G. Michael Oslovar
4425 La Portalada
Carlsbad, CA 92008
(760) 720-9712

SOFTWARE QUALITY & PROJECT/PROGRAM MANAGMENT
Process Improvement- Strategic Planning

Hands on leadership experience building effective QA teams developing products serving various industries. Built and lead teams conducting Program Design, Technical Support, Configuration Management, and test planning/execution. Well versed in software project management, software development methodology generation and implementation. Background includes experience in software quality assurance, process development (using SEI's *CMM*, *Microsoft Solutions Framework* ^{TM} , and *Rational Unified Process* RUP) strategic plan development and deployment, software systems development, systems integration and systems management in an Object Oriented GUI/WEB (MS Windows, .NET, 2K/NT/XP, Java, WebObjects) environment.   Twenty-three year record of achievement augmented by MS degree in Systems Management and BS degree from the United States Naval Academy.

Major Areas of Experience

Leadership	**Team Building**
Software Quality Management/Configuration Management	**Methodology Design/Development**
Software Program/Project Management	**Process Design/Improvement**

Education

M.S.   University of Denver, 1991
                Systems Management

B.S.   United States Naval Academy, 1978
                Management and Technology

Teaching Synopsis

1999 - 2016 Principals of Leadership for Technical Leads (Financial Profiles and Order Fusion)
- Developed and presented a 4 session, in house leadership seminar for technical leads.

1999 – 2000 New Employee Training (OrderFusion)
- Developed and taught employee orientation of OrderFusion's Software Development Process using a Systems Approach to software development.

1997 & 2000 Lecture "Is that a Manager or a Leader…" (PSQT conference and at SSQ San Diego Chapter)
- Developed and presented seminar distinguishing the difference between leadership and management.

1996 Lecture "Starting a QA department, Use a Systems Approach" (PQST Conference)
- Developed and presented seminar incorporating a Systems Approach to corporate Quality Strategies.

1981 – 1983 Fleet Anti-Submarine Warfare (ASW) Training Center, Pacific
- **Responsible** for **development** and **implementation** 12 week of course instruction at Pacific Fleet ASW Training Center

DEVICE QUALITY MANAGER (Lead Auditor)
Hospira a Pfizer Company – San Diego CA   **2011 - Present**

Responsible for Quality Assurance function for various software and hardware Quality Engineers, providing regulatory compliance for various intravenous pump systems and supporting software systems. Pumps are classified as Class III, Supporting Software systems are Class II.

- **Supervise the Development** of software Standard Operating Procedures to insure compliance with Federal Regulations as well as IEC 62304 and ISO 13485 and ISO 14971 standards for the design and manufacture of medical devices. Drive compliance of these requirements across various functional elements within the organization.
- **Lead the effort** in conducting **Formal System Audits** in accordance with **21 CFR part 820 FDA regulations,** as well as **Design History File (DHF) assessments** of various project DHFs to insure compliance with governing regulations as well as corporate policies and procedures.
- **Manage** the day to day activities for quality engineers to insure compliance with **21 CFR part 820 FDA regulations.** These engineers:
  * **Participate** in Design Reviews for software installed in programmable IV pumps (Class III)
  * **Conduct** Code Review & Unit Test inspections
  * **Provide** Feedback into Regression Analysis
  * **Conduct** with Project Audits
  * **Assist** with Quality Systems, Process, and Design Controls Audits to make sure we are in compliant with corporate and FDA guidelines
  * **Assist** with automated tool validation, including COTS, SOUP, and internally developed tools in accordance with *General Principles of Software Validation; Final Guidance for Industry and FDA Staff AAMI TIR 36-2007 Validation of software for regulated process.*
- **Supervise** Corrective and Preventive Action **(CAPA)** investigation/completion for various projects
  * **Generated** Audit reports for review and inclusion in various repositories
- **Participated** in various internal and external agency audits.
  * FDA QSIT audit (July 2015)
  * BSI certification Audit (Feb 2016)

DIRECTOR, SOFTWARE QUALITY   **2005 – 2009**
PatientSafe Solutions - San Diego, CA (formerly Intellidot, Inc)

Responsible for the proper function/integrity of the 'CAREt' wireless bedside medication safety system generated for external sale and downloaded to customer sites via B2B VPN connection.

- **Director** and principle contact for all Software Testing issues for the BMA system.
  * **Established** the QA test team to address the major areas requiring testing including:
    * **Recruited, interviewed,** *and* **Hired** qualified test engineers to augment the current staff.
    * **Functional Testing –** Using black and white box tests (Unit, Integration, Regression, Systems) to review the system for correctness, resiliency, responsiveness, latency, and usability.
    * **Performance Testing** – Reviewing the system for load, capacity, endurance, and stress.
    * **Wireless Systems Testing** – Roaming using various protocols (WPA WPA-PSK, WPA Enterprise WEP) under 802.11 standards (a, b, g).
    * **RF Characterization** – Characterization of the wireless handled device re: power output and receiver sensitivity.
  * **Introduced** and **facilitated** the implementation of an *Agile Development Process* in the entire development organization.
  * **Coordinated** the development and submission of a **510K package** for FDA clearance using **21CFR part 820.**
    * **Managed** two consultants to generate and then audit the Intellidot Quality system submitted in the **510K package**,
    * **Recruited** and hired a Quality Systems manager with extensive FDA experience.

- ∗ **Responsible** for **coordinating** and having staff **conduct** all internal audits of the Quality System and presenting results to the executive team in accordance with **21 CFR Part 820**.
- ∗ **Implemented** a 'VMware' test environment leveraging the 'cloning' and snapshot capability of the VM software to the point it validated a second deployment strategy, e.g. physical machines or VM instances.
- ∗ **Heavily Leveraged** the use of the automated test suite to perform both functional and performance testing.
  - ∗ **Developed** strategies to utilize JAVA script and PERL scripting to simulate user activity on both the server and wireless handheld device.
  - ∗ **Coordinated** the day-to-day operation of 8 Quality Assurance Engineers (Verification/Validation)

DIRECTOR, SOFTWARE QUALITY/ CONFIGURATION MANAGEMENT   2002 – 2005
Financial Profiles
Carlsbad, CA

Responsible for the proper function/integrity of all financial planning software products generated for external sale.

- **Director** and principal contact for all Software Quality and Configuration Management issues.
  - ∗ **Re-Organized** the QA team to address the major areas requiring testing including:
    - ∗ **Functional Testing –** Using black and white box tests (Unit, Integration, Regression, Systems) to review the system for correctness, resiliency, responsiveness, latency, and usability
    - ∗ **Performance Testing** – Reviewing the system for load, capacity, endurance, and stress

    Calculation testing – Reviewing the validity of various system calculations as well as integrity of financial plans produced.

  - ∗ **Leveraged** the use of automated test strategies to save the company $350K annually in labor costs by using the automation strategies.
    - ∗ Evaluated current tool against testing needs
    - ∗ Recommended changes as a result of evaluation, and had staff executed these changes within the tool. changes included:
      - ▪ Producing a vision for an internal tool using command line hooks placed in the application.
      - ▪ Development of requirements specification for the automated tool
      - ▪ Monitoring development of 'rapid prototype, test and evaluation
      - ▪ Comparison of results to current tool output
      - ▪ Implementation
  - ∗ **Coordinate** the day-to-day operation of 15 Quality Assurance Engineers, 1 Configuration Management Engineer.
  - ∗ **Planned & Implemented** offshore testing for functional testing of both desktop and Web products, as well as performance tests of the Web based products. Currently **managing** 4 QA engineers offshore in Sri Lanka.
  - ∗ **Manage** the development source repository, production 'builds' for the QA environment, major, minor, service pack and patch releases using *MS Visual Source Safe* and *IBM Rational ClearCase.* Archives of previous releases as well as maintaining escrow accounts for selected customers.
- **Developed** long-range strategies for test planning and execution involving Functional, Automation and Calculation testing of all FPI Products
- **Developed** and **taught** a Quality Engineering seminar for in the QA area using IEEE, CMM and MS SDD models.
- **Developed** and **taught** a leadership seminar for Leads in the QA/CM area.
- **Generated and Distributed** the FPI Quality Strategy.
- **Assisted** the introduction of the *Rational Unified Process (RUP)* and used this format to drive quality forward into the development life cycle of the FPI products.
- **Coordinated** the move of the entire source repository form *MS Visual SourceSafe* to *Rational ClearCase* setting policy and strategy for the source repository structure

DIRECTOR, SOFTWARE QUALITY/CONFIGRUATION MANAGEMENT   2001 – 2002
Syntricity
San Diego, CA

Responsible for the proper function/integrity of all integrated circuit test software products generated for external sale.

- **Director** and principal contact for all Software Quality Management, Documentation and Configuration Management issues.
    - ∗ **Coordinated** the day-to-day operation of 5 Quality Assurance Engineers, 2 Configuration Management Engineers, and one Technical Writer.
    - ∗ **Oversaw** the execution of integration, regression, and systems testing.
    - ∗ **Managed** the development source repository, production 'builds' for the QA environment, major, minor, service pack and patch releases using _Starteam._ Archives of previous releases as well as maintaining escrow accounts for selected customers.
    - ∗ **Coordinated** the inputs to user documentation, release notes, and known issues for inclusion in various system documents
    - ∗ Managed the review of the automated tool suite for the data Conductor tool including:
        - Developed business requirements for tool
        - Initiated research into acquiring/upgrading the automated tool suite
        - Developed tool evaluation criteria based on need, ease of use, reporting, cost etc.
        - Tested various tool candidates and selected tool most capable for the task.
- **Developed** long-range strategies for test planning and execution involving transition from a CGI based technology to a Java based technology.
- **Performed** responsibilities of **Program Manager** for the _dataConductor_ product.
    - ∗ Defined how the project will operate, and managing the interrelations of the functions require to deliver a quality product.
    - ∗ Managed four release projects. Developed project plan using MS Project;
    - ∗ Collated the project schedule from each team's milestones, generating and managing the master schedule for the release of two service packs and one point release.
- **Managed** the development source repository, production 'builds' for the QA environment, major, minor, service pack and patch releases using Star Base's _Starteam_ and archives of previous releases as well as **maintained** escrow accounts for selected customers.

PROGRAM MANAGER   1999 – 2001
OrderFusion
San Diego, CA   _(This position was a collateral task to the Director of QA/TS.)_

Program Manager for the entire _Orders of Magnitude_ system. _Orders of Magnitude_ is a suite of fully integrated eCommerce B2B sell side software using both GUI and Web applications. Implemented Microsoft's _Solutions Development Discipline_ (SDD) for nine (9) releases of the Orders of Magnitude system over two years.
- **Performed** responsibilities of **Program Manager**.
- **Managed** nine (9) release projects. **Developed** project plan using MS Project; set up milestone using the SDD process model and applied these milestones to the release schedule (project was date driven).
- **Managed** risk to the project and **developed** contingencies when milestones were threatened.
- **Briefed** executive management team regarding project progress, risk and contingencies.

DIRECTOR, SOFTWARE QUALITY & TECHNICAL SUPPORT   1998 - 2001
OrderFusion
San Diego, CA

Responsible for the proper function/integrity of all e-Commerce B2B software products generated for external sale. Responsible for ensuring customers receive friendly, reliable and competent technical support from the technical support staff.

- **Director** and principal contact for all Software Quality Management issues.
  - ∗ **Established** *(from scratch)* a disciplined software development process containing process for developing sound conceptual, logical and physical requirements. Review process for these requirements and an approval process to insure appropriate elements are involved in the entire development process. This process included elements from Marketing, Development, Testing, User Education, Documentation, and Logistics.
    - This effort resulted in a bug reduction of 271% in the first release this process was used.
  - ∗ **Established** *(from scratch)* the Quality Assurance Organization, and successfully **implemented** an overall strategy of process and productivity improvement through out the entire company. Brought a disciplined approach to the Quality Assurance organization at OrderFusion to include:
    - Coordinated the introduction of the *Microsoft Solutions Framework* and used this format to drive the development of the OrderFusion Product Cycle
    - Established a team-based approach to software development.
    - Researched and established automated strategy for the *Orders of Magnitude* product using a disciplined requirements/selection process. Process included:
      - Creating vision document of business need
      - Setting system requirements for use
      - Evaluating vendors
      - Selection of system and annual maintenance (fees and upgrades)
      - Vendor management
  - ∗ **Coordinate** the day-to-day operation of 12 Quality Assurance Engineers
  - ∗ **Developed** long-range strategies for test planning and execution involving an object oriented direct marketing software package. The goal was to drive quality forward in the software development life cycle.
  - ∗ **Directed** the development of requirements for use of automated test and load tools. Directed the evaluation of commercially available solutions.
- **Director** and principal contact for all Technical Support issues
- **Managed** the successful implementation of Microsoft Solutions Framework's *Solutions Development Discipline*, a process for formulating Process, Application and Team models throughout the company.
- **Developed** and **taught** a leadership seminar for supervisors in the QA/TS area.
- **Lectured** regarding Project Management, organizational development, leadership and system quality the *Society for Software Quality San Diego Chapter*, and at *Colman College.*

MANAGER, SOFTWARE QUALITY/CONFIGRUATION MANAGEMENT   1993 - 1998
Software Products Division
Bankers Systems Inc. St. Cloud MN.

Responsible for ensuring requirements compliance and the proper function/integrity of all software banking products generated for external sale.

- **Manager** and principal contact for all Software Quality Management issues.
  - ∗ Established the Quality Assurance Organization, and successfully implemented an overall strategy of process and productivity improvement through out the division.
  - ∗ Coordinated the day-to-day operation of 25 Business Analysts and Software Engineers operating in three teams.
- **Managed** the development and successful implementation of BSI's *Systems Development Methodology*, (SDM) an in-house generated method based on the CMM for documented and repeatable process in generating software deliverables using a *Systems Approach* to software development.

- **Developed** and **taught** a Quality Engineering seminar for in the QA area using IEEE, CMM and MS SDD models.
- **Lectured** regarding Systems Approach to Software Quality at the 'Practical Software Quality Techniques' conference. Guest **lecturer** at the *St Cloud State University* School of business, and *University of St Thomas*, regarding leadership organizational development, team building, and 'Life after graduation'
- **Established** the Configuration Management (CM) function of the Software Products Division.
    * Organization established to integrate software builds in support of ongoing software development operating in a MS Windows 95 and NT environment.
    * Set a goal to substantially affect productivity improvements through the use of automated software build tools.

STAFF MEMBER /PGM. MANAGER /DIRECTOR of OPERATIONS   1983-1993

Whittaker Electronics Inc. (Formerly Ocean Technology)
San Diego, CA.

Responsible for day to day operation and regional business operations for contractor meeting technical and administrative requirements in production of Command and Control and Acoustic software systems for the U. S. Navy.

- **Director of Operations** and principal contact with customer and six subcontractors.
    * Coordinated initial proposal development for prime contract.
    * Performed overall management of major Life Cycle Management contract ($25M) in CPFF, FP, CPIF and T&M contract environments.

- **Review initial Draft of CMM**. Reviewed and comments against the initial drafts of the Capability Maturity Model for DoD sponsor at the Naval Ocean System Center (NOSC)

UNITED STATES NAVY   1978-1983
Fleet Anti-Submarine Warfare (ASW) Training Center, Pacific (81-83)
Held responsibility for development and implementation of course material at Pacific Fleet ASW Training Center

- **Coordinated** twelve week course of instruction for junior officers

    * In depth instruction on wide variety of weapon and sensor deployment for Anti Submarine Warfare.
    * Provided training and evaluation of senior (Rear and Vice Admiral) operational staffs.