell Culture Production facility. Managed the Fluor Contractors who performed computer system validation activities. Reviewed the vendors' AB RSLogix PLC code and made comments and recommendations.
- The initial responsibilities were to develop Automation Functional Requirements by merging Honeywell DCS requirements with the Vendor supplied FS requirements. To save time and money, I made a suggestion based on GAMP to help the Vendors help us (Genentech, Inc.) develop the requirements documents. As a result, I developed the: Functional Specification, Software Detail Design Specification, and the Hardware Detailed Design Specification templates that were approved by Genentech and distributed to the Vendors as part of their procurement award package. This recommendation won support by management and has worked out well for the Vendors. Interfaced with the DCS development team to resolve coordination control issues and basic supervisory control.

08/2002 – 07/2004
Eli Lily, Tippecanoe Laboratories
Technical Leader / PM
Duties:

- Led the team effort to implement the Rockwell Automation and Eli Lilly's Automation Quality Initiative (AQI) at Tippecanoe Laboratories in Lafayette, IN. I was responsible for providing direction to several sub-groups: Critical Operating Data (COD) which determined both the useful and validated ranges of system operation, Maintenance Strategies which defined the proactive, preventative, and predictive maintenance strategies for automation equipment, Modicon, Allen Bradley, and DeltaV

reprogramming and revalidation. The installed DeltaV systems did not take advantage of ISA S88 logical fundamentals and were subject to intermittent hangs.

- In addition to coordinating AQI mandates and implementing GAMP methodologies, I was responsible for investigating Emerson DeltaV code and making recommendations to improve coding. ISA S88 was employed to help organize fractured code into a more coherent, defensible structure better aligned with the Process Flow Diagram logic. Helped company achieve corporate compliance objects on time by fostering an atmosphere of cooperation and good communications. My very first day on the job as the Project Leader, I was thrust on a job to reprogram and validate a Milling machine needed to manufacture Duloxatine for clinical trials. The Milling machine used a TI PLC. With assistance from another automation engineer we were able to complete this effort in four weeks. This set the momentum and tone for the project, and the initial documentation was used as a basis for going forward with the GAMP approach. When the project concluded, I was asked to investigate a failed PLC hit by lighting. This PLC was used to control the natural gas furnace for burning off the fermentation nitrous gases. This non-GMP system had no back-up and was reprogrammed from scratch, saving the company $1.9 million.

10/2000 – 07/2002
Perrigo, Inc
Project Manager / Technical Leader
Duties:

- Worked at Perrigo, Inc., a generic manufacturing pharmaceutical firm, performing Automation Systems Validation and Computer Software Validation as part of on-going validation and revalidation effort.
- Developed the Vendor Audit SOP, and conducted Perrigo's first vendor audit at Thomas Engineering, a manufacturer of tablet making equipment.
- Other projects involved making a LIMS system Part 11 compliant, and developing protocols based on GAMP.
- Completed the nasal spray line concurrent engineering and validation in time for an FDA pre-approval inspection.
- Developed and executed IQ/OQ protocols for GMP systems, and wrote many SOPs, and coordinated other contractors with the validation efforts.
- Additionally, prepared bulk tanks for batch control employing AB ControlLogix Processors and eventually RSBatch.

03/1998 – 10/2000
Voest Alpine Industries
Project Manager / Technical Leader
Duties:

- My initial responsibility was to determine the engineering cost (HW & SW) for incoming RFPs. Company depended on my estimates to secure jobs. Warner-Lambert, who was under a consent decree, approached my company for technical engineering and validation support. I was selected to provide a cost estimate to revalidate and reprogram 30 process control systems. WL budgeted over $1,000,000 for this effort, but I was able to complete the project for $450,000 fixed price.
- Another challenging project involved concurrent installation/commissioning and validation of a new blood protein derivative line for Aventis Behring.
- My team was responsible for installing and configuring Intellution iFix and iBatch to run batch recipes for processing a particular blood derivative called alpha protease inhibitor. We used ISA S88 as the basis for designing unit procedures, operations and phases. Successfully directed, coordinated, and implemented a GAMP approach toward validation.

- As Technical Lead I helped foster a good working relationship between engineering, IT, QC, and the installation contractors. I was responsible for developing IQ/OQ protocols for the Oracle 8i process data server, redundant SCADAs, and networked PLCs. Successfully commissioned and validated an ISA S88 Batch Control system, and implemented GAMP to achieve cGMP and 21 CFR Part 11 compliance.
- Technical leader on multiple automation and computer validation projects.
- Designed automation and SCADA systems
- Designed Railyard Management System using AB SLCs interfaced to DEC mainframe
- Led evaluation of compliance to cGMP, GAMP and 21 CFR Part 11
- Audited SOPs, validation packages.
- Developed User requirements, Functional Specification, Design Specifications, and SOPs and wrote / tested IQ/OQ protocols for CSV.
- Executed IQ/OQ protocols for CSV

03/1990 – 03/1998
South Carolina Electric and Gas
Senior Systems Engineer
Duties:

- Supported plant computer and nuclear real time simulator computer systems at VC Summer Nuclear Power Plant. Worked on a two man team to migrate simulator control from a main frame system to a distributed network by writing software drivers to interface with PLCs, modified PLC for embedded Ethernet control, and converted Fortran 77 to C. Project was very successful – first networked main control board running on NT 4.0 in the country (17,210 I/O points).
- Validated and verified simulator operation to meet Design Basis engineering requirements as required by the Nuclear Regulatory Commission. Wrote an inventory control system for simulator equipment. Designed and implemented many PLC hw/sw improvements.
- Used HP logic analyzer to trace data and command words from mainframe memory to PLC backplane for troubleshooting intermittent lockups.
- Investigated latent semiconductor failures that appeared masked by routine plant main control board IC maintenance fixes.
- Responsible for specifying simulator equipment such as chart recorders, meters, switches, and all electronic devices. Worked hand in glove with Human Factors Engineering to implement MCB design changes in the simulator.

01/1989 – 03/1990
Savage Engineering
CAD Manager
Duties:

- Led a team of seventeen (17) engineers /draftsmen creating “as built” field verified mechanical/electrical/architectural drawings.
- Put a number of hospitals and universities on CAD, such as, Harvard, Cornell, USC, and University of Pennsylvania.
- Redesigned their accounting system and migrated db application from a slow network (peer to peer) system to a PC based multi-user / multitasking system.
- Designed an Oracle db for Beneficial Finance of Peapack, NJ.

03/1984 – 01/1989
Gould, Inc. CSD
Senior Systems Engineer
Duties:

- Worked at MIT Lincoln Labs providing mainframe computer technical support for Marshall Island radar tracking project. Supported United Technology Research Center's Titan booster rocket project, which helped determine the cause of the Challenger rocket failure.
- Supported Sikorsky Aircraft's X-Wing project and various real time flight simulations. Supported Groton, CT Submarine simulator and worked on encryption interface with Univax. Installed and supported Northeast Utilities nuclear real time simulator. Installed and supported Renssalear Polytechnic Institute internal email system.
- On a special assignment, resolved PLC and MCB to mainframe interface issues at Boston Edison.
- Worked as a consultant at NYPA's Indian Point Nuclear Plant nuclear training simulator, interfacing, specifying MCB instrumentation, and coordination with HFE for a successful effort to achieve NRC compliance.
- Held DOE and DOD Top Secret clearances and worked on many government projects. At an advanced mainframe architecture course, wrote I/O drivers and developed a working disk based operating system.

01/1980 – 03/1984
Rexon, Inc.
New England Technical Leader
Duties:

- Programmed and installed many multi-user / multi-tasking computer systems used for integrated accounting. System was designed to replace Basic 4 computer systems. Used BASIC to program and modify software modules such as, job costing.
- Selected by Rexon management to install their computer system in the White House.
- Installation was very successful and led to additional government installations.
- Programmed EPROMS for Insurance companies for interfacing computers to printers.

10/1976 – 01/1980
Pratt & Whitney Aircraft
Engineer in Training
Duties:

- Worked in all the branch plants learning all aspects of aircraft engine manufacturing.
- My primary responsibility was programming, troubleshooting, and maintaining production machine controls such as Allen Bradley, Digital, Cincinnati Millicron, and GE Fanuc.
- Designed and implemented integrated circuits and printed circuit boards to solve various manufacturing problems.

EDUCATION

1996
Charter Oak State College, CT
Bachelor of Science: Information Technology

1979
University of Hartford, CT
Bachelor of Science: Electrical Engineering

PROFESSIONAL AFFILIATIONS

- Current member - Institute of Electrical and Electronic Engineers (IEEE)
- Current member - The Society for Pharmaceutical Engineers (ISPE)
- Current member – Amateur Radio Relay League (ARRL) Call sign: W8QQ
- FCC Licensed Commercial RF Engineer (PGGB01270)
- American Society of Quality (ASQ) – Certified Quality Engineer

ADDITIONAL TRAINING

- ASQ – CAPA
- ISPE - Computer Systems Baseline Validation
- ISPE – Good Automation Manufacturing Practices (GAMP 3, 4, 5)
- ISPE - cGMP 21 CFR Part 210 & 211
- ISPE - 21 CFR Part 11 ER / ES
- ISPE - Certified Auditor
- ISPE – ASQ Quality Author Handbook
- ISPE - Auditing for GMP
- ISPE - Computer Systems Validation using GAMP 4, Level II
- ISPE – CPIP training course: Annex 11, Eudralex, cGMPs
- Pratt & Whitney Aircraft – QA / QC / QRB training
- Automation Programming - Allen Bradley, GE, DEC – CNC programming
- Emerson DeltaV Operate Implementation
- Emerson DeltaV Systems Batch Implementation
- Honeywell Experian Advanced Configuration
- OSI - PI Administration
- Oracle Administration - 8i, 10i, 11i
- SAP – Business Intelligence
- Werum – MES: PAS|X Administration
- Rockwell – MES: Propack PMX Implementation
- SEL Gould CSD - Encore Nuclear RT Computers – Mainframe Advanced Software Architecture
- General Physics – Nuclear Power Plant Design & Operation
- New York Power Authority (IP3) – Nuclear Simulator scenario training
- SCE&G - ISO 9000 and 10 CFR
- SCE&G - Nuclear Reactor Theory
- Many automation, QA, and computer training courses

GOVERNMENT CLEARANCES

- Held DOD and DOE “Top Secret” Security clearance for MIT Lincoln Labs (missile tracking - Marshall Islands; submarine tracking -Andros Island, Groton Subbase (cryptography and port simulation), Naval Nuclear Underwater Warfare, and all New England Nuclear Power Plants, DLA inventory logistics management
- Held Secret Service “Secret” clearance – Whitehouse computer system installation
- Pfizer – medical devices for administering Nerve Gas Antidote for US Army clearance