Shubham Kumar Kushwaha

Assistant Manager – Quality Assurance

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As a hard and smart working individual, who loves to listen & learn new concept that could drive win-win solution for all stakeholders, the aim would be to create a sustainable niche for the company products and to fulfil the requirements needed.

Area of Expertise

Audit Compliance | **Serialization** | **Qualification/ Validation** | **QMS Activities**

Quality Risk Management | **Product Release Planning** | **Internal Audit** | **APQR**

Vendor Management

Experience

2019 – PRESENT

Assistant Manager - Quality Assurance at Cadila Pharmaceuticals Limited

- Co-ordinate with the auditor (Regulatory as well as client) for requirements necessary in execution of audit, verification & implementation of CAPA and ensure readiness for audit.
- Co-ordinate with cross-functional team to provide the necessary CAPA plan, prepare compliance report and response to auditor.
- Schedule and conduct internal audit and vendor audit, prepare audit report, verify and ensure the CAPA effectively implemented.
- End-to-end trial and implementation (L1 to L4), on boarding, Master Data Management (EU, USA & Russia market) & Alerts handling (EUFMD).
- Investigate the root cause of complaint and deviation or any non-conformance & prepare the investigation report.
- Initiate, review and closure of Change Control, CAPA, and its effectiveness.
- Qualification or re-qualification of equipment, area and utilities to provide a certain level of assurance for critical parameters to be remain specified within the acceptable limits.
- Assess the risk (QRM) related to existing system/ change in existing system/ new system installation and propose CAPA to minimize the risk up to acceptable limit.
- Co-ordinate with cross-functional team to provide timeline for batch disposition activity, to ensure timely execution, avoid any shortcomings & harmonization the product release activity.
- Preparation & review of Annual Product Quality Review (APQR).

Projects at Cadila Pharmaceuticals Limited

1. Serialization
   - Implemented Serialization for Russia in the organization.
   - Implemented master data management system in the organization.
   - Stabilized the serialization procedure in the organization for EU market as well as for US market.

2. Market Complaint Investigation
   - Interest of the investigation is to find out the causes potentially leads to complaints and to eliminate the possibilities responsible for potential root cause and reduction in compliant received observed approximately 7%.

3. Service Level Agreement (SLA)
   - Gap Assessment – Mapped functions of the department to identify the bottlenecks to smoothen the process flow.

Academic Qualification

Course	Institution	CGPA/Percentage	Year
M.Tech	Indian Institute of Technology, Guwahati	7.57	2019
B.Tech	Ashoka Institute of Technology & Management, Varanasi	75.14%	2015

Projects

- **Numerical study of fluid flows and their stability** (Department of Mechanical Engineering - IIT Guwahati).
- **Dynamic analysis of Spring-Mass-System** (Department of Mechanical Engineering – AITM Varanasi).
- **Drawing and Auto-CAD Learning** (HINDALCO Industries Limited- Renukoot).

Technical Skills

- **Software:** Auto-CAD, Ansys, COMSOL, LIMS, rfxcel, Verishield, SAP*
- **Operating System:** Linux, Windows
- **Programming Language:** C, Fortran90

  * *Elementary Proficiency*

Position of Responsibility

- Investigate the alert generated in EU FMD for serialized products.
- CFT member for factory 10 (US Market) as QA personnel.
- Conduct Quality Review Meeting to discuss Quality KPIs, prepare MOM and to ensure timely execution.
- Quality representative in monthly EC meeting within the organization.