**SIDDHESH SUTHAR**

**ASSISTANT MANAGER**



**About Me**



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24 August, 1983



Total 12 Years experience



siddheshsuthar@gmail.com



Khambhat, Anand, Gujarat

* Pharma professional (B.Pharma.) with 9+ years of experience in Quality Assurance department.
* More than 5 years of experience of working in regulatory approved plant.
* Exposure of various regulatory audits (USFDA, MHRA, ENVISA, etc)
* Exposure of various documentation SOPs, Batch documents, protocols, stability studies, etc.
* Highly trustworthy, ethical, and discreet; committed to give best performance. Motivated, self-starter and successful professional with abilities like decision making, attention to detail, maintaining team, strategizing and executing work plans under tight timelines.



**Education**

* **B.Pharma (Pharmacy)** 2005 APMCCPER, Himmatnagar HNGU, Patan 64%
* **Class XII (Science)** 2001 My Own High School, Himmatnagar Gujarat Board 77%
* **Class X** 1999 Modern High School, Himmatnagar Gujarat Board 87%



**Work Experience**

**Assistant Manager - Quality Assurance From Jun 2017 - At Present**

**Baroque Pharma Pvt. Ltd. Khambhat, Anand, Gujarat, India**

* Planning and implementation of Quality system / GMP system at New Cephalosporin Plant
* Qualification activities for Facility, Utilities, Equipments, etc.
* Documentation such as SOPs, Policies, Study protocols, etc.
* Trainings, Technology transfer and other activities for New Cephalosporin Plant
* Monitoring, supervision and review of all types of cGMP validations (Equipment, Instrument, Facility, HVAC and Water Systems, Process and Cleaning Validation) and maintaining all documents as per cGMP.
* Self inspection, Annual Product Quality Review, Stability studies, retain Sample management and taking corrective action on noncompliance.
* Implementation and monitoring quality systems such as Change controls, Deviations, market complaints, investigations, CAPA, risk assessment and other related QMS related activities.
* Handling regulatory and customer audits, observations/queries & its compliance Management.
* Monitoring of IPQA activities such as Granulation, Compression, Coating, etc.
* Document control activities for SOPs, Specifications, Methods, Formats, etc.
* Vendor/ supplier evaluation and qualification

**Executive – Quality Assurance** **From Feb 2012 - May 2017**

**Intas Pharmaceuticals Ltd. Pharmez, Ahmedabad, Gujarat, India**

* Stability batches tracking for different countries through Change control procedure, Deviation, SAP transactions & RTD, etc.
* Review of stability study protocols, data reports-summaries-trends, post approval commitment, etc.
* Communicate and Co-ordinate with regulatory department for timely submission of stability related documents.
* Review of documents like, change controls, SOPs, Incident reports, OOS, CAPA reports and PQRs.
* Supervising routine activities like charging, withdrawal, reconciliation and destruction of stability samples, etc.
* Execution of Quality system, qualification, calibrations, maintenance, etc.

**Officer - Quality Assurance From Feb 2010 – Jan 2012**

**Yash Medicare Pvt. Ltd., Himmatnagar (SK), Gujarat, India**

* IPQA activities such as line clearance, Material verification, Start up and samplings to ensure compliance of GMP during manufacturing and packing
* Preparation and review of documents like BMR, BPR, SOPs, Calibration records, Validation records, etc.
* Sampling of RM, PM and Finish Goods, etc.

**Officer - Clinical Research From Jun 2006 – Feb 2009**

**Claris Lifesciences Ltd., Ahmedabad, Gujarat, India**

* Project management activities to get the scientific and ethical clinical studies completed on time (under the guidance of Head of department) to support the product registrations,
* Clinical trial site selection, site monitoring and close-out visits,
* Document preparation include Clinical Study Protocol, CRFs, IBs, ICDs, Study Reports, Clinical and Non-clinical summary reports, SOPs, etc.,
* On-line medical and clinical databases/literature searching for preparation of such documents,
* Work closely with the Regulatory Affairs Departments to support their needs for documentations.

**Production Chemist From Jul 2005 – Jun 2006**

**Salus Pharmaceuticals., Himmatnagar (SK), Gujarat, India**

* Preparation of advance monthly requirement of Raw Material, Packing Material etc. in rough format.,
* Take production as per mention Master Formula Card,
* IPQC Activities, BMR/ BPR preparation,
* Provide daily production report to the production manager,
* GMP Documentation for fumigation, cleaning, calibration, trainings, SOPs, etc.,
* Testing of non-perail sugar seed.



**Other Details**

* **Languages Fluency :** English, Hindi, Gujarati.
* Male, Married
* **Father’s Name :** Arvindkumar R Suthar
* **Skills :** Ability to work on multiple tasks; Learning behavior at all times; Self motivated with strong interpersonal communication skills.
* **Reference** : Produced If Required
* **Declaration :** I hereby declare that the information given above is true to the best of my knowledge.

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Siddhesh Suthar