JAMES G. ROBERTSON, P.E, CISA

EDUCATION AND CERTIFICATION

- MSEE, University of Washington, 1964
- BSEE, University of Washington, 1963
- CISA, Certified Information System Auditor, 2007
- Audited Communications Theory Courses, Stanford University, 1967
- Registered Electrical Engineer (P.E.), State of California License #E10043
- Pilot, Private, Single Engine, Land, Instrument
- Continuing education in pharmaceutical computer related and IT system compliance, GAMP, PDA, ISPE, ISACA

PATENTS

- "Apparatus and Method for Recording Jaw Motion", Patent Number 5,340,309, Issued 1994
- Named on two patents from EDC in the 1977 time frame.

PUBLICATIONS

- "Software/System Architecture Design as a Method to Simplify Validation.", Journal of Validation Technology, May, 2000.
- "IT Governance and Controls for FDA & SOX Compliance" Webinar, Compliance Online, 9/2006
- “How to assess risk for the validation of Quality System software.”
- “Using Risk Assessments to scale the software validation tasks: Minimize the software validation costs.”
- Contributed the Pharmaceutical Compliance chapter “Governance, Risk and Compliance Handbook” from Wiley.

PROFESSIONAL AFFILIATIONS

- IEEE, Institute of Electrical & Electronic Engineers, Senior Life Member
    - IEEE Computer Society
    - IEEE Engineering in Medicine and Biology Society(EMBS)
    - 1995 to 1997 PACE Chairman San Francisco Section
    - 1994 to 1995 Vice Chairman, San Francisco Chapter IEEE Computer Society
    - Championed Internet Security Seminar with Speakers from FBI, NSA, Bell Labs, SRI, Stanford
- ISPE, International Society of Pharmaceutical Engineers, Member
- PDA, Parenteral Drug Association, Member
- ISA, Instrument Society of America, former Member

- NSPE, National Society of Professional Engineers, former Member
- ISACA, Information Systems Audit & Control Association, Member
- CSI, Computer Security Institute, Member

FORENSIC ENGINEER, CONSULTANT & EXPERT WITNESS

Marshall, Gerstein & Borun LLP, Chicago, 2007-2008
Patent matter for air quality data monitoring and archiving system

Foran Glennon Palandech & Ponzi PC, Chicago 2007-2008
Consulitng on controls for 7000HP motor in steel rolling mill, Insurnace matter

Foran Glennon Palandech & Ponzi PC, Chicago 2006-2007
Consulting on role of controls and software in boiler explosion, Insurance matter

Duane Morris LLP, Maimi, 2004
Controls for municipal water plant

Howrey, Simon, Arnold & white, LLP, 2003, Washington, DC
SCADA and PLC software patent issue.

Sidley, Austin, Brown & Wood, 2003, Dallas
SCADA and PLC software patent issue.

Krieg, Keller, Sloan, Reilley & Roman LLP, 2003, San Francisco
Clean Room HVAC controls & SCADA (BAS/BMS), provided Rule 26 expert's report for Fedearl Court

Heller, Ehrman, White & McAuliffe LLP, 2002, San Francisco
Process Control software patent prior art

Shearman & Sterling, 2002, Meno Park, CA
Pharmaceutical process control (fermenter) software patent prior art.

Carroll, Burdick & McDonough LLP, 2001, San Francisco
Consultant on control device as possible fire ignition source.

Monteleone & McCrory, LLP, 2000, 2001, Los Angeles
Expert for plaintiff in case about the control system (SCADA) for water treatment plant. Testified in court and in deposition.

Zelle, Hofmann, Voelbel & Gette, 2000, Minneapolis
Expert for plaintiff in matter involving the control system (PLC) for a gas turbine powered electricity cogeneration plant.

Golden Eagle Insurance (Guardian Group), 1999, San Diego
Forensic engineering for claim consultant. Matter involved an electrical contractor with contract for controls, DCS and Supervisory Control and Data Acquisition (SCADA) on a water treatment plant.

Ropers, Majeski, Kohn & Bentley, 1998, San Jose, CA
Testified in deposition. Case involved software integration for SCADA and controls of a large water treatment plant in Los Angeles Metropolitan Water District.

Myers, Widders, Gibson & Long, 1996, Simi Valley, CA
Metropolitan Water District v. JWP Controls, Inc.
Case involved SCADA system to manage a large water supply system.

1988 to current
INDEPENDENT CONSULTANT

Specializes in consulting and project management for Supervisory Control and Data Acquisition (SCADA), System Integration and Industrial Controls including Pharmaceutical industry regulatory compliance of software, automation, information technology and computer related systems. Strong technical background in SCADA and PLC computer-based industrial controls and networks including 21 CFR Part
11 electronic records and electronic signature requirements..

Extensive experience with hardware and software for Allen Bradley (Rockwell Automation) Programmable Logic Controllers (PLC & SLC), Wonderware and Intellution graphical interface products and ABB Distributed Control System (DCS). Experienced with Pharmaceutical Current Good Manufacturing (cGMP) environment and Validation of computer software systems for Pharmaceutical and Biotechnology process controls. Expert with the with Good Automated Manufacturing Practices (GAMP) and Good Electronic Records Management (GERM) methodologies for compliance with FDA software regulations.

Very experienced with contracting and competitively bid supply to the construction industry for SCADA systems to control piplines, water treatment plants and process controls. Experienced with electronic microsystem development with embedded software and design of innovative high-tech systems and products supporting diverse industries including, medical equipment, semiconductor manufacturing equipment, environmental, petroleum (gas), pharmaceuticals, and engraving equipment. Experience in defense industry with satellite communications, navigation computers used on Polaris submarines and the navigation computers for the aircraft. Additional experience with feasibility studies,

engineering reviews, business plan development, market evaluation, funding research, patent application and corporate evaluations for venture capital. Client/consulting projects include:

Boston Scientific, 2006-2007 (through Validant Consulting)

Consulted on the implementation of the corporation's procedures and practices for the life cycle process to acquire, implement, validate and maintain information applications that are regulated by the FDA and reside in the IT infrastructure. Led the validation of an information system for Part 11 data. Gave presentations on the application of risk analysis (FMEA) for scaling computer validation and for the application of the CSV policies and procedures. Developed SOPs for managing change, controlling access, managing data and maintaining systems. All consistent with 21 CFR Part 11 and ISO requirements. These systems reside on servers in the IT infrastructure to collect, store, and archive data as well as generate reports for management, regulators and auditors.

Ft. Detrick, Army Medical Research Laboratory, 2006 (through Mandaree Enterprise Corporation)

Wrote computer system validation documents to qualify a StarLIMS LIMS to be deployed at numerous sites for DNA analysis. This was part time working off-site with a team focused on implementing this system for the Army. At the same time I was writing a book on combined IT controls for meeting FDA and SOX requirements

Eyetech, New York, 2004-2005

Assessed the quality system, validation and IT operating controls of the entire IT infrastructure (including computerized equipment and quality system implementation) for compliance with FDA 21 CFR Part 11 and Sarbanes-Oxley. Trained staff and made presentations on IT controls and infrastructure validation to management. Prepared complete Sarbanes-Oxley Act compliant IT Controls Framework and GXP Computer Quality System based on a robust life cycle model consisting of about 30 policy documents and 40 SOPs. Includes risk assessment based approach which flows throughout the life cycle from concept through validation. The policies include asset classification, information security, life cycle process, IT and user responsibilities, training and security architecture. Procedures include change management process, implementation and commissioning process, risk assessments, preparation of engineering and specification documents, preparation of master plan and validation plan, and preparation of computer system validation protocols and test scripts.

McKesson Bioservices, Maryland, 2004 (through Stelex)

Wrote major contributions the Software Design Specification for a custom enterprise and inventory management system that is used for managing clinical trials materials. The system tracks materials and specimens from their source, through storage, distribution, testing and return. It incorporates full audit trail capability and over 200 reports. Worked with developers and users in the definition and description of this system with focus on the software compliance issues including 21 CFR Part 11 and life cycle methodology. System is written in Visual Basic for MS SQL database.

Wyeth, New York, 2002

Managed a team to validate a Class 100 suite and laminar flow hood with focus on the HVAC, Building Management System (BMS) and equipment. Also coached on validation methodologies for computer related systems according to the GAMP model. The BMS is Siemens with active pressure control and Infocenter part 11 data archiving/reporting. Reviewed all protocols and managed the approval process. Wrote the validation plan.

ALZA Corporation a Johnson & Johnson Company, 2001 & 2002

Oversaw the preparation of validation protocols for a complex computer controlled transdermal patch manufacturing process. Coached QA on computer related compliance requirements for equipment. I championed the validation of a first of type, BMS/DCS system with 21 CFR Part 11 requirements for electronic records. Coordinated with vendors, contractors and project engineers. Introduced the Good Automation Manufacturing Practices (GAMP) methodology for control system validation.

.**B. Braun Medical, 2001**

Senior Validation Specialist. Good Automated Manufacturing (GAMP) and 21CFR Part 11 (electronic signatures and records) resource. Wrote procedures, protocols & templates for validation (testing) of control systems and human machine interface (HMI) software used in manufacture of pharmaceuticals. Performed risk assessments. Reviewed, for approval, computer, software and PLC validation protocols. Performed training on computer validation methods and procedures.

Covance Biotechnology Services, 2000

Performed validation of computer control systems for compliance with FDA requirements. Wrote Computer/Controls Operational Qualification and Performace Qualification protocols for PLC based centrifuge equipment and for UNICORN based Amersham Pharmacia chromatography skids. Oversaw execution of OQ and PQ protocols on six skids. Dealt directly with QA, Manufacturing management, Engineering, and Validation management.

Obsidian Inc. (now Applied Materials), 1999

Championed the integration of a Nova semiconductor metrology unit into the company's product, a wafer chemical mechanical polishing (CMP) tool. Wrote Allen Bradley PLC programs, modified Wonderware graphical Human Machine Interface (HMI), coordinated services with vendor, wrote plan for field upgrades, tested and proved out the system on two machine models. Performed Y2K upgrades to the machine control computers.

Bayer Pharmaceutical, Berkeley, California, 1997 to 1999

Reverse engineered control system, prepared engineering documents and drawings, prepared plans for outside contractors, coordinated and oversaw vendor, Landis & Staefa (Siemens Building Technologies) , provided programming services and equipment modifications. Prepared and executed validation protocols and documents for FDA compliance of software controlling Purified Water and Air Handling systems. Wrote Allen Bradley software to upgrade a steam sterilizer control system to add the functionality necessary to validate equipment. Programmed Intellution SCADA software.

Temescal - BOC Coating Technology 1996 to 1997

Programmed the second generation controls on the Temescal e-beam evaporator for semiconductor deposition. System uses Allen Bradley SLC500 controller in concert with Wonderware Intouch HMI/SCADA and three dedicated deposition controllers that communicate with a Wonderware Intouch HMI through custom RS232-to-DDE interface drivers.

LifeScan, Inc., a Johnson & Johnson Company, 1995 to 1996

Programmed the computers to control a new packaging line. Wrote printer drivers in C on PC platform for bar code printers. Programmed the Allen Bradley PCL/5 programmable logic controller and developed the human/machine interface (HMI) on Allen Bradley ControlView. Project evolved into an integration of semi-automated packaging into a previously manual manufacturing process.

U.S. Trade Development Agency (TDA), 1994

Definition Mission Contract to evaluate proposed Geographic Information System (GIS) project feasibility in the GAP Region in Turkey. Retained a GIS implementation expert and conducted a mission to Turkey. Interviewed government officials, supplier companies, The World Bank and prepared an extensive report with recommendations to the U.S. Trade Development Agency for GIS projects in Turkey.

Powell Industries, 1994

Performed due diligence in the acquisition of the SCADA and controls division of JWP. This operation became Transdyne Controls. Examined

ongoing contracts, interviewed the technical personnel and prepared a report for Powell Industries.

Diomed, Inc., 1993 to 1994

Developed extensive contacts at The World Bank in telecommunications and energy sectors for technical consulting assignments. Also networked in the U.S. Trade Development Agency and several major consulting firms involved with international consulting. Recruited portfolio of candidates for telecommunications, Informatics and SCADA engineering for energy applications.

U.S. Trade Development Agency, TDA, 1993

Definition Mission Contract to evaluate proposed Chile Port Authority and Customs Electronic Data Interchange, EDI, implementation project. Retained two experts in telecommunications and EDI. Interviewed Transportation Ministry, Finance Ministry, Port Authority, Customs and EDI Chile Standards organization and prepared extensive report and recommendations for TDA.

Pipeline Systems, Inc., 1994

Prepared a Supervisory Control and Data Acquisition (SCADA) tendering specifications for Saudi Consolidated Electric Company (SCECO). Specification was for a backup SCADA system to provide minimal control capability should the primary system fail. Specified Unix Workstations with a distributed database sharing the existing telemetry with the primary system. The system serves about 50 substations in the distribution grid in Eastern Saudi Arabia.

Pipeline Systems, Inc, 1993

Reviewed conceptual design of computer controls, SCADA, for the Polish natural gas transmission system. Prepared report with input from the PSI team and presented it to Polish executives and technical experts. Examined reasonableness of compromise between technology and price, feasibility, conformance with standards and present practices and overall benefit. Examined telecommunications options, private versus public, for SCADA data network. The system is comprised of 1,600 km of medium and high-pressure transmission pipeline with 160 instrumented stations. There are 6 regions, each with its own SCADA center that is coordinated through a central center and backup in Warsaw, Poland.

Pipeline Systems, Inc, 1992

Task leader for the SCADA, fiber optic, telecommunications and mobile radio systems in the project management team of the natural gas pipeline in Greece. This is a $22M portion of a $1.8B project. Reviewed the engineering for completeness and suitability and prepared an extensive report. Coordinated preparation of the contract documents with engineering and tendering of the contracts. The system involves 1,000 km

of fiber optic telecommunications at 32 Mbps that connects 90 stations with 48 mobile radio stations and two fully computerize control centers. Included administration of large contracts, land and property issues, and work in multinational environment. Negotiated telecommunications with the Greek PTT (OTE) on behalf of the Greek Transmission Company DEPA. Very complex issues of the PTT monopoly in face of changing laws and privatization, quality requirements, redundancy of service and international communications rights were at issue.

Diomed, Inc., 1990 to 1992

Invented a new medical motion imaging technique and carried the product idea through to patent application. Applied for Small Business Innovative Research (SBIR) grant and approached venture capitalists,epared business plan and market evaluation. Prepared patent application with patent attorneys. This Diomed project was funded personally by Mr. Robertson.

Developed computer controls, Allen Bradley, programmable logic controllers (PLC), for a portion of a Coca Cola formula plant and programmed PLC controls for a research process at Genentech. Wrote procedures for FDA approval testing. Designed SCADA conceptual system for an oil pipeline utilizing HIP-800 and HP-1000 series computers with USData software.

ABJ Subsidiary of BHP (Now Sanitaire), 1985 to 1992

Devised innovative proprietary process control implemented with PLCs which increased the efficiency of the company's product and was presented at several conferences. Put in place an electrical engineering capability and set up standards for the controls. Designed and programmed 40+ PLC, Allen Bradley-based SCADA control systems for environmental water treatment processes in conformance with consulting engineer's plans and specifications. Most systems included motor control centers and the electric power distribution for the controlled equipment. Provided the interface details and loop diagrams for the instruments and controlled equipment. Developed a Bills of Materials data base for the control systems, engineering and procurement. This work extended over seven years on a part time consulting basis for a subsidiary of BHP Australia in San Francisco.

Guy F. Atkinson, Atkinson Systems, Inc., 1989

Conducted review of SCADA operations and large SCADA project for the Calavaras dam power plant that utilized minicomputers, radio and microwave links with thousands of points. Reviewed several 911 systems including communications equipment, dispatch computers and message handling systems.

PANTOGRAPH CORPORATION OF AMERICA (now Newing-Hall)
Vice President Engineering, 1986 to 1988

Responsible for the electronic, software and mechanical engineering components of the $5 million company including sustaining functions. Operated within budget, and achieved significant product innovation with high productivity from the group. Achieved technical leadership in the computerized engraving machine industry within two years. Produced the software and versions of the products for nine countries and languages. Recommended to this position by a venture capitalist firm based on the reputation from work with ultrasonic imaging equipment at CooperVision below.

COOPERVISION (Alcon Surgical)-Irvine, California, 1984/1986
Software Engineer (Contract as part of Robertson Engineering below)

Developed the GUI, control strategy and the embedded software for two ultrasonic ophthalmic imaging instruments. These products were manufactured and marketed for approximately ten years. Worked closely with the marketing staff to ensure that market realities drove the engineering decisions. Software was in assembly and Pascal for an Intel 80x86 powered system. Involved a custom video scan converter and a custom real-time operating system with 20 external hardware interrupts. Technologies include video scan conversion, four layer digital video stream, articulated ultrasonic transducer and one/two dimensional data display.

ROBERTSON ENGINEERING
Independent Consultant and Development Laboratory, 1978 to 1986

Performed contract research and development in private laboratory and at CooperVision (now Alcon Surgical). Products were primarily microsystem-based systems with embedded real time software. Most projects included both custom hardware and software. Developed two CNC controllers for press brake applications. Provided all the embedded software and system integration for two medical ultrasonic imaging instruments. The products have achieved market success and dominate their marketplace. Played a key roll in the development of these products, including integration. Products involve real time scan conversion, sophisticated graphics and custom circuitry. Used HP 64000 development system with Pascal and assembly languages.

EDC
Instrumentation Manager, 1976 to 1978

Responsible for the management of engineering department that developed PLC based industrial controls for water treatment systems. Designed control panels, field wiring, and control programs. Performed start up.

RAYCHEM CORPORATION
Electrical Engineer, 1974 to 1976

Developed digital electronic controls to automate manual wire spoofing machines. System incorporated solid state Numalogic control modules from Westinghouse. Worked with variable speed DC drives for plastic extruder applications. Involved with the controls for precision temperature control of the extruded plastic covering over electrical wiring specific for aircraft use,

INDEPENDENT CONSULTANT
1970 to 1974

Developed early digital electronic consumer product. Attempted to manufacture and market one of the first digital electronic clocks as a boutique type commercial product. Other consulting in the electronics area.

ESL (Now TRW)
Member of Technical Staff, 1966 to 1970

Performed communications system analysis, link calculations, noise analysis and worked with error detecting and correcting codes. Used statistical communications theory and audited courses at Stanford University for this purpose. Devised computer models of. communications systems for performance prediction. Member of team managing large aerospace contracts. Evaluated bid proposals from aerospace companies.

AUTONETICS DIVISION NAA (Now Boeing formerly Rockwell International)
Submarine Navigation System Programmer, 1964 to 1966

Programmed computers embedded into inertial navigation systems for Polaris nuclear submarines. Worked on submarines at Groton Connecticut Electric Boat Yard, rode sea trials and worked with all aspects of the inertial navigation systems.

OTHER PROFESSIONAL EXPERIENCE

Hardware and instrumentation expertise includes programmable logic controllers, ladder logic, SCADA graphic systems, Allen Bradley PLC5, PLC2, SLC, Control View and DTL for Unix, Factory Link, Wonderware Intouch, Intellution Fix 32, control panels, variable frequency drives, level instruments, flow instruments, pressure instruments, temperature instruments, PanelView Terminals, Nematron Terminals and Opto 22, ultrasound imaging, scan converters, Hewlett Packard In-Circuit Emulators, digital hardware. Software expertise includes real time

firmware for the Intel X86 family, embedded software for Z80, 6502, 8OX86 microprocessors, Operating systems: DOS, Windows NT, Windows 2000, Linux, OS/2. PC Application languages: Pascal, C, Assembly. Applications software expertise includes Visio, MS Word, MS Excel, MS Powerpoint, MS Project, Lotus Word Pro, Lotus 123, Lotus Freelance, dBASE III, Pagemaker, Designer, Generic CADD, MS Windows, OS/2 applications for PCs, Scitor Project Scheduler, Super Project, Picture Publishers, Computer Associates Super Project, Gopher, Wais, Usenet, Describe, Ami Pro, and Quatro Pro, Photoshop, Filemaker Pro, Dreamweaver, WebSphere Sudio Homepage Builder, MS Outlook, Palm, Palm synchronization, Blackbery

BIOGRAPHY

After earning BSEE and MSEE degrees at the University of Washington, Mr. Robertson programmed the inertial navigator computers used on the Polaris submarines at Autonetics (now Boeing). Following that, he joined ESL (now TRW). After four years as a member of the technical staff there, he entered the civilian realm and managed a small department that engineered the control systems for water treatment plants. This led to his own consulting operation in Mountain View where he continued the industrial control work for other companies and also worked with CooperVision (now Alcon Surgical) on the development of ultrasonic scanning instruments for ophthalmic surgery.

His reputation with the ultrasonic instrumentation led to being tapped by a venture capital firm to join a start up, Pantograph, in Larkspur, CA. to produce and market computerized engraving machines. After two years as VP Engineering there, the company was sold and he began consulting on the EC, World Bank and US Trade Development Agency projects. Subsequent to this he has returned to applications of industrial controls in the pharmaceutical industry and consulting to the legal community.

CONTACT

James G. Robertson
North Bethesda, Maryland