Contact information:

Please send resumes to Christina Goodreds at cgoodreds@germerintl.com.

#2908 Director of QA, Manufacturing

Purpose of the Position:

Lead and direct the daily activities of the Quality Assurance team supporting the Company's aseptic manufacturing operations. Develop, implement, maintain, and improve upon the cGMP compliant systems in alignment with the company and corporate quality strategies and objectives.

Responsibilities:

- Direct staff to ensure the timely delivery and right first-time execution of Quality Assurance tasks in support of the organization's manufacturing operations in accordance with Customer, Company, cGMP and other applicable requirements.
- Collaborate effectively with manufacturing operations management to review and approve: SOPs, protocols, reports, equipment qualifications and calibrations, change controls, specifications, batch records, trend reports, investigations, and other exception management documentation.
- Oversee cGMP and aseptic training programs to ensure current regulatory guidelines are effectively communicated to the staff.
- Assume ownership of assigned quality documentation, such as exceptions, change controls, and CAPAs, ensuring that documentation is initiated and closed on time, required actions are thorough and meet procedural requirements as well as customer needs.
- Lead and direct the implementation of FDA Readiness plans for the facility. Provide support for all regulatory audits as well as internal or external inspections.
- Lead and direct the Corrective and Preventative Action program. This may include chairing the Material/Quality Review Board and conducting QA investigations as per internal procedures.
- Oversee customer complaint investigations, as needed. Ensure effective corrective actions have been implemented and ensure timely closure in accordance with internal procedures. Communicate with Customer's quality assurance counterpart to ensure client needs are being met with proposed CAPA(s).
- Execute management duties in accordance with company policies and applicable laws, including interviewing, hiring and training employees; planning, assigning and directing work; appraising performance; rewarding and disciplining employees; addressing complaints and resolving problems.
- Mentor, motivate and challenge to drive high performance and develop team members, encouraging them to reach their full potential.
- Maintain workspace cleanliness by adhering to the 5S method of organization.
- Ensure all staff follow site safety requirements, promote a culture of safety, whereby all accidents are preventable and support site safety initiatives.
- Abide by safe work practices and adhere to general safety rules, performing all duties in a safe manner and never placing yourself or those around you in an unsafe condition. Report all unsafe conditions to your supervisor.
- This list of duties and responsibilities is not all inclusive and may be expanded to include other duties and responsibilities, as management may deem necessary.
- Core Competencies:
- Accountability - Making a commitment to the organization and meeting obligations, adhering to policy, and accepting responsibility.
- Ethics & Integrity - Exhibiting personal integrity and professionalism, aligning with organizational values, and modeling ethical behavior.
- Interpersonal Competencies - Contributing to the team, communicating effectively, working cooperatively, resolving conflict, building team capability, and celebrating success.

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- Strategic Competencies - Identifying what needs to be done, taking action, adding value and participating in positive change.

Qualifications - Experience and Education:

- A minimum of 10 years, 12+ years preferred, industry related work experience.
- Bachelor's degree or equivalent in scientific discipline required. Advanced degree preferred. ASQ certification preferred.

Knowledge, Skills, and Abilities:

- Advanced knowledge of cGMP regulations, and FDA and ICH guidelines as they pertain to aseptic manufacturing operations.
- Advanced knowledge of USP, Pharm. Eur. (Eudralex), ISO 13485, and other applicable standards.
- Advanced knowledge of root cause investigation and problem solving; experience in the use of 5 Whys and/or other appropriate root cause investigation tools.
- Strong interpersonal skills. Must be able to express oral and written communication in a clear and concise manner and effectively present information and respond to questions from managers, customers and employees.
- Strong project management skills with demonstrated ability to take programs from concept to execution and manage all stages.
- Effective organizational and time management skills with the ability to multi-task and prioritize assignments as needed.
- Demonstrated problem-solving /decision-making skills with the ability to prepare contingency plans and future strategies proactively.
- Ability to work on problems of diverse scope in which analysis of data requires evaluation of identifiable factors, exercising judgment within generally defined practices and policies in selecting methods and techniques for obtaining solutions.
- Ability to manage effectively, setting clear expectations, establishing accountability, monitoring progress and outcomes.
- Ability to work effectively and diplomatically in resolving conflicts.