

JAMES G. ROBERTSON, M.Sc, P.E.
SCADA/Control System Engineer-Consultant

forensic investigation, incident analysis, regulatory compliance

Expert witness – Litigation Consultant

Web Site: <http://www.jgrobertson.com>

Mr. Robertson has extensive experience in Silicon Valley as an engineer, manager, owner of a small development lab that focused on machine controls and as a vice president of a start-up. Following on, he consulted to the EU & World Bank on the Supervisory Control and Data Acquisition (SCADA) system for a large gas pipeline project and was contracted to engineer about 60 water treatment control systems for multiple companies. As VP at Pantograph Corporation (now Newing-Hall Inc.), an engraving machine manufacturer, he was responsible for all engineering and product development. In recent years James has consulted to numerous pharmaceutical and medical device companies on compliance of computerized systems and information technology with security and FDA quality regulations. He has been an expert witness and consultant in more than 25 legal cases. Recent cases include an ICC mediation concerning a \$77 million SCADA system for a 2000 km natural gas pipeline in central Asia. Several cases involved the role of control systems in natural gas caused explosions and one involved the \$2.25 billion penalty case brought by the State of California against the utility PG&E over natural gas pipeline explosion and fire. James holds BS and MS (thesis program) degrees in Electrical Engineering and is a Registered Electrical Engineer, P.E., in California (E10043). He served active roles in the Institute of Electrical & Electronic Engineers (IEEE). He holds one patent and is named on several others.

Mr. Robertson's professional and technical career focus includes these areas:

- SCADA and PLC based process control systems and process instrumentation design, implementation and commissioning – approximately 60 small to medium systems mostly for water treatment. Worked to consulting civil engineer's plans and specifications under various supply contracts. Included electric power distribution for large machines.
- EU and World Bank large SCADA projects – natural gas pipelines – electric power grid – telecommunications
- Expert witness/litigation consulting including forensic investigations – over 26 cases involving SCADA, control systems, equipment. The cases involved supply contracts, patents, equipment failures, equipment & control system safety, SCADA system architecture, and SCADA telecommunications / infrastructure.
- Computerized system, Information system and IT security including data integrity in pharmaceutical, biotechnology & medical device manufacturing. Quality system development and risk based validation for compliance with FDA and SOX regulations.

- Custom machine controls and motion controls – board level, digital & analog circuit design, firmware and software. Devices include medical instruments, machine tools, hydraulic presses, submarine and aircraft inertial navigation systems, and engraving machines.

Mr. Robertson has been employed in these capacities over his career:

- Practicing electronics design and microsystem development engineer
- Owner of a small microsystem development lab in Silicon Valley
- Engineering management – PLC, SCADA and control systems
- Vice President of Engineering – Pantograph Corporation of America
- Consultant on large SCADA projects – Greece, Poland, Saudi Arabia
- Consultant to pharmaceutical/medical device companies

FORENSIC ENGINEER, CONSULTANT & EXPERT WITNESS

Some cases where Mr. Robertson provided testimony, deposition or report.

ICC Mediation conducted in Singapore, in 2017, involving the Supervisory Control and Data Acquisition (SCADA) system for a 2000km natural gas pipeline in central Asia. This involved the SCADA computers and software, fiber optic cable and electrical power lines, a terrestrial radio system for maintenance communications, security systems for stations, and a replaced pipeline cathodic protection system. The system has six regional centers, five compressor stations and 86 distribution stations in addition to the primary and redundant control centers. Mr. Robertson testified at the hearing in Singapore after providing three reports including a rejoinder reply and a joint expert report.

PLC and SCADA controls for a municipal bus compressed natural gas (CNG) fueling facility explosion and fire. Performed an extensive analysis of available data to construct sequence of events from recorded data and assessed the role of the control system as a cause for the incident. Provided report for mediation.

California Public Utilities Commission, Safety Division, San Bruno, CA natural gas explosion and fire. Performed a forensic investigation of PLC and SCADA control system and provided written testimony for the administrative proceedings determining penalties against the utility, Pacific Gas and Electric. This work contributed to the decision in September 2014 by the commission to levy a \$1.4 billion fine on the utility. Provided 1 direct and 2 rebuttal reports, witnessed three depositions.

BLUtag Satellite GPS tracking device employed by the DC court for monitoring activities of persons under supervision. The issues were reliability, maintenance and management of the device regards multiple reports of malfunctions by enrollees.

Controls for municipal sewer system Wisconsin. Mr. Robertson analyzed identified numerous contributing failures of the control system that contributed to backup and flooding of about 100 homes. Provided report.

Semiconductor Fab Clean Room HVAC controls & SCADA, Contract scope and industry standard practice issues. Plant in China, case in San Francisco. Provided Rule 26 expert's report to Federal Court for owner plaintiff - Motorola

SCADA control system for water treatment plant. Expert for plaintiff. Issue was the contractor's compliance with contract specifications and the technical appropriateness of installed system. Testified in court and in deposition. Los Angeles.

Los Angeles Metropolitan Water District. Case involved System Integrator contract for supply of SCADA and controls of a large water treatment plant. Issue was dispute about whether the system supplied by the contractor met the engineer's specifications and if it was suitable for the intended purpose. Testified in deposition for plaintiff.

Some patent cases where Mr. Robertson consulted to the attorneys.

Patent infringement matter involving the automated control system for vacuum deposition equipment used to coat glass and computer hard drive platters.

Patent infringement case for air quality data monitoring and archiving system supplied by a major manufacturer. Minnesota.

Patent infringement case involving the firmware and electronic design of Programmable Logic Controllers (PLC) produced by a major manufacturer. Role was to testify for defendant. Case resolved without testimony.

Patent infringement case claiming royalties for use of equipment with firmware alleged to infringe that was supplied by a vendor. This case was merged with the one above. Dallas.

Patent infringement case: Process control system software alleged to infringe. Performed prior art search. San Francisco.

Patent infringement case: Pharmaceutical process control (fermenter) software patent prior art search. San Francisco

Some cases where Mr. Robertson consulted to the attorneys on non-patent technical matters.

Natural Gas boiler explosion. Case involved the combustion and boiler PLC control system as cause of the explosion. Kansas.

Insurance matter: 4000HP motor in steel rolling mill failed and issue was responsibility for damages. Performed a forensic investigation of control system programming, maintenance and operation. Pennsylvania.

Insurance matter: Boiler explosion. Performed forensic investigation of role of proprietary control electronics as cause. Wisconsin.

Water treatment plant case. Civil suit about damages resulting from failures. Advised on the technical issues of the control systems. Georgia.

House fire ignition case. Mr. Robertson consulted to the company insuring the manufacturer of the electrical timer that was suspected as the ignition source. Examined the device, inspected the site including its electrical wiring. Reported findings to attorney. Woodside, California

Cogeneration plant explosion and fire. Expert for plaintiff. Provided opinion on the mechanism for failure of the control system. The control system failed which resulted in the explosion of the gas turbine engine. Question was whether the failure was design or maintenance related. Boulder Colorado

Contractual scope of supply for waste water plant control system. Performed forensic engineering for claim consultant. Opined on the suitability of the system the contractor proposed to supply and whether it met the engineer's specifications. Los Angeles.

SCADA control system being supplied by contractor to the plaintiff, Los Angeles Metropolitan Water District. Dispute over suitability of substitute system.

1988 to current

INDEPENDENT CONSULTANT

Consulting and project management for Supervisory Control and Data Acquisition (SCADA), network and IT infrastructure Information Security, System Integration and Industrial Controls including Pharmaceutical industry regulatory compliance of software, automation, information technology and computer related systems. Mr. Robertson specializes the risk based life cycle quality & validation methods.

Pharmaceutical, Biotech & Medical Device Clients Include:

2011: Bioreliance, Inc. – IT & Instrument data integrity, validation

2010: Consultant: Abbott Structural Heart (Menlo Park, CA) – IT, database and instrumentation data integrity and compliance –risk assessment

2006 – 2009: Boston Scientific (Quincy, MA and Miami, FL) HVAC, preventative maintenance system and non-conforming

- materials database, software, and computer system compliance.
- 2006: Ft. Detrick, Army Medical Research Laboratory – Laboratory instrument system (LIMS) data integrity, compliance and operational validation
- 2004 – 2005: Eyetech, New York – Developed a new compliance program of policies and SOPs for both FDA and Sarbanes Oxley Act compliance.
- 2004: McKesson Bioservices, Maryland – database data integrity validation.
- 2002: Wyeth, New York – managed compliance verification of new sterile filling facility. Siemens HVAC and data archiving system.
- 2001 – 2002: ALZA Corporation a Johnson & Johnson Company – Sterilization.
- 2001: B. Braun Medical, California – Compliance for LIMS and automation equipment.
- 2000: Covance Biotechnology Services, North Carolina – Compliance and validation computerized systems, DCS, chromatography, filtration, instrumentation.

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. Investigated electronic noise interference issues in the motion control equipment. Wrote Allen Bradley PLC programs, modified Wonderware graphical SCADA 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. Presented noise analysis paper to Exponet.

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 – HVAC (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. Assessed HVAC system and controls for clean room operations. Programmed PLC for sterilization controls in sterile filling area.

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.

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 computerized 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 obtained a patent. Applied for Small Business Innovative Research (SBIR) grant and approached venture capitalists, prepared business plan and market evaluation.

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

ABJ Subsidiary of BHP, 1985 to 1992

Devised innovative proprietary process control implemented with PLCs and SCADA software packages 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. Engineered, designed and programmed 30+ PLC, Allen Bradley-based SCADA control systems and control panels for environmental water treatment processes in conformance with consulting engineer's plans and specifications. Most systems included motor control centers and the 480 volt 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 Calaveras 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. The products have achieved market success and dominated their marketplace. Played a key role in the development of these products, including integration. Used HP 64000 development system with Pascal and assembly languages.

ROBERTSON ENGINEERING

Independent Consultant and Development Laboratory, 1978 to 1986

Mr. Robertson operated under the name Robertson Engineering a small development laboratory in Silicon Valley that was focused on the development of microsystems and SCADA for water treatment plants. Most projects were to develop board level electronics and firmware for mask programmed COPS 400 microprocessors from National Semiconductor. Some Projects he completed during this time are:

- Two ultrasound ophthalmic imaging instruments for CooperVision (now Alcon). He developed the software and firmware. One was a single axis "A" scanner and the other a complex two axis "B" scanner. The hardware was controlled interactively in real time by the firmware. These tasks required in-depth integration of both hardware and software.
- Automatic control electronics for two large Brake Presses for Pacific Press & Shear. Mr. Robertson developed complete systems with custom electronics and user interface software communicating with firmware to drive the hardware. These had user selectable part programs and included many safety features as well as automatic compensation for flexing during operation of the large presses.
- Robotic two axis nuclear fuel rod profilometer for GE. Mr. Robertson developed custom hardware and software to drive the stepper motors on the robotic measurement device. The device traveled the length of the fuel rod in a helical pattern and incorporated sensors to measure deformation. This subsystem communicated with a supervisory PLC controller.
- Process controls for several water treatment plants. These projects encompassed including large 400 HP centrifuges, extensive instrumentation, SCADA controls, multiple filter presses, central control panels and motor control centers.
- Smaller projects include programming of a hand held game for Atari, electronic controls for a Thermadore

electric range, a prototype entertainment system design for Ford and a memory car power seat controller.

ENVIRO DEVELOPMENT CORPORATION (EDC)
Instrumentation Manager, 1976 to 1978

Responsible for the management of engineering department that developed PLC based industrial controls with instrumentation and SCADA for about 30 water treatment systems. These were all designed to satisfy engineer's plans and specifications for the various new treatment plants. Designed control panels in all detail including field wiring, control panel hardware, programs. Included motor control centers and 480 volt power distribution. Selected and designed the instrumentation and electrical communications between devices. Performed start up and commissioning for some of the projects.

RAYCHEM CORPORATION
Electrical Engineer, 1974 to 1976

Developed digital electronic controls to automate manual wire spooling machines. System incorporated solid state Westinghouse Numalogic control modules. 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.

ELECTROMAGNETIC SYSTEMS LABORATORIES (ESL)
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 missile carrying nuclear submarines. Wrote a complete system

description of the system for the field support engineers and technicians. 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

While still a student, engineered and constructed a solid state aircraft navigation receiver employing leading edge electronics for that time. He published an article describing this design in "Electronics Magazine."

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. Technologies include: 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, 80X86 microprocessors. Experience with older operating systems including: DOS, Windows, Linux, and OS/2. Software expertise includes Visio, MS Word, MS Excel, MS Powerpoint, MS Project, MS Windows, OS/2 applications for PCs, Super Project in addition to PCL languages.

EDUCATION AND CERTIFICATION

- MSEE, University of Washington – thesis program
- BSEE, University of Washington
- CISA, Certified Information System Auditor, 2007 (non-practicing)
- 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, COBIT

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, former Member
- PDA, Parenteral Drug Association, former Member

- ISA, International Society of Automation, former Member
- NSPE, National Society of Professional Engineers, former Member
- ISACA, Information Systems Audit & Control Association, former Member

PATENTS

- "Apparatus and Method for Recording Jaw Motion", Patent Number 5,340,309, Issued 1994
- Named on two patents for water treatment process control systems. Licensed to EDC in the 1977 time frame.

PUBLICATIONS

- "QA vs. IT: Who Does What When to Maintain FDA Compliance," FOI Teleconference, April, 2011.
- "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, 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."
- Authored a chapter in the "Governance, Risk and Compliance Handbook" published by Wiley.

CONTACT

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