KHAMAR SONALI A

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A DEDICATED PROFESSIONAL

A result-oriented professional with excellence in implementing quality mechanisms to deliver desired output
Seeking challenging assignments in **Quality Assurance** With an organization of repute

PROFILE SUMMARY

- **A dynamic professional** with 7.2 years of exeperince in Quality Assurance & 9 months of experience in ADL
- **Sucessfully faced** USFDA, MHRA, MCC, Regulatory Audit of Ministry of Health, Ukraine
- **Expertise in ensuring** compliance of various quality measures by maintenance of appropriate requisite documentation/ records
- **Skilled in coordinating** with QA / QC personnel at various manufacturing sites for implementation of the current / revised standards, testing procedures and specifications for new products
- **Deft in preparing** documentation of quality management system.
- **An effective leader** & planner with proven abilities in leading teams during the project phase and guiding team members and enabling knowledge sharing among the team

CORE COMPETENCIES

- Implementing quality tools to ensure process capability per specification requirements, monitoring by preparing control plan and implementing improvement and corrective action plan
- Preparing, coordinating, facilitating and following up process audit
- Developing quality plans and ensuring quality assurance for new products/equipment in manufacturing by inspection control in various stages, process control as per standard at various stages
- Maintaining the quality standards for incoming materials ensuring stringent adherence to quality standards, norms & practices
- Generating a framework of quality standards, procedures & systems and overseeing smooth implementation
- Reviewing SOP's/technical specifications/ batch manufacturing record / validation protocols, validation reports and other quality documents/ change-control procedures for SOPs

ORGANIZATIONAL EXPERIENCE

Currently work at Intas Pharmaceuticals Limited, Matoda as Executive- QMS department since June 2017

- To ensure the compliance of CGMP during processing activities.
- Co-ordination, monitoring & logging of Market complaint, OOS, Adverse rug reaction, Change request, Deviation and CAPA.
- Handling of Change request forms, deviation, market complaint, adverse drug event, vendor complaint, OOS/OOT investigation.
- Co-ordinating with other departments, regulatory agency, client/ MA holder/ PL holder for change request, deviation approval, Market Complaint investigation and OOS/OOT investigation.
- Preparation and review of SOPs related to QMS system.
- Review of manufacturing and packing related documents.
- Prepare trend for QMS i.e. Market complaint, Deviation etc.

Previously work at Nabros Pharma Pvt. Ltd., at Kajipura dist Kheda as Sr Executive - Quality Assurance Department from February 2016 to June 2017
Role:

- Preparation and reviewing process validation protocol & report
- Preparation and reviewing APQR
- Ensuring the fill up Change Control, Deviation & Non Conformance Report
- Evaluating Master Formula & Batch Manufacturing Record
- Managing the IPQA activity in semisolid formulation
- Responsible for executing the process validation at each process stage
- Handling of SOP & Instrument Qualification
- Handling of qualification documents
- Handling self inspection and its documentation

Previously work at Divine Life care Pvt. Ltd. Plot No.220, At Moraiya, TA-Sanand, Dist-Ahmedabad as Executive - Quality Assurance Department From December 2014 to February 2016
Role:

- Preparation and reviewing process validation protocol & report
- Preparation and reviewing APQR
- Ensuring the fill up Change Control, Deviation & Non Conformance Report
- Evaluating Master Formula & Batch Manufacturing Record
- Managing the IPQA activity
- Responsible for executing the process validation at each process stage
- Handling of SOP & Instrument Qualification
- Handling of qualification documents

Previously work at Nabros Pharma Pvt. Ltd., at Kajipura dist Kheda as Executive - Quality Assurance Department From May 2013 to December 2014
Role:

- Evaluating Master Formula & Batch Manufacturing Record
- Managing the IPQA activity of Semisolid
- Responsible for executing the process validation at each process stage
- Overseeing issuance and reviewing documents
- Ensuring the fill up Change Control, Deviation & Non Conformance Report
- Handling of SOP, Market Complaints, Vendor complaints & Instrument Qualification

Previously work at Baroque Pharma Pvt. Ltd., Khambhat as officer - Analytical Development Department From June 2012 to Feb 2013
Role:

- Carried out method development & validation for Bulk Drug & Pharmaceutical Products
- Conducted stability study of pharmaceutical products
- Developed and reviewed Stability Study Protocol
- Performed comparative dissolution profile study for pharmaceutical dosage form
- Created written reports & other documentation relating to projects being carried out
- Optimized the method development for new products into the developing facility for finished product & completed the required method validation according to standards
- Accountable for evaluating analytical data during product development

IT SKILLS

- SAP, Q-EDGE, Microsoft Office (Word, PowerPoint, Excel & Project) and Statistical Analysis (Graph Pad in Statistics).

KNOWLEDGE PURVIEW

- HPLC, (Shimadzu) & UV-Visible Spectrophotometer (UV-Shimadzu 1700& 1800)
- FTIR, Colorimeter, pH Meter & Conductometer
- Dissolution & Disintegration Apparatus
- Roche Friabilator

EDUCATION

- **M.Pharm. in Quality Assurance** from Ramanbhai Patel College of Pharmacy, Charusat, Changa with 8.46 CGPA in 2012
- **GPAT in** 2010
  - *Achieved All India Rank of 1628*
- **B.Pharm. from** L.B.R.I.P.E.R Khambhat, Gujarat University with 67.6% in 2010
- **D.Pharm.** M.N.C.P., Khambhat, Gujarat University with 68% in 2007

PROJECTS HANDLED

- Development & Validation of Stability Indicating RP-HPLC Method for simultaneously estimation of Citicoline Sodium & Piracetam in Bulk Drug and Pharmaceutical Dosage Form at RPCP, Charusat, Changa
- Development & Validation of Spectrofluorophotometry Method for estimation of Citicoline Sodium in Bulk Drug and Pharmaceutical Dosage Form

PAPER/PRESENTATION

- **"Supercritical Fluid Chromatography- Mass Spectroscopy"** at AVALANCHE '12 held at Ramanbhai Patel College of Pharmacy, Charusat, Changa

PERSONAL DETAILS

Date of Birth:	4th October 1987
Languages Known:	English, Hindi and Gujarati
Permanent Address**:**	J/575 Shejpari, Khedawala ni pole , Khambhat.
Present Address:	B-103, Tirth apartment, Opposite Devine life school, narol lambha road, Narol, Ahmedabad, 382405.