VENKATA RAMANA REDDY. YALLANURU

Pharma QA (/ Corporate QA)

***HYDERABAD, Contact No.:** 9951660005, **e-Mail :** REDDYYV@YAHOO.COM*

CAREER OBJECTIVE:

~20 years (4 Year as Quality Head) of vast experience in QA (14 Years) & Corporate QA (8 Years, Audits & Compliance) in Active Pharmaceutical Ingredients Operations (with familiar companies like AUROBINDO, NATCO etc.), driven by integrity and strong ethical principles.

AREAS OF EXPERTISE:

cGMP Operations, Vendor Development, Audits & Compliance, Quality / Materials Management, IPQA, Regulatory Inspection, Risk Management, Technology Transfer, Validations & Qualification, Trainings, Operational Excellence and Net Working.

PERFORMANCE BENCHMARKS:

- *~20 years of experience in implementation of GMP in Active Pharmaceutical Ingredients Operations.*
- *Participated ~15 regulatory inspections including USFDA, Cofepris, EU-GMP, EDQM, PMDA, KFDA, TGA, WHO & ISO etc.*
- *Contributed over 25 API Process Development, Technology Transfer, Process Validation and supports to Regulatory team during regulatory dossier preparation and submission.*
- *Planning and Execution of Vendor Audits [~300 vendor audits attended].*
- *Execution of contract manufacturing facility audits and sharing the process for manufacturing.*
- *Contributed in Design, Implementation and Maintenance of Quality System to exceed International Regulatory and Customer expectations.*
- *Oversee the… Change Controls, Deviations, Customer Complaints, Product Reviews, Validations, Calibrations, Qualifications, Failure Investigation, OOS, OOT & Implementation of CAPA.*
- *Thorough knowledge on IPQA Activities, BPCR Issue Controls & Equipment Functions.*

ACHIEVEMENTS:

- *Co-ordinate and successfully completion of Regulatory & Customer audits. Through this good exposure and experience on regulatory requirements and documentation systems.*
- *Practical application of ICH, USFDA, MHRA, EU-GMP, EDQM, Cofepris, PMDA, KFDA, TGA, WHO & ISO guidelines for API to ensure regulatory compliance for different markets.*
- *Demonstrated transformational leadership to provide training on QMS, cGMP, SOPs EHS etc.*
- *Assisted various departments like Corporate QA, R&D, Regulatory to strengthen QMS.*
- *Guided the Quality Assurance people to meet the requirements as per FDA norms and successfully faced the FDA / Regulatory Bodies / Customer audits.*
- *Frequently attending more seminars & workshops on 'Quality Management Systems'.*

PROFESSIONAL HISTORY:

Last Four Years as 'QUALITY HEAD':

- *Lead the team in establishing quality system that suits Advance Intermediates, CRO / CDMO, International Regulatory requirements.*
- *Lead the team at regulatory inspections. [TGA (2022), EDQM (2022) & WHO GMP (2024)]*

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- *Ensure timely, efficient, high quality delivery of products and activities to exceed the customer expectations.*
- *Tracking and updation of Regulatory / Corporate commitments.*
- *Lead the QC Team to follow the analysis as per established methods, stability monitoring & necessary guidance through trouble shooting.*
- *Oversee the DMF updations (for 5 APIs), Process Development, Technology Transfer, Process Qualification and Validation of different products.*
- *Guide to the QA, QC & RA people to meet the current requirements as per FDA norms and to face the Regulatory Bodies / Customer Audits successfully.*

~14 Years as MANAGERIAL CADRE:

- *Key member of the Auditee team during Customer and Regulatory audits. Accountable for establishing the audit compliance against inspections in coordination with related team.*
- *Review of Level – I documents such as SMF, VMP, Quality Manual and System Procedures conforming to cGMP and Regulatory needs. Establishing Vendor Qualification & Change Control System.*
- *Investigation of Customer Complaints and Salvage of Return Goods in coordination with the related departments. Reviews of Customer Agreements / Questionnaires.*
- *Reviews of Technology Transfer documents with GMP perspective, and facilitated technology transfer in close coordination with Process R&D and Production team.*
- *Ensuring the Critical Deviations and Out of Specifications recorded are investigated & resolved and Training Program implementation as per SOPs in coordinate with related dept's.*
- *Supporting to the 'Regulatory Affairs' team, by providing the Product data required for Drug Master File preparations / Annual updates and Technical information to Regulatory Bodies / Customers.*

~4 Years as EXECUTIVE CADRE:

- *Contributed in all QA & IPQA activities from Document Control to Product Release.*
- *Primary reviews of BPCRs / Change Controls / OOSs / Deviations / Customer Complaints / Returned Goods / Product Reviews / Process Validations etc.*
- *Preparation (Draft Copy) of Trending Reports / Minutes of Meetings / Management Reviews to evaluate of QMS activities. And, Quality Assessment Reports for Quality Systems and for all the APIs.*
- *Organizing the 'Internal Audits' as per the pre-schedules and monitoring of effectiveness of corrective & preventive actions taken.*

WORKED AT:

- *M/s. KOPALLE PHARMA GROUP OF IND. [Since 2023, as Quality Head]*
- *M/s. ENAL DRUGS LTD. (/Group of M/s. MSN Labs) [as General Manager - Quality & Regulatory]*
- *M/s. NATCO PHARMA LTD. [Asst. Manager - QA to Manager - CQA]*
- *M/s. AUROBINDO PHARMA LTD. [Trainee - QA to Sr. Executive - QA]*

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