

ABHIJEET S. NIKAM

Planner and implementer with multi-cultural experience in quality with hands- on experience in Quality control, Quality assurance and Development Quality assurance ,with strict compliance to statutory norms.

Profile Summary

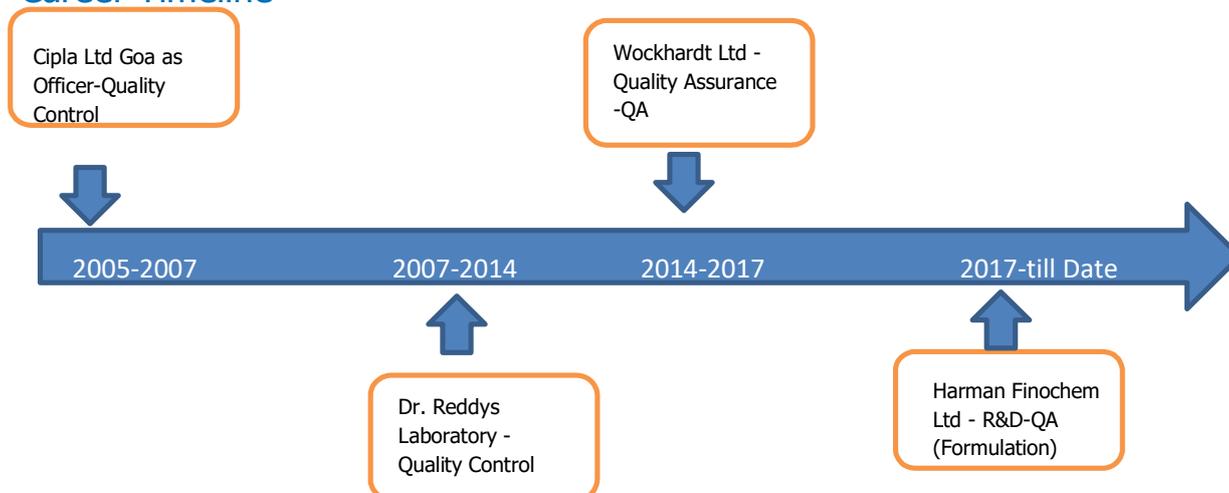
Effective planner, communicator and coordinator with strong analytical, problem solving skills

Personal Details

Date of Birth: 5th May 1983
Email: abhisn9280@gmail.com
Languages Known: English, Hindi and Marathi
Address: Flat No-C101, Harman residency, Shendra MIDC, Chatrapati Sambhajinagar
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- A result-oriented Professional offering over 19 years of extensive experience in managing the Quality control, QMS and entire Quality functions of manufacturing unit
- Proficient in Quality functioning such as QMS, Training, Quality remediation, Analytical Method Development, Method Transfer and Method Validation, Vendor management, CSV, investigation, Qualification of Equipment and Instrument and stability management.
- Providing technical support to manufacturing facilities and Third party manufacturing
- Skilled in providing direction to quality control, inspection systems; taking CAPA measures and reporting procedures
- Excellence in managing the entire product development process with quality adherence, conducting various tests and inspections to ensure compliance with pre-set quality specifications
- Capable of ensuring optimal utilization of resources, undertaking process initiatives to enhance efficiency and productivity and implementing quality standards
- Involve in supplier/Vendor qualification process and initiating audit request

Career Timeline



Core Competencies

Plant Quality Control

Quality Management System

Project Planning & Execution

Service Delivery

Audits & Compliances

Cross-functional Coordination

Budgeting & Cost Optimization

Relationship Management

Organizational Experience



Harman Finocem Ltd. Manager, Head QA -R&D

May'17-til date

Key Result Areas:

- Spearheading a team of 5; managing the entire of quality activities of the R&D and customer query related to dossiers support, compliance of regulatory audits, stability management and employee training on quality guidelines
- Quality compliance support to the project teams.
- Participate to execute customer audits and internal audit and vendor management.
- Work experience in Green field project as set up of new formulation R&D.
- Ensure all formulation and analytical developments will have executed as per regulator Norms.
- Complete review of documents generates to support ANDA filling for completeness and accuracy.
- Involve in investigation of OOS and OOT and technology transfer documentation preparation and review.
- Technical review all analytical method development report, product development report and method validations with current regulatory guideline.
- Tracking regulatory Commitment and execution of project management.
- Self-inspection and participation in internal quality audits.
- Implementing the quality system policies in the company at R&D-Formulation.
- Contributing towards the seamless interface & performance of IQ, OQ, PQ and calibration of equipment/instrument
- Implementation and involve to perform CSV of chromatographic and non-chromatographic system
- Review and drafting of Standard Operating procedure (SOP), Guidelines and policies

Significant Accomplishments:

- Established a new analytical and formulation development Lab.
- Played a key role in review the compilation of dossier related documents.
- Implementation of Document management system (Caliber DMS)

Wockhardt Ltd., Aurangabad

June'14-May'17

Growth Path:

June'14-July 15- as Sr. Executive-Lab-QA

July'15-May'17 as Assistant Manager -R&D-QA

Key Result Areas as Assistant Manager Analytical-QA:

- Monitor overall quality system R&D (Global Technology Services UK)
- Involve in remedial action to review retrospective method validations and method transfer activities.
- Interfaced with Regulatory Affairs Department for data sharing
- Worked in Emerging market registration of key products in 47 markets.
- Prepared responses to regulatory queries received from different regulatory agencies Directed the investigations of lab agencies, OOT, OOS results as per respective SOPs





Dr. Reddy's Laboratories Ltd., FTO-3 Hyderabad

March'07-May'14

Growth Path:

March-07- Jan-08 as Sr. Executive–Stability

Jun-08- June-11 as Jr Manager – New product Launching

Jun-11- May-11 as Team Leader (AM) – New product Launching

Key Result Areas as Team Leader-New Product Launching:

- Spearheading a team of 12;
- Technically evaluation New Product w.r.t analytical Methods and process.
- Global Analytical method transfer of finished product for Assay, Dissolution and Related
- Substances tests etc.
- Planning and Execution of Stability sample, Finished Sample and In-process validation sample
- Handling of Out of Specification (OOS), Out of Trend (OOT), Quality Impacting/Non impacting incident documents.
- Increased the output of Quality Control department for day-to-day activity like analysis of
- Blend, Finished, Stability, In-process and validation samples.
- Preparation and Review Master Documents like Stability Specifications, stability Protocols, stability Schedules, and summary reports all batches of different products.

Previous Experience

Cipla Ltd, Goa as Officer - Quality Control

June'05-March'07

- Analysis of Raw material, in-process, Finished samples and stability as per procedure.

Academic Details

- **MBA (Total Quality Management)** from Sikkim Manipal University in 2013
- **Masters in Science (Analytical Chemistry)** from Shivaji University Kolhapur Maharashtra in 2005
- **B.Sc. (Chemistry)** from Y.C collage of Science Karad, Maharashtra in 2003

Achievements Details

- **Approved Technical Staff As per drug cosmetics act 1940**
- **Two-month work experience in Dr. Reddy's laboratory UK.**

Skill Set

