NILESH R KHULE

Curriculum Vitae

NILESH R. KHULE

M. Pharm. (P'ceutics)

Sr. Executive (CQA)

+919890897349

nileshkhule20@yahoo.com

GMP AUDITS EXPERIENCE:

USFDA, MHRA, TGA,
WHO Geneva

EDUCATION:

M. Pharm., Pune University
B. Pharm., Pune University
H. S. C., Pune Board
S. S. C., Pune Board

PERSONAL PARTICULARS:

DOB: June 05, 1989
Marital Status: Married

Address: Flat no. 301, 3rd floor, Pratham Plaza, Sector 9, Airoli-400708, Navi-Mumbai.

APPROACH:

Quality Assurance professional with M.Pharm degree and 8 years of experience in Site Quality Assurance, Corporate Quality Assurance, Validation, Audit Compliance, Audits (internal and self), QMS, IPQA and Quality management/systems.
Looking for an organization where I can utilize my skills and expertise to achieve projects from conception to completion.

SKILL:

Hands on System: **SAP** (Implementation, Development, Validation), Minitab 17 application.

Hands on Area: **CSV** (Mfg. & R&D), Manufacturing Batch card review & Release, Audit preparation & Compliance, APQR, Validation and CQA Documentation.

WORK EXPERIENCE:

- ✓ **Tevapharm India Pvt. Ltd. Mumbai -** Senior Executive - CQA
  Jul 2018 to Present Date
- ✓ **M/s Ajanta Pharma Limited, Dahej (Gujrat) -** Officer - QA
  Dec 2015 to Jun 2018
- ✓ **M/S Emcure Pharmaceuticals Ltd., Pune -** Officer - QA
  Sep 2014 to Dec 2015
- ✓ **M/S. Milan laboratories (I) Pvt. Ltd.** - Officer QA
  May 2013 to Sep 2014

KEY SKILLS:

- **Batch Release**: Batch card review, compliance, release slip, SAP / ERP release.
- Quality Management review of GMP documents for regulatory filling and submission.
- Compilation and Review of APQRs and CPV execution team for Canada and US based client (Review of Batch disposition/Release status, Change Controls, Investigations, QTA, and Stability Reports etc.).
- Responsible for handing **QMS** activities.

- Hands on **SAP** (**SAP S4 HANA 1511**)**:**- Development, Qualification, Implementation, **CSV** Validation.
  CSV: GxP system knowledge, GAMP5, 21CFR Part 11 software validation, prepare CSV lifecycle document/ qualification protocols (like URS, FRS, FRA, DS, IQ, OQ, PQ, RTM) preparing test scripts annexures. SAP CSV experience, Mfg. CSV, Laboratory CSV.
- Audit Preparation and compliance & follow ups, internal audit, Review & approval of documents like SOP, specification, APQR etc.
- Imparting on the job trainings to Production staff and IPQA team.
- Supervise and carry out the all IPQA activity for: Tablets, Capsules, Powder.
- Review and verify process documents stage-wise (BMR & BPR) & facilitates timely release of batches in SAP. Responsible for Process Validation.
- Hands-on experience in working with computer systems:
  - SAP system for documentation control.
  - LIMS (Caliber)
  - Hot Doc (for PQR management)
  - Oracle (ERP)
  - Track wise Harmony and 7 (Sparta System)
  - Knowledge tree (DMS software)
  - Fundamentals of computers, MS-DOS, MS-OFFICE, Internet concepts.

DECLARATION

I hereby declare that above mentioned information is true and to the best of my knowledge.

Place: Mumbai **Nilesh R. Khule**