Senior Quality Engineer

AREAS OF EXPERTISE

- **Quality System**
- **CAPA**
- **Validation**
- **Quality Assurance**
- **Root Cause Analysis**
- **Six Sigma**
- **ISO 13485**
- **GMP**
- **Quality Auditing**
- **Design Control**
- **V&V**
- **21 CFR Part 11**
- **GxP**
- **Quality Control**
- **Testing**
- **Lean Manufacturing**
- **R&D**
- **SPC**
- **Regulatory Affairs**
- **ISO 14971**
- **Process Simulation**
- **GAMP**
- **Supplier Quality**
- **ISO 9000**
- **DMAIC**
- **GD&T**
- **SOP**
- **Change Control**

INTRODUCTION

Consultant has 31+ years in quality and engineering, including 15 years in Medical Devices, nine years in Pharmaceutical, four years in Biotechnology and two years of Nuclear. A certified lead Auditor through ISO since 1994 and performed audits worldwide to identify compliance gaps opportunities for improvements. Extensive experience managing multiple CAPA Projects, including associated DMAIC and Problem-Solving Skills. Validated facility, utilities, equipment and processes through PAI (Pre-approval Inspections), as well as sustaining existing operations and providing objective evidence of remediation for Pharmaceutical, Medical Device & Biotech companies. Provided guidance and management to a state of validation for manufacturers under a consent decree while training the personnel of the facility to carry on the validation process to enable the facility to remain in a state of control.

WORK EXPERIENCE

10/2017 – Present
Industry Consultant
Example Engagements

- Prepare and execute audits for evaluating Interim Control (IC) initiation and application to the manufacturing processes.
- Perform support function in the backroom of a certification audit from January 15-19, 2018.
- Prepare audit schedule for 3rd round of auditing for manufacturing sites to evaluate the state of quality within each manufacturing cell and work center.

08/2017 – 10/2017
Arthrex-Ave Maria, FL
Senior Quality Engineer
Duties:

- Assigned to resolve and track NCR's initially and work with manufacturing to improve the quality of the process in order to reduce NCR's and repeated occurrences.
- Provided a significant reduction in open NCR's,
- Prepared IP Sheets and Ballooned DWG's in support of NPI and the associated ECO's.
- Provided technical support for process improvement in the management and execution of the NCR program and related CAPA's along with SCAR recommendations in support of Supplier Quality functions.

02/2017 – 08/2017
Zimmer-Warsaw, IN
Senior Quality Engineer
Duties:

- Preparation and executions of the HHE process for Knees, transitioned into NPI for Persona revision knee development.
- Performing review and approval of Special Work (SW) Router Request, FCA/FCP, Design review, Print Review, Define and establish Inspection Methodology and selection of gaging device.

11/2016 – 02/2017
Smith's Medical-Plymouth, MN
Senior Quality Engineer
Duties:

- Establish the process and procedures for the Supplier Selection and Maintenance Process.
- Managed the personnel and project controls for review and resolution of SCARs.

06/2015 – 11/2016
Tecomet, IN
Project Manager
Duties:

- As a member of project FOOT PRINT team and under the Tecomet organization of Sales and Procurement, my duties would include proper guidance and support to transfer the products and processes from one facility to another through interstate transfer.
- This would mean planning with the customers to ensure proper bank build was established from the sending site so that there was no gap in the product chain during the transfer and validation within the receiving site.
- The qualification of the facility, utilities, equipment and processes that were to be used for the manufacturing of Class I, II & III medical devices must be established prior to submission of First Articles to the customers.
- This activity included the planning and execution of decommissioning equipment and processes for relocation to include resolution and closure to CAPA issues identified during the process.
- Provided leadership and guidance in the development of TMV process, Commissioning, Validation and MVP document.

03/2015 – 06/2015
Lonza, Portsmouth, NH
Senior Quality Engineering II
Duties:

- Develop form based protocols to execute for biological production systems to include Ultra Filtration Skids, CIP Skids, Tank modifications, Agitator placements, WFI distribution piping systems.
- Executions include review and approval of ETOP and FAT punch list closures, system walk-downs using P&ID drawings and Ladder Logic Diagrams for panel emplacements to control the systems.
- Write summary and final reports for protocol closure Provide peer review for associates validations activity and report writing for the completed protocol.

11/2014 – 03/2015
Monosol Rx, Portage, IN
Facility and Utilities SME
Duties:

- Develop and execute protocols (CQ, IQ, OQ, and PQ) for the facility HVAC systems (AHU01, AHU03, AHU05, AHU06, AHU22, & AHU23), High Purity Water Systems (USP18), BMS software system and BAS software systems and Gamma Sterilization.
- Provide peer review for associates validations activity and report writing for the completed protocols.

07/2014 – 11/2014
Terumo CVS, Ann Arbor, MI
Senior Quality Engineer
Duties:

- As a member of the quality team, my duties would include remediation activities for Test Method Validation within the Incoming Quality Assurance (IQA) for dimensional checks for both variable and attribute conditions.
- Remediation of training, procedure development and calibration were included in the requirements to ensure a viable and accurate inspection system.

07/2013 – 07/2014
Zimmer-Warsaw, IN
Senior Quality Engineer
Duties:

- As a member of the quality team for Trauma, my duties would include remediation activities for Process Validation (IC-9) within packaging and labeling, Remediation of NCR's that were long overdue for corrective action, establishing product specific packaging requirements and remediation of the Design History Files (DHF) for the Class II & III product lines, implants and instruments.
- Utilized Zimpack to identify the packaging setup sheets with instructions for use (IFU) and the labeling requirements for the product use, identification, storage and handling.
- Interfaced with the suppliers to identify resolutions for the NCR's related to their products and use of material by Zimmer.

09/2012 – 07/2013
Invacare, OH
Project Manager
Duties:

- As a member of the GxP Systems team and under the Invacare organization of Process Engineering, my duties would include proper guidance and support to commission and validate the facility, utilities, equipment and processes that will be used the manufacturing of Class I & II medical devices.

- This activity included the planning and execution of decommissioning equipment and processes for relocation from US to Mexico.
- Instrumental in developing a validation system within quality to ensure adequate testing for reliability and reproducibility of the manufactured parts and assemblies.
- Provided leadership and guidance in the development of TMV process, Commissioning, Validation and MVP document.

05/2011 – 09/2012
Zimmer-Warsaw, IN
Senior Quality Engineer
Duties:
- As a member of the product development team and the organization of quality, my duties would include proper guidance and support to verify and validate the equipment and process that will be used to produce the new product design.
- This activity included the planning and execution of transferring the equipment and processes from the US to PR and Ireland. Generated project plans, schedules, cost analysis and coordination of contractors to facilitate the installation and commissioning of the equipment and processes.
- Prepare appropriate measurement techniques and methods that would provide an accurate representation of the product specifications to the design drawing.
- Prepare documentation and validation for product transfer for domestic and international involvement.

03/2011 – 05/2011
Beckman Coulter, Chaska, MN
Senior Quality Engineer
Duties:
- Perform gap analysis of the quality system.
- Develop Master Validation Plan and revise procedures to remediate the observations noted in preparation for revalidation activity that would close the gaps and increase the confidence level going forward.

11/2010 – 03/2011
St. Jude Medical, Irvine, CA
Senior Quality Engineer
Duties:
- Define, document and implement validation master plans for remediation activity associated with EP Catheters.
- Safire BLU, Safire TX, Cool Path Contact, Uni-directional and Bi-Directional catheters.
- Developed and executed attribute and variable Test Method Validation protocols and reports for the inspection processes.
- Developed and executed Process Performance Qualification protocol and reports for EP Catheters.
- Safire BLU, Safire TX, Cool Path and Bi-Directional Cool Path catheters as a base line for the transfer to Costa Rica.
- Provided guidance, support and planning to cost the transfer of equipment and processes.

08/2010 – 11/2010
Abbott Diabetes, Whitney, UK
Senior Quality Engineer
Duties:
- Performed quality assessment, gap analysis of the production processes utilized in production of diabetes strips at the Whitney, Oxfordshire facility.

- Reviewed the findings with the management team for Abbott and to discuss remediation activities necessary to remedy the gaps that would restore the confidence in the product produced in the manufacturing.

03/2010 – 08/2010
Gyrus, Minnetonka, MN
Supplier Quality Auditor
Duties:
- Submitted pre-audit surveys to suppliers providing services to Gyrus, Olympus.
- Prepared audit schedule for suppliers needing to be audited by classification.
- Prepare audit agenda for full quality audits to ISO 13485 or specific audit to ISO 17025.
- Led audits per established agendas.
- Submitted closing oral and written reports at the end of the audit to Gyrus for their review and continued evaluation.

11/2009 – 02/2010
Stryker Medical, Portage, MI
Project Manager, Quality
Duties:
- Remediated 483 Observations identified in a 2009 audit.
- Prepared and presented responses to the regulatory agency as to the plan progress and performance of the remediation activity, and provided technical support to quality and regulatory personnel that achieved a higher level of regulatory compliance.
- Prepared and implemented a QSIP program to improve product quality and compliance with regulations.
- Led critical CAPA projects associated with field product failures, including root cause analysis and implementation of corrective actions.
- Additionally, developed SOP's and Work Instructions, Training Curriculum, Validation and CAPA Project Plans, Requirement Specifications, Traceability Matrix, IQ/OQ/PQ or CQ protocols with associated Test Cases and Final Reports.
- Also, audited training programs and provided training to the trainers.

04/2008 – 10/2009
Zimmer, Warsaw, IN and Bloomington, MN
Sr. Quality, Validation Engineer
Duties:
- Responsibilities as the Sr. Quality Engineer included development and execution of a shelf life process that would comply with domestic and international regulations.
- Started at the Minneapolis facility and transferred to a facility in Warsaw, IN for Global Quality Improvements.
- Owned multiple CAPA's related to shelf life, contract manufacturing and product functionality, and drove these CAPA's to closure.
- The products that are revalidated will in many cases extend the expiry date from a 3-year shelf life to 5 or even 10 years.
- This effort will reinforce the present claims as well as extended the storage life of the product for longer periods of time.
- The procedure, protocol template and report template was developed in this process to expedite the use and training of this procedure.
- Training was performed for manufacturing engineering, product development and marketing.

- Performed risk analyses on existing products by define the process flow and determining through fault tree analysis what potential failures could occur.
- The potential failures were examined for redesign, control measures or training.
- GAP analysis was performed for the Design FMEA for the product and for the Process FMEA for the manufacturing process to ensure compliance to the end user's specifications as related to the relocation of a manufacturing venue.
- Led a cross-functional team through the development of the project plan for the relocation of a contract manufacturing site from one facility to another within the MN area to include project plan, cost analysis, coordination of contractor support for installation and commissioning, validation, risk assessment, and developed a PFMEA to ensure that the product was maintained in a validated state at the completion of the project.
- The facilities, utilities, equipment were examined closely to ensure proper operation and maintenance reliability.
- Protocols for Cleaning Processes, Gamma Sterilization and Packaging Processes were developed and executed. Additionally, statistical analyses of process capabilities were performed, and the reliability of calibration and maintenance systems was determined.

12/2007 – 04/2008
Angiotech, Reading, PA
Senior Quality Engineer
Duties:
- Developed and executed protocols for facility utilities, equipment, test methods and software validation, and provided validation training and quality support.
- Developed and executed validation documentation for the Class 8 (100,000) Clean Room, steam, Eto and Gamma Sterilization, Instron, Chatillon, shelf-life chambers, Despatch Ovens, Targeted Bar Sealers, Multi-Vac and Klockner packaging systems.

05/2007 – 12/2007
Gyrus ACMI, Bartlett, TN
Senior Quality Engineer
Duties:
- Directed the relocation of manufacturing processes from UK and the USA to a new facility in Mexico.
- Provided scheduling, planning and costing of all aspects of the move through the completion and acceptance through PAI.
- Developed and executed protocols for software validation Gage Insite Calibration Program located in Memphis, TN.
- Provided validation training and quality support of the calibration program at the Memphis facility.
- Developed and executed validation documentation for the Class 8 (100,000) Clean Room and gamma sterilization in Saltillo, MX.
- Audited legacy validation data and facility SOP's per 21CFR-820 and ISO 13485 requirements, then opened and initiated several CAPA's to address system deficiencies that caused the observed gaps, and wrote improved procedures and trained employees.

02/2007 – 05/2007
Boston Scientific, Miami, FL
Senior Quality Engineer
Duties:
- Performed a gap analysis against 21CFR-820 and ISO-13485 requirements for qualification of attribute and variable test methods, and then conducted remediation activities to close the gaps through revalidation and other corrective actions.

- Statistical analyses were performed to determine repeatability and reproducibility of test methods, as well as the process capability to detect defective product from acceptable product.

05/2005 – 01/2007
Military Service, SC Army National Guard
NCOIC/Senior AMDWS Operator
Duties:
- Mobilized May 3, 2005 for initial training and mobilization at Ft. Bliss as a Radar Operator.
- The training was for the purpose of serving in a joint-integrated air defense mission to provide security in the vicinity of Washington, DC.
- Responsibilities included the set up and operation of associated equipment, management and training of 12 subordinates.
- Developed and managed work assignments, transportation and schedules associated with mission requirements. Equipment maintenance requirements were managed and executed within the team.

12/1999 – 2017
Quality System Technologies of Anderson, Inc. (QST), Belton, SC
Director of Operations
Duties:
- Director for over 30 personnel in 7 geographical locations that I have managed from California to the east coast and from Delaware to Florida at facilities such as Playtex Products, Tyco Kendall, Bausch & Lomb, Abbott Labs, Oread, Welch Allyn from Jan 2000 to Jan 2012.
- The personnel I selected, staffed and supported were utilized for new product development, 483 remediation, calibrations, process validation and training.
- Responsibilities included the execution of Validation Protocols (IQ, OQ, PQ, PV, DV, and SW), training client personnel in the current regulations and industry standards in the development of quality documentation to support manufacturing environments such as; Bulk Chemical Pharmaceutical products, Medical Devices, Finished Pharmaceuticals for prescription and over the counter (OTC), Biotechnology services and automated equipment/process systems. Assisted in the development, automation, and implementation of global CAPA systems, Complaint Management Systems, Audit Tracking Programs, Management Review Processes, Risk Management Systems, PLM Systems, Supplier Quality Management Systems using TrackWise, Process Control Tracking and Trending Systems, Verification and Validation Traceability Systems, Recall Management Programs, Training Traceability Programs, and other QMS systems. Validation protocols were developed and executed for several automated manufacturing processes. The scope of the validation process included the development of Standard Operating Procedures (SOP) for the operation, maintenance, calibration, and cleaning processes and Calibration System, Document Control Procedures and Validation Documentation. Quality documents included but were not limited to Master Plans, Protocols (IQ, OQ, PQ, PV, DV, and SW) and production records.

10/1998 – 11/1999
Validation Associates, Inc., Greenville, SC
Director of Operations
Duties:
- Director for a team of 10 personnel in multiple location where the personnel were utilized to perform software validation, process validation, audits, CAPA plans and remediation activity to prevent a consent decree from being issued by the FDA.
- The personnel were working in Glendale, CA; Thousand Oaks, CA, Duarte, CA, LA, CA; Lessines, Belgium; and Austria.

- Developed Validation Master Plans and Validation Protocols (IQ, OQ, PQ, PV, DV and SW) supporting Manufacturing at a Biotechnology Division of Baxter Healthcare.
- Additionally, set up a CAPA program.
- This included initiation, planning, assignment of CAPA Owners and program oversight for multiple CAPA's needed to resolve Quality System and Manufacturing Nonconformities that had been identified through internal audits.

03/1998 – 10/1998
Covance Biotechnology Services, Inc., Raleigh, NC
Senior Quality Engineer
Duties:
- Executed the MES and BMS for a new biotech manufacturing facility, this included basic engineering, detailed engineering and design, construction and start-up of new production facility or modification of existing facilities, as well as the infrastructure.
- Major responsibilities included: Implementation of BMS or MES systems, establishing plant standards, policies/procedures, special studies/analyses of process and control to meet BMS and governmental requirements, Innovation in areas where no precedent exists, Assistance with the effective deployment of business and technical resources in pursuit of engineering opportunities. Development of Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocols. Protocols were developed utilizing the software "WordPerfect 6.1" and P&ID revisions utilizing AUTOCAD rev.12 for sterilization, bioreactors, fermenters, CIP, SIP, Freezers, Cold Rooms, Nitrogen freezers, cryolife processing, Inoculations process of fermentation units. Clean gases, HVAC, WFI water systems, etc.

12/1996 – 03/1998
Kvaerner John Brown, NJ
Project Engineer
Duties:
- Responsibilities include developing and executing for the performance & process validation.
- The process validation consisted of review and approval of the Engineering Installation Manuals produced by Fluor Daniel personnel as substitution for the Installation Qualification (IQ), the development and execution of the Operational Qualification (OQ) and development and execution of the Performance Qualification (PQ) protocols for the facility, utilities, equipment, processes and automated/software systems.
- This contract manufacturing facility is uniquely designed to be totally controlled through automated/software services such as; Building Maintenance Systems (BMS), Manufacturing Environment Systems (MES), and Distributive Control System (DCS).
- These systems monitor and control all of the manufacturing functions for this facility.
- As the Sr. Validation Specialist the additional responsibilities for protocol reviewer for these systems were performed to ensure that the validation effort put forth was satisfactory.
- Worked with Wyeth Ayerst in the validation of the flu vaccine shot manufacturing process.
- This injectable was uniquely located in a new facility to house and manage all facility, utility, equipment and processing of the vaccine product preloaded in syringes for expedient delivery.

06/1996 – 12/1996
TRS Staffing/Fluor Daniel Corporation, Greenville, SC
Senior Project Engineer
Duties:
- Developed Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) protocols for a new Biogen Facility (biotech), located in the Research Triangle Park.

- The protocols developed were for the facility, utilities, equipment and processes. Developed and executed commissioning protocols (IQ/OQ) and PQ protocols for Air Handlers/HVAC System to include BMS System. Performed system walk downs to verify as-built drawings (IQ), performed execution of temperature mapping for static and dynamic conditions, (OQ).
- Commissioned Compressors, Clean Gases, Backup Generators and Chiller/Cooling Towers.
- Was instrumental in clarifying several GMP issues that were in question as they attempted to answer the needs of the protocols.
- Performed training operations to assist fellow colleagues in the cGMP requirements.
- Training included the proper procedure in developing and executing validation protocols.

10/1993 – 06/1996
Validation Associates, Inc.
Senior Quality Engineer
Duties:

- Responsibilities included the development process for quality documentation in support of the manufacturing environments such as; Bulk Chemical Pharmaceutical products, Medical Devices, Finished Pharmaceuticals for prescription and over the counter (OTC), Biotechnology services and automated equipment/process systems.
- Prepare Validation Master Plans and Protocols (IQ, OQ, PQ), Standard Operating Procedures, and production records.
- Validation protocols were developed and executed for systems like the Software for Delta T Illusions Casting Machine, Software and equipment validation for the Auto Inspection System (12), the Print Tint Machine (4), and Optoform 50 Lathe Machines (12), Lyophilizer, Desiccators, Sterilizers-AMSCO/Fedegari/Getinge, Laboratory Analytical Equipment and several manufacturing processes. Developed and executed commissioning protocols (IQ/OQ) and PQ protocols for Air Handlers/HVAC System to include BMS System. Performed system walk downs to verify as-built drawings (IQ), performed execution of temperature mapping for static and dynamic conditions, (OQ). Commissioned Compressors, Clean Gases, Backup Generators and Chiller/Cooling Towers.

10/1987 – 07/1993
Midwest Technical Incorporated
Design Engineer
Duties:

- Primary responsibilities included working in a cross functional team consisting of Validation Technology, Pharmaceutical Services, Production, and Quality Assurance, Research and Development and Analytical Research personnel to ensure that products produced under Process Validation protocols were sampled and tested in strict compliance with requirements.
- Maintained orderly and timely documentation, to include, but not limited to actual physical test data, Process Validation data tabulations, development and execution of validation master plans, protocols, standard operating procedures and final report writing.
- Validated Micro and Analytical Lab environments, utilities and equipment, including a robotic auto sampler, clean gases, Purified water systems, dishwashers, autoclaves, HPLC and GC and other counter top equipment.
- Developed and executed commissioning protocols (IQ/OQ) and PQ protocols for Air Handlers/HVAC System to include BMS System.
- Performed system walk downs to verify as-built drawings (IQ), performed execution of temperature mapping for static and dynamic conditions, (OQ). Commissioned Compressors, Clean Gases, Backup Generators and Chiller/Cooling Towers.
- Develop and executed protocol against URS/FRS (Design Specifications) to qualify a new BMS, MES and PRMS.

- Validated new and modified the design for Purified/CIP Water systems.
- The Purified water system was modified to be continuously sanitized with the use of Ozone and UV lighting.
- The POU was interlocked and controlled with visual and audible indicators in conjunction with ozone detection systems.

EDUCATION

2002
Wiltshire University
Bachelor of Science: Mechanical Engineering

ADDITIONAL TRAINING

- 01/1988 – 12/1991 Tabernacle Baptist College, Biblical Theology
- 06/1994 Stat-A-Matrix Institute, ISO-9000, Certification as a Lead Auditor