ANKIT SONI

QA MANAGER- Audit and Compliance & CSV Specialist.

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| |  |  | | --- | --- | | Quality oriented motivated QA manger with total 12.5 years of experience establishing high quality standard and procedure, ensuring regulatory requirement are accurately executed and monitoring different process.  **PROFESSIONAL EXPERIENCE**  **QA MANAGER- *DISHMAN CARBOGEN AMICS LTD* (MAY-2020 TO TILL DATE)**   * Preparation of **Audit compliance report of ISO:13485/ISO:9001** and submit to respective agency. * Handling and review of Documents related to **Disinfectant (Medical device)** and **Soft gelatin capsule** its Quality documents. * Establishment of New **Quality Management system** with its compliance. * Review of **Equipment/Utility qualification reports** (DQ/IQ/OQ and PQ). * Assessment of Investigation reports i.e. **Deviation, Market complaint, Laboratory incident, Process investigation.** * Handling of **Internal audits** (self-inspection) in manufacturing areas. * Review and approved **Corrective and preventive actions (CAPA); includes tracking, follow up and reporting/trending** and evaluating CAPA for effectiveness. * Review of all **product, facility and equipment etc. of change control** and impact assessment. * Leads the identification and implementation of improvement opportunities for issues related to **Change control, CAPA, investigations.** * Working with all departments to guide the timely completion of **CAPAs relates change control, deviation, investigation** or any other documents.     **QA ASSISTANT MANAGER- ZYDUS *CADILA HEALTHCARE LTD* (JAN-2016 TO MAY-2020) [USFDA,ANSM, ANVISA ,WHO APPROVED PLANT]**   * Handling of **compliance activity in Tablet manufacturing** and   packing activity.   * Handling of **Regulatory, Customers and External SME Audits.** * Preparation of **Audit compliance report** and submit to   respective agency.   * Tracking and **follow up of logged CAPA in track wise** and   verification of CAPA effectiveness check.   * Handling of **Internal audits (self-inspection)** in manufacturing   areas.   * **Computer System validation, Data integrity, CSV Qualification**, Change management through Trackwise. * Works closely with **operations, facilities, manufacturing, automations, validation** and engineering to resolve open issue resulting from **equipment failures, issues and QMS** records reviews. * **Computer System Validation** development for Trackwise   Application for **Change control,CAPA and Market complaints**.   * Preparation of **Quality matrix data** and submit to   Management at monthly.  **QA EXECUTIVE- FAMY CARE LTD ( A DIVISION OF MYLAN LABORATORIES LTD) (OCT-2014 TO DEC-2015) [USFDA APPROVED]**   * To Review of **Filled Batch packaging records** of Tablets   packing.   * To perform **IPQC in Tablets packaging area** (Primary and   secondary) packing line.   * To verify **sequential log cards, machine records and**   **performance check records** of equipment.   * To rise daily **observation and incidence report** and its follow   up for compliance.   * To give **line clearance in all respective area of Tablets**   **packing areas** (Primary and secondary packing line).   * Handling of **Market complaints for packaging** related   Investigation activities.  **QA EXECUTIVE- *TORRENT PHARMACEUTICAL LTD* ( JUL-2009 TO OCT-2014) [ USFDA,ANVISA,MHRA,MCA APPROVED PLANT]**   * To handle change control and other document related to **change control such as those of validation, dissolution profile, stability and review** the change control before closing * To prepare the quarterly review **trend analysis for change control** every quarter to review the trend of open/close CRF for further monitoring. * To Review **of Filled Batch manufacturing records** of Tablets and Capsule. * To perform **IPQC in Tablets and capsule** manufacturing area. * To perform the sampling of **inprocess blend, stratified sampling and finished product** at Manufacturing stage. * To take IQA (internal Quality Audit) and impart training Programme in concern department. * I have also knowledge about **SAP, LIMS, Documentum & Trackwise** in Product batch release and other transaction in QA. * To Prepare **Annual Product Review** and Handling of Retained Samples. * Actively involved in **Trackwise implementation (Development phase)** for Change control, CAPA at site. * To give line clearance in all respective area of Tablets and manufacturing.   **DECLARATION**: I hereby declare that the above-mentioned information is true to the best of my knowledge.  Ankit P.Soni | CONTACT DETAIL D401 Shyam Elegance,B/h Gopi restaurant,Anandnagar road,Prahaladnagar,Ahmedabad-380015. Gujarat, INDIA.  Mobile:+91-9712904356  [ankitsoni2013@yahoo.com](mailto:ankitsoni2013@yahoo.com) SIGNATURE SKILLS  * Change management * Risk assessment review * Regulatory response preparation i.e. USFDA,ANSM,ANVISA,   WHO.   * Audit management * Batch record review * Project Management * Training * CSV/GAMP5 * 21 CFR Part 11.  EDUCATION **2007-2009** Master Of Pharmacy ( Quality Assurance)- SSPC Pharmaceutical science & Research, Gujarat. **(First class)**  **2001-2006** Bachelor of Pharmacy, APMC college of Pharmaceutical Science,Gujarat **(First Class)** PROFESSIONAL DEVELOPMENT Trackwise Management ( 2016-17) Zydus Cadila,  SAP Basic Management,  Lead Auditor for Self inspection Audit. TECHNICAL SKILL ISO13485 Audit Management  Audit management,  Trackwise Development,  SAP,LIMS,Documentum, Audit Portal, Response review, Investigator,CSV and GAMP5. AUDIT FACED USFDA-2014,2016-17,2018,2019.  ANSM-2016,2019  ANVISA-2018  WHO-2016,2017.  COFEPRIS-MEXICO-2017  LACHMAN-2016,2019  5WS-2016,2017,2019  **Project:**   1. Simultaneous Estimation of Pioglitazone and its hydroxyl metabolite from Human blood plasma by using LC-MS/MS method at Torrent Research Centre, Gandhinagar.   Duration: Six months   1. Trackwise Qualification and its implementation at Zydus Cadila (Yr.2016**)** with coordination with Sparta Team Chennai.  REFERENCE: Mr.Mihir Zaveri  Sr.Manager  Cadila Healthcare Ltd.  Moraiya,Ahmedabad  M)9825245018  Email- mihir.zaveri@zyduscadila.com | |  |  | |