20 years of rich experience in Pharma sector | ICH Guidelines

History of Achieving Operations Excellency | Supervise Analytical Work

Quality Management Systems | Internal and External Audits Compliance

Regulatory Audit Experience

USFDA - United States | ANVISA - Brazil | MHRA - UK

KARANKI ANKINEEDU PRASAD

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LinkedIn:
www.linkedin.com/in/ankineedu-prasad-karanki-28344823

Skills

- Quality Management System
- Audits & Compliance
- Handling of regulatory Inspections
- Software implementation & Qualification
- Corporate & Site Quality Assurance
- SOPs Preparation & Implementation
- Documentation
- DQA & AQA Activities
- Stability Management
- Vendor qualification and Site Audit

Languages

★★★★★ Telugu
★★★★★ English,
★★ Hindi,
★★Tamil
★★Kannada

Overall Experience

Syngene
Putting Science to Work — 04/2015 to date

1. Manager-Quality Assurance, **Syngene International Ltd.**

KEMWELL
KEEPING YOU COMPETITIVE — 08/2013 to 03/2015

2. Assistant Manager-Quality Assurance, **Kemwell Biopharma Pvt. Ltd.**

Dr.Reddy's — 07/2006 to 02/2011

3. Junior Manager-Quality Assurance, **Dr. Reddy's Laboratories Ltd.**

Nitya Laboratories Limited 05/2002 to 06/2006

4. Sr. Chemist-QC & QA, **Nitya Laboratories Limited**

Education

भारतीय प्रबंध संस्थान कोषिक्कोड
Indian Institute of Management Kozhikode
Globalizing Indian Thought
2023 - 2025

MBA from **Indian Institute of Management, Kozhikode.**

2000 - 2002

M.Sc. in Biochemistry from **Bharathidasan University, Trichy.**

1997 - 2000

B.Sc. in Biology (CBZ) from **Nagarjuna University, Guntur.**

Experience

Syngene International Ltd (Syngene Bristol Mayer squib Laboratory), Manager – Quality Assurance.

April 2015 – Present

I currently serve as Manager at Syngene International Ltd (Syngene Bristol Mayer Squib Laboratory), where I am responsible for overseeing and managing various aspects of pharmaceutical operations.

- Manage and coordinate pharmaceutical operations to ensure the efficient and timely production of high-quality products.
- Collaborate with cross-functional teams to develop and implement strategies to improve operational efficiency and productivity.
- Monitor and analyse key performance indicators to identify areas for improvement and implement corrective actions.
- Ensure compliance with regulatory requirements and industry standards.
- Provide leadership and guidance to team members to ensure the achievement of business objectives and targets.
- Change control in track-wise system: change control review, impact assessment, action items creation, and timely closure of change controls as per SOP and Customer quality agreement.
- Deviation control: Deviation investigation, review, and timely closure related to formulation &GMP; other cross-functional departments.
- CAPA: To manage /handle/close CAPA-related deviations, complaints, internal/customer audits, etc.
- OOS Investigation: Involved in the investigation of OOS as a part of manufacturing controls.
- Summary preparation for deviation, CAPA as per the defined frequency.
- Handling and investigations of OOT (Out of trend) results.

Kemwell Biopharma Pvt.Ltd,

August 2013 - March 2015, **Assistant Manager – Quality Assurance**

Previously worked as Assistant Manager at M/S Kemwell Biopharma Pvt.Ltd, where I played a key role in managing and coordinating various aspects of pharmaceutical operations.

- Conduct training programs in cGMP including the latest trends in cGMP and regulatory guidance updates using the LMS (Learning management system) application.
- Conducting SOP and Customer Quality agreement training for new joiners.
- Handling of Internal, External, and regulatory audits
- Maintenance and verification of lab compliance as per c GMP requirements and keeping the lab ready for any time audit.

Dr. Reddy's Laboratories Limited,

July 2006 to February 2011, **junior manager – Quality Assurance.**

- Handling of Change controls.
- Control of all master documents and ensure compliance with documentation control procedures.
- Ensuring the storage of executed documents organized as per good documentation practices.
- Reviewing analytical documents (IP / FP / method validations/method transfers/stability studies report.
- Handling of Finished product releases through SAP.
- Arrange necessary documents for finished product releases.
- Coordination with the QA / QC personnel at various manufacturing sites.
- Ensuring the compliance of stability management by the SOP.
- Investigation of abnormal events and deviations for temperature
- Updating and maintenance of stability sample tracker.
- Periodic risk assessment.
- Follow up with the engineering department for Stability chambers PMP and periodic calibration of the sensors.
- Supervise the analysis of stability samples within the window period.
- Review of stability compilation reports.
- Annual stability tracking.
- Ensuring the compliance of control sample management by the SOP.
- Monitoring the temperature and humidity of the control sample room.
- Arranging the sample and issue as and when required.
- Review of control sample as per the planner.
- Preparation of an annual review planner for the control sample.

- Coordination in the calibration of the data logger.
- Conducting vendor site audit and contract testing labs as per the schedule.
- Coordination with SCM to get the necessary documents from the vendor.
- Preparation of approved vendor list.
- Maintenance of vendor full details.
- Tracking and maintenance of vendor site audit due date.
- Quality review of incoming materials from vendors.
- Vendor comparison for alternative vendors.
- Review of artwork for printed packing materials.
- Coordination for regulatory submission of stability exhibit batches.
- Conducting annual product quality reviews.
- Update SMF as per current requirements.

Nitya Laboratories Limited,

May 2002 - June 2006- **Sr. Chemist – Quality Control & Quality assurance**

- Performed chemical analysis and testing of pharmaceutical products to ensure quality and compliance with regulatory requirements.
- Sampling and analysis of raw materials.
- Analysis of in-process and API samples by HPLC, GC, Polari meter, and KF titration.
- Conducted investigations into quality issues and implemented corrective actions.
- Supported process improvement initiatives to optimize operational efficiency and productivity.

Trainings Attended

- Three-day workshop on “QMS Internal audits” by PQMC PVT.LTD, Mr. Samba Siva Rao.
- Training on “cGMP” By Mr. Sridhar Bala Subramanian.
- Training program on “non-conformities and containment” at Hotel Fortune, Hyderabad by ISPE.
- Various other trainings and workshops conducted in-house and by external agencies.

References

Vinayak Parameshwar Nayak
General Manager -Quality
Biocon Biologics Limited, Biocon park
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