QUALITY Assurance Manager

Reports To: Sparsha Pharma USA, Inc. CEO, CTO

Job Overview:

Design, establish, implement, and manage the company's GMP quality system. Leading the sites compliance for required industry standards. The role will also provide support for client business reviews, investigations, complaints, CAPAs, inspections, quality metrics, and continuous improvement initiatives as required by the company.

Responsibilities and Duties:

- Design, implement and improve product quality. Review/improve the quality system.
- Ensure compliance with domestic and international drug, device regulations with a strong focus on the FDA, DEA, and other ex-US regulatory agencies as required.
- Leading and managing strategies necessary to support customer's products as well as hosting and leading both regulatory inspections and customer audits.
- Manage the Customer and Regulatory auditing program by completing required pre-audit documentation, lead audit hosting, developing appropriate corrective actions documented through the audit report responses, and ensuring proper implementation.
- Maintain a systematic approach to sharing audit (customer and regulators) observations and associated corrections with all site team members and the corporate quality team.
- Review and maintain appropriate Customer Quality Agreements.
- Review and maintain appropriate Site Master Files
- Implement and support programs that establish and maintain a culture that fosters compliance with company rules and all applicable federal, state, and local regulations.
- Ensure high level of quality for the protocol, data and report for any type of GMP activities such as tech transfer, scale up, validation, qualification and verification, etc.

- Implements and maintains systems and processes to ensure high quality products and compliance with current Good Manufacturing Practices (GMPs),
- Conducts risk assessments, root cause analyses, and continuous improvement initiatives to identify and address quality-related issues and deviations.
- Support wider aspects of the Quality Management System to maintain compliance and drive improvements.
- Preparation of management review report and annual product review report.
- Train, motivate, coach, and correct employees
- Formulate strategies to increase quality and productivity.
- Determine in-house quality procedures, standards and specifications.
- Assess quality requirements of raw materials with suppliers, in process and finished products.
- Ensure that manufacturing processes comply with GMP pharmaceutical standards at both national and international level.
- Overall responsibility for employee training program
- Act as a catalyst for change and improvement in performance and quality
- Record, analyze and distribute statistical information to management.
- Performs other duties as assigned
- Attendance to work is an essential function of this position

Requirements

- Bachelors' degree and/or Masters' degree in related science field.
- More than five (5) years' experience leading employees, projects and leaders.
- At least six (6) to eight (8) years of experience, demonstrated ability to execute the strategic and tactical objectives provided by senior leaders both within Quality and outside of the function.
- Experience in a GMP environment
- Strong understanding and appreciation for regulatory requirements and quality and compliance standards for the industry
- Overall understanding of risk-based Quality Assurance system and process
- In-depth understanding of Manufacturing/Pharma Business
- Strong team leadership skills

- Strong staff coaching and development skills
- Strong ability to communicate
- Strong ability to influence in a team environment and collaborate with peers.
- Interacts with coworkers to ensure consistency in policies and practices across the company
- Excellent interpersonal skills, including listening, writing, possess great attention to detail.

QA Team Members

- QA Specialist, QA assistant

Work Schedule: Monday to Friday, 8:30 am to 5 pm