



**SUBHAJIT REJ**

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## **Objective**

Experienced Quality Assurance professional with over 12 years of experience in pharmaceutical and biological industry. Dedicated with history of meeting company goals utilizing consistent and organized practices. Skilled in working under pressure and adapting to new situations and challenges to best enhance the organizational brand.

## **Experience**

*05-2022 - Current*

### **Deputy Manager Corporate Quality**

Biocon Biologics Limited

- Coordinating the Global Quality Management Review Process and Executive Leadership Management Quality review
- Review and Analyze the Key Quality Indicators and Key Performance Indicators of sites using various quality tools such as Six sigma to derive improvement opportunities and enhance Quality Performance
- Manage and monitor Quality System Performance for all sites
- Designing of Global procedures, policies using various Quality and Simplifications tools
- Build and integrate Risk based approach in the QMS procedure
- Lead team improvement projects using problem solving and root cause analysis tools
- To follow, improve and harmonize QMS procedures and its implementation
- Management of external and regulatory inspection and audit compliance across all sites Responsible for ensuring quality objectives in the MRM
- Implementation of continuous improvement across all sites
- Ensuring scheduling and conducting the internal audit across the sites
- Participate in customer/ vendor/ supplier audits for qualification and requalification
- Participate in external and internal audit
- Support and coordination of improvement project within team.
- Handling and managing four persons team for QMS.
- Participated in continuous improvement by generating suggestions, engaging in problem-solving activities to support teamwork.
- Created plans and communicated deadlines to complete projects on time.
- Collaborated with team members to achieve target results.
- Lead projects and analyzed data to identify opportunities for improvement.

07-2015 - 05-2022

## **Associate Manager Quality Assurance**

Pfizer

- Strategized and coordinated with manufacturing, laboratory, and quality management to complete investigations within timelines
- Investigate, Review and Approve of investigation with focus on root cause analysis and appropriate corrective/preventive actions and verify effectiveness of proposed actions
- Guide the investigator for effective utilization of the investigation tool like "Fish bone analysis", "Is and Is not", "Why analysis", Cause effect analysis etc
- For assessing to identify the root cause of critical investigation
- Drive the investigations for quality robustness within timelines using Six-Sigma Methodology (DMAIC) and PHP (Pfizer Human Performance)
- Support the Quality Compliance Leader in management of Corporate and Regulatory Inspections
- Responsible for initiating Notification to management (NtM) and assessment for Field Alert Report (FAR)
- Responsible for preparation of Annual Product Quality Review (APQR) chapters related to investigations
- Managing the manufacturing investigations with the team by solving the day-to-day issues and providing the oversight
- Preparation of quality metric prior to presenting management for site quality review meetings (SQRT) and implementation of resulted actions
- Worked with internal team members to accomplish regulatory goals and achieve full compliance with all products
- Created and deployed best practices to improve efficiency and reduce defects
- Management of short term and long-term projects related to investigations and continuous improvements
- Handling and managing Six persons team for Quality Investigation

01-2014 - 06-2015

## **QMS Specialist**

Fresenius Kabi Oncology India Limited

- Handling and managing four persons team for Batch review and release process.
- Responsible for review and approval of Trend report of CPP and NVPC and investigation of root causes of OOT and CAPA.
- Response the Query of batch documents and coordination with USA and UK QP.
- Collected and analyzed activity data and initiated, developed, and recommended improvements to systems, processes, and procedures to increase productivity and reduce cost.
- Ensure compliance to inspection/audit observations and prepare site for inspection readiness.

02-2012 - 12-2013

### Scientific Officer Quality Assurance

Panacea Biotech Limited

- Ensure cGMP Compliance in manufacturing facility QC, Warehouse and Critical Utility System.
- Responsible for IPQA activities on Shop Floor during formulationo Review of BMR and Analytical records to support batch release activity.
- Verification of Dispatch activity for Final ARM

04-2011 - 01-2012

### Microbiologist

Pfizer Animal Health Limited

- Responsible for sampling, Quality control testing (Water, Sterility, BET).
- Ensuring the media preparation and GPT and reconciliation of the Media
- Monitoring and verification of Environmental monitoring of Manufacturing area
- Support the validation team in Validation/Qualification: Qualification of Autoclave and HVAC.

## Education

2009-2011

### M.Sc in Microbiology

Gurukula Kangri Vishwavidyalaya

76%

2006-2009

### B.Sc (Hons) Microbiology

University of Burdwan

70%

## Skills

Quality Management Systems

Quality Risk Management

Audit Management

Training and Development

Deviation Management

Change Management

CAPA Management

GMP, GDP, GXP

21 CFR and ISO 13485

Supplier Audit and Vendor Management

Document Management

Data Integrity and ALCOA

Root Cause Analysis

Teamwork and Collaboration

## Projects

### CIP Remediation

Collaborated with team to complete CIP remediation project at Pfizer, Vizag

### **Yello Belt Project Filter Integrity Failure**

Reduce repeat incident related to filter integrity failure at Pfizer, Vizag.

### **Investigator Qualification**

Implementation of Investigator and Approver Qualification process at Pfizer Vizag

### **Improve Schedule Adherence and reduce loss time**

Improved the schedule adherence and loss time of investigation through DMAIC projects

### **Implementation of Quality Index and Quality management Review process**

- Responsible for publishing the investigation dashboard for CI projects and Quality Dashboard
- Harmonize the KPIs and establish the Quality Indicator to review the Quality Performance across the organisation.

### **Achievements & Awards**

Gold Medalist ( Post Graduation)

GATE 2011 Qualified

### **Languages**

English

Hindi

Bengali

### **Declarations**

I hereby declare that the information furnished above is true to the best of my knowledge