CURRICULUM VITAE

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SUMMARY

Thirty-three years of successful industrial experience in software development, software project management, software process improvement, software testing, software auditing, software project assessments, software quality assurance, medical manufacturing processes, medical computer software, systems engineering, medical device product development and diagnostics research and development; seven years of broad experience in academic laboratories in medical cardiovascular physiology, biochemistry, and organic chemistry. Unique combination of both practical and theoretical experience with good organizational and problem solving skills. Broad knowledge of product development strategies, manufacturing, team-based development and total quality management principles. Expertise in applying group facilitation techniques, people skills and systemic family therapy techniques to organizations and teams.

PROFESSIONAL EXPERIENCE

December 2017 - Current

Software Consultant
Software Auditing, Verification and Validation
Software Project Management, Software Process Improvement, Software Team Building,
Software Retrospectives, Software Assessments.
Various medical, pharmaceutical, industrial, and computer manufacturers in the Southern California area and across the United States.

Provides expert level consulting in various software life cycle activities including ISO 9000-3/TickIT certification, ISO 12207, ISO 14971, SW68, IEC 62304, CMM-Based Appraisal Evaluation (SCE's), software process improvement, software project assessments, software project management, requirements analysis, verification and validation, testing, safety and hazard analysis, software metrics, software quality assurance, software traceability analysis, software process improvement using the SEI CMM. Provides expert consulting in the FDA's Pharmaceutical cGMP's, QSR/GMP's, the FDA's 21 CFR Part 11 (electronic records). Provides assistance in writing and developing FDA's 510k and PMA submissions for computerized devices and software. Provides consulting and coaching in people skills and team facilitation skills, including software team building, software retrospectives, communication models, conflict resolution, change models, Myers Briggs Type Indicator (MBTI) assessments, and experientially-based team training exercises.

December 2017 – Current

Software Consultant
RxSight, Inc.
Aliso Viejo, California

Responsible for assisting in reviewing software documentation and development practices for a PMA submission of UV modified implantable lens. Activities included reviewing software and system requirements, reviewing risk hazard analysis, reviewing software procedures and practices, development of GUI test cases and system level test cases for the PMA release, recommending updated cybersecurity controls for both the software organization and the device software/hardware. Consulting also included general software development best practices.

January 2017 – December 2017

Software Validation Consultant
Glaukos, Inc.

San Clemente, California

Responsible for the validation of a commercial off-the-shelf (COTS) Complaint Management System that included customizations for the Regulatory Affairs organization. Responsibilities included creating software requirements document, risk hazard document, design documentation, testing documentation, and the validation summary report for the deployed system.

July 2015 – December 2017

Software Consultant
Calhoun Vision, Inc.
Pasadena, California

Responsible for assisting in reviewing software documentation and development practices for a PMA submission of UV modified implantable lens. Activities included reviewing software and system requirements, reviewing risk hazard analysis, reviewing software procedures and practices, development of GUI test cases and system level test cases for the PMA release, recommending updated cybersecurity controls for both the software organization and the device software/hardware. Consulting also included general software development best practices.

November 2014 – June 2017

Software Consultant
Alcon LenSx Lasers, Inc.
Novartis, Inc.
Lake Forest, California

Responsible for assisting in updating software validation activities for an existing ophthalmic laser controlled software system. Activities included reviewing and updating software and system requirements, reviewing and updating software procedures and practices, development of unit test cases, gui/integration test cases, system level test cases, and execution of unit, gui/integration, and system level integrated testing on an ophthalmic laser system.

July 2013 – January 2017

Software Consultant
Stroma Medical, Inc.
Irvine, CA

Provided general software consulting on meeting CE, MDD, and FDA software requirements for a cosmetic ophthalmic medical device. Responsibilities included providing templates for basic software plans and software documentation for First In Human Studies. Also reviewed various design and development documents (risk and hazard, software requirements, software architecture and software design documents) and provided recommendations for meeting MDD and CE certification with respect to software. Assisted in creating and executing software testing documentation for initial clinical trials.

May 2015

Software and Regulatory Consultant
Cirle
Miami, Florida

Provided software regulatory consulting for an ophthalmic device to determine IEC 62304 classification. Work included reviewing Risk Hazard Analysis and Operator's manual.

December 2014 – May 2015

Software and Regulatory Consultant
Icare Finland Oy
Vantaa, Finland

Provided software regulatory consulting for an ophthalmic glaucoma device and home version of the device and accompanying control software. Work included reviewing high level software documentation and risk management documents. Provided client with document with recommendations based on a review of the supplied documentation based on risk and previous FDA 510k submissions and inspections. Wrote the software section of the regulatory 510k for the client for inclusion with the device 510k.

January 2013 – March 2013

Software and Regulatory Consultant
IDx, LLC.
Iowa City, Iowa

Provided software validation and software regulatory consulting for a new ophthalmic retinal device and accompanying control software. Work included reviewing high level software documentation and risk management documents. Provided client with a 13 page review document with recommendations based on a review of the supplied documentation based on risk and previous FDA 510k submissions and inspections.

December 2012 – November 2014

Software Consultant
Alcon LenSx Lasers, Inc.
Novartis, Inc.
Aliso Viejo, California

Responsible for assisting in updating software validation activities for an existing ophthalmic laser control software system. Activities included reviewing and updating software and system requirements, reviewing and updating software procedures and practices, development of unit test cases, gui/integration test cases, system level test cases, and execution of unit, gui/integration, and system level integrated testing on an ophthalmic laser system.

January 2012 – June 2012

Software and Regulatory Consultant
Daat, Inc.
Chicago, IL

Provided software and regulatory consulting on meeting the medical device data system (MDDS) requirements for CFR 880.6310 for a web based hematology blood coagulation information system. Provided a technical letter to file to support the classification of the software system as a true MDDS. Reviewed letter to file and associated Quality Plan to meet the QSRs as a MDDS supplier. Also provided regulatory guidance on 513g determination (regulatory classification of medical devices) for software medical products and helped to develop the strategy for submission or registration to the FDA.

March 2011 – April 2011

Software Consultant
Capsovision, Inc.
Saratoga, CA

Provided general software consulting on a meeting HIPPA requirements as it pertains to a medical device data system (MDDS). Provided written opinion on whether new features and functions affect regulatory classification and how to best prevent a change in regulatory classification. Provided client with software requirements for making current application HIPPA ready. Provided regulatory guidance and strategy on validating new features and functions as it applies to current FDA, CE and MDD requirements.

September 2010 - December 2012

Software Consultant
Alcon LenSx Lasers, Inc.
Aliso Viejo, California

Responsible for assisting in software validation activities for a new ophthalmic laser control software system. Activities included reviewing software and system requirements, reviewing and developing software procedures and practices, development of unit test cases, system level test cases, and execution of unit, system level integrated testing on a new ophthalmic laser system.

Also responsible for reviewing and editing various software development procedures and software development plans, participating in lifecycle design and software reviews, code reviews, participating in the software change control board for software errors and new features, and providing various GMP and regulatory determinations for software development activities within the organization. Also participated in internal and external 3rd party audits (software focus) for CE/MDD certification, an Alcon Corporate Audit, a Novartis Corporate Audit and a local FDA site audit.

May 2010 – Aug 2010

Software Consultant
Lumineyes, Inc.
Newport Beach, CA

Provided general software consulting on meeting FDA software requirements for a cosmetic ophthalmic medical device. Responsibilities included providing templates for basic software plans and software documentation for First In Human Studies.

Also reviewed various design and development documents (risk and hazard, software requirements, software architecture and software design documents) and provided recommendations for meeting MDD and CE certification with respect to software. Assisted in creating and executing software testing documentation.

March 2010 – April 2010

Software Consultant
Capsovision, Inc.
Saratoga, CA

Provided general software consulting on a meeting CE mark requirements for a miniature portable gastrointestinal camera. Activities included reviewing MDD and Annex 14 requirements as it pertains to software, reviewing ISO 13485 and IEC 62304 as it applies to their internal software development activities based on MDD device classification, reviewing the applicability of various documents included in their Technical File, providing a template for a validation plan for software, reviewing and providing suggestions on how to use and meet Usability Standards (IEC 60601-1-6 and IEC 62366) as it pertains to software, and reviewing the applicability of the Programmable Medical Electrical Medical System Standard (IEC 60601-1-4) to the embedded software in the portable camera.

August 2009-September 2009

Software Consultant
OD-OS, GMBH
Teltow, Germany

Provided software regulatory consulting on a 510k submission for a new retinal ophthalmic laser system. Activities included reviewing software and system requirements, providing templates for meeting FDA 510k submission requirements for software, reviewing third party software documentation and providing a roadmap to insure that the company receives 510k approval for their software.

June 2008-August 2010

Software Consultant
LenSx Lasers, Inc.
Aliso Viejo, California

Responsible for assisting in validation activities for several 510k submissions for a new ophthalmic laser control software system. Activities included reviewing software and system requirements, reviewing and developing software procedures and practices, development of unit test cases, graphical user interface (GUI) test cases, and system level test cases, and execution of unit, graphical user interface level, system level integrated testing on a new ophthalmic laser system.

Also responsible for reviewing and editing various software development procedures, software development plans, participating in lifecycle design and software reviews, code reviews, participating in the software change control board for software errors and new features, and providing various GMP and regulatory determinations for software development activities within the organization.

February 2008

Expert Consultant
Intota/Guideline Expert Consultation
Armstrong Flooring
Lancaster, PA

Provided expert telephone and email consultation on the key factors for selection and implementation of a Laboratory Information Management System (LIMS) to be used by a R&D and Engineering organization. Responsibilities included identifying the critical application factors and human and organizational factors that impact on the successful implementation of LIMS software package. Background research on LIMS systems and vendor suppliers was addressed as well as recommendations for successful implementation based on my experience with successful deployment of several LIMS systems for past clients.

January-February 2008

Software Consultant
American Medical Optics
Irvine, California

Created and documented unit tests for a new version of software that is used to control an ophthalmic medical laser. Responsibilities included documenting and executing specific unit tests in conjunction with software engineering for specific software modules based on the actual software code, the software architecture and the software design.

July 2007-November 2007

GMP and Validation Consultant
ComplianceOnline
Redwood City, California

Provided online, on-demand and web-based FDA compliance and regulatory presentations and training to paying members and member organizations that subscribe to the various services that the company provides to the industry. Developed training materials for an introductory GMP training class for the dietary supplement industry. In addition to the web training I also provided individual consulting on specific topics of interest (FDA compliance, specific aspects of the cGMPs) to individuals who had specific questions about the training and web conferences that they participated in. As an additional service I also developed various tools, papers and electronic files, training aids and webinar reference materials that were available for sale or download within the online store for the website. Presentations included a webinar on CFR Part 111, the new Dietary Supplement Current Good Manufacturing Practices (cGMPs).

December 2005-November 2006

Software and GMP Consultant
RSI ID, Inc.
Chula Vista, CA
Cordis Division
Johnson & Johnson
Miami, Florida

Provided FDA compliance and regulatory software consulting on software development activities that are being used to develop software to control a cardiovascular stent automated packaging system. Activities involved working with and assisting various subcontractors and a software development organization with the system development life cycle and assessing current software development practices against Johnson & Johnson Corporate Validation practices. The scope of the work included 21 CFR Part 11 evaluation, creation of software and system requirements, and participating in various technical reviews and prototype evaluation.

October 2006-December 2006

Software Consultant
Intralase Corporation
Irvine, California

Responsible for assisting in validation activities for a new 510k submission for laser control software. Activities included reviewing software and system requirements, development of system level test cases, development of and testing of new hardware test fixtures, and execution of system level integrated testing on a new laser system.

August 2005-June 2007

Software and GMP Consultant
AS-Software, Inc.
R&D Department
Englewood, New Jersey

Provided compliance and regulatory software consulting on internal QSR and software development activities that are being used to develop software used for an obstetrics and gynecology ultrasound patient information management system. Activities involved working with a consultant and the Software Development organization and assessing current software development practices. Created a Work Plan to bring the organization into FDA CFR 820 compliance and to meet documentation requirements for premarket approval (510k) for their device software. Created various software development plans/templates for software development in order to meet FDA design controls, premarket approval submissions and regulatory inspections. The scope of the work also included 21 CFR Part 11, HIPPA, HL7, and DICOM compliance.

The second phase involved developing documentation and SOPs to meet the requirements for implementing a Quality System within the organization. Consulting involved developing SOPs (internal auditing, management review, CAPA, MDR reporting, complaints, servicing), creating a Quality Plan and Quality Manual, provide overview training for FDA Inspections, reviewing and providing guidance on other QSR related documentation.

July 2005-June 2006

Software and GMP Consultant
NeuroComp Systems, Inc.
R&D Department
Irvine, California

Provided compliance and regulatory software consulting on internal QSR and software development activities that are being used to develop software used to measure cognitive function loss from neurological degenerative diseases such as Alzheimer's disease. Activities involved meeting with Software Engineering Departments and assessing current software development practices. Created a ISO 14971 compliant Risk Management Document Template, and various software development templates for software development in order to meet FDA design controls, premarket approval submissions and regulatory inspections. The scope of the work included consulting on the HIPPA Privacy Rule and the HIPPA Security Rule, as well as regulatory compliance with Clinical Trials using computerized systems and applications.

January 2004-October 2004

Software and GMP Consultant
Software Verification and Validation
Intralase Corporation
Irvine, California

Responsible for validation activities for a second generation Class II ophthalmic medical laser to insure it meets the current FDA's Good Manufacturing Practices (cGMP's) and Quality System Regulations (QSRs). Responsibilities and work included:

- Co-wrote and reviewed the current Software Development Plan, Software Configuration Management Plan, and the Software Verification and Validation Plan for the software project.
- Co-wrote, developed, reviewed, and coordinated the Software Requirements documents.
- Co-wrote, developed, reviewed and coordinated the Software Architecture document.
- Co-wrote, developed, reviewed and coordinated part of the Software Detailed Design documentation.
- Developed code inspection process for safety critical source code modules. Led, participated in and trained development staff in formal code inspections (Ebenau and Strauss method).
- Developed and co-wrote the Software Traceability Matrix for the entire software system.
- Developed and wrote the all Software Testing Plans (Unit, Integration, System) for the project.
- Developed and wrote all Software Test Cases for systems testing on the project.
- Coordinated all verification activities with the Manager of Software Engineering and coordinated all validation activities with the Laser Physics, Electrical, Mechanical, Manufacturing, and Quality Systems staff.
- Performed state-of-the-art software systems testing on the hardware system and documented all test results. Developed and implemented corrective action process for software changes and software defects.
- Reviewed all software changes and software bug reports for systems testing.
- Developed and wrote the Software Testing Summaries, Software Problem Report Summaries, Release and Version Summaries and Software Certification for the system software.
- Acted as the Technical Software Consultant for Intralase for the entire project with regards to defining FDA compliant standards and internal processes during development and maintenance.

September 2003-December 2003

Software Consultant
Endocare
Regulatory Affairs Department
Irvine, California

Provided compliance and regulatory software consulting on internal QSR and software development activities that are being used to develop control software for a next generation cyrotherapy medical device. Activities involved meeting with Quality, Regulatory Affairs and Software Engineering Departments and assessing current software development practices. Created SOPs, templates,

forms and checklists for software development in order to meet FDA design controls, regulatory inspections, and risk management activities.

March 2003-September 2003

Software and GMP Consultant
NeuroComp Systems, Inc.
R&D Department
Irvine, California

Provided compliance and regulatory software consulting on internal QSR and software development activities that are being used to develop software used to measure cognitive function loss from neurological degenerative diseases such as Alzheimer's disease. Activities involved meeting with Software Engineering Departments and assessing current software development practices. Created a Quality System Manual and software development template for software development in order to meet FDA design controls and regulatory inspections.

June 2003-December 2003

Quality Management/Validation Consultant
Pfizer Global Research and Development (PGRD)
Enterprise Informatics (Ei)
Quality Management Department
La Jolla, California

Provided full technical and regulatory validation support, technical leadership and process consulting for the entire Research Informatics organization (R&D) and for three business lines, which includes Pharmaceutical Sciences, Pharmokinetics/Dynamics/Metabolism, and Safety Science.

Provided internal consulting (software engineering, quality management, GMPs, and regulatory compliance consulting) on several Ri Informatics projects, including Watson LIMS (Laboratory Information Management Systems), Xybion Pathology Toxicology System, Information Management System (IMS), Citrix implementation of LabWare LIMS, Contracts Application Program, Server Consolidation Project, Computerized Vendor Audits, and Part 11 Remediation Projects. Co-developed and led GMP training for computerized applications/systems for 33 Informatics associates. Helped co-develop GLP training for computerized applications/systems for approximately 30 Informatics associates. Facilitated four Project Retrospectives for the various Informatics project teams.

Facilitated a Change Management session for DSi organization during Informatics reorganization. Interviewed candidates for business line scientific and computer positions using performance-based behavioral interviewing techniques. Worked closely with QM colleagues at 4 other sites (Sandwich, Groton, Ann Arbor, St. Louis) and Regulatory Quality Assurance (RQA) in La Jolla.

November 2002-January 2003

Software Validation Consultant
North American Scientific, Inc.
Chatsworth, California
Automation GT, Inc.
Poway, California

Responsible for coordinating the software development life cycle and validation activities for a new manufacturing PLC-based computer controlled radionuclide bead sorting system to insure it meets the current FDA's Good Manufacturing Practices (cGMP's) and Quality System Regulations (QSRs).

- Wrote, developed, planned and scheduled software quality assurance activities.
- Wrote and developed the current Software Verification and Validation Plan.
- Wrote, reviewed, updated and baselined the Software Requirements document.
- Wrote, reviewed, updated and baselined the Software Detailed Design document.
- Reviewed and baselined the Software Code document.
- Developed, documented, and reviewed the System and Software Safety and Hazard Analysis including software fault tree analysis and failure mode and effects analysis (FMEA).
- Developed, documented, and reviewed the Software Traceability of the system against the Software Requirements.

- Developed and wrote the Software System and Acceptance Testing Plans and performed state-of-the-art software testing on the system. Developed and implemented corrective action process for software.
- Performed physical configuration auditing of the software deliverables and software system.
- Acted as the Technical Software Consultant for North American Scientific, Inc. and Automation GT, Inc. for this project.

July 2001-June 2003

Quality Management/Validation Consultant
Pfizer Global Research and Development (PGRD)
Development Science Informatics (DSi)
Research Informatics (Ri)
Quality Management Department
La Jolla, California

Provided full technical and regulatory validation support, technical leadership and process consulting for the entire Development Sciences organization (R&D) and for three business lines, which includes Pharmaceutical Sciences, Pharmokinetics/Dynamics/Metabolism, and Drug Safety Evaluation. Participated in a site wide PGRD 21 CFR Part 11 Assessment. Over 220 systems were reviewed, documented and assessed. The assessed projects included spreadsheets, analytical laboratory systems, IT systems and global Informatics systems. Involved in site wide remediation of these informatics systems.

Provided internal consulting (software engineering, quality management, GMPs, and regulatory compliance consulting) on several DSi/Ri Informatics projects, including LabWare LIMS (Laboratory Information Management Systems), Chromatography Data System (Waters Millennium 4.0), SSI Cyberlab 2.1 data archive, Blue Mountain Calibration Manager, Batch Record Systems, Clinical Material Tracking system, Import/Export application, Peoplesoft Material Management ERP application, Business/Financial Records systems, Investigational Sciences Database, Global Scientific Warehouse, SOP documentation system, and a Training Management (Click2Learn) system.

Assisted in building, organizing and staffing the DSi and Quality Management organization within Informatics. Served as acting QM manager responsible for 1 employee, 3 contractors and 1 consultant. Activities included providing GxP training, writing departmental and Quality Management SOPs, GMP SOPs, validation plans, validation protocols, and validation summary reports. Participated on the Leadership team for the department providing testing, project management, strategic planning, and quality consulting. Participated on number of global organizations including World Wide Quality Management Team, Global Vendor Audit Team, and the Global Part 11 Team. Acted as Line Head for the Quality Management group. Mentored Quality Management colleagues.

July 2001-July 2001

Consultant
21 CFR Part 11 Training
Compass Limited Corporation
Dallas, Texas

Responsible for providing training and consulting on 21 CFR Part11 for an IT consulting organization. Training and information was used to secure consulting contracts on future application development projects.

February 2000 - December 2003

Software and GMP Consultant
Software Verification and Validation
Intralase Corporation
Irvine, California

Responsible for coordinating the software development life cycle and validation activities for a new Class II ophthalmic medical laser to insure it meets the current FDA's Good Manufacturing Practices (cGMP's) and Quality System Regulations (QSRs). Company passed a FDA and California State Health Department facility inspection and design control audit based on supplied deliverables, and the activities and processes utilized as part of my consulting. As a result, the Company received a certificate to sell its medical device in the State of California. Responsibilities and work included:

- Estimated, developed, planned and scheduled software development and validation activities using parametric cost and estimating software programs (Estimate, COCOMO II and Microsoft Project 98).
- Co-wrote and reviewed the current Software Development Plan, Software Configuration Management Plan, and the Software Verification and Validation Plan for the software project.

- Co-wrote, developed, reviewed, and coordinated the Software Requirements documents.
- Co-wrote, developed, reviewed and coordinated the Software Architecture document.
- Co-wrote, developed, reviewed and coordinated part of the Software Detailed Design documentation.
- Developed code inspection process for safety critical source code modules. Led, participated in and trained development staff in formal code inspections (Ebenau and Strauss method).
- Developed, analyzed, revised and documented the Software Safety and Hazard Analysis including fault tree analysis and failure mode and effects analysis (FMEA) utilizing ISO 14971 (Medical Device Risk Management Standard).
- Developed and wrote the Software Traceability Matrix for the entire software system.
- Developed and wrote the all Software Testing Plans (Unit, Integration, System) for the project.
- Developed and wrote all Software Test Cases for all levels of testing on the project.
- Coordinated all verification activities with the Manager of Software Engineering and coordinated all validation activities with the Laser Physics, Electrical, Mechanical, Manufacturing, and Quality Systems staff.
- Performed state-of-the-art software testing on the GUI interface and hardware system and documented all test results. Developed and implemented corrective action process for software changes and software defects.
- Reviewed all software changes and software bug reports.
- Created and developed software metrics for the entire project.
- Developed and wrote the Software Testing Summaries, Software Problem Report Summaries, Release and Version Summaries and Software Certification for the system software.
- Performed and documented both physical and functional configuration audits on the software system and development process before release.
- Acted as the Technical Software Consultant for Intralase for the entire project with regards to defining FDA compliant standards and internal processes during development and maintenance.
- Developed and carried out a Project Post Mortem and Project Retrospective after the completion of the project.

May 2000-October 2000

Software and GMP Consultant
LifetecNet.Com
Westboro, Massachusetts

Provided software project consulting to insure that the new business-to-business (B2B) electronic commerce Web site would meet Food and Drug Administration (FDA) Pharmaceutical and Medical Device Current Good Manufacturing Practices (cGMP's). Responsibilities included creating a project software development plan, project software configuration management plan, and project software quality assurance (validation) plan for the Web site and integrated third party applications. Also, provided a standard operating procedure (SOP) for a specific regulatory procedure. Provided feedback and expert opinion on architecture, design, design control, coding, testing, traceability and version control practices and documents for the project. All project consulting was provided virtually.

March 2000-April 2000

Software Consultant
Warner Bros.
New International Television Division
Management Information Services
Burbank, California

Provided a project assessment of the first phase of a 4-tier Client Server, Java-based, worldwide Intranet application for the New International Television Division. The project assessment covered the development and quality assurance organizations and culminated in a 28 page assessment report with an implementation plan for suggested project improvements. Activities included interviewing project management, developers and support staff for the project and reviewing project processes and documentation. The assessment also included an evaluation of the human aspects of development and recommendations for improving speed for delivery.

December 1998-June 2000

Software Consultant/SQA Engineer
Xerox Corporation
Printing Systems Group (PSG)/Production
Controller Development Team (PCDT)
El Segundo, California

Responsible for assisting in the setting up of a SEI CMM-compliant Software Quality Assurance Department across the organization and across multiple development sites. Participated in several SEI CMM Evaluations and a SEI CMM CBA-IPI assessment leading to Level 2 certification and completion of 50% of the Level 3 activities. Helped develop and review the SQA processes and artifacts to support both project and organizational CMM and SEPG processes. Provided coaching and assessment training to 8 members of SQA group and 40 plus members of the development group. Provided SQA audit support of work products, software processes, and management processes for 4 software projects encompassing up to 3 million lines of code. Other responsibilities included developing assurance plans, metrics, estimation processes for the SQA organization. Provided software process improvement consulting at the project level as well as general CMM consulting since I have been trained as a lead SCE assessor.

October 1999-December 1999

Consultant
Operations Department
Alcon Surgical, Inc.
Irvine, California

Provided validation consulting for a medical ophthalmic ultrasound measuring device. Responsibilities include writing plans, procedures, and validations; and performing reviews and statistical tests to support the FDA Current GMP's, internal regulatory compliance, 510k compliance for ultrasonic devices, verification and validation testing, and software documentation.

April 1998-October 1998

Software Consultant/Software Lead Tester
SAP Validation and Software Testing
IBM Global Services and Kubota Tractor Corporation
Torrance, California

Responsible for test planning, test schedule development, test progress reporting, unit and integration testing of an add-on module for SAP R/3 for a US subsidiary of Japanese Corporation. Team leader for the bolt-on module group, which included two contractors and one IBM employee. Bolt-on software application interacted with SAP MM, FI and SD Modules within the AS/400 environment.

Also responsible for assisting in the set-up of a configuration management system (*Implementer* by Silvon) for a commercial banking package, *Silverlake*. Technically responsible for testing various aspects of the transaction-based banking and loan package which will interface with the SAP system. Testing included Year 2000 assessment and testing. Organized, coordinated and set up the transaction based batch process as well as the banking testing environment on an AS/400 for the entire quality assurance group. Also responsible for assisting in the managing of up to 25 testers, which included both IBM employees and independent contractors. Responsibilities included managing testers and team test leads, resolving technical conflicts, interfacing with developers and super users, generating a software post mortem of the project, and testing/resource planning.

December 1996-April 1998

Consultant
Software Verification and Validation
Ismecam, Inc.
Carlsbad, California

Responsible for managing and coordinating the software quality assurance activities with Integ, Inc. of St. Paul, MN for an automated medical assembly machine to insure it meets the Federal regulatory standards.

- Wrote, developed, planned and scheduled software quality assurance activities.
- Wrote and developed the current Software Verification and Validation Plan.
- Reviewed, updated and baselined the Software Requirements documents.
- Reviewed, updated and baselined the Software Detailed Design documents.
- Reviewed and baseline the Software Code documents.
- Developed, documented, and reviewed the Software Safety and Hazard Analysis including software fault tree analysis and failure mode and effects analysis (FMEA).
- Developed, documented, and reviewed the Software Traceability of the system against the Software Requirements.

- Developed and wrote the Software Testing Plans (Unit, Integration, and System) and performed state-of-the-art software testing on the system. Included Year 2000 assessment, planning, testing and compliance. Developed and implemented corrective action process for software.
- Created and developed software metrics for the validation and testing.
- Performed physical configuration auditing of the software deliverables and software system.
- Acted as the Technical Software Consultant for Ismecam, Inc. and Integ, Inc. for this project.

Sept 1997-Nov 1997

GLP/GMP Computer Consultant
Consolidated Laboratory Services
Van Nuys, CA

Provided consulting in the Good Laboratory Practices (GLPs) and Good Manufacturing Practices GMP's (drugs and biologics) for various drug testing instrumentation and a LIMS systems for a reference laboratory in order to meet FDA GXP guidelines for computerized systems as a pre-inspection assessment. Responsibilities included creating a computerized instrumentation audit plan, various sample templates (including IQ, OQ, and PQ documents), an audit checklist, and a final audit report with recommendations for compliance for the various analytical systems. Responsibilities also included reviewing other computerized systems such as a third party database, and reviewing current plans, procedures, SOP's and validations; to support the FDA Current GXP's.

February 1997-January 1998

Consultant
Operations and Quality Departments
Alcon Surgical, Inc.
Irvine, California

Provided consulting in research and development and manufacturing activities of a medical ultrasound measuring device. Responsibilities include writing plans, procedures, and validations; and performing reviews and statistical tests to support the FDA Current GMP's, ISO 9001, Clinical Field Evaluations, Medical Device Directive, CE certification, IEC 60601-1, IEC 60601-1-4, internal regulatory compliance, 510k compliance for ultrasonic devices, requirements analysis, verification and validation testing, safety & risk hazard analysis, and software documentation. The work encompassed all aspects of development from the feasibility stage to manufacturing release.

Completed written software validation protocols for installation and operational qualifications (IQ and OQ) for manufacturing test equipment used in Metrology, Manufacturing and Production.

May 1996-April 1997

Consultant
SEI CMM and SCE Consulting
Liebert (Emerson) Corporation
Irvine, California

Provided consulting in various key software process areas for the Software Engineering Institute's (SEI's) Capability Maturity Model (CMM) and CMM-Based Appraisal Evaluation (Software Capability Evaluation's or SCE's). Responsibilities included performing and documenting product requirements and software requirements procedures, software configuration management plans and procedures, software project planning and control procedures, and software project tracking plans and procedures. Also audited the software development group against the CMM, version 1.1, and performed general software process improvement consulting.

August 1995-May 1997

Consultant
Software Verification and Validation
Alcon Surgical, Inc.
Irvine, California

Validated key components of an IBM AS-400 custom Material Resource Planning (MRP) software program used within the company by the receiving, quality, and manufacturing organizations. Major responsibilities included 1) creating a software quality assurance plan for the MRP project, 2) creating software validation project schedules and updates for each of the modules, 3) creating software functional requirements for these software modules in order to test against the specifications, 4) creating test cases for each of the modules, 5) executing the tests cases, 6) recording and tracking any discrepancies or software errors, and 7)

performing regression tests to fixed software. Also was responsible for putting together the final certification summaries for each of the MRP modules. Also validated and tested the following additional software systems:

- Microsoft Access Complaint Handling System under Windows 3.1/Windows 95
- Technical Support (Help Desk) Software package (Astea) under SCO Unix
- Manufacturing Statistical Sampling Package under DOS.
- Supplier Corrective Action Program (AS 400/MRP system)
- Created SQA Plans for each above projects.

October 1993-April 1995

Consultant
Software Verification and Validation
Ismecam, Inc.
Carlsbad, California

Responsible for managing and coordinating the software development activities with Ohmeda, Inc. for an automated medical assembly machine to insure it meets the current FDA's Good Manufacturing Practices (cGMP's).

- Developed, planned and scheduled software development activities.
- Wrote the current Software Development Plan, Configuration Management Plan, and the Software Verification and Validation Plan.
- Wrote, developed and coordinated the Software Requirements documents
- Wrote, developed and coordinated the Software Architecture document.
- Wrote, developed and coordinated part of the Software Detailed Design documentation.
- Developed and documented the Software Safety and Hazard Analysis including fault tree analysis and failure mode and effects analysis (FMEA).
- Developed and wrote the Software Testing Plans (Unit, Integration, System, and Acceptance) and performed state-of-the-art software testing on the system. Developed and implemented corrective action process for software.
- Created and developed software metrics for the entire project.
- Acted as the Technical Software Consultant for Ismecam, Inc. and Ohmeda, Inc. for this project.

April 1994-May 1994

Consultant
ISO 9000-3 Auditing
Emulex, Inc.
Irvine, CA

Performed preliminary ISO 9000-3 and TickIT software audit for the network products development group. Company received ISO 9001 certification and TickIT certification from the British Standards Institute.

August 1990-October 1993

Senior Research Scientist
Advanced Development Group,
Developmental Engineering
Paramax Chemistry
Baxter Diagnostics Inc.
Irvine, California

Responsible for managing and supervising one Associate Research Scientist. Coordinated all aspects of computation and computational requirements for the next generation instrument.

- Developed, planned, scheduled and implemented a software prototype for computation on a next generation clinical diagnostic instrument. Performed extensive software validation and verification.
- Demonstrated feasibility of new computational methods on a new instrument using multivariate and chemometric data analysis techniques.
- Wrote and reviewed all calculational specifications and documented the design using structured analysis and structured design techniques.

- Investigated CASE, new software development methodologies, new software methods and ISO 9001/9000-3 for the division to cut costs and reduce development time.
- Member of a Company Quality Measurement group to implement measurement and statistical-mindedness within all disciplines of the company.
- Participant writer on the 1992 Baxter Quality Award application, which was modeled after the Malcolm Baldrige National Quality Award.
- Sole Baxter representative for the Irvine Research Unit in Software (IRUS) and the Southern California Software Process Improvement Network (SPIN).

April 1988-August 1990

Research Scientist
Advanced Development Group,
Systems Integration
Paramax Systems Division
Baxter Healthcare Corporation
Irvine, California

Played a key role in a UNIX-based software simulation and modeling of a future instrument. Performed and designed response surface optimization of various instrument parameters in order to specify the design of a new instrument. Wrote requirements specifications and software code for a non-linear calibration and calculation software package. Designed a software testing methodology and performed extensive software testing of a nonlinear calculational package on VAX hardware. Developed a new robust kinetic algorithm that would improve the performance of several kinetic chemistries. This entailed performing linearity, interference, and correlation studies on the current instrument. Demonstrated feasibility of a new hypertext textual database that is to be used on the new instrument project and master project file. Principles of human factors and human computer interaction were used in the development of the prototype system. Arranged and organized an in-house C programming class for the Diagnostics and Systems Engineering groups. Evaluated several novel data analysis techniques for use in the new instrument using chemometrics and advanced signal processing techniques. Assisted in the evaluation of using CASE, artificial intelligence, object oriented programming, expert systems, and advanced statistics in the new instrument.

March 1986-April 1988

Assistant Research Scientist
Sensor Diagnostics, Inc.
Irvine, California

Responsible for the assembly and physical characterization of a multiple conductivity immunodiagnostic sensor. Assisted in the research and development of a solid-phase immunodiagnostic instrument and associated reagents. The technology for this instrument is based on optical detection of antibody-analyte complex. Evaluated, recommended, and set up company personal computer systems and software. Screened monoclonal antibodies for binding specificity, kinetics, cross reactivity, and affinity using radioactivity. Performed lyophlization of screened antibodies. Performed and designed experimentation for the development of an assay for therapeutic drug monitoring. Areas included curve optimization, reproducibility, and instrument troubleshooting. Performed curve fitting analysis using digital filtering and wrote software to control breadboard instruments. Assisted in organizing a chemical database system and creating a company documentation system. Was appointed fire-safety coordinator and hazardous waste coordinator. Organized radiation safety material for company. Supervised four students with various laboratory responsibilities. Trained employees in software use on the Macintosh and IBM systems as well the TOPS local area network. Handled the purchasing, setup, and maintenance of all computer systems.

June 1984-September 1985

Chemistry Technician,
Cardiovascular Devices, Inc.
Irvine, California

Responsible for the research and development of a fiberoptic carbon dioxide intravascular blood gas sensor. Other responsibilities included general chemistry techniques, fluorescence analysis, silicone chemistry, probe/sensor documentation and manufacturing techniques, participation in protocol design, surgery, blood compatibility animal studies, testing and PC data analysis of engineering models and prototypes, microphotography, and drug interference testing.

April 1984-June 1984

Staff Associate
Department of Chemistry
Pomona College

Pomona, California

Responsible for the maintenance of the prokaryote, Myxococcus xanthus, as well as experiments to determine the nature of transmembrane signaling in this organism. Duties included SDS-gel electrophoresis, radioactive labelling of proteins (14-C and 3-H), darkroom set up and developing, autoradiography, liquid scintillation counting, centrifugation, UV spectrophotometry, and general sterile microbiological techniques. Assisted in radiation safety procedures.

OTHER EXPERIENCE

6/83-9/83

Graduate Student Research Rotation
Division of Pulmonary Medicine,
Baltimore City Hospitals,
The Johns Hopkins Medical Institutions
Baltimore, MD

Assisted in experimentation to elucidate the pulmonary mechanics and circulatory interactions during conventional and modified forms of cardiopulmonary resuscitation. Responsible for animal anesthesia, intubation, ventilation, the performance of open-chest surgery, femoral cut downs, Starling Heart-Lung preparations, right-heart bypass, heart and pulmonary vasculature catheterization and cannulation, calibration and operation of high fidelity micromanometer catheters and aortic flow probes, and the operation of a Gould optical recorder.

6/82-9/82

Physical Scientist Specialist
Summer Employment Program,
The National Institutes of Health,
National Heart, Lung, and Blood Institute,
Laboratory of Technical
Development and the Laboratory
of Animal Medicine and Surgery
Bethesda, MD

Investigated the pathogenesis of sudden infant respiratory distress syndrome (SIDS or Hyaline Membrane disease), meconium aspiration, barotrauma caused by high pressure ventilation, high altitude pulmonary edema, and adult respiratory distress syndrome. Responsible for blood gas analysis (IL 213), acid/base determination and correction, animal anesthesia/euthanasia, Swan-Ganz catheter placement, measurement of FRC, tidal, residual, and minute respiratory volumes, intravenous fluid replacement, chest x-ray exposure and x-ray film development, lung lavage for surfactant, lung sectioning and fixing for histology, animal necropsy, use and calibration of high fidelity pressure transducers, and the operation of a multi-channel Gould optical recorder and Siemans servo ventilator.

6/81-9/81

Research Assistant
National Science Foundation
Undergraduate Summer Research Fellowship Program,
Department of Chemistry, Thimann Laboratories,
Division of Natural Sciences,
University of California, Santa Cruz
Santa Cruz, California

Carried out the total organic synthesis of stereospecific natural products. Responsible for the synthesis, separation, and identification of several biologically active natural products. Work involved the use of thin-layer chromatography, Fourier transform NMR, IR spectroscopy, Mass spectroscopy, combustion analysis, general analytical chemical techniques, advanced organic chemistry lab techniques (special organic reactions, distillations, separations, and isolation techniques) and literature search techniques.

6/80-10/80

Research Associate
American Heart Association
Student Research Program,

Harbor-U.C.L.A. Medical Center
Torrance, CA

Assisted in the investigation of the hemodynamics of conventional and modified forms of cardiopulmonary resuscitation (CPR). Responsible for animal surgery, oxygen inhalation, animal care, catheter positioning, defibrillation/fibrillation, optical recorder operation, cineangiography-fluoroscopy, programmable chest compressors, general anesthesia, micromanometer pressure transducer and catheter positioning, flow probes, basic electrocardiography, resuscitation techniques, slide and videotape production, 16mm film development and production, and the analysis and correlation of flow and pressure data. Also spent one week in collaborative research with John P. Rosborough, Ph.D., D.V.M. at the Baylor College of Medicine in Houston, Texas investigating the hemodynamics of CPR.

EDUCATION

Graduate Studies 1983
Doctoral Program
Department of Environmental Physiology
The Johns Hopkins University School of Hygiene and Public Health

B.A. Chemistry 1982
B.A. Biology
Double Major
University of California, San Diego

PROFESSIONAL SKILLS

Quality Function Deployment (Software and Manufacturing Applications)
Design of Experiments
Taguchi Design
Response Surface Modeling
Process Development and Optimization
FMEA
FMECA
Fault Tree Analysis
Safety and Hazard Analysis (Hardware and Software)
Software Reliability
Software Risk Management
Reliability Engineering
Systems Engineering
Statistical Process Control (Software and Manufacturing Applications)
Cost Analysis/Trade Off Studies
Application of ISO 9001/9000-3 To Software
Formal Quality and Management Auditing
Formal Software Inspections
Design Reviews
Software Configuration Management (RCS, MKS, Clearcase)
Software Metrics
Software Process Auditing and Assessment
Software Capability, Process and Maturity Assessment
Software Testing Techniques (Domain Testing, Equivalence Partitioning, Structural Testing, Cause and Effect Graphs, White Box Testing, and Black Box Testing)
Web, E Business and Internet Testing
Logic and Decision Table Formulation
Requirements Generation and Capture
Structured Analysis with Gane-Sarson and Yourdon-DeMarco Methods (Systems Architect, CADRE Teamwork)
Structured Design with Structure Charts and Entity Relationship Diagrams (System Architect, CADRE Teamwork)
Languages: C, BASIC, Other Macro Languages
Operating System Knowledge: VMS, Unix, DOS, Windows, Windows 95/98/NT, QNX, OS 400, and MAC-OS
Commercial Software Programs: Word, Excel, Powerpoint, Access, Lotus 123, MS Project, Flowcharter, Lotus Notes
Knowledge and Skill In Setting Up A Software Quality Assurance Group/Plan
Knowledge and Skill In Validating and Verifying Medical Devices
Knowledge and Skill In Validating and Verifying Pharmaceutical Processes
Knowledge and Skill in Total Quality Management (TQM)
Software Auditing
Vendor/Supplier Auditing for Computerized Systems and Software (PDA Vendor Audit Process Reviewer 1999)
Extensive knowledge of FDA and GMP Regulations
Knowledge and use of human computer interaction/human factors principles in software design
Motorola Quality System Review (QSR) especially for software
ISO 9000-3/TickIt Software Auditing and Certification
Software Project Estimation and Planning
Software Estimation with COCOMO II, REVIC, and ESTIMATE PROFESSIONAL
Software Project Management Skills and Techniques
ISO 12207 Software Lifecycle Processes
Automated Software Testing with Rational SQA Suite Team Test 6.1 -SQA Process, SQA Robot, SQA Manager, SQA Site Check, SQA Load Test
HACCP (Hazard Analysis and Critical Control Points) Technique
Electronic Records, 21 CFR Part 11 Compliance, Computerized Records Validation
Participatory Decision - Making and Group Facilitation Skills
Teaching and using Systemic Family Therapy concepts (Satir Based) in an organizational context
Team and Organizational Facilitation Skills (team building, conflict resolution, communication models, change models)
Skill and Knowledge in creating, building and staffing an Information Technology (IT) organization
Leading, teaching and applying Project Post Mortems, Lessons Learned and Project Retrospectives
Leading and Designing Experiential Designed Training Simulations

Teaching basic GMP/GLP Training for Computerized Systems and Applications
Teaching Validation Concepts for Computerized Systems and Applications
Leading Change Management and Change sessions for Software and Information Technology Organizations
Leading Team Building for organizations, departments, development and software teams
Applying System Thinking to organizations for internal, organizational and process change
Applying and Administering Myers Briggs Type Indicator (MBTI) Instrument for individuals, teams and groups
Leading, using and organizing Open Space Technology (OST) for organizational and system change
Coaching project management and development personnel within organizations and teams

PROFESSIONAL TRAINING COMPLETED

Clinical Statistics (10 week course)
Digital Signal Processing (10 week course)
Introductory Project Management (2 day management seminar)
Response Surface Modeling With ECHIP (1 week intensive course)
ASQC Reliability Engineering Review (10 week course)
Software Quality Engineering (1 week intensive course with Michael Deutsch)
Rapid Software Prototyping (3 day intensive course)
Software Testing and Reliability (10 week course)
Technical Marketing (3 day intensive course)
System Engineering Management (3 day intensive course with Benjamin Blanchard)
Manufacturing Operations and Technology (10 week course)
Design For Manufacturability (10 week course)
Interpersonal Impact and Communication (3 day management seminar)
System Failure Analysis (13 week course)
System Engineering (seminar)
ISO 9001/9000-3 For Software (seminar)
TQM For Software (seminar)
Formal Software Inspections (seminar)
Software Metrics (seminar)
Structured Analysis and Design (seminar)
Object Oriented Analysis and Design (3 day seminar)
SEI CMM Based Appraisal Evaluator Training, Version 2.0 (1 week course)
SEI CMM Based Appraisal Evaluator Training Version 3.0
British Standards Institute (BSI) ISO 9000-3 TickIT Lead Auditor Training Course (1 week intensive course)
Software Risk Management (IEEE seminar)
FDA Good Manufacturing Practices (MDDI seminar)
FDA Design Controls Inspectional Strategy Training (OCRA 2 day seminar)
Y2K Testing and Reporting Seminar and Presentation (SCQAA and AITP half day seminar)
Year 2000 IBM AS/400 Technical Workshop (half day seminar)
Leading Successful Software Projects (3 day seminar with Tom DeMarco and Tim Lister)
Rational SQA Team Test 6.1 Quick Start and Advanced Training (4 day intensive hands-on training)
FDA HACCP Training Seminar (2 day seminar)
Problem Solving Leadership (PSL) Workshop with Gerald M. Weinberg (6 day seminar)
Quality Functional Deployment Seminar and Workshop (INCOSE 1 day seminar)
Rapid Development By Steve McConnell, Software Productivity Consortium (SPC) Video Training Course
Change Shop Workshop with Gerald M. Weinberg/Jean McLendon (6 day seminar)
Understanding and Applying PLC in Electrical Controls – Industrial Text and Video Course
Process Validation Management Seminar (2 day GMP Institute/ISPE seminar)
Web and E commerce Testing Seminar (SQE 2 day seminar)
FDA Compliance Investigator Training for 21 CFR Part 11, Electronic Records and Computerized Systems, (with Martin Browning, former FDA Compliance Software Expert, AAMI 2 day training seminar; Note: this is the same training that all field inspectors participate in before auditing to 21 CFR Part 11)
Participatory Decision - Making Facilitation Seminar (1 day seminar with expert facilitator, Sam Kaner)
Software Validation Seminar (with Dave Bergerson, former FDA National Software Expert, RAPS 1 day seminar)
FDA 21 CFR Part 11 Validation Draft Guidance Document Audio Conference, FDA News, 2.5 hours
Yearlong Satir Performance Development Program with Jean McLendon, Satir Institute of the Southeast, (1 week in March, July, and October 2001, North Carolina)
Principles of Managing Iterative Development, Rational Unified Process (RUP), Rational University, San Diego, CA November 2001

Managing Requirements with Use Cases, Rational University, San Diego, CA December 2001
Systems Effective Management (SEM) Workshop, 4 separate 3 day management workshops with Gerald Weinberg, Feb. to Aug. 2002
Electronic Records and Electronic Signatures SOP Training, 21 CFR Part 11 Training, Pfizer Global Research and Development La Jolla, CA May 2002
GMP Overview Training, Pfizer Global Research and Development, La Jolla, CA April and May 2002
Amplifying Your Effectiveness (AYE) Conference Participant, Phoenix, AZ; 3 day conference, Nov. 2000-2005.
Satir Congruent Leadership Development Program with Jean McLendon, Satir Institute of the Southeast, March 4-6, 2003.
Retrospectives Facilitators' Gathering 2003, Newport, Oregon, April 21-25, 2003 4 day Workshop and Training Session.
Introductory GMP Training, Pfizer PGRD Research Informatics, La Jolla, CA May 2003
Introductory GLP Training, Pfizer PGRD Research Informatics, La Jolla, CA June 2003
2nd Annual Symposium on Risk Management, USC, Los Angeles, CA June 11-12, 2003.
Leaders Forum, Crested Butte, CO, 1 week management workshop with Strider and Cline, Inc. June 21-June 27, 2003
Experiential Design Simulation Workshop, Rio Rancho, NM 1 week workshop with Gerald Weinberg, July 28-Aug 1, 2003
ISO 14971 Risk Management Workshop, 2 day workshop, Carlsbad, CA Sponsored by Virginia Tech, Oct. 31-Nov. 1, 2003.
Writing Workshop, Rio Rancho, NM 1 week workshop with Gerald Weinberg, March 22-27, 2004
Myers Briggs Type Indicator (MBTI) Qualifying Class (CPP, Inc.) and Facilitation Workshop with Linda Berens, Huntington Beach, CA Aug. 9-Aug. 14, 2004
Organizational Workshop and Merging Cultures Workshop, Barry Oshry, San Francisco, CA 2 day seminar, Sept. 21-22, 2004
Retrospectives Facilitators' Gathering 2005, Phoenix, Arizona, Feb. 28-Mar 4, 2005 4 day Conference and Training Sessions.

PROFESSIONAL CERTIFICATIONS

1. American Society For Quality, Certified Software Quality Engineer (CSQE) Cert. No. 00105 (Retired 2008)
2. American Society For Quality, Certified Quality Auditor, (CQA) Cert. No. 25961 (Retired 2008)
3. Certified Software Capability Evaluator, Version 2.0 and 3.0 Method Description, Software Engineering Institute (SEI)
4. Quality Assurance Institute, Certified Software Test Engineer (CSTE) Cert. No. 42 (Retired 2008)
5. Qualified by CPP, Inc. to administer the Myers Briggs Type Indicator (MBTI) instrument, ID No. 320363

INDUSTRY CONSULTING

1. *Virtual Domain Expert (Medical and Software Industries)* - Giga Information Group, Santa Clara, CA, ExperNet Consultant, 12/97 – 3/2003, located at www.gigaweb.com.
Clients consulted include: 1**). Fleet Financial, Inc** New Jersey, November 1998 Topic: Return on Investment with the SEI/CMM, Cost Factors with CMM in non-DOD environment. 2). **Bristol & West PLC**, United Kingdom, December 1998 Topic: Pursue ISO 9001 or the SEI CMM for business software process improvement. 3) **Meijer**, Grand Rapids, Michigan June 1999 Topic: Whether to pursue SEI CMM for IT business improvement. Required information for senior management recommendation. 4) **Boeing Corporation**, Everett, Washington March 2001 Topic: Relationship of ISO 9001 to a system development methodology, and relationship of ISO 9001 to a process improvement process. 5) **Gillette Corporation** May 2001 Topic: Feasibility of outsourcing global licensing agreements. 6) **CFIA**, Canada July 2001, Criteria for choosing automated testing tools.

2. *Medical Device Software and GMP Compliance Expert* – Intota.com, Minneapolis, MN. October 2007-Present
Intota, formerly known as Guideline.com and Teltech connects business, technical and legal professionals with rigorously screened, peer-reviewed experts for Expert Consulting, Expert Witness, and Expert-based Research services covering a wide variety of needs such as market research, product development, materials sourcing, manufacturing production, and litigation consulting. Intota is a business-to-business service connecting business, technical and legal professionals to over 10,000 rigorously screened peer-recommended experts in over 30,000 areas of science, engineering, medicine/healthcare, regulation, and business. Intota is not a directory and our experts do not pay to be listed. Experts may be engaged for quick telephone or e-mail consulting or extended consulting engagements which may include both remote and on-site work.

BOARD OF DIRECTORS

Member, Board of Directors, Satir Institute of the Southeast, Non-Profit Organization, Chapel Hill, North Carolina, Feb. 2004 to present.

PROFESSIONAL SOFTWARE ASSESSMENTS

1. ISO 9001 and ISO 9000-3 TickIT Assessment, Southern California Computer Manufacturer (Confidential), 1994
2. ISO 9000-3 (TickIT) Assessment, Emulex Corporation, Costa Mesa, CA, April-May 1994.
3. SEI CMM Evaluation Level 2, Xerox Corporation, PCDT/PSSU/PSG, El Segundo, CA February 1999 (Participant).

4. SEI CMM Evaluation Level 3, Xerox Corporation, PCDT/PSSU/PSG, El Segundo, CA December 1999 (Participant).
5. CBA-IPI SEI CMM Assessment, Xerox Corporation, PCDT/PSSU/PSG, El Segundo, CA October 1999 (Participant).
6. Development and Project Management Assessment, Warner Bros., NITD Division, MIS Group, Burbank, CA March-April 2000.
7. Formal Vendor Audit for LabWare, Inc, Product: LabWare LIMS, for Pfizer PGRD, La Jolla, CA Nov 2003.

PROFESSIONAL SOCIETY MEMBERSHIPS

International Council on Systems Engineering (ICOSE)
Society of Logistics Engineers (SOLE)
Society of Reliability Engineers (SRE)
IEEE Computer Society (IEEE)
Association for Computing Machinery (ACM) (SigSoft, SigLink, and SigChi Chapter Member)
American Society for Quality (ASQ) (Software and Statistical Member)
Chemometics Society
Independent Computer Consultants Association (ICCA), Member # 15713
The Society of Pharmaceutical and Medical Device Professionals (ISPE), Member # 49978
Association For The Advancement of Medical Instrumentation (AAMI), Member # 346408
Regulatory Affairs Professional Society (RAPS), Member # 036945
Member of Gerald Weinberg's SHAPE Forum

TEACHING EXPERIENCE

Chemometrics Training Class July 1992, Paramax Chemistry, Baxter Healthcare Corporation
Teaching Assistant, Organic Chemistry 1979-1981, Dept. of Chemistry, U.C.S.D.
Teaching Assistant, General Chemistry, 1980, Dept. of Chemistry, U.C.S.D.
Teaching Assistant, Introductory Biology 1981, Dept. of Biology, U.C.S.D.
Tutor, Biology/Chemistry, OASIS Undergraduate Teaching Program, 1980, U.C.S.D.
Introductory SQA Training, Xerox Corporation, PSSU/PSG/PCDT, (about 40 developers/managers trained) August 1999.
Introduction to 21 CFR Part 11 Training, Compass Enterprise Technologies Ltd, Dallas, TX, June 2001
Regulated Industry FDA Validation Overview Training Class, Pfizer PGRD, La Jolla, CA March 2002
Introductory GMP Training, Pfizer PGRD Research Informatics, La Jolla, CA May 2003
Software Validation Overview Training, Pfizer PGRD, Research Informatics, La Jolla, CA August 2003
Introduction to CFR Part 111, The Dietary Supplement CGMPs, Redwood City, CA October 2007

PUBLICATIONS: PAPERS

1. "The History of CPR," The University of California, San Diego Journal of Undergraduate Research, Vol. 1, Number 2, 1981.

2. J.M. Criley, J.T. Niemann, J.P. Rosborough, S. Ung, J. Suzuki, "The Heart as a Conduit in CPR," Critical Care Medicine, 9:, 373, 1981.

3. S. Ung, J.T. Niemann, J.P. Rosborough, J. Suzuki, J.M. Criley, "Determinants of Systemic Venous Return during Cardiopulmonary Resuscitation," Circulation, 64(Suppl IV):IV-302, 1981.

4. J.T. Niemann, S. Ung, J.P. Rosborough, J. Suzuki, J.M. Criley, "Preferential Brachiocephalic Flow During CPR--A Hemodynamic Explanation," Circulation, 64 (Suppl IV):IV-303, 1981.

5. J.M. Criley, S. Ung, J. Niemann, J. Suzuki, J. Rosborough, "Cough CPR" revisited--A Model for Improving CPR?, Proceedings of the 30th Annual Meeting of the Association of University Cardiologists, January 1981.

6. M.J. Hausknect, R.A. Wise, R.G. Brower, C. Hassaypoyannes, M.L. Weisfeldt, J. Suzuki, S. Permutt. "The Effects of Lung Inflation on Blood Flow During Cardiopulmonary Resuscitation in the Canine Isolated Heart Lung Preparation," Circulation Research, 1987.

7. T. Chan and J. Suzuki, "Life Cycle Cost Analysis With Two Reliability Models: A Systems Engineering Approach," Proceedings of The Third Annual International Symposium of the National Council on Systems Engineering, Arlington, Virginia, 1993.

8. J. Suzuki and T. Chan, "An Introduction to Systems Engineering for Medical Device Development," Baxter Technical Journal, Fall/Winter 1993, pp. 15-29.

9. J. Suzuki and K. Lai, "Improving Software Quality with Decision Tables," *Proceedings from the Third International Conference on Software Quality*, Lake Tahoe, Nevada, October 4-6, 1993, pp. 173-180.

10. J. Suzuki, "Documenting the Software Validation of Computer-Controlled Devices and Manufacturing Processes: A Guide for Small Manufacturers," Med Dev Diag Indust, January 1996.

11. J. Suzuki and D. Karolak, "Software Risk Management : Not Just for the Big Manufacturers?," Med Dev Diag Indust, June 1997, pp. 73-78.

12. Leslie Lane and J. Suzuki, "Software Development Trends Mean Challenges for Small Manufacturers," Inside MD&DI, Med Dev Diag Indust, June 1997, p 19.

13. J. Suzuki, "Y2K Validation Of A Medical Manufacturing System," Proceedings of the SPG Year 2000 Conference and Expo, CD-ROM, Los Angeles, CA, September 16-18, 1998.

14. J. Suzuki and G. McKewen, "Practical Lessons Learned in the Coordination of a Multi-Site SQA Team," *Proceedings of the 18th Annual Pacific Northwest Software Quality Conference*, Portland, Oregon, October 17-18, 2000, pp 237-251.

15. J. Suzuki, "Distributed Teams" Software Testing and Quality Engineering, Volume 3, Issue 5, September/October 2001, pp 26-32.

16. J. Suzuki, "My Company Won't Pay! How To Get Approval To Attend Conferences or Training," published on the Amplify Your Effectiveness (AYE) conference website, www.ayeconference.com, July 2002.

PUBLICATIONS: BOOKS

1. *Software Development For Medical Devices*, Edited by Canon Communication, Canon Communication, Los Angeles, CA, 1998. Articles reprinted from Medical Device and Diagnostics Industry. 2 articles featured in text.

2. *Shaping Projects: A Roundtable on Best Practices*, edited by James Bullock, Gerald M. Weinberg, and Marie Benesh, Dorset House Publishing, N.Y, N.Y, May 2001. Contributing author to a section within the book.

PATENTS

TITLE: Improved Gas Sensor
United States Patent Number: 4,867,919
Filed: October 31, 1986
Inventor: Mas Yafuso and John Suzuki
Assignee: Cardiovascular Devices, Inc.

TITLE: Gas Sensor
United States Patent Number: 4,824,789
Filed: October 31, 1986
Inventor: Mas Yafuso and John Suzuki
Assignee: Cardiovascular Devices, Inc.

TITLE: Improved Gas Sensor
European Patent Number: 87308883.5
Filed: October 31, 1986
Inventor: Mas Yafuso and John Suzuki
Assignee: Cardiovascular Devices, Inc.

PRESENTATIONS

1. "The Hemodynamics Of CPR," Presented to distinguished visiting medical physiologist, Arthur C. Guyton, M.D., Harbor-U.C.L.A Medical Center, September 1980, American Heart Association sponsored seminar, Torrance, CA.

2. “Life Cycle Cost Analysis: A Comparative Study Using Exponential and Weibull Models,” The University of Arizona, The 30th Annual Reliability Engineering and Management Institute, November 19, 1992, Tucson, Arizona.

3. “Life Cycle Cost Analysis With Two Reliability Models: A Systems Engineering Approach,” The Third Annual International Symposium of the National Council on Systems Engineering, July 26-28, 1993, Arlington, Virginia.

4. “Improving Software Quality with Decision Tables,” The Third International Conference on Software Quality, Lake Tahoe, Nevada, October 4-6, 1993.

5. “Y2K Validation Of A Medical Manufacturing System,” Software Productivity Group (SPG), Year 2000 Conference and Expo, Sept. 16-18, 1998 Los Angeles, CA.

6. “Y2K Testing in Medical Devices and Medical Manufacturing Systems,” Software Productivity Group (SPG), Year 2000 Conference and Expo, Sept. 16-18, 1998 Los Angeles, CA.

7. “Coordination of Multi-site SQA Teams,” Eighteenth Annual Pacific Northwest Software Quality Conference, Oct. 17, 2000, Portland, Oregon.

8. “Project Retrospectives: Improving Team, Organizational, and Project Management Performance and Learning,” Southern California Quality Assurance Association (SCQAA), San Fernando Valley Chapter, April 6, 2005.

9. “An Introduction to the Dietary Supplement Good Manufacturing Practices CFR Part 111,” ComplianceOnline Webinar, October 2, 2007, www.ComplianceOnline.com.

CONFERENCE PANELS

1. Y2K Testing Panel, SPG Year 2000 Conference and Expo, Los Angeles, CA September 16-18, 1998.

2. Capability Models (including the CMM) for Teams and Organizations, AYE Conference, Scottsdale, AZ November 6-8, 2000.

CONFERENCE ABSTRACT REVIEWER

1. Irvine Research Unit in Software (IRUS), Software Symposium, April 1992, Irvine, California.

2. Irvine Research Unit in Software (IRUS), Software Symposium, April 1993, Costa Mesa, California.

PROFESSIONAL JOURNAL ACTIVITIES

1. Paper Submission and Abstract Reviewer for *Software Quality Professional* Journal, ASQ Press, March 1999-2014. Current editor is Dr. Mark Paulk, Carnegie Mellon University and Software Engineering Institute (SEI).

BOOK PROPOSAL REVIEWER

1. Category: Pharmaceutical ERP Validation Book, CRC Press, A Division of Taylor and Francis, Inc. for Stephen M. Zollo, Senior Editor Life Sciences Division, March 2005.

PROFESSIONAL INDUSTRY ACTIVITIES

1. Member of a Volunteer Industry Task Force to Develop a Software Quality Audit Standard for the Medical Device and Diagnostic Industries with Health Industries Manufacturing Association (HIMA, now Advamed) and Food and Drug Administration (FDA) 1998-2002. Committee met at least two to three times a year around the United States and has created a software quality assessment standard for industry guidance.

2. Member of a Volunteer Industry Task Force to Develop a Software Validation Standard for computerized manufacturing systems and quality systems with the Association for the Advancement for Medical Instrumentation (AAMI) standards group and the Food and Drug Administration (FDA) April 2003-2006. Committee has created a technical paper (TIR) for industry on the Validation of Software Regulated Processes published through AAMI in 2007.

3. Participant in the ASQ, Software Division, Standards Review Group, 2001-2004. Responsible for reviewing various internationals software standards and providing industry feedback on new standard and revisions to existing software-related standards.

4. Participant in the IEEE Agile Software Development Working Group, 2005-2006. Responsible for creating and reviewing various drafts of a technical report on recommended Agile software development practices.

5. Participant in the IEEE P730 Software Quality Assurance Working Group, 2011- 2012. Responsible for reviewing and participating in multiple technical reviews and commenting on various aspects of the new draft IEEE 730 Software Quality Assurance Standard and Annexes for the software industry. The output will be a new industry IEEE Software Quality Assurance Standard. Also included being a member of a select group of industry professionals voting for approval of the new standard to be released publically.

AWARDS AND HONORS

1. Dean's List U.C.S.D.
2. American Heart Association Student Research Associate Fellowship 1980 Harbor UCLA Medical Center, Torrance, CA
3. University of California, San Diego, SCURI Grant Award for the Project: "The Mechanisms of Blood Flow in CPR", 1981
4. National Science Foundation Undergraduate Research Fellowship in Chemistry, University of California, Santa Cruz, 1981.

ADDITIONAL EXPERIENCE

1. Conceived, organized and raised funding for the Society of Reliability Engineers Conference on Quality and Customer Service featuring the Malcolm Baldrige Award Winners from Cadillac Motors, Federal Express and IBM Rochester, November 1990, Red Lion Inn, Costa Mesa, California. Personally raised over $2000 in corporate sponsorships to fund seminar. Attended by over 200 participants.

2. Planned, organized, and advertised the Society of Reliability Engineers seminar on Systems Engineering Management held on February 8-10, 1993, Newport Beach Marriot Hotel, Newport Beach, California.

3. Participant in the 5th Annual Software Engineering Process Group National Meeting, Sponsored by the Software Engineering Institute and the Southern California Software Process Improvement Network (SPIN), Costa Mesa, CA April 26-29, 1993.

4. Participant reviewer (Correspondence Group) for the Software Engineering Institute's Capability Maturity Model update and revision process.

5. Participant in the 1996 HIMA/FDA Medical Device Software Conference, September 25-26, 1996, Washington, D.C.

6. Participant in the 1998 HIMA/FDA Medical Device Software Conference, October 14-15, 1998, McLean, VA.

7. Participant in the 2005 Advamed/FDA Software Conference, Nov. 2-3, 2005, Washington, D.C.

8. Participant FDA Public Workshop, Mobile Medical Application Guidance, Sept. 12-13, 2011, Washington, D.C.

REFERENCES

Available upon request.