MANJUNATH. PG

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Senior Management Professional - An Overview ~

Quality & COMPLIANCE (Sterile & non-sterile, Formulation / API)

Since April 2017 employed at HETERO Labs Limited - as Head – Quality / Ass.Vice President- QUALITY for Oral Solid dosage form(s). Job Location: Unit-III, HYDERABAD, INDIA.

PROFESSIONAL ABRIDGEMENT

A competent professional with nearly **24 years** Industrial experience in cGMP systems, Total Quality Management, and Process Improvement, manufacturing, validation, qualifications and Resource Management in Pharma Industries (Formulation / API's).

Presently leading the Quality Team(s), Compliance & Risk management team for developing & streamlining systems with proven ability to enhance operational effectiveness and meet organizational goals within the cost, time & quality parameters.

Hosting the Regulatory audits (National / International) & providing the adequate CAPA in compliance to Corporate systems & Culture. **During the year 2018,** Successfully lead the, three back-to back USFDA audit(s) & one each of WHO, EU, MCC & BRAZIL audit(s). Additionally, successfully **lead / hosted USFDA-2016, For-Cause audit for APOTEX-India, resulting in closure of FDA WL.** Overall, More than 40+ regulatory audit experience.

Guiding / coaching investigation team for effective Investigations, customer complaints management, failures assessments, OOS investigation along with implementation of effective CAPA with Risk Assessment, Validation management, Stability management, etc.

Hosting QRM with corporate management and responsible person for all the regulatory communications with reference to Quality services.

Align with Corporate / site team(s) for developing & streamlining systems with proven ability to enhance operational effectiveness and meet operational goals within the cost, time & quality parameters.

Hands on experience on production, technology transfer and validation, Quality Control, Qualifications of all equipment, utilities, process and computerized systems.

Hands on experience on reviewing of, Risk assessment / Gap analysis / CAPA Management/Training and various in-license applications.

Having experience of performing / Supervising of contract manufacturing organizations, both formulations and API (**Sterile / non-sterile**). Experience with around **500+ CMO's visit.** for previous employers. (ACTAVIS & APOTEX).

Lead / participated in around 40+ regulatory audits, include: **US FDA, UK MHRA, TGA, MCC-SA, WHO-Geneva, ANVISA, EDQM, Health-Canada, PMDA-Japan &** other international regulatory agencies.

Strong abilities in performing Functional, Regression and Integration. Adept in developing a framework of quality standards, procedures & systems; provided support in problem & defect analysis in manufacturing, packaging, testing & supplier quality related issues. Effective troubleshooting and interpersonal skills with proven ability in driving numerous quality enhancement, process improvement and cost saving initiatives during the career span.

Managerial Skills	Functional Skills
Excellence in Analysis and Problem Solving	Quality Management Systems
Sound Judgement	Audit readiness for API / Formulation sites
Decision Making Skills	Improvement Initiatives
Achievement Oriented Team Builder	Internal & external Auditing & Inspections
Skilful Execution	Team Management, Specialized in
Job specific Training	Dudiligence & PAI Audits API/Formulations

CAREER CHRONOLOGY (Year 1995-2019)

1. **Since, April 2017 with HETERO LABS LTD**, Joined at CQA, later shifted to unit-III, OSD site as Quality Head for Tablets, Capsules, Liquids & pellets manufacturing site. QA & QC direct reporting. (Team 450 persons).
2. **From September 10, 2015 to March 31st, 2017**- GM- Compliance at Apotex Bangalore. Team-80 persons.
3. **From Dec 2009 to September 9, 2015** ACTAVIS/ TEVA Pharmaceuticals as General Manager-Global Compliance for Third party manufacturing responsible for Asia-Pacific zone. API & formulation sites.
4. **From September 2005-November 2009**- Quality -Lead for APOTEX Bangalore, completed green filed project for Formulation / API. Ground breaking to regulatory commercialization level.
5. **From 2003-2005** with Dr. Reddy's Laboratories-Hyderabad as Dy. Manager-Quality Assurance.
6. **From March 2002-Dec-2003** with Medireich pharmaceuticals as Quality HEAD for unit-I.
7. **From 1996-2002** with CIPLA Pharmaceuticals Bangalore, GOA sites.
8. **From 1995-1996** with AMAZON Drugs- Bangalore.

CORE COMPETENCIES:

QMS Implementation

- Involved in achieving quality certification as per regulatory standards as well as appraising the status of system implementation.
- Maintaining the relevant documents like change control, deviations, risk analysis and other contemporary documentation & Harmonization of practices and lead cross-functional team member.
- Supervising system audits, transfer of products, validation, change control management, deviation & exception, technology transfer, Periodic Product Review (APQR) etc.

Quality Assurance

- Conducting validation, stability studies, quality audits, self-inspections, facility-scale-up to meet the requirements of regulated markets.
- Ensuring that the teams adhere to all the quality standards and procedures through precision / calibration and monitoring sessions.
- Review and approval of contractors, quality documents and approve in SAP /Trackwise systems & Electronic data management. Additionally, art work management through electronic storage system.
- Preparing, reviewing and approving the vendor audit schedules and auditing the CMO's as per the schedule
- Assessment of CMO's performance and vendor rating.
- Review of contract manufacturing facilities, Around 500+ facilities have audited. Both sterile/Non-sterile Formulations & API's at Asia Pacific. Include API, OSD, semi-solid, sterile /injectable CMO's, excipient suppliers and Primary packaging material suppliers.
- Dudiligence Audits / PAI review(s) at CMO's / Routine GMP/GLP audits / For Cause audits
- Transit evaluation and supply chain monitoring.

. Quality Compliance & Control

- Reviewing SOPs / technical specifications / batch manufacturing records / analytical reports / validation protocols, validation reports and other quality documents / change-control documents.
- Extending complete support to regulatory submissions and online quality control activities.
- Conducting stability studies, validation, calibration and qualification of instruments / equipment's.

Team Management

- Imparting training to subordinates on instruments, procedures, and analytical assurance & safety measures.
- Creating an environment that sustains & encourages high performance; motivating teams in optimising their contribution levels.

- Organising training programs for subordinates on cGXP, Presentation and Communication skills.
- Manpower planning / Annual budget planning for the team/ team building

Regulatory Affairs

- High level coordination with internal RA-team, for effective submission of DMF/Dossiers/ANDA/NDA to regulatory agencies. Compliance to Schedule-M.

Present Responsibilities

- Responsible for site quality compliance with guiding QA and QC teams for routine activities. Six Billion dosage form capacity site.
- Management and handling regulatory audits, customer audits. Proving adequate CAPA to all.
- Training for QMS procedures. (PAI and routine GMP audits). Review of Regulatory agencies CAPA / risk assessment at all sites as a management team member.
- As applicable, review and approval of policy documents, Quality Manual, Site Master File, Validation Master Plan, Batch documents, Validation documents, SOP's and Quality risk assessments.
- To manage a team of QA / QC personnel to enforce policies and procedures so as to maintain consistent quality of products across all the business units.
- Implementing current regulatory expectations like, DI policies and practices, unannounced audits practices.
- Co-ordinating for the Investigation to the Market Complaints, Review of Market Complaints Investigation report and monitoring the Implementation of CAPA in all Formulations units.
- Correspondence with the customers, marketing partners, manufacturers, suppliers related to entire quality aspects.
- Managing CMO's technical agreements review, Change Controls, OOS, CAPA, Incidents & Deviations. Track-wise /SAP & ERP system / LIMS execution. As applicable performing Self-inspection / internal quality audits.
- Procedures /practices and process harmonization.
- License Application for new products & corporate stability management.
- Review of tech transfer activities & DQA related activities.
- Ensuring adherence to corporate Quality Assurance Procedures and SOPs.

Summary of Significant Highlights across Tenure:

- ✓ As a part of QA team with lead responsibilities, successfully completed the Qualification and validation of two new facilities in line with various regulatory norms with successful regulatory accreditation.
- ✓ Stabilized the Tablet and Hard gelatine capsule Production department of a brand new Organization by means of continuous education and training of absolutely new work force.
- ✓ Successfully & repeatedly, got through Regulatory audits of USFDA, ANVISA, Health-Canada, TGA, MCC, MHRA, WHO-Geneva and other many more approvals.
- ✓ Cross functional and procedures/ practices harmonization.
- ✓ Successfully completed around 500 Plus Compliance audits at Formulation & API facilities across Asia-Pacific zone.
- ✓ Third party audit and batch releases for Europe and regulated Markets
- ✓ Dudiligence Audits for global acquisitions for current company.
- ✓ External manufacturing review of DMF/Dossiers/Annual Quality Reports
- ✓ Technical guidance for contract/external manufacturing facilities to implement CFR & EU guidelines.
- ✓ External Laboratories audits and review.
- ✓ Capable for handling Sterile/Non-sterile formulation (oral solids/liquids/semi-solids/inhalers/injectable & oncology/hormonal formulations) & API quality systems.

Audit(s) Management (For API's / OSD/Liquid/Semi-solid & sterile formulations)

- ✓ USFDA, MHRA, UK, Health-Canada, TGA, AUSTRALIA, MCC, SOUTH AFRICA
- ✓ WHO-GENEVA
- ✓ PMDA-Japan
- ✓ ANVISA – Brazil and Other Lesser regulated market audits
- ✓ EDQM & Many European Union Audits. MORE THAN 100+ INTERNATIONAL CUSTOMER AUDITS.

PROFESSIONAL TRAININGS

- GMP/GLP training from International group(s)
- Undergone training on TIME MANAGEMENT by external faculty.
- Training on SAP/ERP / six-sigma /TQM topics.
- Official Trainer for CDSCO / WHO Inspectors- Government of India in the year 2015.

EDUCATIONAL PROFILE

- **Graduation in Pharmacy** / Bachelor of Pharmacy- B. Pharma from Bangalore University., INDIA
- **Diploma in Pharmacy** – D. Pharmacy- From Drug Control Board, Karnataka, INDIA
- **MSc** - Master's In science (General-Chemistry) From Rajasthan University-INDIA. Distance Education mode.
- **MBA**-Master's in business management from NIMS-INDIA – Distance Education mode.

PERSONAL PROFILE

Contact Address : Resident of Bangalore- Karnataka. Currently located in HYDERABAD.

Date of Birth : July 27th 1968

Nationality : Indian

References on Request and Emoluments shall be shared during person discussion.

Place: Hyderabad

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