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Priyam Vaghela

Quality Assurance

Deputy Manager in Quality Assurance with experience in Minitab software, LIMS Software, Product quality review, Documentation and submission of documents to regulatory affairs, having Master's degree in Good manufacturing practice. Academic achievements supplemented by technical knowledge and experience.

SUMMARY

- Technical and Analytical skills refined and demonstrated through experience in Pharmaceutical Industry.
- Excellent knowledge of Product quality review preparation and review.
- Self motivated and focused achiever dedicated to producing consistently superior outcomes.
- Extensive working experience with Data collection, Data management and Report tools in pharmaceutical industry Generated through use of Statistical tools like Minitab.
- Preparation and review of Standard operation procedure for different functional areas of Quality Assurance.
- Co-ordination with different functional area's for the collection and review of documents for the submission of regulatory.
- Ability to interact with different functional areas with excellent interpersonal, written and presentation skills.
- Digital issuance of documents to different department.

ADDITIONAL TECHNICAL SKILLS

Operating System	Windows 98/2000/XP
Database	MS-Excel
Minitab Skills	Interpretation of data, Use of different charts for preparation of Product quality review.
LIMS Skills	Knowledge of all the activities like from Initiating charging of stability batches to Approval of batches in LIMS, Change control , Deviation in LIMS
Adobe Acrobat	For digital issuance of documents.
Additional	Review and Analyze SOP, other documents.

Professional Experience (Confidential)

Cadila Pharmaceuticals Ltd,

Department: Quality Assurance **Duration:** August, 2022 till date

The Job Responsibility:

- To ensure timely signature and approval of documents.
- To look after smooth functioning and proper day to day activities related to Document Management and PQR.
- To ensure for proper handling, issuance, retrieval, distribution and archival of quality documents, SOPs

  etc.
- To ensure the PQR prepared, Review & Approved Properly.
- To ensure cGMP related training program for all concerned man power.
- Responsible for assigning appropriate job responsibility to subordinate and train them for completion of

  activity in compliance with cGMP.
- To assign JOB role/ TNI of subordinates in TIMS.
- To generate final completion certificate for new joiners after completion of their training.
- To approve Change control, Deviations and CAPA in LIMS.
- Approval of all master and functional documents
- Any other jobs assigned by Head QA.

Intas Pharmaceuticals Ltd, Pharmez.

Department: Quality Assurance **Duration:** June, 2013 to August,2022

The Job Responsibility:

- Preparation and review of Product Quality Review.
- Review of documents like CRFs, Deviation, OOS, OOT, OOC, market complaints for PQR.
- Initiating, review of Change control on based of PQR.
- Training coordinator for scheduling training for quality assurance department and other training related activities.
- Preparation of SOP's.
- Review of batch manufacturing record and batch packing record.
- Review of document submitted to regulatory.
- Issuance of BMR and Formats to particular department.
- Preparing Site Master files Annexure as per requirements.
- Performing SAP transaction as required.
- To ensure charging of stability sample as per approved protocol, withdrawal of stability sample as per schedule, approval of LIMS stability protocol /summary and test data report.
- To review and approval of Stability protocol and stability study summary reports.
- To perform activities like initiating, review, tracking task closing of CRF's related to stability studies.
- Retained sample management.
- Responsible for preparation and review of other quality related documents.

Dishman Pharmaceutical & Chemicals Ltd , Bavla

Department: Quality Assurance **Duration:** Feb, 2012 to June, 2013

The Job responsibility:

- Dispensing of raw material, primary packaging material.
- To give line clearance and batch release procedure.
- In process quality verification. Handle in process checks and its recordings during batch manufacturing, packing and its recollection, verification and storage effectively as per GMP norms.
- Process Validation compilation for API.
- To control, distribution, review, revision and retrieval S0Ps.
- To handle the deviation and change control activity and OOS.
- Handle, maintain and assure that all activity done as per GMP norms.
- Issuance of BMR and Formats.
- To handle the semi finish goods related activity before packing for Quality as per required norms.
- To collect, storage and record of retain (control) sample as per predefined procedure and maintain as per regulatory norms.
- To sample the in process and finished product and sent to Q.C. for analysis and follow up for timely release for further process and dispatch purpose as per stipulated time period.
- To prepare annual product review.
- Verifying the filling procedure and doing in process check of the products is in specification of Batch Manufacturing Record

Marck Bioscience Limited, Kheda.

Department: Quality Assurance **Duration**: Aug, 2011 to Jan, 2012

The Job responsibility:

- In Process Quality Assurance and cGMP Compliance:
- Carrying out in Process Quality Checks during the manufacturing process.
- Carrying out Line Clearance before the commencement of production operations.
- Carrying out Line Clearance before the commencement of packing operations.
- Carrying out sampling and documentation for In-process and finished product samples and submitting them to QC for analysis.
- Monitoring and documenting the production activities to ensure regulatory compliance (SOP compliance) throughout the production cycle.
- Managing the shop floor quality issues. Carrying out internal audits as per planned schedule.
- Reviewing the Batch Records, Log Books, Inward and outward document records, issuance of batch records to production, issuance of protocol of analysis and workbooks to the QC departments.
- Preparation of APQR.

EDUCATION

Academic Credentials	Board\University	Year	Aggregate
Master of science (Goods & Manufacturing Practices)	Swinburne University, Melbourne, Australia	2011	1st class
B.Pharm	Rajiv Gandhi University of Health sciences, Bangalore	2008	1st class
H.S.C.(Science)	Gujarat Higher Secondary Education Board	2004	60%
S.S.C.	Gujarat Secondary Education Board	2002	70%

Declaration

I hereby declare that the information given above is genuine at its best. If I will be given an opportunity to work in the esteemed organization, I will put my best efforts to enhance the outcomes of the organization.
Thank you.

Priyam Vaghela .