MOHAMMED ZIAUDDIN
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An established Engineer with extensive experience in the medical device industry. Provided positive solutions in the manufacturing, packaging and the design of medical devices and ancillary components. Strengths in working within an ISO 013485 and FDA GMP (Good Manufacturing Practices) environment. Spearheaded numerous teams on new product development, manufacturing process development, cost improvements, and manufacturing process improvements.

- Good understanding of standards like ISO 13485, ISO 14971 and ISO 11607.
- Involved in Process Validation and Test Method Validation.
- Experience using continuous improvement tools, such as FMEA, Root Cause Analysis, SPC analysis.
- Knowledge of ISO, ASTM and ISTA Packaging Standards.
- Experience using Statistical Process Control and process analytics.
- Emphases in sterile product packaging, manufacturing, business operations, and systems integration with diverse operational experience in management, strategic business planning, quality assurance, information systems, sales, FMEA's, ISO13485, ISO11607, 21CFR820.
- Ability to assist in test method/setup optimization, test fixture optimization, test data and yield.
- Skilled in problem solving techniques involving Lean/Six Sigma statistical tools such as: Minitab, Crossed & Nested Gage R&R studies.
- Experience with medical device compliance requirements based on FDA Quality Systems Regulations.
- Experience on working with spinal cord surgical instruments and orthopedic devices.
- Experienced in understanding the SDLC and good in analyzing the System requirements and Business requirements and develop test plans and test cases out of the requirements.
- Proficient in MS Excel and other MS office tools.
- Excellent knowledge of computer systems such as Documentum, Share point, my workplace, QMS.

Education: Bachelor's of Science

Professional Experience

Shire Pharmaceuticals - Round Lake, IL **Nov 2017 to present**
Sr Packaging Engineer

Responsibilities:

- Generated packaging specification profiles for existing and new products, which included primary, secondary and tertiary packaging.
- Responsible for continuously reviewing FDA regulations, ISO standards, quality control philosophy, practice, and procedure to recommend compliant procedures and cost-effective solutions.
- Created machine requirements and created IQ/OQ/PQ protocols with reports. Approved vendor created packaging tools.
- Medical device packaging development for NPD, sterilization, aging, testing and evaluation as per ISO11607.
- Supported in new packaging development in early stage, worked with third party to conduct tests, documented test reports and supported in the packaging materials selection.
- Responsible for the execution of packaging validations for new, or existing products, following ISO11607 regulations.
- Responsible for assuring all required design inputs are captured and incorporated into product labeling development and design changes for labeling content.
- Preparation and review of sterilization documentation, procedures, and specifications to ensure sterilization compliance with FDA and corporate requirements.
- Reviews product labeling for accuracy, completeness, content and regulatory compliance.
- Created timeline for new project, maintain and present it to the product team on weekly meeting.
- Improve existing packaging for cost saving purpose.

- Strong working knowledge of 21 CFR Section 820, ISO 13485, EN45502, ISO14708, ISO27186, ISO14971, ISO10555, ISO11070, ISO11607, ASTM F1980, ISO10993, ISO11135.
- Reviewed and approved all equipment IQ/OQ protocols and reports, processing and packaging validation protocols and batch records.
- Worked with marketing, Quality, product team and suppliers on new packaging design.
- Conducted packaging distribution tests for new packaging design, selected best materials within budget.
- Documented test reports and specifications, ensured the packaging meet quality requirements.

Par Pharmaceutical, NJ **Feb 2016 to Oct 2017**
Packaging Engineer

Responsibilities:

- Managed implementation and support of end-to-end roll-out of serialization line upgrades on four packaging lines to meet FDA regulatory compliance requirements .
- Led packaging validations and shelf life evaluations per ISO11607 for CRMD products.
- The creation, revision, and control of customer labeling, with a primary focus on documentation control through all phases of the change control process.
- Wrote criticality assessments for assigned facilities, systems, and equipment, wrote and executed commissioning or qualification (IQ/OQ/PQ) protocols and reports.
- Designated FDA presenter for sterilization and aseptic topics.
- Write and edit documents to support Labeling Development in compliance with ISO, cGMP, and FDA guidelines.
- The creation, revision, and control of customer labeling, with a primary focus on documentation control.
- Act as technical subject matter expert on packaging operations and troubleshooting to support Par global serialization and line performance initiatives.
- Launch digital transformation initiatives including implementation of overall equipment effectiveness (OEE) software to improve visibility of line performance .
- Lead the development, execution, review and closure of validation protocols (IQ/OQ, PQ) and computer system validations for serialization solutions and packaging packaging line equipment.
- Assisted in the resolution and approval for CAPA identified issues on sterilization and environmental
- microbial controls and implementing proactive programs.
- Collaborate with global Quality Assurance, Engineering, Global Packaging Solutions and Advanced Operations to ensure compliance with required standards conforming to company, cGxP, SOPs, and regulatory regulations and guidelines.
- Carried out investigations on customer complaint and non-conformances by performing root cause analysis and determined corrective and preventive actions.
- Knowledge of FDA CFR 21 Part 820 (QSR), ISO 13485, and other domestic and international regulations.
- Spearheaded packaging validations and shelf life evaluations per ISO11607 for all CRMD products.
- Works with packaging supervisors, production crews, and maintenance to troubleshoot packaging problems and develop corrective actions to eliminate the return of those problems.

- Member of the safety committee, performing safety audits on the manufacturing floor and develop equipment, processes and work environment that meet safety codes, policy and guidelines.

Cook Medical - Bloomington, IN **Jan 2015 to Dec 2015**
Packaging Engineer

Responsibilities:

- Worked as a Test Method Validation Engineer as a part of the Remediation project for the sterile barrier packaging process.
- Packaging and labeling design based on corporate procedures.
- Support design, development, validation and execution of test method for visual inspection of packaging for foreign matter and tensile testing of packaging pouches and trays.
- Performing test method validations as per FDA regulations and ensure product compliance.
- Writing test method validation protocols and trained inspectors on new methods prior to protocol execution.
- Analyzing experimental data using Excel and/or Minitab.
- Performed Gage R&R studies to ensure that the test methods are valid for their intended purpose.
- Working closely with manufacturing engineering, sustainability engineering, supply engineering, design engineering and quality control departments.
- Execution and Documentation of IQ/OQ and PQ for process equipment, utilities, facility, manufacturing equipment and validation protocols.
- Documentation of protocols and reviewing final reports for various equipment and facility.
- Incorporates required regulatory standards (FDA, ISO) in developmental and/or sustaining engineering projects including written protocols, test methods, assembly processes and the design history file.
- Involved in maintaining the electronic records in compliance with 21 CFR Part 11 regulations.
- Ensured strict compliance with standards and templates in relation to the writing of Technical Documentation.
- Revising and/or originating procedures in order to comply with Quality Plan, CAPA System requirements and operational needs.
- As a Quality engineer involved in Manufacturing process by using lean methodology of Quality tools like Pareto charts and Histograms to spot problems.
- Assisted the Sustaining Engineering team in preparing the DFMEA and PFMEA documents related to the project.

Geometrix Laser Solutions, India **Jan 2014 – Dec 2014**
Assistant Quality Engineer/ Laser Welding

Responsibilities:

- Responsible for management of the Laser Welding Department and the manufacture of medical devices that include: cutting, marking, and welding.
- Knowledge and understanding of integration/brazing of high speed RF connectors to housings and packages.
- Fixture design for assembly, adjustment and alignment of fiberoptic components, lasers and opto-mechanical systems.
- Fixture design for laser welding and RF testing.
- Established network of machine shops and prototyping facilities.

- Ownership and management of supplier network. Personal contacts with sales representatives and application engineers.
- Initialized conceptualization of machinery, kick-off preliminary machine layouts, and performed design of mechanical and laser systems.
- Inspected the incoming quality of the material and submitted the final reports to the Metallurgist
- Visually inspected post processing of the components
- Preparing, filing and upkeep of daily incoming/outgoing quality reports Procuring quality checking
- Prepare timelines, schedules, and progress reports; communicate project status to executive management and the end users.

Activities

- Active Contributor to the Manufacturing Community at SME.
- Received Certificate for successful completion of The Certwise Learning System for PMP.
- Received Certificate for continuous Commitment to advancement of professionalism & learning in International Manufacturing Community from SME tooling .