

Dr. Andrew J. Perry, P.E. Curriculum Vitae

Professional Summary

Dr. Andrew Perry is a professional engineer with over 30 years of experience as a Quality Management System Consultant, and has also been an expert witness and/or technical consultant for matters involving the following industries: Medical, Aerospace, Automotive, Computers, Telecommunications, Silicon technology, Energy / Power, Optics, Electronics, Electromechanical.

Dr. Perry is the President of New World Consulting Service which develops cost-effective Quality Management Systems for companies. He is knowledgeable in AS 9100/ ISO 9001/ 16949/ 13485/ FDA/ QSR/ cGMP/ CMDCAS and QC 080000 IECQ-HSPM Quality Management Systems, including Validation/ Revalidation Programs, Quality Audit Programs (internal and external), Corrective/ Preventive Action Systems, Document Development, Implementation and Control functions, and Engineering/ Technical Program/ Project Management activities.

Dr. Perry offers expertise in marketing, design, manufacturing and quality assessment guidance to assess the compliance and effectiveness of internal company processes and their supplier organization. His company offers set-up and direction of customer, quality, reliability, design, manufacturing; set-up of global customer feedback systems working in an international environment, including the European and Asian Market; comprehensive evaluation (gap analyses) of business processes; direct *Problem* solving and continuous improvement activities; and teaching, organizing and managing of cross-functional teams.

Expertise

- Engineering Management
- Quality Assurance: AS 9100/ ISO 9001/ 16949/ 13485/ 14971 QC 080000 IECQ-HSPM standards
- FDA QSR-cGMP (U.S.), CMDCAS (Canada), MDD (Europe) and PAL (Japan) regulations

Education

<u>Year</u>	<u>College or University</u>	<u>Degree</u>
May 2005	Suffield University, Twin Falls, Idaho	Ph.D., Engineering Management
May 1981	Suffield University, Twin Falls, Idaho	M.S., Industrial Engineering
May 1978	Suffield University, Twin Falls, Idaho	B.S., Manufacturing Engineering

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Additional Education and Training:

Johns Hopkins University, McCoy College of Engineering, Baltimore, MD.	Applied towards B.S., Electrical Engineering
De Anza College, Cupertino, CA	Nondestructive Testing, Reliability Engineering, Computer Science, Digital & Logic Circuits, State & Federal Law
City College, Santa Barbara, CA.	Nondestructive Testing, Reliability Engineering, Computer Science, Digital & Logic Circuits, State & Federal Law
U.S. Army Ordnance School, Officer Training Div. Aberdeen, MD	Industrial Engineering, Industrial Management, Production Management

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Professional Experience – Direct Management Positions

Consulting Projects

From: October, 1977
To: Present
Organization: New World Consulting Service (NWCS), Mountain View, CA
Title: President

Client List of Special Products
(see also Attachment 1)

Client/Acting Role	Product Line
Lucas NovaSensor, Fremont, CA Director, Quality & Reliability Assurance	ASICS, PCBAS, Fluidic And Optic Sensors and Silicon Microstructures for Automotive, Medical, Computer, Communications, and Industrial Applications
G. Hartzell & Son, Concord, CA Director, Quality Assurance	Dental Instruments
Huntington Mechanical Labs, Mountain View, CA Director, Quality Assurance	Aerospace Vacuum Products and Prototype Mechanical Assemblies
Shin-Etsu Polymer Corp., Fremont, CA Director, Quality Assurance	Medical and Automotive Instrument Panels
National Nuclear Corp., Sunnyvale, CA Director, Quality Assurance	Medical, Security, Radiation Monitoring Equipment and Instruments
TIW Systems, Inc., Sunnyvale, CA Director, Quality & Reliability	Aerospace Satellite Antenna Systems And Telecommunications Equipment

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Consulting Engagement:

Client: **Integrated Composites Inc. (ICI), Marina, CA**
Services Provided: *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.

Consulting Engagement:

Client: **Evans Analytical Labs, RTP Div., Santa Clara CA**
Services Provided: *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.

Consulting Engagement:

Client: **Digi-Com Electronics, Richmond, CA**
Quality Circuit Assemblies, San Jose, CA
EMED Technologies, El Dorado Hills, CA
Services Provided: *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.

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Consulting Engagement:

Client: Vital Wear, Inc., South San Francisco, CA
Services Provided: 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.

Consulting Engagement:

Client: Focus Diagnostics, Inc., Cypress, CA
Focus Laboratory Services, Cypress, CA
Services Provided: 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.

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Consulting Engagement:

Client: Invitrogen, Zymed and Caltag Laboratories, South San Francisco, Burlingame, Camarillo, CA
ISO 13485:2003 / FDA cGMP/QSR Consultant

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

Problem: Corporation certified to ISO 13485. (1) Recently acquired Caltek Labs, Burlingame, CA and Zymed Labs, S. San Francisco, CA and is undergoing relocation to S. Cal. (Camarillo); Registrar Assessment scheduled next month to cover all locations which have had extensive organizational changes. Some key positions are still vacant. (2) Various system *Problems* detected by FDA on last inspection still unresolved. (3) There are currently no Internal qualified Auditors capable of detecting underlying *Problems* and recommending fixes.

Action: In progress. Currently reviewing documented Quality System and submitting recommendations for changes as well as procedures to assure successful relocation with minimal cost and schedule impact.

Results: Anticipate Company being able to revise QMS documentation and deploy effective implementation in time to pass scheduled ISO 13485 Registrar Assessment and satisfy FDA findings in time allotted (30 days).

Consulting Engagement:

Client: Biosense Webster, Inc. (Johnson & Johnson), Irwindale (LA Area), CA and Juarez, Mexico
Services Provided: Position: ISO 13485:2003/ FDA/ CMDR/ MDD/ Pre-BSI Consultant

Product Line: Advanced diagnostic and therapeutic electro-physiological catheters, and 3-dimensional, real-time cardiac color-coded mapping, navigation and ablation systems.

Problem: Similar to above. Corporation certified to ISO 13485:2003. Registrar Assessment scheduled next month. Extensive organizational changes and key positions vacant. Internal Audits not conducted per the Standard due to the Internal Audit Manager's leaving without notice.

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Action: In 2 weeks, (1) Reviewed documented Quality System and submitted recommendations for changes. (2) In the absence of qualified internal auditors, 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 failed their BSI Assessment and was going to lose their ISO certification, which would have resulted in losses of millions of dollars in sales in Canada and Europe. The BSI Lead Assessor knew of me and knew I was in the plant at that time finishing my audit. Upon receiving my report, BSI advised the Company to implement all my recommendations and they could retain their ISO certificate. As a result, they also asked me to audit Juarez, which will be completed next month.

Consulting Engagement:

Client: Intuitive Surgical, Inc., Sunnyvale, CA.
Services Provided: Position: ISO 13485 / FDA cGMP/QSR, MDD and CMDCAS Consultant

Product Line: 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 and subsequent FDA audits.

Consulting Engagement:

Client: SurgRx , Incorporated, Palo Alto, CA.
Services Provided: Position: ISO 13485 / FDA cGMP/QSR, MDD and CMDCAS Consultant

Product Line: State-of-the-art Electronic/Electromechanical 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 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. (4) Received a referral to the above company after assignment completed.

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Consulting Engagement:

Client: International Remote Imaging Systems, Chatsworth, CA
Services Provided: Position: ISO 13485/ FDA/ cGMP/ QSR/ CMDCAS Consultant

Product Line: International Remote Imaging Systems, Chatsworth, CA.
Remote imaging systems for medical diagnosis and surgery.

Problem: Company certified to ISO 9001:1994. ISO 13485/CMDCAS Registrar Certification Assessment scheduled next 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 and ISO 19001.

Results: Company able to revise QMS documentation and deploy effective implementation in time to pass scheduled ISO 13485/CMDCAS Registrar Certification Assessment. Received referral for subsequent consulting assignment from QA Director.

Consulting Engagement:

Client: Applied Materials/AKT, Santa Clara, CA
Services Provided: Position: ISO 9001 Program Director

Product Line: Capital Equipment For Manufacture Of Flat Panel Displays.

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.

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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 (see attachment Refs.doc, pages 11 and 26).

Consulting Engagement:

Client: NASA/Ames Research Center, Moffett Field, Mountain View, CA
Services Provided: Position: ISO 9001 Advisor and Lead Auditor

Product Line: Medical and Aerospace Research

Problem: Majority of client personnel were Civil Service Management or Ph.D. researchers not in agreement with ISO management and organizational concepts and controls.

Action: Developed ISO 9001 QMS in three Directorates. Performed Pre-Assessment 3 months before Certification date which detected 48 Major Nonconformances and indicated severe lack of implementation. Vigorously worked to attain required implementation.

Results: NASA/Ames passed their certification audit without one Major Nonconformance. Received Letter of Commendation from NASA Center Director and ISO Program Director.

Consulting Engagement:

Client: Pulnix America Corp., Sunnyvale, CA
Services Provided: *Position:* Director, TQM/ISO Program
Product Line: 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.

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Consulting Engagement:

Client: OmniTel, Inc., Fremont, CA

Services Provided: *Position:* Director, Quality & Reliability
Product Line: 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: Successful organization.

Consulting Engagement:

Client: TIW Systems, Inc., Sunnyvale, CA

Services Provided: *Position:* Director, Quality & Reliability

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.

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Consulting Engagement:

Client: General Electric Nuclear Energy Business Operations, San Jose, CA
Services Provided: Position: Technical Program Manager

Problem: Numerous complex, critical technical and commercial issues at 12 client Nuclear Power Plant sites.

Action: Coordinated with various company and customer engineering organizations.

Results: Resolved all issues. Client plants continued operation with minimal schedule-impacts, redesign efforts and parts procurement expenditures. Received Letters of Commendation from different Program Directors. Client plants continued their excellent business relationships with G.E.

Consulting Engagement:

Client: Bunker Ramo/Amphenol, Nuclear Products Division
Services Provided: Position: Sr. Project Engineer, reporting to VP Engineering

Problem: Due date passed for qualifying Reactor Penetration Assemblies for seven client Nuclear Power Plants and design effort had not commenced for this program. Subsequent agreements made to concurrently qualify all client product requirements in 6 months with limited budget (\$1.5M).

Action: (1) Choose select group of design specialists (mechanical and electrical engineers, technicians and draftsmen) designated "Tiger Team"; (2) direct their design activities; (3) coordinate with Nuclear Regulatory Commission, Architects and Engineering firms, Utilities, and other in-plant Departments; (4) qualify, approve and supervise outside test facilities; (4) design and supervise construction of remote control test facility adjacent to main plant to perform special combinations of tests under unique environmental conditions.

Results: Qualified two Reactor Penetration Assemblies as "worst case" configurations representing all customer requirements ahead of schedule and within budget. Received numerous Letters of Commendation from all departments. Client plants continued their excellent business relationships with Bunker Ramo/Amphenol.

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Consulting Engagement:

Client: G.E. Advanced Reactor Systems, Sunnyvale, CA
Services Provided: Position: Sr. Q.A. Project Engineer

Product Line: Clinch River Fast Breeder Nuclear Reactor Plant

Direction of in-plant and site quality activities from procurement and throughout manufacture, shipping and installation of equipment. Heavy customer involvement and site coordination. Received letter of commendation and article and photo in Newspaper.

Problem: Make up lost time (5 months) for procurement, manufacture, shipping and installation of Steam Generation and Intermediate Heat Transfer (Sodium) Systems for Clinch River FAST BREEDER REACTOR PLANT.

Action: Directed supplier, in-plant and site activities/customer coordination.

Results: Assigned plant systems were first to ship to site, one month ahead of time. Letter of Commendation and article/photo in local newspaper.

Consulting Engagement:

Client: Honeywell Aerospace, Instruments Division, Minneapolis, MN
Services Provided: Position: Sr. Q.A. Project Engineer

Product Line: Spacecraft Indicators and Meters

Control of hardware, documentation and special processes. Chairman: MRB; Failure Analysis Board and First Article Engineering Analysis/Design Review.
Problem: Delays in production and delivery, and high customer return rate for critical spacecraft indicators and meters.

Action: Prepare and issue Quality System Plan, Quality Program Plan and supporting QMS documentation. Assessed controls for design, suppliers, production, special processes, personnel qualification, final acceptance and noted deficiencies. Choose select group of Design and Manufacturing Engineers to participate with me as Chairman of "Blue Ribbon Committee" to assure corrective action for systemic product *Problems* and act as MRB, Failure Analysis Board, and First Article Engineering Analysis/Design

Review/Results: Received numerous Letters of Commendation from all departments. Offered permanent job as Sr. QA Project Engineer.

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Consulting Engagement:

Client: General Electric, Television Division, Syracuse, NY
Services Provided: Position: Operations Consultant

Product Line: Color Television Receivers

Analysis of production and quality assurance operating systems for the manufacture of large-screen TV receivers. Recommendation of improvements for providing increased production yields/quality levels and increased field reliability/customer satisfaction at lower manufacturing costs.

Problems: Delays in production and delivery, poor production yields. High customer return rate, low customer satisfaction. Low field reliability,.

Action: Analysis of design, production and quality systems. Created detailed comprehensive system flow chart. Recommended improvements for each affected process step.

Results: Recommended specific additions, deletions and revisions of process steps to increase production yields, quality levels, field reliability and customer satisfaction at lower costs.

Consulting Engagement:

Client: G.E. Project Engineering Operations, San Jose, CA
Services Provided: Technical Program Manager

Product Line: BWR Nuclear Power Plants

Responsible for technical program and management focus for critical engineering issues with sub-contractors, customers (plant site), and GE engineering groups. Heavy customer involvement. Received Letters of Commendation.

Consulting Engagement:

Client: Intel Corporation, Santa Clara, CA
Services Provided: Quality Engineering Consultant

Product Line: Microcomputer Memory Systems, Workstations, and Peripherals

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).

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Professional Affiliations, Achievements & Awards

- Board Member, Member of Technical Review Board, Chair of Ways & Means, *International Electrotechnical Commission (IECQ)*, Electronic Components Certification Board
- Fellow Candidate/Senior Member; Instructor; Auditor, *American Society for Quality (ASQ)*
- P.E., Registered in California
- Technical Expert for Examination Development Unit, California Board of Reg. for P.E.s
- Technical Expert for Enforcement Unit, California Board of Reg. for P.E.s
- Member, *National Society of Professional Engineers (NSPE)*
- Member, *Bar Association of San Francisco and Sacramento*
- Member, *The Association for the Defense Counsel*
- Who's Who Worldwide
- Experts.com (Who's Who for Experts)
- *Technical Expert - Reqs. for Licensed Engineers*, Univ. of California, Institute for Social Research
- Certified Lead ISO 9001/ 13485 QMS Auditor, *RABQSA International*
- Lead Auditor, *British Standards Institute (BSI)*, leading and conducting third-party Registrar ISO 9001/ 13485 QMS Certification audits
- Instructor, *British Standards Institute (BSI)*, Conducting public and on-site seminars for RABQSA Certified ISO 9001/ 13485/ 19011 Lead Auditor, and courses including implementation of ISO 9001/ 13485/ 14971 Quality Management Systems.
- Awarded commendations from V.P. and President of BSI

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Litigation Support Experience

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, Quality Assurance.
Disposition: Settled Jan. 2006 based on above Expert Report.

Expert Engagement:

Type of Matter: California Superior Court, Liability
Law Firm: Venardi Elam LLP
Case Name: Phoenix Logistics vs. EDO
Services Provided: Quality Assurance Analysis
Disposition: Settled Aug. 2005 based on above Expert Report.

Expert Engagement:

Type of Matter: Indiana Superior Court, Liability
Law Firm: William C. Wagner, Esq., Sommer Barnard Attorneys, PC
Case Name: Eceasis, LLC et.al. vs. Inok Investments, LLC, et. al.
Services Provided: Wrote Expert Report, Quality Assurance Issues. ISO1345 for Medical Devices; ISOAS9100 for Aerospace.
Disposition: Settled June 2005 based on above Expert Report.

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.

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NSPE, IECQ-ECCC, RABQSA-LA, ASQ-CQA

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**Attachment 1
Permanent Direct Management Positions Held
at Consumer Product Manufacturers**

10/1981 - 04/1985 Memorex Communications Group, Cupertino, CA

Quality Engineering Mgr. & Member Tech. Staff

Product Line: Computer Peripheral Products (Terminals, Keyboards, Printers)

Supervision of Reliability/Quality Engineers, and QC Inspection/Test personnel and suppliers. Developing and conducting management interdepartmental plant training program (SPC, Team-Building).

10/71 - 04/76 Joslyn Electronics Systems, Santa Barbara, CA

Project Engineer

Product Line: Spark Gaps, Lightning Arresters, and Over-Voltage Surge Protectors

Design of special test equipment and procedures for in-plant product testing and for sale to customers. Oversight of in-plant R&D, qualification, production tests, and special tests at outside facilities.

05/66 - 10/66 Pace Communications Corp., Los Angeles, CA

Quality Assurance Director

Product Line: Citizen-Band Radios and accessories

Establishment and management of all QA, QE and QC functions. Approval of QA and Manufacturing procedures, documentation, and instrumentation. Oversight of internal/supplier corrective/preventive action. Chairman of Design Review and MRB.