**Quality Assurance**

I am a QA Professional with hands-on experience in Quality Assurance & Project Management.

I am highly experienced and results-oriented in managing, directing, developing & implementing entire QA Systems. Additionally, I am very experienced in developing, managing, mentoring, and leading direct reports, as well as, having successfully supported others in multiple team environments.

I work comfortably and effectively with suppliers/vendors and customers in North America, Europe & Asia solving problems, improving these relationships, & their respective systems.

I am an experienced facilitator in problem solving efforts, and ensuring assignment and completion of CAPA efforts with quality engineering, senior management, associated program departments, other employees, vendors & customers.

# EDUCATION:

# University of Arkansas at Fayetteville – Bachelor’s Degree (Major: Physics; Minor: Electronics)

**KNOWLEDGE & skills summary:**

* 10 plus years working in manufacturing/assembly company/corporate as QA manager/director
* Total Quality Management – TQM program implementation, oversight, and management
* ISO/AS codes and standards – ISO 9001, ISO 13485, ISO 14969, ISO 14971, AS 9100, EU Medical Device Directive (93/42 EEC) and EN 46001
* Scheduling/Conducting Internal Audits, External Audits & working with the external ISO/AS certification auditor(s)
* Management Representative for Quality Management System (QMS), the Quality Manual and Procedures.
* 21 CFR 820 – Title 21 Code of Federal Regulations Part 820
* cGMP – current Good Manufacturing Practices
* Supplier Quality – US, North America, Europe & Asia

# CAPA – Corrective and Preventative Actions

* QS Remediation – Quality Systems Remediation
* MSA – Measurement System Analysis (gauging)
* pFMEA – process Failure Mode Effects Analysis
* PPAP – Production Parts Approval Process
* UDI – Unique Device Identification
* Quality Process Monitoring
* Process Flow Maps
* Control Points & Control Plans
* TMV – Test Method Validation processes
* V&V – Verification & Validation process
* QA Inspection and Testing of materials and products
* Training of employees and engineers on Quality Compliance and Systems

**Career History Details:**

**B&H Quality Assurance Management Solutions - LLC**

**Automotive, Aerospace, DOD, Medical Device, Commercial & Scientific Manufacturing/Industries**

**(Owner) Quality Assurance Manager/Director – (2016 to Present)**

* Medical Device, Automotive, Aerospace, DoD, & commercial manufacturing Quality Assurance Manager/Director
* An expert in managing, developing, improving & implementing entire Quality Assurance Systems and personnel.
* Experienced in managing, developing, improving & implementing all elements of a company’s compliance with ISO 9001, ISO 13485, ISO 14969, ISO 14971, AS9100, Mil-Stds, Quality System Regulations (QSR), Good Manufacturing Practices (cGMP), FDA, Customer expectations, Corporate/company requirements & other guidelines.
* Perform internal audits of all departments & organizations.
* Perform external audits of vendor quality systems.
* Manage/direct the following Quality functions and my employees efforts to assure compliance with the company's Quality Management System (QMS): Customer Affairs, Quality Engineering, Contract Review, Software/Hardware/Process & Equipment Validation, Design Control, Documentation Services, CAPA, MRB, Procurement, Supplier Quality, Metrology, Product Release, Continuous Improvement, Receiving Inspection, In-process Inspection, Final Inspection & Test, Shipping, and other aspects of Quality Control.
* Provide direction to ensure compliance with all customer requirements & government regulations involving product quality.
* Manage employees in their activities to maintain & assure continuous improvement of the Quality Systems to achieve corporate, company & customer goals.
* Hire, train & develop Quality Engineers & Inspection Personnel to ensure quality goals are achieved.
* Provide support & leadership in Quality Engineering for existing & new product development (NPI).
* Identifies needs, and develops the Quality Engineering function. .
* Develop, implement, & monitor performance against short & long-range plans to achieve Quality engineering objectives.
* Ensure deployment of suitable quality planning (APQP – Advanced Product Quality Planning).
* Manage CAPA (Corrective Action & Preventive Action) program that will drive down rework & warranty costs while improving Customer Satisfaction.
* Direct and/or participate on the Material Review (MRB) and Corrective Action (CAB) Boards.
* Support and maintain appropriate metrics to measure the company’s performance against company quality objectives, including customer satisfaction measurements and Cost of Quality (CoQ).
* Directly interface with both customer quality and respective engineering representatives.
* Direct and support Supplier Quality Engineers in the development of a robust supply chain.
* Develop systems to monitor supplier performance / improvement against contract / quality requirements.
* Provide direction and assistance to procurement, supply chain / suppliers to obtain equitable resolutions to both technical and quality issues.
* Develop and implement processes and procedures for product testing and reliability for incoming receipts and life cycle monitoring.
* Develop or modify quality procedures, metrics and processes to achieve quality and on time delivery goals.
* Assist as required in all technical quality functions.
* Assist in proposals efforts.
* Assure effective communication and reporting to customers.
* Experienced Project Manager.
* Certified Leadership Trainer.
* Certified Customer Service Trainer.
* Knowledgeable in MS Project and MS Office.

**Connectronics Corp**

**High Voltage Cable Industry supplying product for the Automotive, Commercial, Military, Medical, & Scientific Sectors**

**Plant Quality Assurance Manager for Manufacturing/Machining Facility – (2013 to 2016)**

* As the plant’s Quality Assurance Manager , Operated and Managed the quality department and was responsible for all quality concerns for the manufacturing departments and the machine shop
* Manage QA personnel, adjusting workloads as needed, in receiving inspection, in-process inspection, final inspection and shipping, the calibration department, supplier quality, customer source inspection, and failure analysis.
* ISO 9001 & AS9100 compliance to include scheduling quarterly Management Review meetings, acting as the Management Representative for our Quality Management System (QMS), scheduling/conducting internal audits, & working with the external ISO/AS auditor for our annual audits, the Quality Manual and Procedures.
* Owner/Manager of the CAPA Review Board (CRB)
* Customer issues, supplier quality issues, customer quality surveys, customer assessments, MRB, CAPA, AS 9102 FAIRs, and SCARs.
* QA requirements review for contracts, sales acknowledgement, purchase orders, and Certificates of Conformance.
* Engineering Change Order (ECO) reviews & approvals for testing and QA requirements.
* Oversee Engineering requested special testing and assignment of QA personnel or outside lab services as necessary to assure the conformance to product requirements.
* Age sensitive items (AGE) used in the product are up to date.
* QA Training for AS9100/ISO9000, FOD, Counterfeit Parts (SAE AS5553), “Red Plague”, & similar projects
* Responsible for the RMA (Returned Material Authorization) process to include issuance of RMA numbers, determine the cause of the failure of the product, and issuance of RMA reports to the customer.

**B&H Quality Assurance Management Solutions - LLC**

**Aerospace, DOD, Automotive, Medical Device, Commercial & Scientific Industries**

**(Owner) Quality Assurance Manager/Director/Consultant – (2002 to 2013)**

* Quality Assurance Manager/Director
* An expert in developing, improving & implementing entire Quality Assurance Systems.
* Experienced in all elements of a company's Quality System to ensure its compliance with ISO 9001, ISO 13485, ISO 14969, ISO 14971, AS9100, Mil-Stds, Quality System Regulations (QSR), Good Manufacturing Practices (cGMP), FDA, Customer expectations, Corporate/company requirements & other guidelines as applicable.
* Perform internal audits of other departments.
* Perform external audits of vendor quality systems.
* Ensures the following functions and their compliance with the company's Quality Management System (QMS): Customer Affairs, Quality Engineering, Contract Review, Software/Hardware/Process & Equipment Validation, Design Control, Documentation Services, CAPA, MRB, Procurement, Supplier Quality, Metrology, NPI, Product Release, Continuous Improvement, Receiving Inspection, In-process Inspection, Final Inspection & Test, Shipping, and other aspects of Quality Control.
* Provide direction to ensure compliance with all applicable customer requirements & government regulations involving product quality.
* Manage staff in activities to maintain & assure continuous improvement of the Quality Systems to achieve corporate, company & customer goals.
* Hire, train, and develop Quality Engineers & Inspection Personnel to ensure quality goals are achieved.
* Provide support & leadership in Quality Engineering for existing and new product development (NPI).
* Identifies needs, and develops the Quality Engineering function. .
* Develop, implement, & monitor performance against short and long-range plans to achieve Quality engineering objectives.
* Ensure deployment of suitable quality planning.
* Manage CAPA (Corrective Action & Preventive Action) program that will drive down rework & warranty costs while improving Customer Satisfaction.

**B&H Quality Assurance Management Solutions – LLC EXPERIENCE CONTINUED:**

* Directly interface with both customer quality and respective engineering representatives.
* Direct and support Supplier Quality Engineers in the development of a robust supply chain.
* Develop systems to monitor supplier performance / improvement against contract / quality requirements.
* Provide direction and assistance to procurement, supply chain / suppliers to obtain equitable resolutions to both technical and quality issues.
* Develop and implement processes and procedures for product testing and reliability for incoming receipts and life cycle monitoring.
* Support and maintain appropriate metrics to measure the company’s performance against company quality objectives, including customer satisfaction measurements and Cost of Quality (CoQ).
* Direct and/or participate on the Material Review and Corrective Action Boards.
* Develop or modify quality procedures, metrics and processes to achieve quality and on time delivery goals.
* Assist as required in all technical quality functions.
* Assist in proposals efforts.
* Assure effective communication and reporting to customers.
* Experienced Project Manager.
* Certified Leadership Trainer.
* Certified Customer Service Trainer.
* Knowledgeable in MS Project and MS Office.

**TeraRecon, Inc. – Medical Device Industry**

# Director of Quality Assurance and Regulatory Affairs (February 2002 to October 2002)

* This Position has oversight responsibility for all Regulatory Affairs (RA),
* Quality Assurance (QA) & Quality Control (QC) functions with the responsibility of managing personnel of the Quality Departments.
* Serves as the Quality Management System (QMS) Representative for the company.
* Experienced in FDA Good Manufacturing Practices (GMP), ISO 9000, ISO 13485, 93/42/EEO MDD, & EN 46001.
* Ensure all elements of the company's Quality System are in compliance with Quality System Regulations (QSR), cGMP, FDA 510(k)'s, corporate & other guidelines.
* Oversees the following functions and ensure their compliance with the company's Quality System:
  + Customer Affairs,
  + Quality Engineering,
  + Software/Process and Equipment Validation,
  + Design Control,
  + Documentation Services,
  + MRB (Material Review Board),
  + CAB (Corrective Action Board),
  + Compliance,
  + Microbiology,
  + Stability,
  + Supplier Quality Assurance,
  + Metrology,
  + Product Release,
  + Receiving Inspection, In-process Inspection, Final Inspection & Shipping,
* Direct staff in activities to maintain and improve the Quality system to achieve corporate goals.
* Schedule and facilitate quarterly QMS Reviews to monitor the effectiveness of the company's Quality System.
* Provide monthly trending on key elements of the Quality System to monitor process and product performance.
* Schedule and conduct internal and supplier Quality System compliance assessments.
* CAPA (Corrective Action & Preventive Action) Review Board.
* Manage inspections performed by outside regulatory bodies and customers.

**TeraRecon, Inc. – EXPERIENCE CONTINUED:**

* Ensure timely resolution of observations.
* Support Regulatory Affairs in preparing regulatory submissions.
* Prepare and manage the QA/QC departmental budgets.
* Ensure competent staffing & organization of resources achieving corporate goals and compliant execution of all QA/QC functions.
* Update Quality Manual (QM) & quality procedures.

**Motorola Incorporated – Semiconductor Products Sector**

**Senior Sector Manager of Software Quality Engineering** **(September 1999 to February 2002)**

* Established domestic and international software (SW) development strategies and methodologies for all of Motorola’s Semiconductor Sector (Division).
* Directed the management of software quality assurance for the sector.
* Established SW project management processes, testing processes, configuration management (CM) processes, SW quality assurance (QA) processes, and SW engineering development processes for products and for testing environments that support Six Sigma (6-Sigma), S.E.I. C.M.M. and I.E.E.E. standards for SW development.
* Provided coaching and mentoring services for sector and worldwide Motorola facilities on new and existing projects.
* Established and managed SW QA organizations on sector projects to include broadband, transportation, home entertainment, and personal communications.
* Managed the CAPA Review Board (CRB)
* Interfaced with executive management, as well as management teams for Design and SW Engineering.
* Responsible for metrics programs identifying project goals and measurements toward achieving those goals.

**Lockheed Martin Corporation – Aerospace and DOD Industries**

**Senior Quality Assurance Manager (1996 – 1999)**

* Provided domestic and international management, mentoring, coaching, teaching, and training services in Object Oriented Technology (OOT) for multiple commercial and department of defense (DOD) clients throughout North America. Specialized in Engineering Processes, Project Management (PM), Test Methods, and Quality Assurance Strategies.
* Provided consulting for LMC client companies on new and existing projects.
* Established and provided project management, testing, CM, QA, and engineering processes for client-server and mainframe environments that support C.M.M. and I.E.E.E. standards.
* Developed supplier quality metrics programs and measurements.
* Provided training in Object Oriented Analysis and Design (OOAD); and, Integral Quality through Inspection and Test
* Interfaced with executive management and program managers of Design, SW Engineering, Information Management (IT), Marketing, Customer Training, and Technical Support for LMC and multiple client companies to provide solutions.
* Responsible for establishing divisional requirements for test methodologies, test processes, test concepts and test strategies employed, and test standards for multiple SW development contracts in the object oriented (OO) environment for the U.S. Mid-West Region.
* Responsible for all aspects of test functions for design, requirements capture, unit case model development, class test strategy, system integration test, system test, and release of SW products.
* Composed the Master Test Validation and Verification (V&V) Plan. Managed and directed the efforts of multiple test leads and their testing teams.
* Successfully tracked, shortened, and completed through means of proper methodology and testing tools, the prescribed product release timelines. The goals of the released features were always achieved.
* Interfaced with executive management and program managers of Design, SW Engineering, Marketing, Customer Training, and Technical Support.

**Siemens Medical Systems – Medical Device Sector**

**Chairman of the Quality Implementation Team (QIT) (1995 – 1996)**

* Developed, and directed corporate reliability standards for Siemens Medical Systems. Successfully leveraged reliability throughout the design, development, and roll out phases of product development by establishing overall corporate guidelines.
* Responsible for all system test functions for design, development, and manufacturing of a Nuclear Imaging Camera.
* Created the Master Validation and Verification Plan for the Design & Development Planning, Design Review, Design Verification, Design Validation, Design Transfer, Design Changes, Defect Tracking, System Release Process and Design History File Maintenance. Accomplished the above effort with a small team of 7 full time engineers and 16 staff from multiple departments.
* Interfaced with executive management, as well as the associated managers of Hardware and SW Engineering, Marketing, Regulatory Affairs (FDA), Manufacturing, Customer Training, Technical Support, and Service.
* Provided proper methodology and testing tools, which supported the prescribed product release and the project goals of the released features.
* Implemented an on-line automated System Requirement Specifications Tracking System. Linked the design documents, the test plans, the test procedures, and defect reports to maintain the traceability, which was assessable from any platform with any web browser.
* Enacted improvements of the quality systems within the corporation.
* Coordinated the cross-divisional establishment, use, and training of SOPs (Standard Operating Procedures), Hazard/Risk Analysis, and SW Verification and Validation (V&V) Training.

**LOCKHEED mARTIN – Missiles and Space Systems**

**Quality Assurance Engineering (1983 – 1995)**

**- Quality Testing Engineer**

* Designed, developed, and executed tests plans and procedures.

**-Program Office Quality Assurance Engineer**

* Performed various Quality Engineering (QE) functions for compliance of ISO 9000, DoD Quality Systems, and Mil-Spec for systems, Hardware (HW), and Software (SW).

**-Quality Assurance Engineering Field Representative**

* Performed extended contracted field assignments to establish, maintain, and support Quality Assurance (QA) requirements.

**ROCKWELL INTERNATION – SHUTTLE ORBITER DIVISION, Johnson Space Center (JSC)**

**Project Engineer (1981 – 1983)**

* NASA project Engineer on the Space Shuttle program at Johnson Space Center, Houston, Texas
* Guidance, Navigation, and Flight Dynamics Engineer
* Compiled and assessed the NASA Space Shuttle’s navigation system, the Inertial Measurement Unit (IMU) operations, rendezvous radar and proximity operations. Responsible for any anomaly detection and resolution thereof.
* Provided system test support to the Shuttle Avionics Integration Laboratory (SAIL) at JSC.
* Provided engineering support for the testing of the payloads of the Space Shuttle.
* Interfacing between NASA personnel and plant engineering to coordinate the tasks among Houston, Texas and Downey, California facilities with emphasis on the shuttle payload systems.
* Maintained configuration control of NASA’s space shuttle vehicle - OV 95. Reviewed, approved, and coordinated hardware deliveries and modifications.

**WHIRLPOOL CORPORATION – FORT SMITH DIVISION**

**Quality Control Supervisor (1976 – 1981)**

* Directly supervised Quality Control (QC) technicians in Whirlpool’s manufacturing Quality Laboratory.
* Directly supervised Quality Control (QC) Inspectors in the Receiving Inspection Department, the In-Process Manufacturing Quality Control (QC) Inspectors on the manufacturing lines, and Quality Control (QC) Inspectors in the final quality inspection and shipping departments.
* Worked with suppliers in the resolution of quality issues.
* Worked with Whirlpool design and production engineers in the resolution of product quality issues.
* \*Prepared daily and weekly Quality Control status reports for upper management.
* Participated in the resolution of customer quality issues on returned units.
* Performed analysis on quality control issues that occurred in the manufacturing plant