

PETER VENTRY [PVENTRY@YAHOO.COM](mailto:PVENTRY@YAHOO.COM) 716-344-4586 LONGMONT, CO

Quality Specialist with 10 years of experience in Pharmaceutical manufacturing, CMO manufacturing, and Biotech Pharmaceutical operations. Proven record of quality leadership, innovation, and problem-solving with forward thinking. Strategic in planning, critical thinking, organization, and effective team communication, to achieve processes of high-quality and outstanding integrity standards which generate opportunities for sustainable company growth.

#### **QA PROJECTS SPEICALIST**

##### **CORDEN PHARMA 04/22- present**

- Commercial manufacturing of API Active Pharmaceutical Ingredients, Research, and Manufacturing Support clinical and commercial manufacturing and process development. Supervises a team of QA Project Specialists. Team collaborator of work assignments, coaches, and develops direct reports to ensure successful completion of projects
- Organized quality oversight for clear, direct, and appropriate communication in manufacturing interactions.
- Design and development of procedures and decisions affecting product quality.
- Develops and issues communications and reports to customers as required, including Annual Process Reviews.
- Serves as liaison between management, customers, and other personnel in formulating and establishing company policies, operating procedures, and goals.

#### **QUALITY OPERATIONS SPEICALIST (Ipharma Consulting) Contract**

##### **PFIZER 06/21 – 04/22**

- Provided Quality Assurance oversight of the manufacturing floor team, supporting deviations and providing real time quality impact support for the C19 Vaccine Drug Product Operations
- (SME) consultant's specialist team to ensure consistent methodology and to implement an effective quality assurance policy to establish to align all those aspects for the current project as well as across projects and departments.
- Inspection raw material staging for pre-press set-up.
- QA review of SAP inventory
- Regulated Quality oversight of manufacturing operations of C19 vaccine, production teams, and to ensure cGMP operations independently provide real time Quality assessments of events, investigations, and cGMP compliance.
- Expertise of manufacturing process from compounding through to refrigeration of vaccine
- Applied ability to resolve complex and detail situations with analysis of process and product impact.
- Conducted and communicate, Audits, Gemba's, Events, and Deviations. Utilize tools and effectively leads communications /cross-functional team investigations.

#### **QUALITY ASSURANCE CONTROL LEAD SPECIALIST III MANUFACTURING OVERSIGHT (Contract)**

##### **ADMA BIOLOGICES 06/20 – 06/21**

- Provided Quality oversight of manufacturing by confirming all products adhered to company standards and followed FDA regulations. Provide supervision of QA oversight of warehouse, manufacturing production, shipping and receiving.
- Reviewed and approved investigations to, real-time manufacturing batch record review, review of manufacturing documentation, and resolution of issues on the manufacturing.
- Oversight of Quality control of labs, cleanrooms, aseptic filling, and warehouse operations
- Organized Quality Systems (e.g., Deviations, Corrective and Preventive Action reports {CAPAs}, Change Controls, and Out of Specifications {OOSs}).
- Collaborate, review and release of Plasma pools to manufacturing, review all manufacturing support documentation, review, and release of raw materials in LIMS/SAP.

### **QUALITY COORDINATOR INSPECTOR (Contract)**

#### **Tulip Richardson 01/20 – 06/20**

- Evaluation of corrective action for nonconforming products and the associated recommended corrective action
- Precision mechanical inspection tools
- Inspecting machined parts, castings mechanical assemblies, tooling, brazing, plating, finishes, painting
- First Article Inspection, Oversight of Deviations, Corrective and Preventive Action reports {CAPAs}, Change Controls, and Out of Specifications {OOSs}
- Inspection and movement of product inventory (loading and unloading)

### **QUALITY FILTRATION TECHNICIAN III**

#### **THERMO FISHER 06/19 - 12/19**

- Exceptional knowledge and experience with GMPs, batch record operations, standard operating procedures, compounding, filling, compliance, regulated documents, and aseptic behavior, sterile clean room operations of procedures.
- Operational experience in cell culture filtration. Quality Control and Component Preparation.
- Review of cGMP and compliance of manufacturing oversight within production along with coordinating and monitoring operations.
- Monitoring and review of inventory controls, batch records and components allocation,
- Oversight of Deviations, Corrective and Preventive Action reports {CAPAs}, Change Controls, and Out of Specifications {OOSs}
- Experience in operations of cell culture media in accordance with Quality Assurance of GMP practices adhered to compliance of proper aseptic technique.

### **QUALITY OVERSIGHT SPECIALIST III FRESenius KABI 05/13 – 05/19**

- Pharmaceutical manufacturing oversight of medicines for infusion, transfusion, and clinical nutrition processes in cGMP compliance operations.
- Design and organize training to increase knowledge and skills of cGMP operations.
- Operational experience Aseptic cleanrooms preparation, aseptic filling, aseptic formulation, aseptic capping.
- Experienced in Deviations, Corrective and Preventive Action reports {CAPAs}, Change Controls, and Out of Specifications {OOSs}
- Plan and schedule trainers and coordinate on going learning programs.
- Assist and coordinate the revision of SOPs for improvement, safety, and compliance
- Oversight of quality controls of labs, PLS, LIMS, and Sap polices and operations.

### **Accomplishments**

Created and implemented quality assurance procedures to identify and eliminate all process errors resulting in reduced error rate by 40% and increase in overall efficiency.

Developed and Produced Quality Assurance Oversight training in aseptic techniques to ensure cGMP 21 CFR Part 210 and 211 meets FDA compliance regulations

Converted inventory control systems to increase and maximize profits with minimum inventory investment, without impacting customer satisfaction levels.

Facilitate the design and development of training programs, evaluations, and organizational structure of training process. Standardized in documenting updates to manufacturing processes with manufacturing, engineering, and validation.

Built, implemented, and established security compliance operations, and delivered saving \$750,000.00

Improved and restructured Warehouse Quality Operations, to yield saving of over \$315,000.00

Proven organizational leadership, strong interpersonal and communications skills written and oral.

High diligence able to lead by example, work in team environment or independently with minimal guidance.

Demonstrated desire to understand how things work, effectively manage high pressure situations with timelines of results.

Lean Manufacturing Knowledge, 5 s training, Root Cause Analysis, Corrective and Preventative Action Systems knowledge