**SAMIR GIRISHBHAI PATEL**

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**EXECUTIVE SUMMARY**

* Bachelor of Pharmacy with First Class (2008, Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka, India).
* **Total 13 years and 7 months working experience** in Quality Assurance department.
* Currently working at Torrent Pharmaceuticals Limited **Since October 2012 (10 years) as a “Quality Assurance Executive”**.
* Formerly working at Zydus cadila (Cadila Healthcare Limited) **From April 2010 to October 2012 (2 years 5 months) as a “Quality Assurance Technical Supervisor”**.
* Earlier working at Lincoln Pharmaceuticals Ltd. **From March 2009 to April 2010 (1 years 1 month) as a “Quality Assurance Officer”**.
* Execute and maintain compliance of Quality Management System (QMS) along with Standard Operating procedures (SOP) of company and current Good Manufacturing Practices.
* Monitor and Assess Strength, Purity, Quality and Stability of Drug and Pharmaceutical products throghout the manufacturing process.
* Ensure finished Pharmaceutical products have passed all Quality Control tests as per specification before release for distribution into the market.

**CAREER OBJECTIVE:**

Looking for an appropriate position where I can utilize my proven experiences, excellent communication skills, and extensive knowledge of **Quality Management System** forthe growth of the company**.**

**EMPLOYMENT HISTORY:**

* **Name of the company:** Torrent Pharmaceuticals Limited, Plant-Indrad

**Duration:** 11th October 2012 - till date

**Position Held:** Quality Assurance - Executive **(1st April 2017 – till date)**

Quality Assurance - Technical Assistant **(11th October 2012 – 31st March 2017)**

* **Key Responsibilities:**

**Central Investigation Team:**

* Investigation and review of OOS, Deviations, Market Complaints for adequacy and accuracy check and assessment of various relevant documents for root cause, causative factors and CAPA.
* Evaluate the repetitive trend failure/ event for global improvement plan.
* Preparation and review of SOPs associated with quality management system.
* To report critical and major observations to Quality Head.

**Validation and IPQA:**

* To review the Standard Operating Procedures (SOPs) compliance and bring improvements in present operation.
* To conduct regular sampling during Process Validation, Cleaning Validation/Verification studies and Hold Time study.
* To carry out Process Validation activity including execution of validation batches, protocol and report review.
* To prepare protocol, carry out Transport validation activity as per SOPs and report.
* To handle In-process Sample, Retain Sample and Stability Sample.
* To verify Material Requisition Note against Quantitative Formula Card.
* To carry out In-process Quality Control checks during process and to keep a record of it for every batch and product.
* To ensure that In-process materials are labeled as per their status and properly coded and sealed and stored as recommended.
* To report and investigate any deviation related to product, process and practices to their superiors and ensure that they are approved.
* To ensure calibration and recalibration of equipments and instruments are in compliance with calibration programme and its status labeled.
* To ensure preventive maintenance of equipments and machines are performed as per program and status labeled.
* To report critical and major observations to Quality Assurance Head.

**SOP and Training:**

* To prepare SOPs related to Quality Assurance department as well as Modules related to different GMP subjects.
* To maintain the record of original copies of SOPs of the whole plant and arrange for the distribution of current SOPs as & when required by the same.
* To arrange for the retrieval of controlled photocopies of superseded/obsolete SOPs from the various departments & maintain their records.
* To prepare yearly training Schedule for GMP/ Technical skill/Quality Systems and ensure its compliance.
* To handle Induction as well as On-job training of the employees.
* To prepare Training Matrix.

**Document Cell, Retain Sample Room and Regulatory & Customer Submission:**

* To maintain the record of retain samples of formulation & ensure for their storage in designated area in accordance to their storage condition.
* To observe the retain sample physically for their description initially and periodically and issue the samples for Market Complaint, CDP analysis or any Quality issues from Retained Sample Room.
* To maintain and control distribution of BMR, BPR, COA, Product Specification & ensure for their storage in the record storage room.
* To prepare, maintain and update the list of expired retain samples and BMRs for destruction and arrange for the removal of the same from archival area.
* To ensure for smooth retrieval of batch records from the record storage room as & when required for the review purpose either by the Production, QC, TRC and RA.
* To co-ordinate with TRC and to arrange for Batch records which are to be submitted to RA.
* To provide scan documents to Customer as per technical agreement and co-ordinate for the same in case of query.
* **Name of the company:** Zydus Cadila (Cadila Healthcare Limited), Plant-Moraiya

**Duration:** 22nd April 2010 – 08th October 2012

**Position Held:** Quality Assurance - Technical Supervisor

* **Name of the company:** Lincoln Pharmaceuticals Ltd., Plant-Khatraj

**Duration:** 21st March 2009 – 19th April 2010

**Position Held:** Quality Assurance – Officer

* **Key Responsibilities:**
* To ensure the compliance of cGMP during the Oral Solid Dosage Forms manufacturing and packaging.
* To carry out In-process Quality Checks during manufacturing and packaging stage.
* To give the area, machine and line clearance during manufacturing and packaging stage.
* To verify Material Requisition Note against Quantitative Formula Card.
* To calibrate IPQC instruments as per schedule.
* To review of the GMP document like BMR, BPR and Logbooks etc.
* To withdraw sample of semi-finished and finished product in all validation and commercial batches.
* Handling of hold time study sample.
* To withdraw control sample, stability sample and finished product analysis sample at packaging stage.
* To perform swab sampling of manufacturing equipment.
* To review COA before the release of semi-finished and finished goods for further stage in SAP.
* Review, preparation and drafting of SOPs pertaining to Quality Assurance Department.
* To Assist QA Executive and Manager in Evaluation & Investigation of product failure and market complaint.

**SKILLS:**

* Expertise working on MS-Office and other computer applications
* Excellent documentation and record keeping skill
* Interpersonal communication
* Confident and Self-motivated

**AUDIT ATTENDED:**

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| --- | --- |
| * USFDA | * ANVISA |
| * MHRA | * MCC |
| * TGA | * CUSTOMER AUDIT |

**DECLARATION**

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

**Samir G. Patel**