**RONALD L. MCKINNEY**Shreveport, LA71129

**QUALITY ASSURANCE**

Manager of Operations/QualityConsultant skilled in Change Control, Risk Assessment / Risk Review, ASEPTIC OPERATIONS: Vendor Management, Vaccine manufacturing, euthanasian manufacturing animal control, solid dosage manufacturing, liquid manufacturing process scale-up, technical services, and product development in **c**GMP environment. Held efficiency-conscious positions in Project Management and Quality Management in charge of Change Control Review and Approval of all process documentation in the areas of Quality Systems, Assurance, & Control Planning, Scheduling, Validation, Deviation, Conduct Internal/External Investigation in all cGMP related Occurrences, SOP Changes, Equipment Preventative Maintenance Program, Batch Records, Vendor Management, Internal /External Auditor. QA Trainer quality focused, record review, well organized, and deadline oriented with familiarity of regulatory requirements (21 CFR 210-211-820-FDA, QSR, cGMP, KPI, HACCP, OSHA, NDT, EPA, SQF, & DEA) and safety issues (HSE).  Experience in FDAmulti-product establishment and inspection process. Enjoy coaching employees in their professional career development and process improvements, and improving customer relations.

**AREAS OF EXPERTISE**

|  |  |
| --- | --- |
| * ASEPTIC OPERATIONS (Management) * Experienced in MHRA and FDA Audits * Quality Management * Operations Management * Aseptic Quality Investigation Review * Remediation Project Plan/Support | * Cross-Functional Team Leadership * Writing Investigations/Report * Quality Risk Assessment/ Risk Review * SOP Development and Delivery |
| * cGMP Compliance | * Process Improvement |
| * Regulatory Affairs | * Continuous Improvement |
| * Internal/ External Audits * Internal/External Investigation * Documentation Management * Preventative Action Plan | * Training Assessment, * CAPA Program * Root Cause Analysis * Complaints |
| * Vendor Management * Equipment Validation * Change Control | * Project Management * Sterile Manufacturing |

**PROFESSIONAL EXPERIENCE**

**Oxford - Texas**

**01/17- present**

Engaged in support of executing a comprehensive quality plan to structurally address the identified deficiencies both at the plasma collection centers and with Corporate Quality Systems.

* Travel to centers as well as work remote, working on remediation/backlog of Investigation
* Properly Risk Management/ Risk Table
* Help coach staff on make decision making on investigations
* Items previously or newly identified as moderate or major have been assigned to a CAPA.
* Communicate Items that have not been appropriately assigned to CAPAs to center staff.
* Audit logs generated between determine if the misclassification of items is continuing.
* Determine if new processes, SOPs, and forms have eliminated the need for review and analysis of logs created after implementation.
* Quality Overview of Staff, Operation Support
* Ensure items have been documented with sufficient information to determine they have been classified correctly. Implement new risk table

**Pro Pharma- Maryland**

**07/16- 11/16**

Aseptic operations- Perform impact risk assessments as well as assist in root cause determination and recommend appropriate corrective action and preventative action (CAPA). Assist in the tracking and trending of corrective and preventative action to assure timely closure. Additionally, perform reviews and evaluate sensitive, confidential information and develop recommendations for use by the plant quality assurance department. Work directly with plant personnel currently responsible for writing investigations.

My objective will be to help reduce the backlog of site investigations by providing experienced resources that can be rapidly and effectively mentor current staff and perform the work that needs to be completed to decrease the current backlog at each site. I will help to improve the investigation process to standardize, streamline steps taken and improve the overall process for documentation.

Major duties and responsibilities of the Investigator will include:

∙ Conduct and write investigation reports with the assistance of plant personnel

∙ Perform impact risk assessments as well as assist in root cause determination and recommend appropriate CAPA plans

∙ Track and trend CAPA to assure timely closure

∙ Perform review and evaluate sensitive, confidential information and develop recommendations for use by the plant quality assurance department.

**Validant-New York– Consultant 06/16- 7/16**Engaged in support of executing a comprehensive quality plan to structurally address the identified deficiencies both at the plasma collection centers and with Corporate Quality Systems.

* Consultant with the quality team in its support to develop new products in a sterile environment.
* Working with the manufacturing team to assist with batch records and product review.
* Assist in leading investigations and process of CAPAs, Change Controls, and Deviations.
* Provide project support on site manufacturing as well as remote locations, Responsibilities:
* GMP, Quality investigations, Write and Execute- Batch records, CAPA(s), Change Controls, Sterile products, Pharma.
* Assist in company-wide program focus on operating Blood Plasma Manufacturing used in the manufacture of a wide range of plasma derived pharmaceuticals.
* Work with sterile product and communicate findings to Company management.

**Validant. – Consultant**

**02/16-06/16**This critical program has company-wide program focus on operating blood plasma collection centers used in the manufacture of a wide range of plasma derived pharmaceuticals. Engaged in support of executing a comprehensive quality plan to structurally address the identified deficiencies both at the plasma collection centers and with Corporate Quality Systems.

* Travel to centers as well as work remote, working on remediation/backlog of Investigation
* Help coach staff on make decision making on investigations
* Items previously or newly identified as moderate or major have been assigned to a CAPA.
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* Ensure items have been documented with sufficient information to determine they have been classified correctly. Implement new risk table

**DR. REDDY’S LABORATORIES, Shreveport, La. 05/14-01/16**

***Quality Manager Quality Systems, Vendor Management, Change Control Manager, Internal/External Auditor, Operations Support Manager***

* Created and maintained the Vendor Management, Review Quality Control Test Reports, Planning, Scheduling, Material Processing Change Control Systems. Review and approve all documentation including Validations, Protocols and Audit Reports-Vendor / Solution Evaluation & Management- Vendor Auditing in case no feasible internal solution is arrived upon.
* Worked with internal groups including purchasing, supply chain, and operation teams to analyze and assess the best possible application in the market that suits the requirement.
* Facilitated vendor evaluation: conduct technical evaluation (with help from internal team) after considering integration with existing systems, give inputs to SAP.
* Hosted external audits whether it is from FDA, OSHA, and Health Department, etc.
* Conducted internal audits as a means of process improvement, implementing CAPAs were needed to increase up time and decreasing down time.
* Directed and assisted in analyzing data for trends and CAPAs.
* Directed oversight of employees in the Quality Processes area, primarily of the customer complaints and investigation.
* Ensured the development and performance management of direct reports including training, coaching, mentoring, goal setting, performance evaluation and feedback.
* Oversaw cGMP compliance in accordance with SOP root cause investigations of routine customer complaints. Directed and performed SOP root cause deviation investigations of customer product/quality complaints within Operations, Packaging and Granulation. Duties included:
  + Investigating deviations in Operations
  + Conducting root cause analyses, identifying and implementing CAPAs
  + Review/approval of deviations in CAPAs, and SOPs
  + Providing monthly metrics data
  + Assisting with regulatory and third party audits
  + Conducting QA meetings and training with various Operational sectors
  + Conducting weekly communication meeting with external customers related to pending investigations and CAPA implementation
  + Oversaw Vendor Management process.
* Approval of all changes to the plant including those needed for cost savings.

**GRIFOLS, Shreveport, LA**

**7/09- 05/14**

***Talecris Plasma Resources***

***Quality Center Manager***

Ensured the center compliance with quality standards and regulations. Hosted audits. Directly reported to the RQM interacting with the Center Manager. Observed processes and ensured center compliance with all applicable state, federal, and company-designated regulations.

* Ensured Standard Operating Procedures (SOPs) are updated and validated and that staff performs according to all SOPs.
* Oversaw shipments: ensures shipments meet specifications and requirements; ensures accurate labeling and documentation; authorizes final shipments.
* Documented and tracked trends, center quality incidents and follows-up on incidents/errors as required.
* Ensured accuracy of donor files.
* Ensured that all supplies and materials ordered meet quality regulations.
* Directed the maintenance and calibration of equipment and documentation of procedures.
* Ensured that Clinical Laboratory Improvement Amendments (CLIA) proficiency test surveys, complaint investigations, and training were properly documented.
* Monitored training documents to ensure compliance with all applicable policies and procedures.
* Ensured that job and Current Good Manufacturing Practice (cGMP) training is completed, documented, and on file.
* Oversaw execution, documentation, and review of internal and external audits.
* Tracked and followed-up on corrective actions and preventative measures (CAPA).
* Ensured that quality control (QC) checks are performed as required and are in acceptable ranges for test reagents.
* Updated the Center Procedure Manual with the most recent approved procedures and forms.
* Implemented continuous quality improvement.
* Prepared quality analysis reports to track issues and set goals.
* Built rapport with donors to ensure overall customer satisfaction with the Center to support long-term donation.

**DEAN FOODS (FOREMOST DAIRY), Shreveport, LA 12/07- 07/09**

***Quality Manager***

This is technical and supervisory work in processing dairy food products in a dairy plant used for instructional and research purposes. Responsible for supervising the processing of milk products, performs quality control tests, and assists research personnel in developing and evaluating food processing techniques. Duties include the responsibility for instructing students/employees in dairy plant operation. Work is reviewed by the Dairy Plant Manager for maintaining required standards.

* Identified training needs throughout the organization, preparing the content and delivering the training across the organization vialeading-edge training programs.
* Interfaced with all departments; impact the way Foremost conducts training within the company.
* Managed the daily operations/manufacturing areas.
* Assure all cGMP compliance issues are addressed.
* Trained personnel in operations, safety, cGMP and FDA inspections.
* Troubleshoot product issues.

**SANDOZ INC. formerly known as: Geneva Pharmaceuticals {Novartis}: Broomfield, CO 05/01-11/07**

***Quality Manager Trainer (7/04-11/07)***

* Responsible for ensuring that all supervisors have appropriate data to issue effective assignment of personnel to tasks with consideration for completed training.
* Conducted training needs assessments. Develops training curriculum. Conducts training effectiveness. Develop and maintain LMS system. Delivered training and coordinated training prepared by external professionals.
* Understood all company practices and interfaces with many management levels.
* Viewed as a technical resource internally.
* Establishes/maintains systems for defining training requirements, qualification of training methods, reporting/communicating training needs and documenting/maintaining training records.
* Complex data analysis requiring input from multiple sources and innovative problem-solving.

***Manufacturing Manager (05/01-11/07)***

* Management/Supervise 27 production personnel highest level.
* Managed the daily operations of solid-dosage manufacturing areas.
* Assured all cGMP compliance issues are addressed.
* Trained personnel in operations, safety, cGMP and FDA inspections.
* Troubleshoot product development issues.
* Operate, maintain and troubleshoot equipment for blending, granulation, compression, coating and packaging. Schedule manufacturing personnel.
* cGMP and FDA inspections.
* Improve Cycle time by implementing changes in all areas decreasing down time.
* Troubleshoot product development issues.

**BIOVAIL TECHNOLOGIES, Chantilly, VA 05/00-05/01**

***Manufacturing Manager***

* Training production personal on running new equipment and following SOPs.
* Motivate staff to meet or exceed production goals.
* Review Batch records, Protocols, Sops and Validation Documentation.
* ASEPTIC OPERATIONS (Management)
* Exceeded customer product expectations by maintaining equipment to produce quality products.
* Completed all repairs and maintenance work to company standards.
* Planned work and determined appropriate tools and equipment.
* Reduced downtime during production by maintaining equipment and reducing unnecessary maintenance.
* Responsible for promoting safe and clean working environment.
* Kept supervisor informed of job progress and material requirements.
* Managed work with little supervision.
* Notified supervisors of faulty operations and defective materials.
* Water Tower Operations on VRC's used for cooling.
* Knowledge of C.I.P's, Sterilization Practices.
* Knowledge of CCP's.
* Knowledge of Chemicals, and their uses, and MSDS.
* Involvement with Q.A/Management when problems arise. Trained in Lock-Out/Tag-Out

**HESKA. CO DIAMOND ANIMAL HEALTH, Des Moines, IA 02/99-05/00**

***Production Supervisor***

* Managed the daily operations of solid-dosage manufacturing areas, assuring all cGMP compliance issues are addressed.
* Trained personnel in operations, safety, cGMP and FDA inspections.
* Troubleshoot product development issues.
* Operated, maintained and troubleshoot equipment for blending, granulation, compression, coating and packaging. Schedule manufacturing personnel.
* Motivated staff to meet or exceed production goals.
* Interfaced with other departments to achieve company's objectives.
* Wrote SOP's for manufacturing area. Worked closely with QA to reduce product holds and customer returns. Ensured validations were complete prior to approval in the areas of equipment, process, and cleanings.
* Interfaced with FDA as needed.
* Oversaw the purchasing of new and used equipment.
* Experienced with QAD and fourth shift material management software.

**SAGE PHARMACEUTICALS, Shreveport, LA 02/96-02/99**

**Senior Production Supervisor**

Responsible for cGMP training for all personnel in multiple shift operation, for FDA and OSHA compliance for handling of potent compounds.

* Report directly to President and CEO.
* Responsible for blending, granulation, compression, coating, encapsulation and packaging.
* Coating experience includes film coating, sugar coating, and Wuster coating.
* Broad equipment experience.
* Facility manufactures generic solid dosage Rx products, controlled products, and OTC cough/cold products.

Selected Accomplishments:

* Selected by company President to oversee production operations.
* Motivation of production personnel to exceed production deadlines. Have met every production deadline.
* Successfully negotiated a contract to purchase guaifenesin at 54% savings as well as other raw materials. Identified opportunity to purchase equipment at over 50% savings.
* Substantially decreased down time between product changes by implementing new cleaning validation procedures, compression, granulation, dispensing, process and cleaning of equipment- write SOP's.
* Worked with facility owner to develop new aqueous coating method.
* Developed close working relationship with QA to reduce product holds and customer return.

**IVAX/ZENITH GOLDLINE PHARMACEUTICALS, Miami, FL 11/90-2/96**

***Formulation Assistant, Formulation Technician/Technical Services, Production Supervisor***

* Responsibilities included supervision of production during the manufacturing of clinical supplies and Bio batches.
* Testing of new equipment and writing of SOPs for equipment and its usage.
* Assisted in formulation of Verapamil, ferrous sulfate, captopril and estrogen products.
* Participated in preparation of batch records.
* Provided training on new product procedures.

Selected Accomplishments:

* Trained new personnel on production procedures.
* Help developed new coating procedures.
* Have written and implemented New SOPs and Procedures.
* Reduced product rejection by improving compression techniques.
* Provided hands on feedback to formulations department on process scale-up and process improvements.
* Assist with Validation ensuring documentation are prosiest, legal, evidence demonstrating that a procedure, process, or activity carried out in production or testing maintain the quality of operations.
* Staged production and dispensed raw materials.

**UNITED STATES ARMY, Fort Lenardwood, MI /AIT-VA 12/88-3/90**

***M.O.S-76 Victor***

**EDUCATION, PROFESSIONAL DEVELOPMENT AND AFFILIATIONS**

**AIU UNIVERSITY**

B.A. in Management- Healthcare

**WOODLAWN HIGH SCHOOL, SHREVEPORT, LOUISIANA**

Graduated

**APPLICATIONS / TECHNICAL SKILLS**

Proficient in all Microsoft Office Products including Word, Excel, Excel Label Printing and PowerPoint. In addition, Lotus Notes, Citrix Data Base, Dropbox, Deltex Time Reporting, Word Perfect, DOS, Track wise, Infinity (SPC) system (etc.) Pathlore, Compuware and PeopleSoft (LMS), SAP, Arabia, QSR Quality Systems regulations. Donor ISO9000/Management System (DMS), ASQ Concept, Six Sigma/ Lean Manufacturing.