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National Society for Professional Engineers

Consultant / Sr. Quality Professional / Instructor
Lead Auditor / Project Manager (Power) / Technical Expert

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 [1]HSF requirements, QC 080000 [2]IECQ [3]HSPM for [4]WEEE and [5]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.

3. ISO 9001/13485 / AS 9100C Lead Auditor (Temp.)
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.

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

[1]Hazardous Substance Free. [2] International Electrotechnical Commission Quality Assessment System for Electronic Components. [3]Hazardous Substances Process Management. [4]Waste of Electrical and Electronic Equipment. [5]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. USNC/IECQ ECCC-IAB 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.

2. 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).

3. IECQ Lead Assessor, QC 080000 IECQ-HSPM, *Hazardous Substances Process Management* / WEEE / RoHS

D1. 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. **Trimedyne, Inc**., Lake Forest, CA (12/2010-Present)

   Product: Surgical lasers, Holmium products, surgical fibers, handpieces and laser accessories
   Position: ISO 13485/FDA/CMDR/MDD Consultant
   Action: On-going internal audit of the quality management system and two technical files

2. **Integrated Composites Inc. (ICI)**, Marina, CA (07/2011-Present)

   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: Obtained AS9100 Rev. C registration. On-going internal audits conducted.

3. **Evans Analytical Labs, RTP Div.**, Santa Clara CA (01/2011-Present)

   Position: ISO 9001 / ISO 17025 Consultant
   Product: Design, development, and reliability testing services for product qualification.
   Problem: ISO 9001 / 17025 initial certification within 9 months, lacking QMS documents and implementation.
   Action: Created Quality Manual, procedures and forms. Conducted ISO 9001 / ISO 17025 Lead Internal Auditor training
   Results: Registration obtained.

4. **Digi-Com Electronics,** Richmond, CA (09/2009-Present)
5. **Quality Circuit Assemblies**, San Jose, CA (11/2009-Present)
6. **EMED Technologies**, El Dorado Hills, CA (12/2009-Present)

   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.

7. **Vital Wear,** S. San Francisco, CA (07/2008-03/2009)

   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.

8. **Focus Diagnostics, Inc.,** Cypress, CA (11/2007-05/2008)
   Focus Laboratory Svs., Cypress, CA (11/2007-05/2008)

   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.

9. **Biosense Webster, Inc. (Johnson & Johnson),** Irwindale (LA Area), CA and Juarez, Mexico (02/2006-12/2007)

   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 mapping, 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.

10. **Invitrogen,** Camarillo, CA (Merger) (06/2006)
    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 o 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 (09/2005-03/2006)

    ***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 (07/2005-08/2005)

    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 041/2004)

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 (09/2004-10/2004)

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 (**SQA), Santa Clara, CA (03-2000-02/2001)

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 9001ahead 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 (11/1997-03/1998)

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 3rd party Certification to all Quality Systems. Statistical Q.E. voted "Employee of the Month".

17. **KAMET Precision Machining,** Santa Clara, CA (09/1996-09/1998)

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 (06/1995-07/1996)

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 (01/1993-04/1993)

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 three months.
Results: Successful organization relocated to Japan.

20. **Pulnix America Corp.**, Sunnyvale, CA (05/1992-02/1995)

Position: *Director, TQM/ISO Program*
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 (09/1989-02/1992)

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 (06/1988-06/1989)

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 01/1987-06/1988
Position: Quality Assurance Director
Product: R&D/Prototype Precision Machining
Problem: set up of IS0 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 (05/1986-12/1989)

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 (11/66-09/67)

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.

Intel Corporation, Santa Clara, CA (10/1981)
Position: Quality Engineering Consultant
Product: Microcomputer memory systems, workstations, and peripherals
Action: Set up and direction of Quality Engineering, Inspection and Test activities relative to procurement of parts/ assemblies and OEM products (power supplies, disc drives, PCB's, etc.), in-process manufacturing/ assembly/ shipping functions. Coordinating transfer of staff, documentation and equipment to Puerto Rico plants for manufacture of new product lines (fluent Spanish required).parts/assemblies and OEM products (power supplies, disc drives, PCB's, etc.), in-process manufacturing/ assembly/ shipping functions.
Results: Completed coordinating transfer of staff, documentation and equipment to Puerto Rico plants for manufacture of new product lines. Offered permanent management position but opted for Memorex instead.

D2. 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 (04/1998 – 06/1999)
   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 (05/1985-04/1986)
   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 (05/78-06/1981)
   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 (10/67-11/67)
   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	**British Standards Institute,** Reston, VA	*ISO Lead Assessor and Instructor*

1. Leading and participating in teams conducting third-party Registrar Certification Assessments to global standard ISO 9001:2000.

   - 2003-06-03 SMA-Cortec
   - 2003-06-23 Gallo
   - 2003-08-26 Sharp TJ*****
   - 2003-10-21 Tanner
   - 2003-10-31 ASIC Adv-Sv
   - 2003-11-03 Alcoa CSI-Ensnda
   - 2003-11-05 Robt Bosch-Ont-CA
   - 2003-11-17 Tanner
   - 2003-11-25 Annacis Auto Terminals-Vancouver, Canada

2. Conducting public seminars and training courses at company sites for:
   a. *RAB-Certified ISO 9001:2000 Lead Auditor* per ISO 19011 guidelines
   b. *RAB-Certified ISO 13485:2002 Lead Auditor* per ISO 19011 guidelines
   c. ISO 14971 Risk Management, FDA cGMP-QSRs Regulations, Canadian CMDCAS Regulations.
   d. *Understanding and Management Concepts* for ISO 9001 and ISO 13485 Quality Management
   e. *Transition/Conversion Methods* from ISO 9001:1994 to ISO 9001:2000 Quality Management Systems
   f. *Transition/Conversion Methods* from ISO 9001:1994 / ISO 13485:1996 / EN 46001 to ISO 13485:2003 Quality Management Systems

   - 2002-08-30 SGI
   - 2002-9-30 Morgan Hill
   - 2002-10-28 UMCQP
   - 2002-11-18 Dallas
   - 2003-04-23 San Diego
   - 2003-07-16 Morgan Hill
   - 2003-08-02 PR-Synovis Caribe*
   - 2003-10-16 Digene-Gaithersbg
   - 2003-10-28 N. Dig-Toronto
   - 2003-11-11 IntraLase-Irvine

* Received numerous commendations from client personnel, and from the BSI President and Vice President for
   (1) Conducting an ISO 9001/2000 course in ***Spanish*** at **Synovis Caribe,** Puerto Rico
   (2) Leading an ISO 9001:2000 Certification Assessment in ***Spanish*** at **Sharp Electronica** Mexico.

04/2009 - Present	**ABS Quality Evaluation Registrar,** Houston, TX	*ISO Lead Assessor*

Conducting third-party Registrar Certification Assessments to ISO 9001:2000.

- 2009-04-07 Bara Infoware
- 2009-07-28 TechRef
- 2009-09-02 Streamline Tech
- 2009-10-20 TTI-Tech
- 2009-11-10 KIE-CON

02/2006 – Present	**Marion Weinreb & Associates**, San Francisco, CA	*Associate and Supervising Assessor*
05/2010 - 05/2011	**Ethicon, Johnson & Johnson,** Somerset, NJ	*Lead Contract Supplier Auditor*
05/2011 - Present	**Medpoint, LLC,** Greenville, SC	*Contract Lead Auditor & Consultant*

Conducting audits of suppliers certified to ISO 9001 / 13485 and FDA-GMP-QSR and review/approval of corrective action plans.

- 2010-09-06 Minitubes, France
- 2010-09-16 Hoosier Springs, IN
- 2010-11-16 Needletech, MA
- 2010-11-17 Lacey, CT
- 2010-12-02 Steven Label, CA
- 2010-12-07 Pacific Rubber, CA
- 2010-12-08 NuSil, CA
- 2010-12-15 Trimedyne
- 2011-03-15 FzioMed, CA
- 2011-03-23 Dako-Acerna
- 2011-03-17 Applied Silicon, CA
- 2012-05-15 Zefon, Tijuana, Mex.
- 2012-09-10 NSL, Cleveland
- 2012-11-28 Trimedyne

F1. *PERMANENT* DIRECT MANAGEMENT EXPERIENCE

1. **Memorex Communications Group**, Cupertino, CA (10/1981-04/1985)

   Quality Engineering Mgr. & Member Tech. Staff

   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 (04/1976–10/1977)

   Project Engineering Mgr.

   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 (04/1976–10/1977)

   QA Laboratory Dept. Head

   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 AEROSPACE 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)

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.

5. Expert Engagement:

Type of Matter:	California, Alabama, Mississippi and New York Superior Court, Class Action
Law Firm:	Riley & Jackson, Birmingham, AL; Becnel Law Firm, Reserve, LA; and others
Case Name:	Various vs. medical device company (to be disclosed at a later date)
Services Provided:	Review of failure/malfunction of surgical instrumentation, and review of business processes (Quality Management Systems and Clinical Trials) of an international medical device company to determine accountability and culpability.
Disposition:	Commenced October 2012; in process.

H. EDUCATION

(For Ashley U. details and verification, go to http://drandrewperry.com/pdf/dr-andrew-perry_PhD.pdf. Also see Section J)

1. Ashley University, Los Angeles, CA. (GPA 3.92)
   Ph.D. – Engineering Management, June 27, 2005
2. Ashley University, Los Angeles, CA. (GPA 3.38)
   M.S. – Industrial Engineering, June 29, 1981
3. Ashley University, Los Angeles, CA. (GPA 3.18)
   B.S. – Manufacturing Engineering, June 26, 1978
4. School for ***Technical Experts***, Conducted by the California Board of Registration for Professional Engineers, Long Beach, CA
5. Johns Hopkins University, Baltimore, MD.
   Toward BSEE
6. De Anza College, Cupertino, CA
   City College, Santa Barbara, CA.
   Nondestructive Testing, Reliability Engineering, Computer Science, Digital & Logic Circuits, State & Federal Law
7. U.S. Army Ordnance School, Officer Training Div. Aberdeen, MD.
   Industrial Engineering, Industrial Management, Production Management

I. AFFILIATIONS

(For details click on links in website)

1. Electronic Components Certification Corp. (ECCC)
   International Electrotechnical Commission (IECQ)
   a. USNC/IECQ ECCC-IAB Member
   b. ECCC Technical Review Committee
   c. IECQ Lead Assessor, HSPM/QC 080000/WEEE/RoHS
2. California Board of Professional 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
   a. Member
5. Quality Digest
   a. Consulting & Training
6. American Society for Quality (ASQ)
   a. Senior Member
   b. Instructor
   c. Certified Quality Auditor
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. Los Angeles County Bar Association
   a. Technical Expert, Expert Witness
10. San Francisco Bar Register of Experts
    a. Technical Expert, Expert Witness

J. ASQ BIOMEDICAL COURSES

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

05/2003 Sterilization Methods, Monitoring and Validation.

06/2003 Eight Discipline (8d) Problem Solving, Root Cause Analysis, Corrective Action and Preventive Action

08/2003 Complaint Investigation, Handling, Reporting, Record Keeping, Advisory Notices and Recalls.

09/2003 510k's (Pre-market Notification), PMAs (Pre-market Approval), and FDA Review Process.

09/2003 Adding Value for an Organization utilizing ISO 9000:2000 and ISO 13485, Including Human Elements.

10/2003 FDA Quality System Regulation and Audit Process (QSIT).

10/2003 Risk Management, FMEA, FTA, HACCP.

01/2004 Design Control for Medical Devices

03/2004 Electronic Signatures/Records per 21 CFR Part 11.

04/2004 FDA Pre-Validation and Process Validation.

06/2006 Labeling, Handling, Disposition of Electronic Equipment and Hazardous Substances – U.S., Europe, Japan ([1]HSF, [2]WEEE, [3]RoHS, page 1).

02/2009 Facilitating *Project Management* Success

K. ON-SITE COURSE / SEMINAR INSTRUCTOR

Quality System Courses	Duration
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

ISO 9001:2000/ISO 13485:2003 Auditor Courses	Duration
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 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.

N. SKILLS

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

KEYWORDS

ISO 13485 Consultant
AS9100C Consultant
QMS Instructor
ISO 9001 Consultant
ISO 13485 Auditor
AS9100 Auditor
QMS Lead Auditor
ISO 9001 Auditor
ISO 13485 Instructor
AS9100 Instructor
QMS Expert Witness
ISO 9001 Instructor
Lead Auditor
Lead Assessor
Technical Expert
Expert Witness
Business Processes
Quality Management System