Suyog Janakray Shah

C-PH03 Pacifica Reflections Vaishnodevi Circle, Ahmedabad, Gujarat 382421.
Mobile No. 9574151116, 9823628720

Objective:

I wish to have a career which Employs my skills and expertise fully, which exploits my potential to its maximum, which does not let me stagnant but help me evolve as a better QA professional in a dynamic and progressive pharmaceutical company throughout my career.

Job Profile Summary:

- Dynamic career of **23 years** that reflects rich experience & year-on-year success in **Corporate Quality Assurance, Quality Assurance** and **Quality Control** across **Pharma/Healthcare** Sector
- Experienced in **EU-MDR, IMDR-2017, MDD, ISO 13485:2016**, **cGMP** and **regulatory environment**
- Skilled in review & approval of:
  - All quality critical documents BMR, BPR, Stability studies, Validation, Calibration, NC, CAPA, Deviation and Complaint Handling.
  - Specifications, COA's and Standard Operating Procedures (SOPs)
  - Changes that potentially impact product quality (change control management)
- Proven excellence in data integrity by challenging & implementing Validation and Quality Assurance Strategies through risk-based evaluation
- Prepared internal & corporate quality documentation & reports by collecting, analyzing and summarizing trends for recalls of aseptic and microbiological query and providing response to regulatory agencies
- Successfully examined the operational practices, identifying the areas of obstruction / quality failures and advising on system as well aseptic practices and process changes for qualitative improvement and cost and energy conservation
- Proven record of establishing processes & SOPs, streamlining workflow and creating healthy environment to enhance productivity & quality
- A forward thinking person with strong communication, analytical & organizational skills; well organized with a record that demonstrates self-motivation & creativity to achieve corporate quality goals
- Stability Study as per ICH, WHO and ISO guidelines
- Audit Faced: EU MDR, ISO 13485:2016, 510K registration, KFDA, ANVISA, WHO-GMP, Various Vendor Audit**.**
- Handling Market Complaints

Work Experience and Job Responsibility:

Since May 2017 Till date: Biotech Vision Care Pvt. Ltd. Ahmedabad as QA Asst. General Manager

- Implementing QMS System, EU MDR Implementation,
- Audit exposed: EU MDR, IMDR-2017, WHO GMP, ISO 13485: 2016, CE Certification, 510K Registration, ANVISA, KFDA, Various vendor Audit.
- MDR Implementation
- Design Dossier, Technical file updating for CE marking and US FDA
- Reviewing and approval of QA related documents like SOP, RMS, PMS FG Specification, SCP`s
- Handling of customer audits, Regulatory audits & CAPA related audits.
- Reviewing and verifying Validation Master Plan`s.
- Handling Stability study as per ICH, WHO and ISO guidelines
- Handling of non-confirming products, CAPA, Re-call.
- Handling of rejected and recalled materials, products OOS & OOT.
- Core committee member of EHS and implementing related procedures
- Preparing site master, file ISO documentation, Biocompatibility of products etc.
- Process validation, Test method validation and Analyst qualification.
- Product Artwork design and developments.
- Handling Supplier Quality Management
- Reviewing documents, validation protocol, reports, & batch records.
- Handling of Market Complaints

Since March 2013 to April 2017: Meril Endosurgery Pvt. Ltd. as QA Manager –

- QMS Implementation
- Regulatory approval for Site Plan, Drug License & Mfg. License etc.
- Design Dossier, Technical file updating for CE marking and US FDA
- Reviewing and approval of QA related documents like SOP, RMS, PMS FG Specification, SCP`s
- Handling of customer audits, Regulatory audits & CAPA related audits.
- Reviewing and verifying Validation Master Plan`s.
- Handling of non-confirming products, CAPA, Re-call.
- Handling of rejected and recalled materials, products OOS & OOT.
- Core committee member of EHS and implementing related procedures
- Preparing site master, file ISO documentation, Biocompatibility of products etc.
- Process validation, Test method validation and Analyst qualification.
- Product Artwork developments.
- Reviewing documents, validation protocol, reports, & batch records.

Since April 2005 to March 2013: Johnson & Johnson limited, Ethicon Division Aurangabad. as QA Executive–

- Responsible for making and reviewing SOP's SCP's & QAP's.
- Quality Management System Documentation.
- Artwork Approval
- Validation and Calibration of entire QC Instrument
- Residual Ethylene Oxide testing on GC, Triclosan determination on Drug coated suture.
- Market Complaint Handling Process
- Handling Supplier Quality Management
- Stability Study as per ASTM, ISO and ICH Guideline
- GTIN Implementation Project
- Annual Product Summary Report

- Environment, Health and Safety
- Testing of Sutures, Needle & Packaging Material.
- Exposed to Audits: RE: TUV Surveillance Audit - ISO 9001:2000 & ISO 13485:2003, QCS Assessment

➢ **Since Mar 2002 to March 2005: Macleods Pharmaceuticals Pvt Ltd. As a QC Officer**

- Responsible for analysis of raw material, finished product & related documentation.
- Preparation of working standards, primary standards & its protocol preparation.
- Stability Study: Conducting stability study Real-time and Accelerated stability study.
- Validation: Retrospective validation, Method validation & Cleaning validation
- Documentation: Preparation of SOP & RMS.
- In process Testing: In process testing of tablets, liquid orals, dry syrups & capsules.
- Exposed to Audits: FDA WHO Geneva

➢ **Since Sept 1999 to Feb 2002: INDOCO Remedies Pvt Ltd. As a QA Officer**

- Responsible for analysis of raw material, finished product & related documentation Preparation of working standards, primary standards & its protocol preparation.
- Stability Study: Conducting stability study Real-time and Accelerated stability study.
- Validation: Retrospective validation, Method validation & Cleaning validation
- In process Testing: In process testing of tablets, liquid orals, dry syrups & capsules.
- Documentation: Preparation of SOP & RMS. Exposed to Audits: FDA WHO Geneva, Uganda, and Sanavita, Ghana. Etc.

❑ Educational qualification:

- M.Sc. (Analytical Chemistry) From North Maharashtra University 1999-2000
- B.Sc. (Chemistry) From North Maharashtra University 1995-96

❑ Training and seminar and certified course

- Certified ISO Internal Auditor ISO 13485:2016 (SGS)
- Certified EU MDR Implementation (SGS) and (BSI)
- Certified Medical Device Risk Management as per ISO14971:2019(SGS)
- Certified RCA, 7 QC Tools Training (DNV)
- Approved in Chemical & Instrumentation from FDA Maharashtra.

❑ Personal Details:

Name : Suyog Janakray Shah

Date of birth : October 21st 1976.

Languages Known : English, Hindi, Gujarati & Marathi

Marital Status : Married

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Place: Ahmedabad
Date: 12th July 2023 **Suyog Shah**