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| **Ankit Porwal**  **G-201, Hariom Elegance Godhavi**  **Ahmedabad, Gujarat 382115**  **Phone: 800 043 7142**  **E-Mail: ankit.porwal83@gmail.com** | |
| **Area of Expertise**  Corporate Quality Assurance  Quality Review & Supervision  Quality Control Operation  Audit and Compliance  QC Oversight & Data integrity  Investigations (OOS/Incident)  Training management  Stability  Method validation  QMS documentation  **Experience: 14+ Years**  **Executive Qualities**  Efficient trainer  Ability to think differently  Solution oriented  Process simplification in Quality control  Team building & management  Strong in follow up, lead to target completion  **Performance Excellence:**  Participate in LIMS 3.4.0 E updated version with paperless facility successfully implemented at 04 sites (Zydus Life Science Ltd- Baddi, SEZ, Topical and ZAHL sites).  Participate in Chromeleon 7.2 ver. updated version successfully implemented at all respective assigned sites.  Participate in Quality Control lab setup with all compliance at **ALIDAC -Yangon (Myanmar).**  **Technical Approval**  Approved Chemist by Food & Drug Control Administration, Gandhinagar, Gujarat State under the **license No. G/1486 & G/1081** (section: Chemical and Physio Chemical Testing).  **ACADEMIC:**  M.Sc. (Biotechnology) | **PERSONAL SUMMARY**  High performance pharmaceutical professional, having more than 14+ years of progressive experience, with a focus in the area of Quality Control, Corporate and Quality Assurance. Well versed in Conducting Audits Audit’s preparations & management, compliances, SOP’s gap assessment, Change Control/Deviation management, Investigation management (OOS/Lab Incidents/OOC), Corrective and Preventive action, Stability of Drug Product/Drug Substance, Method Validation and Transfer & training management etc. |
| **WORK EXPERIENCE**  **1. Zydus Life Science Limited, Ahmedabad**  **Associate Manager – Corporate Quality Assurance (Analytical Assurance)** May 2015 – till date   * Review of QMS document e.g. Change control / CAPA /Deviation, Laboratory failures i.e. OOS, OOT, OOC, Incidents, etc. * Review of investigations and supported for hypothesis for root cause identification. * Track release status of different sites and follow up weekly. * Review of Stability Protocol, Hold time study sheet and Stability Summary sheet before regulatory Submission. * Tracking of CAPA for different site and its implementation. * Conducting audit for the different sites of Zydus Cadila Healthcare and vendor. * Prepare the sites for the Audits and Audit management. * Gap assessment between Quality Policies and Plant SOPs, prepare the Quality Policies. * Review of analytical data of Exhibit Batches before Regulatory Submission. * Review of other company’s FDA 483’s and Warning letter observations and ensure compliance at site by providing training. * Assist for continuous improvement of Lab documentation system to increase efficiency and cGLP/cGMP compliance. * Participates in Management Review Meeting and Quality Team Meetings. * Participating in regulatory inspection e.g. USFDA and various other agency/customer audits. * Participating in designing and finalizing Quality Policy, Global CAPA tracker and its implementation. * Accountable for Data integrity review and QA oversight for QC department. * Operating Trackwise (for QMS documentation), Documentum (for Document management) and Zytims (for Training and Analyst qualification management) software.   **QUALITY EXCELLENCE:**  To support QC Laboratories under CQA sites to maintain lab compliance as per current GMP requirements and regulatory commitments.  **QC COMPLIANCE:**  Visit at sites for compliances & upgradation of software: To support laboratory investigation and compliance verification.  Visit to CQA sites.   * Zydus Life Science Ltd. -***Baddi*** * Zydus Life Science Ltd. – *(SEZ- Matoda)* ***Ahmedabad*** * Zydus Animal Health and Investments Ltd. – (*SEZ- Matoda)* ***Ahmedabad*** * Zydus Life Science Ltd. –*Topical* ***Ahmedabad***   **Training management:**   * Ensure the training management of the site employees with respect to analyst Qualification Reviewer Qualification and its completeness of the training documents using Zytims Software **(Training Management).** * Ensure the 100 % annual training matrix and its categories of respective areas of the site Quality employees. * Participate in regulatory and internal audits and its compliances.   **QUEST:**   * Participate the Quest Activity and generate the Quality Related Ideas.   **SLIM:**   * To prepared the ramp up plan for SLIM Ideas and presentation. * Ensure the implementations of Quality Related Quest and SLIM ideas. * New Quality initiatives and ensure the implementation there of. |
| **SOFTWARE HANDLING:**   |  |  |  |  | | --- | --- | --- | --- | | **Laboratory Software** | | | | | LIMS 3.4.0 E | Chromeleon (7.2) | Lab solution | Tiamo Software | | SAP | Documentum | Trackwise**®** (CAPA / Market complaint / Change control/OOS/OOT) | | | **Management Software** | | | | | Zydus Portal | SLIM Portal | **Zytims (Training Management)** | | | Darwin box | Spectra | Zylearn- training software | | |
| **2. Rexcin Pharmaceuticals (Sun Pharmaceuticals Ind. Ltd.) Baddi, Himachal Pradesh**  [**Quality Control - Sr. Officer** (September 2011 to May 2015)]   * Work as a Reviewer to achieve the Target without compromising any Quality Parameter. * Execution of internal audits at Rexcin Sites. Identify gaps and improvement opportunities in existing systems. * Support Ranbaxy sites during regulatory audits, customer audits and its compliance. * Preparation and reviews of audit reports. * Review of Audit compliance reports. * Planning of In-process Samples for Analysis (Like Injection, Tablets, Liquid, Cream, ointments.) with proper communication & Co-Ordination with analyst. * Planning of Raw Material Samples for Analysis (Like-API & Excipients). * Departmental review of analytical documents. * Responsible for investigation of OOS, OOT and Laboratory incidences. * To coordinate with regulatory affairs as and when required. * Routine GLP Maintenance in the laboratory. |
| **3. Pfizer India Limited Haridwar, Uttarakhand**  [**Quality Control Analyst –Officer** (March 2007 to September 2011)]   * Analysis of Raw material, Packing Material, finished Product and Stability samples. * Release the samples after analysis in SAP. * Calibration of Laboratory Instruments. * Preparation and review of SOP and other QC related documents. * Preparation of working Standards and maintaining records, Chemical Inventory. |
|  | **EDUCATION CREDENTIALS**   |  |  |  |  | | --- | --- | --- | --- | | **Sr. No.** | **Class** | **College / School / Organization** | **Year of Passing** | | 1 | Master of Science (Biotechnology) | Jiwaji University Gwalior, MP | 2005 | | 2 | Bachelor of Science | CSJM University Kanpur, UP | 2003 | | 3 | 12th Class | UP Board, Allahabad, UP | 2000 | | 4 | 10th Class | UP Board, Allahabad, UP | 1998 |   **PERSONAL DETAILS:**   |  |  | | --- | --- | | Date of Birth | 5th Nov 1983 | | Nationality | Indian | | Sex | Male | | Marital Status | Married | | Language Known | English, Hindi,  Gujarati (reading and understanding) | |
| **DECLARATION**  I hereby declare that the above-furnished particulars are true to the best of my knowledge and belief. If given chance, I will prove my efficiency, loyalty & willingness to work in a good environment.  **Ankit Porwal** | |