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National Society for  
Professional Engineers



## **Consultant / Sr. Quality Professional / Instructor Lead Auditor / Project Manager (Power)**

### **A. OBJECTIVES**

#### **1. Consultant.**

a. Training and consulting with *senior management and functional groups* to impart understanding of the following new Standards and Regulations, and how compliance can be achieved by a leading international provider of medical, electronics, semiconductor, wireless, telecommunications, aerospace, optics, computer products, or power generation, with *minimal effort and schedule impact* to the following standards and regulations:

- AS 9100/ ISO 9001/ 16949/ 13485/ 14001 / 14971 International Quality Management Systems (QMS)
- FDA QSR-cGMP (U.S.), CMDCAS (Canada), MDD (Europe) and PAL (Japan) Medical Device Regulations
- Int'l. Standard for assessing electronic components and production processes according to <sup>1</sup>HSF requirements, QC 080000 <sup>2</sup>IECQ <sup>3</sup>HSPM for <sup>4</sup>WEEE and <sup>5</sup>RoHS

b. Development and implementation of a QMS using "Process Mapping" with the above standards to identify, capture and implement "best practices".

c. Acting as Director of Quality / QMS Management Representative, including establishing and directing Supplier Control, Internal Quality Audit, Corrective / Preventive Action (CAPA), Document Control, Validation / Revalidation, ISO 14971 Risk Management, coordination with customers, and interfacing with Notified Bodies (Registrars); acting as champion for Quality and Customer Satisfaction in a leading international provider of products compliant with the standards and regulations referenced in Objective 1a.

#### **2. Directing 510k (Pre-market Notification) and PMA (Pre-market Approval) activities.**

Assuring compliance with requirements for submitting 510k and PMA applications for medical devices to the FDA, including:

- When these submissions are required
- Information required in each submission
- FDA review process involved.

#### **3. ISO / AS Lead Auditor (Part-Time).**

Planning, preparing and leading QMS audits for an international Certified Body (Registrar), or managing a company Internal Audit programs in the above fields, utilizing "Process Mapping" to identify, capture and implement "best practices" that enhance compliance with the standards and regulations referenced in Objective 1a.

#### **3. Engineering/Technical Program/Project Manager - Energy/Power (Temp).**

Program Management and contract execution for Energy/Power Generation. Interface with subcontractors, customers, government agencies, and plant site functions. Technical program and management focus for engineering issues. Design and development support. Resolution of critical technical issues. Verifying proper application / use of parts. Management of suppliers and internal support staff. Negotiating and managing change orders. Providing balanced decisions between technical requirements, schedule, cost, and quality.

#### **4. QMS / Technical Expert and Expert Witness**

for the Plaintiff or Defendant, with *expertise* in the (1) standards, regulations and activities referenced in Objective 1a, (2) Engineering/ Technical Program/ Project Management activities, and (3) investigative process, case review procedures, report preparation containing expert opinion; providing depositions and court testimony.

### **B. SUMMARY**

Experience in variety of product lines includes (1) developing relationships with key customers, (2) determining customer expectations and assuring implementation company-wide (3) setup and direction of Customer, Quality, Reliability, Design, Manufacturing, Crisis Management, Continuous Improvement activities, (4) setup of global customer feedback systems working in an international environment, including the European and Asian Market, (5) establishing corporate strategic plans and objectives to exceed customer requirements, (6) oversight of Risk Management activities per ISO 14971.

<sup>1</sup>Hazardous Substance Free. <sup>2</sup>International Electrotechnical Commission Quality Assessment System for Electronic Components.  
<sup>3</sup>Hazardous Substances Process Management. <sup>4</sup>Waste of Electrical and Electronic Equipment. <sup>5</sup>Reduction of Hazardous Materials.

## C. INTERNATIONAL STANDARDS EXPERIENCE

09/2006 - Present

**THE ELECTRONICS COMPONENTS CERTIFICATION CORPORATION (ECCC)**  
U.S. National Authorized Institute for the International Electrotechnical  
Commission Quality Assessment System (IECQ) for Electronic Components

### **1. ECCC Technical Review**

Review and approval of Certification Body (Registrar) applications for certifications of companies assessed to International Standard QC 080000 IECQ-HSPM, *Hazardous Substances Process Management* (now over 1,000 world-wide).

### **2. ECCC Board Member**

- Participation in planning and oversight of the execution of the goals and activities of the former ECCB.
- Participation and oversight of the finalization of the IECQ HSPM and ECMP pilot projects.
- Participation in providing input to the IECQ.

### **3. NSSA, SSA, and Rules of Procedure Review Committee**

Participation in the review, revision and reissuance of the original:

- ECCB Rules and Regulations
- IECQ-ECCB NSSA and SSA U.S. and International Standards and documents;  
also see Section L. **PUBLICATIONS**

## D. CONSULTING EXPERIENCE

10/1977 - Present

**New World Consulting Service, N. Calif.** (Mountain View Office) **and S. Calif.** (Perris Office)  
*Principal/Sole Proprietor* (position/title at client companies *italicized*).

### 1. Integrated Composites Inc. (ICI), Marina, CA

**Position:** AS9100-C Consultant

**Product:** design, development, and manufacturing company specializing in high-performance structures and assemblies for aerospace, defense, and industrial applications.

**Problem:** Lacking complete QMS Internal Audit to the AS9100 Rev. C with major customer and registrar audits imminent.

**Action:** Conducting complete QMS Internal Audit and identification of corrective action requirements.

**Results:** On-going.

### 2. Evans Analytical Labs, RTP Div., Santa Clara CA

**Position:** ISO 9001:2008 Consultant

**Product:** Design, development, and reliability testing services for product qualification.

**Problem:** ISO 9001:2008 initial certification within 9 months, lacking QMS documents and implementation.

**Action:** Creating Quality Manual, procedures and forms as needed, and conducting complete QMS Internal Audit.

**Results:** In-process.

### 3. Digi-Com Electronics, Richmond, CA

### 4. Quality Circuit Assemblies, San Jose, CA

### 5. EMED Technologies, El Dorado Hills, CA

**Position:** ISO 13485:2003/ FDA Consultant

**Product:** Printed circuit assemblies and equipment for all industries.

**Problem:** ISO 13485: 2003 initial certification within 6 months, lacking complete QMS Internal Audit.

**Action:** Revised Quality Manual, created procedures and forms as needed, and conducted complete QMS Internal Audit.

**Results:** Completed on time; registration obtained.

### 6. Vital Wear, Inc., South San Francisco, CA

**Position:** ISO 13485:2003/ FDA/ CMDR/ MDD/ Consultant

**Product:** Thermal/compression systems for use in managing chronic pain and accelerating the recovery from injury.

**Problem:** Transition from ISO 9001 to 13485 with CE mark to meet marketing goals to commence European and Canadian sales within 8 months.

**Action:** Created detailed milestone chart of entire program, reviewed entire QMS system, revised and added Quality Manual, procedures and forms as needed.

**Results:** Completed on time.

7. **Focus Diagnostics, Inc., Cypress, CA**  
**Focus Laboratory Services, Cypress, CA**

**Position:** ISO 13485:2003/ FDA/ CMDR/ MDD/  
Consultant

**Product:** Advanced Healthcare

- Reference Laboratory
- Diagnostics Products
- Clinical Trials

**Problem:** (Similar to Biosense Webster below) Corporation certified to ISO 13485:2003. Registrar Assessment scheduled the following week. Extensive organizational changes and key positions vacant causing doubt as to whether company was still compliant.

**Action:** In 3 days, performed Gap Analysis which (1) Reviewed *documented* Quality System and submitted recommendations for changes. (2) Assessed all departments and recommended Corrective Actions, (3) Conducted Closing Meetings for each of the above facilities to provide ISO 13485 QMS training to Senior Management to identify major nonconformances detected that day, and recommend effective corrective action, (4) Conducted ISO 13485 Orientation Classes with all management and professional personnel.

**Results:** Passed TUV Assessment and recertification, and received an annually-renewable contract to plan, conduct and report company-wide Internal Audits and review proposed corrective actions.

8. **Biosense Webster, Inc. (Johnson & Johnson),**  
**Irwindale (LA Area), CA and Juarez, Mexico.**

**Position:** ISO 13485:2003/ FDA/ CMDR/ MDD/  
Pre-BSI Consultant

**Product:**

- Advanced diagnostic and therapeutic electro-physiological catheters
- 3-dimensional, real-time cardiac color-coded map-ping, navigation and ablation systems.

**Problem:** Corporation certified to ISO 13485:2003. Registrar Assessment scheduled following month. Extensive organizational changes and key positions vacant resulting in Internal Audits not being conducted.

**Action:** In 2 weeks, (1) Reviewed *documented* Quality System and submitted recommendations for changes. (2) Planned and conducted complete ISO 13485/ CMDCAS/ FDA QMS Assessment of all departments and Executive Management, and recommended Corrective Actions, (3) Conducted daily wrap-up meetings to: a) provide ISO 13485/ CMDCAS QMS training to Senior Management to identify major nonconformances detected that day, and recommend effective corrective action.

**Results:** Irwindale site failed BSI Assessment and was going to lose ISO certification, with losses of millions of dollars in international sales. The BSI

Lead Assessor knew of me and knew I had just finished my audit.

Upon receiving my report, BSI advised the Company that if they implemented all my recommendations they could retain their ISO certificate. As a result, the Company also asked me to audit Juarez, after which this site implemented my findings and passed their BSI Assessment. I now have annually-renewable contract to plan, conduct and report company-wide Internal Audits and review proposed corrective actions.

9. **Boston Scientific Corp., Minneapolis, MN, San Jose, CA**

**Position:** ISO 13485:2003/ FDA Consultant

**Product:** Advanced diagnostic and therapeutic electro-physiological catheters

**Problem:** Confidential.

**Action:** (1) Reviewed *documented* Quality System and submitted recommendations for changes. (2) Planned and conducted ISO 13485/ CMDCAS/ FDA QMS Assessment of Production Control, Process Control and Executive Management, and recommended Corrective Actions.

**Results:** Continued compliance with ISO 13485 and FDA QSR requirements.

10. **Invitrogen, Camarillo, CA (Merger)**  
**Zymed Laboratories, South San Francisco**  
**(Merger)**  
**Caltek Laboratories, Burlingame, CA (Merger)**

**Position:** ISO 13485:2003 / FDA cGMP/QSR,  
MDD and CMDCAS Consultant

**Product:** Manufacture of RUOs, ASRs and IVDs and ancillary GPRs), majority of products antibody based with applications in IHC and Flow Cytometry.

**Problem:** Invitrogen certified to ISO 13485. (1) Recently acquired Caltek and Zymed and is undergoing relocation to S. Cal. (Camarillo); Registration/Upgrade Assessment to cover all locations which with extensive organizational changes. Various key positions are still vacant. (2) Various system problems detected by FDA on last inspection unresolved. (3) Currently no Internal qualified Auditors or QA personnel capable of detecting underlying problems and recommending fixes.

**Action:** Completed audit of complete QMS and closed out audit CAPAs and previous FDA findings a week ahead of schedule to assure successful relocation with minimal cost and schedule impact.

**Results:** Company passed ISO 13485 Registrar Assessment and satisfied FDA findings in time. Received verbal commendation and opportunity for an ongoing business relationship.

11. Intuitive Surgical, Inc., Sunnyvale, CA,

**Position:** ISO 13485/ FDA cGMP/QSR, MDD and CMDCAS Consultant

**Product:** State-of-the-art "Intuitive" Motion Enhanced 3-D Vision Laparoscopic Surgical Robotic Surgical Systems

**Problem and Action:** Same above except that it was the VP of Quality who left.

**Results:** Company passed the ISO audits and FDA inspection.

12. SurgRx, Inc., Palo Alto, CA

**Position:** ISO 13485 / FDA cGMP/QSR, MDD and CMDCAS Consultant

**Product:** State-of-the-art Electronic/ Electro-mechanical Rapid Vessel Sealing and Transection Hemostasis Systems.

**Problem:** Start-up, pre-IPO Corporation desiring certification to ISO 13485:2003 and a system compliant with FDA cGMP/QSR, MDD and CMDCAS. ISO Registrar Assessment and FDA Inspection scheduled next month. Quality Management System had not been fully documented.

**Action:** In 2 weeks, (1) Reviewed *documented* Quality System and submitted recommendations for changes. (2) Created a detailed 20-page Risk Management System Audit Checklist, (3) Created an Audio-Visual PowerPoint Presentation on CD of the requirements for implementing ISO 13485:2003 which was distributed world-wide.

**Results:** Received a referral to the above company after assignment completed.

13. Welsh-Allyn, Inc., San Diego, CA

**Position:** ISO 13485 / FDA cGMP/QSR, MDD and CMDCAS Consultant

**Product:** Electronic/Electromechanical Coronary Diagnostic Equipment

**Problem:** Numerous deficiencies noted in the functions noted below by the Registrar and FDA.

**Action:** In 1 week, reviewed Complaint Investigation, Handling, Reporting and Document Control Systems and in one week submitted a detailed action plan for all departments.

14. Int'l. Remote Med. Imaging Sys., Chatsworth, CA,

**Position:** ISO 13485 / FDA cGMP/QSR and CMDCAS Consultant

**Product:** Remote medical imaging systems

**Problem:** Company certified to ISO 9001:1994. ISO 13485/CMDCAS Registrar Certification Assessment scheduled following month. Internal Audit conducted month previous with no findings detected. New QA Director convinced (1) numerous undetected system problems existed, and (2) internal auditors not capable of finding problems. (3) Senior management gave QA Director 2 weeks to a) train auditors, b) find all significant problems, and 3) implement adequate corrective action.

**Action:** In 2 weeks, (1) Reviewed *documented* Quality System (Level 1 and 2 documents) and submitted recommendations for changes. (2) As internal auditors were in name only and totally unqualified, planned and conducted complete ISO 13485/CMDCAS QMS Pre-Assessment and recommended Corrective Actions, with internal auditors observing. (3) Conducted daily wrap-up meetings to: a) provide ISO 13485/ CMDCAS QMS training to Senior Management and internal auditors, b) identify major nonconformances detected that day, and recommend effective corrective action. (4) Trained and certified auditors to ISO 13485:2003 and ISO 19001:2000.

**Results:** Company revised QMS documentation and effectively implemented in time to pass ISO 13485/ CMDCAS Registrar Certification Assessment. I received referral for subsequent consulting assignment from QA Director.

15. Applied Materials/AKT, Santa Clara, CA, (Contracted with SQA)

**Position:** ISO 9001 Program Director

**Product:** Capital equipment for the manufacture of Flat Panel Display silicon material

**Problem:** Corporate requirement for all 15 business units world-wide (who commenced 3 months previously with full staff) to implement ISO 9001 and be registered in 14 months.

**Action:** With only one assigned assistant, developed aggressive, comprehensive "catch-up" plan, established and implemented ISO 9001 ahead of schedule.

**Results:** Received ISO 9001 Certification ahead of 5 other business units. Received Plaque and Letter of Commendation from President and Executive Staff sent world-wide, mentioning above problem and solution.

16. Lucas Novasensor, Fremont, CA,

**Position:** Director, Quality & Reliab. Assur. Director  
**Product:** Fluidic/Optic Sensors, Silicon Microstructures.  
**Problem:** (1) Previous QA&R Director left suddenly to assume position as BART Reliability Directory. (2) TS 16949 (Auto), ISO 13485 (Medical), and AS 9100 (Space) Quality Management Systems all needed to be upgraded and recertified. Department needed reorganization and morale boost. Statistical Q.E. about to be terminated for productivity and organizational issues.  
**Action:** Performed fixes for the above issues in 3 months.  
**Results:** Received 3<sup>rd</sup> party Certification to all Quality Systems. Statistical Q.E. voted "Employee of the Month".

17. KAMET Precision Machining, Santa Clara, CA

**Position:** Director, Quality & Reliability Assurance  
**Product:** R&D/Prototype Precision Machining  
**Problem:** Start-up company needed a ISO 9001 Quality Management System to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality System.

18. Huntington Mechanical Labs, Mountain View, CA

**Position:** Director, Quality Assurance  
**Product:** Aerospace Vacuum Products and Prototype Mechanical Assemblies.  
**Problem:** ISO 9001 (Industrial) and AS 9100 (Space) Quality Management Systems needed to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality Systems and conducted various training courses.  
**Results:** Successful organization relocated to larger facilities.

19. Shin-Etsu Polymer Corp., Fremont, CA,

**Position:** Director, Quality & Reliability Assurance  
**Product:** Medical and Automotive Instrument Panels.  
**Problem:** (1) Previous QA&R Director left without replacement. (2) TS 16949 (Auto) and ISO 13485 (Medical) Quality Management Systems needed to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality Systems in 3 months.  
**Results:** Successful organization relocated to Japan.

20. Pulnix America Corp., Sunnyvale, CA,

**Position:** Director, TQM/ISO Program  
**Product:** Aerospace/ Medical Security, Video, Photoelectric Instruments/ Controls.  
**Problem:** (1) Previous Director left without replacement. (2) ISO 9001 (Industrial), ISO 13485 (Medical) and AS 9100 (Space) Quality Management Systems needed to be prepared, implemented and certified.

**Action:** Set up and implemented Quality Systems and conducted various TQM training courses.  
**Results:** Successful organization relocated to larger facilities.

21. National Nuclear Corp., Sunnyvale, CA,

**Position:** Director, Quality Assurance,  
**Product:** Aerospace/ Medical/ Security Radiation Monitoring Equipment  
**Problem:** (1) Previous Director left without replacement. (2) ISO 9001 (Industrial) and ANSI 10CFR50 (Nuclear) Quality Management Systems needed to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality Systems.  
**Results:** Successful organization was incorporated into the corporation location. Received Letters of Commendation from the President, VP and Director of Eng.

22. OmniTel, Inc., Fremont, CA

**Position:** Director, Quality & Reliability  
**Product:** Modems  
**Problem:** Start-up company needed a ISO 9001 Quality Management System to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality Systems.  
**Results:** Organization was successful until I left.

23. J. R. Technology, San Jose, CA

**Position:** Quality Assurance Director  
**Product:** R&D/Prototype Precision Machining  
**Problem:** set up of ISO 9001 Aerospace Quality Management System needed to be prepared, implemented and certified.  
**Action:** Set up and implemented Quality Systems.

24. TIW Systems, Inc., Sunnyvale, CA

**Position:** Director, Quality & Reliability  
**Product:** Aerospace Satellite Antenna Systems and Telecommunications Equipment  
**Problem:** MIL-STD-9858C Aerospace Quality Management System needed to be prepared, implemented and DCAS-approved.  
**Action:** Set up and implemented Quality Systems.  
**Results:** Successful organization relocated to larger facilities.

25. Honeywell Aerospace, Instruments Division Minneapolis, MN,

**Position:** Sr. Q.A. Project Engineer  
**Product:** Spacecraft Indicators and Meters  
**Problem:** Delays in production and high customer return rate.  
**Action:** Prepared and issued Quality System Plan, chose select "Blue Ribbon Committee" to assure effective corrective action. Acted as Chairman of MRB, Failure Analysis Board, First Article Engineering Analysis and Design Review  
**Results:** Received numerous Letters of Commendations and references toward my P.E. license.

#### **D. OTHER CONSULTING EXPERIENCE**

(Asterisks [\*] indicate where Letters of Commendations were received. Copies will be provided upon request)

1. NASA/Ames Research Center, Mountain View, CA, **Position:** ISO 9001 Advisor and Lead Auditor  
**Problem:** Majority of personnel against ISO, Pre-Assessment indicated severe systemic problems.  
**Action:** Conducted training classes, performed coordination with top management and process owners, and worked with groups to prepare needed documents.  
**Results:** Created appreciation for the benefits of the ISO program, obtained cooperation needed, implemented ISO program ahead of schedule, and obtained ISO certification without one Major Nonconformance.  
\* Received Letter of Commendation from NASA Center Director and ISO Program Director.
2. GE Nuclear Energy Business Operations, San Jose, CA,  
**Position:** Technical Program Manager  
**Problem:** Numerous complex, critical technical issues at 12 Nuclear Power Plants.  
**Action:** Coordinated with various company and customer engineering organizations  
**Results:** Resolved all issues with minimal cost and schedule impacts.  
\* Received two Letters of Commendation from Senior Program Management.
3. G.E. Advanced Reactor Systems, Sunnyvale, CA,  
**Position:** Sr. Q.A. Project Engineer  
**Problem:** Entire project behind schedule.  
**Action:** Performed detailed planning, using results of planning, directed supplier, in-plant and site activities and performed project/customer coordination.  
**Results:** My assigned plant systems were the first of all plant systems to ship to site, arriving ahead of schedule. The local newspaper interviewed me and featured an article with a photo of myself next to the extensive system hardware at the plant site.  
\* Received Letter of Commendation from QA Director.  
\* Received Letter of Commendation from QA Director.
4. General Electric, Television Div., Syracuse, NY  
**Position:** Operations Consultant  
**Problem:** Poor field reliability, low customer satisfaction, high manufacturing costs for large-screen Color TV consoles.  
**Action:** Prepared the first process flow chart the facility had ever developed for production and QA systems. Analyzed these systems and documented detailed recommendations for improvements.  
**Results:** Realized immediate increased production yields/quality levels and increased field reliability/customer satisfaction at lower manufacturing costs.

**E. AUDITING AND TRAINING EXPERIENCE**

(Asterisks [\*] indicate where Letters of Commendations were received. Copies will be provided upon request)

09/2002 - Present	<b>British Standards Institute, Reston, VA</b>	<i>ISO Lead Assessor and Instructor</i>
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| <ol style="list-style-type: none"> <li>1. <u>Leading and participating in teams conducting third-party Registrar Certification Assessments</u> to global standard ISO 9001:2000. <ul style="list-style-type: none"> <li>• 2003-06-03 SMA-Cortec</li> <li>• 2003-06-23 Gallo</li> <li>• 2003-08-26 Sharp TJ*</li> <li>• 2003-10-21 Tanner</li> <li>• 2003-10-31 ASIC Adv-Sv</li> <li>• 2003-11-03 Alcoa CSI-Ensnda</li> <li>• 2003-11-05 Robt Bosch-Ont-CA</li> <li>• 2003-11-17 Tanner</li> <li>• 2003-11-25 Annacis Auto Terminals-Vancouver, Canada</li> </ul> </li> <li>2. <u>Conducting public seminars and training courses at company sites</u> for: <ol style="list-style-type: none"> <li>a. <u>RAB-Certified ISO 9001:2000 Lead Auditor</u> per ISO 19011 guidelines</li> <li>b. <u>RAB-Certified ISO 13485:2002 Lead Auditor</u> per ISO 19011 guidelines</li> <li>c. ISO 14971 Risk Management, FDA cGMP-QSRs Regulations, Canadian CMDCAS Regulations.</li> <li>d. <u>Understanding and Management Concepts</u> for ISO 9001 and ISO 13485 Quality Management</li> </ol> </li> </ol> | <ol style="list-style-type: none"> <li>e. <u>Transition/Conversion Methods</u> from ISO 9001:1994 to ISO 9001:2000 Quality Management Systems</li> <li>f. <u>Transition/Conversion Methods</u> from ISO 9001:1994 / ISO 13485:1996 / EN 46001 to ISO 13485:2003 Quality Management Systems <ul style="list-style-type: none"> <li>• 2002-08-30 SGI</li> <li>• 2002-9-30 Morgan Hill</li> <li>• 2002-10-28 UMCQP</li> <li>• 2002-11-18 Dallas</li> <li>• 2003-04-23 San Diego</li> <li>• 2003-07-16 Morgan Hill</li> <li>• 2003-08-02 PR-Synovis Caribe*</li> <li>• 2003-10-16 Digene-Gaithersbg</li> <li>• 2003-10-28 N. Dig-Toronto</li> <li>• 2003-11-11 IntraLase-Irvine</li> </ul> </li> </ol> <p>* Received numerous commendations from client personnel, and from the BSI President and Vice President for</p> <ol style="list-style-type: none"> <li>(1) Conducting an ISO 9001/2000 course in <b>Spanish</b> at <b>Synovis Caribe, Puerto Rico</b></li> <li>(2) Leading an ISO 9001:2000 Certification Assessment in <b>Spanish</b> at <b>Sharp Electronica Mexico</b>.</li> </ol> |
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04/2009 - Present	<b>ABS Quality Evaluation Registrar, Houston, TX</b>	<i>ISO Lead Assessor</i>
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1. Conducting third-party Registrar Certification Assessments to global standard ISO 9001:2000.
  - 2009-04-07 Bara Infoware
  - 2009-07-28 TechRef
  - 2009-09-02 Streamline Tech
  - 2009-10-20 TTI-Tech MikeJackson
  - 2009-11-10 KIE-CON

05/2010 - Present	<b>Ethicon, Johnson &amp; Johnson, Somerset, NJ</b>	<i>ISO Lead Assessor</i>
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Conducting audits of suppliers certified to ISO 9001 / 13485 and FDA-GMP-QSR and approving corrective action plans.

**F1. PERMANENT DIRECT MANAGEMENT EXPERIENCE**

1. **Memorex Communications Group, Cupertino, CA**  
*Quality Engineering Mgr. & Member Tech. Staff*  
**10/1981 - 04/1985.** Supervision of Reliability/Quality Engineers, and QC Inspection/Test personnel and suppliers for domestic and international coordination computer peripheral products(terminals, keyboards, printers). Conducting management interdepartmental plant training program (SPC, Team-Building).
  - \* Letter of Commendation.
2. **Bunker Ramo/Amphenol, Nuclear Products Div, Chatsworth (LA Area), CA,**  
*Project Engineering Mgr.*  
**04/1976 – 10/1977.** Due date passed for qualifying Reactor Assemblies for 7 Nuclear Power Plants. Obtained agreements to con-currently qualify all product requirements in 6 months with extremely limited budget; chose select "Tiger Team" and directed design activities; coordinated with Nuclear Regulatory Commission, Architects, Utilities; approved and supervised outside test facilities, designed and supervised construction of test facility to perform special tests. Qualified "worst case" configurations ahead of schedule and within budget.
  - \* Received numerous Letters of Commendations and references toward my P.E. license.
3. **Bunker Ramo/Amphenol, Space & Missiles Systems Division, Chatsworth (LA Area), CA**  
*QA Laboratory Dept. Head*  
**04/1976 – 10/1977.** Concurrent with the previous position. Direction of the Tool & Gauge Room, the Electronics Laboratory, and the Mechanical/ Materials/ Environmental Test Laboratory in the performance of R&D tests, production support tests, and measuring/test equipment repairs/calibration. Coordinating with outside facilities for performance of special tests for complex AERO-SPACE Cable/Harness Assemblies and Electric Penetration Assemblies for NUCLEAR REACTORS. Design of remote control test facility adjacent to main plant to perform Loss of Coolant Accident/Thermal Conformance/Short Circuit Current nuclear qualification tests. Heavy customer involvement.
  - \* Received numerous Letters of Commendations.

## **F2. TEMPORARY MANAGEMENT EXPERIENCE**

While consulting, also served as Director of TQM, QA & Reliability for:

09/96 - 11/97 KAMET Precision Machining, Santa Clara, CA (R&D/Prototype)  
11/97 - 03/98 Lucas NovaSensor, Fremont, CA (ASICs, PCBAs, Sensors, Silicon Microstructures)  
10/96 - 04/98 G. Hartzell & Son, Concord, CA (Dental Instruments)  
06/95 - 07/96 Huntington Mech. Labs, Mountain View, CA (High-Vacuum Assemblies)  
05/92 - 02/95 Pulnix America, Sunnyvale, CA (Security, Video, Photoelectric Controls)  
01/93 - 04/93 Shin-Etsu Polymer, Fremont, CA (Medical/Automotive Molded Products)  
09/89 - 02/92 National Nuclear Corp., Sunnyvale, CA (Radiation Monitoring Equipment)  
06/88 - 06/89 OmniTel, Incorporated, Fremont, CA (Modems)  
01/87 - 06/88 J. R. Technology, San Jose, CA (Hi-Tech Machine Shop)  
05/86 - 12/89 TIW Systems, Inc., Sunnyvale, CA (Satellite/Telecommunications Antennas)

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## **G. LITIGATION SUPPORT EXPERIENCE**

(Copies of Legal CV and authorization letters for these litigations will be provided upon request)

03/1994 - Present

### **Expert Witness and Technical Expert**

*San Francisco Bar Association, Association for Defense Counsel; Expert.com*

#### ***1. Expert Engagement:***

Type of Matter: Indiana Superior Court, Liability  
Law Firm: William C. Wagner, Esq., Sommer Barnard Attorneys, PC  
Case Name: Ecesis, LLC et.al. vs. Inok Investments, LLC, et. al.  
Services Provided: Wrote Expert Report detailing inconsistencies with Quality Management System requirements as specified in ISO 13485 for Medical Devices and AS 9100 for Aerospace Products.  
Disposition: Settled September 2006 based on above Expert Report.

#### ***2. Expert Engagement:***

Type of Matter: California Superior Court, Class Action  
Law Firm: Green Welling, LLP & Kershaw, Cutter & Ratinoff, LLP  
Case Name: G. Welling, LLP & Kershaw, Cutter & Ratinoff, LLP vs. Hewlett-Packard  
Services Provided: Review of available documents to determine the expected useful life of HP Pavilion notebook computers to be used as a basis for determining the class range.  
Disposition: Settled June 2007 based on above Expert Report.

#### ***3. Expert Engagement:***

Type of Matter: Missouri Circuit Court, Liability.  
Law Firm: LOO Ronnie Penton  
Case Name: Adams et.al. vs. DPC Enterprises, LP, et. al.  
Services Provided: Reviewing Scene of Accident, Reviewing business processes (Quality Management Systems) to determine factors contributing to the accident.  
Disposition: Settled August 2007 based on Expert Reports.

#### ***4. Expert Engagement:***

Type of Matter: California State Arbitration, Liability.  
Law Firm: Bridgford, Knottnerus & Gleason  
Case Name: TMX vs. Allez Spine  
Services Provided: Reviewing business processes (Quality Management Systems) to determine culpability.  
Disposition: Settled October 2007 based on Expert Reports and Testimony.

**H. EDUCATION** (also see Section J)

(Transcripts provided upon request)

1. Suffield University, Twin Falls, Idaho (GPA 3.7).  
Ph.D. – Engineering Management, May 2005
2. Suffield University, Twin Falls, Idaho (GPA 3.7).  
M.S. – Industrial Engineering, May 1981
3. Suffield University, Twin Falls, Idaho (GPA 3.6).  
B.S. – Manufacturing Engineering, May 1978
4. Johns Hopkins University, McCoy College of Engineering, Baltimore, MD.  
Toward BSEE
5. De Anza College, Cupertino, CA; City College, Santa Barbara, CA.  
Nondestructive Testing, Reliability Engineering, Computer Science, Digital & Logic Circuits, State & Federal Law
6. U.S. Army Ordnance School, Officer Training Div. Aberdeen, MD.  
Industrial Engineering, Industrial Management, Production Management
7. School for *Technical Experts*, Conducted by the California Board of Registration for Professional Engineers, Long Beach, CA

**I. AFFILIATIONS**

(Letters provided upon request)

1. Electronic Components Certification Board (ECCB)  
International Electrotechnical Commission (IECQ)
  - a. Board Member
  - b. Technical Review Committee
  - c. Chairman, Ways & Means
  - d. HSPM / QC 080000 / WEEE / RoHS Lead Assessor
2. Calif. Board of Registration for Prof. Engineers
  - a. Registered Professional Quality Engineer (PE);
  - b. Technical Expert for *Examination Development Unit*;
  - c. Technical Expert for *Enforcement Unit*
3. University of Calif., Institute for Social Research
  - a. Technical Expert – Requirements for Licensed Engineers
4. National Society of Professional Engineers (NSPE)
  - a. Member
5. American Society for Quality (ASQ)
  - a. Senior Member
  - b. Instructor
  - c. Certified Quality Auditor
6. Who's Who Worldwide
  - a. Lifetime Member
7. RABQSA International
  - a. Certified ISO 9001 and ISO 13485 Lead Assessor
8. British Standards Institute (BSI)
  - a. ISO 9001 and ISO 13485 Lead Assessor
  - b. Instructor
9. San Francisco Bar Association
  - a. Technical Expert, Expert Witness

**J. ASQ BIOMEDICAL COURSES**

(Certificates of completion and detailed course descriptions available upon request)

1. FDA Quality System Regulation and Audit Process (QSIT).
2. 510k's (Pre-market Notification), PMAs (Pre-market Approval), and FDA Review Process.
3. Adding Value for an Organization utilizing ISO 9000:2000 and ISO 13485, Including Human Elements.
4. FDA Pre-Validation and Process Validation.
5. Complaint Investigation, Handling, Reporting, Record Keeping, Advisory Notices and Recalls.
6. Sterilization Methods, Monitoring and Validation.
7. Eight Discipline (8d) Problem Solving, Root Cause Analysis and CAPA.
8. Electronic Signatures/Records per 21 CFR Part 11.
9. Risk Management, FMEA, FTA, HACCP.
10. Facilitating *Project Management* Success
11. Labeling, Handling, Disposition of Electronic Equipment and Hazardous Substances – U.S., Europe, Japan ('HSF', 'WEEE', 'RoHS, page 1).

**K. ON-SITE COURSE / SEMINAR INSTRUCTOR**

<b>Quality System Courses</b>	<u>Duration</u>
1. Executive Overview	1 day
2. Employee Transition Awareness	1 day
3. Understanding the Quality System	1 day
4. Interpreting the Quality System	1 day
5. Quality System Documentation	1 day
6. ISO 9001:2000 to ISO 13485:2003 Conversion	3 days
7. Implementing the Quality System	2 days
<b>ISO 9001:2000/ISO 13485:2003 Auditor Courses</b>	<u>Duration</u>
1. Certified ISO 9001:2000/ ISO 13485:2003 Internal Auditor	3 days
2. ISO 9001:2000/ ISO 13485:2003 RABQSA Certified Lead Auditor	5 days

## L. PUBLICATIONS

### *Published by Amphenol – Bunker Ramo:*

1977 Generic Qualification Test Program for Nuclear Power Generating Station Electric Penetration Assemblies (101 pages)

### *Published by NASA, Ames Research Center, Moffett Field, CA*

1998 NASA Reference Publication NRP4-14, “A Guide to Implementing ISO 9001, Clause 4.14; Corrective and Preventive Action”

### *Published by International Quality Assessment System for Electronic Components (IECQ) with John Fink:*

2006 Assessment Procedures for Acceptance of Candidate Subject Matter Experts (SME's) in the IECQ Scheme

### *Published and sold by New World Consulting Service:*

- 1996 The Path to ISO 9001 Registration
- 2001 NWC ISO 9001:2008 “Process vs. Evidence (Look At Look-For)” Checklist (with 800 separate questions and answers). Also published as an article on *Experts.com*
- 2005 NWC ISO 13485:2003 “Process vs. Evidence (Look At Look-For)” Checklist (with 1,100 separate questions and answers)
- 2005 NWC ISO 13485-QSR-14971-Mgt. Resp. Audio-Visual Training CD “Implementation of ISO and Risk Management Standards for Medical Devices”

## M. AWARDS AND HONORS

- 2002 **British Standards Institute (BSI)** President and Vice President commendation for excellence in conducting an ISO 9001/2000 course in Spanish at Synovis Caribe, Puerto Rico and leading an ISO 9001:2000 Certification Assessment in Spanish at Sharp Electronica Mexico.
- 2001 **Applied Materials/AKT**, Santa Clara, CA. Plaque and world-wide Letter of Commendation from President and Executive Staff
- 2001 **University of California, Institute for Social Research**, commendation for leading a panel of experts in determining the standard educational requirements applicable to Licensed Professional Engineers
- 1998 **NASA/Ames Research Center**, Mountain View, CA. Commendation from NASA Center Director and ISO Program Director.

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## N. SKILLS

- Desktop Applications Advanced 25+ yr.  
Microsoft Office (MSWord, Excel, Power Point), Microsoft Project, Microsoft Internet Explorer, Outlook Lotus Notes, Eudora
- Graphics Applications Advanced 25+ yr.  
Various, including Paint Shop Pro
- Analytical Skills Expert 40+ yr.  
QA Internal and Supplier Auditing, TQM, SPC, 6-Sigma, Reliability Engineering
- Management Abilities Advanced 35+ yr.  
Corporate Leadership, Direction, Setting, Executive Responsibilities, Contractor/Supplier Management, Business Processes
- Project Planning Advanced 35+ yr.  
Project Leadership, Planning, Scheduling, Control, Resource Management, Project Change Management, Project Quality Assurance
- Sales Abilities Expert 30+ yr.  
Customer Coordination, Proposal Writing
- Development Skills Expert 30+ yr.  
Design, Functional, Technical Specs, Requirements Definition, Tech Writing
- Teaching Skills Expert 35+ yr.  
Tech. Training Course Development  
Instructor – ISO, QMS, TQM, SPC  
Instructor – Customer Service, Decision Making, Effective Meetings
- Quality Management Systems Expert 35+ yr.  
Concepts, Management, Standards, Plans, Procedures, Forms, Quality Control (Inspection/ Test)
- Language Expert 35+ yr.  
Spoken/Written *Spanish*

## KEYWORDS

ISO 13485 Consultant	ISO 13485 Auditor	ISO 13485 Instructor
AS9100 Consultant	AS9100 Auditor	AS9100 Instructor
QMS Instructor	QMS Lead Auditor	QMS Expert Witness
Business Processes	Technical Expert	Expert Witness
Quality Management System	Lead Auditor	