**RESUME**

**Ms.BIJAL JAIMIN BHAVSAR**

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**BD15155_**

**QUALITY ASSURANCE PROFESSIONAL - PHARMACEUTICAL INDUSTRY**

*Seeking challenging assignments with an organization of repute across the industry.*

**BD15155_**

* Competent and diligent professional **with experience of 11 years in conducting analysis and implementation of quality systems & procedures across the Pharmaceutical Industry** and currently spearheading as  **Team Leader with Strides Shasun Limited, Bangalore.**
* Knowledge of **review of documents** (i.e., API & raw material specification, in process, finished product & shelf life specifications & standard test procedure (STP), in process & finished product sampling protocols,Master Formula Card (MFC), Stability Study Protocols etc.) for **US / EU / Brazil / Canada / ROW / Domestic market for Oral solid, liquid and Injectable preparations.**
* Knowledge of review of **Product Development Reports as per Quality by Design (QBD) principles**  like DOE,Design space,Process optimization, formula optimization , Quality risk management and as per regulatory requirement.
* Experienced in **Quality Assurance for System development, document review and approval based on Regulatory requirement ,Part of Customer Audits & Internal Audit, Approval of Standard Operating Procedures, Analytical Method Validation study ,Analytical Method Equivalency Study, Annual Product Quality Reviews of Pharmaceuticals.**
* Exerience in QMS elements
* Experience in handling various regulatory audits like **MHRA, USFDA, ANVISA** etc.
* Knowledge of **ICH Guidelines, GMP principles, ICH Q8 (Pharmaceutical development), Q9 (Quality risk management) and Q10 (Pharmaceutical Quality System) guidelines.**
* **Knowledge of ICH M4 (Oragnization of CTD)**
* Knowledge of **vendor development** activities for KSM,API,Raw material.
* Knowledge of preparation of summary of Management Review Meeting.
* Knowledge of **SUPAC** guidance.
* Knowledge of Dossier Review for regulated market.

**Core Competencies**

**BD15155_**

♦ Documentation /Reports ♦ Quality Management System♦Technology Transfer from R&D to mfg location ♦Audit /Inspection ♦ Calibration/ Validations/Qualification♦ Process Validation ♦ Method Validation♦Change Control ♦ Deviation & CAPA ♦ System Improvement ♦ OOS evaluation♦ SOP

**PROFESSIONAL EXPERIENCE**BD15155_

♦**Current Employer :Strides Shasun Limited, Bangalore**

♦ **Designation: Team Leader**

♦ **Duration : Since April-2016**

* Responsible for review and approval documents related to US / EU / South Africa /Australia / Domestic market for Oral solid,Topical and liquid preparations.
* Review and approval of Product Development Reports as per Quality by Design (QBD) principles like DOE,Design space,Process optimization, formula optimization , Quality risk management and as per regulatory requirement.
* Involved in review & approval of Technology Transfer document from R& D to concerned manufacturing location for formulation . i.e.Master Formula Recor (MFR), Master Packing Record (MPR) etc.
* Review of DQ,QRM,IQ/OQ/PQ protocols and reports and review of Preventive Maintenance reports.
* Preparation and review of departmental SOPs and review of SOPs of other department s.
* Review and approval of BMR,BPR of formulations.
* Responsible for performing internal audits and preparing various regulatory and customer audits.
* Interacting with various departments (FnD, RA, ADL,Plant etc.) for technical inputs and accomplishing activities and smoothening of future tasks.
* Associated with handling regulatory audits of USFDA and other company/customer specific audits.
* Ensuring Quality System compliance and system improvement in organization through internal audits.
* Involved in SAP activities related to Quality Assurance systems.
* Ensuring compliances of audit observations through self inspection, handling external audits by regulatory authorities and external clients.
* Accountable for review of change control form for various changes including Pharmacopoeial Updation, Regulatory query response, Quality improvement & revision of Formulation and/ or process parameters.
* Establishing quality standards and implemented stringent quality systems to enhance quality of products.
* Setting up quality systems and procedures and driving quality system initiatives to ensure strict conformance to laid-down quality parameters.
* Developing and implementing various quality assurance system, generating related documents in tune with national and international guidelines.
* Adhering to the various quality measures and functioning as an instrumental member for implementation of quality assurance methods.

♦**Previous Employer :Intas Pharmaceutical Limited** -**Astron Division, Ahmedabad**

♦ **Designation: Research Scientist (Assistant Manager)**

♦ **Duration : Feb’14 - Feb'16**

* Responsible for review and approval documents related to US / EU / Brazil / Canada /Australia/ ROW / Domestic market for Oral solid, liquid and Injectable preparations.
* Review and approval of Product Development Reports as per Quality by Design (QBD) principles like DOE,Design space,Process optimization, formula optimization , Quality risk management and as per regulatory requirement.
* Involved in review & approval of Technology Transfer document from R& D to concerned manufacturing location for formulation . i.e., API & raw material specification, in process,finished product release & shelf life specifications & Method of Analysis (MOA), Master Formula Card (MFC), Master Packing Document,Stability Study Protocols etc.
* Responsible for review,approval and evaluation of stability study reports of Development, Exhibit , Validation & Commercial batches.
* Responsible for review and approval of Analytical Method Validation (AMV), Method equivalency ,Method transfer Protocol and report.
* Review of IQ/OQ/PQ protocols and reports and review of Preventive Maintenance reports.
* Preparation and review of departmental SOPs and review of SOPs of other department s.
* Review and approval of BMR,BPR of formulations.
* Review & approval of Stability study,Thermal Cycling/Transit study,Dilution study, Reconstitution study,Photostability study, Stress study,Inuse study,hold time study protocol and report.
* Responsible for performing internal audits and preparing various regulatory and customer audits.
* Interacting with various departments (FnD, RA, ADL,Plant etc.) for technical inputs and accomplishing activities and smoothening of future tasks.
* Associated with handling regulatory audits of MHRA, USFDA and other company/customer specific audits.
* Ensuring Quality System compliance and system improvement in organization through internal audits.
* Involved in SAP activities & OASIS (LIMS Software) activities related to Quality Assurance systems.
* Ensuring compliances of audit observations through self inspection, handling external audits by regulatory authorities and external clients.
* Accountable for review of change control form for various changes including Pharmacopoeial Updation, Regulatory query response, Quality improvement & revision of Formulation and/ or process parameters .
* Accountable for review of Deviation Report and Out of specification report for evaluation and closure with proper documentation.
* Establishing quality standards and implemented stringent quality systems to enhance quality of products.
* Setting up quality systems and procedures and driving quality system initiatives to ensure strict conformance to laid-down quality parameters.
* Developing and implementing various quality assurance system, generating related documents in tune with national and international guidelines.
* Adhering to the various quality measures and functioning as an instrumental member for implementation of quality assurance methods.
* Conducting Induction Training for the new joiners of the Organization.

**♦Previous Employer: Torrent Research Centre, Gandhinagar**

♦**Designation:Senior Scientist-II**

**♦Duration: Feb’06-Feb’14**

* Responsible for review of documents related to US / EU / Brazil / Canada / ROW / Domestic market for Oral solid, liquid and Injectable preparations.
* Review of Product Development Reports as per Quality by Design (QBD) principles like DOE,Design space,Process optimization, formula optimization , Quality risk management and as per regulatory requirement .
* Ensuring all the products have clearly defined specifications with careful & sophisticated quality control measures in compliance to the international standards.
* Adhering to the various quality measures and functioning as an instrumental member for implementation of quality assurance methods.
* Involved in review of Technology Transfer document from R& D to concerned manufacturing location for formulation with Risk Assessment . i.e., API & raw material specification, in process, finished product & shelf life specifications & standard test procedure (STP), in process & finished product sampling protocols, Master Formula Card (MFC), Stability Study Protocols etc.
* Responsible for evaluating stability study reports of Development, Exhibit, Validation&Commercial batches.
* Establishing quality standards and implemented stringent quality systems to enhance quality of products.
* Responsible for review and approval of Analytical Method Validation (AMV) ,Method Equivalency Protocol and report.
* Responsible for performing internal audits and associated with various regulatory audits of MHRA, USFDA, ANVISA etc. and other company/customer specific audits.
* Interacting with various departments (Find, RA, ADL, Patent, TCM, Plant, General stores etc.) for technical inputs on Tech transfer issues.
* Responsible for the task of review of annual product quality reports.
* Ensuring Quality System compliance and system improvement in process.
* Involved in SAP activities related to Quality Assurance systems.
* Ensuring compliances of audit observations through self inspection, handling external audits by regulatory authorities and external clients.
* Accountable for review of change control form for various changes including Pharmacopoeial Updation, Regulatory query response, Quality improvement & revision of Formulation and/ or process parameters .
* Accountable for review of Deviation Report and Out of specification report.
* Setting up quality systems and procedures and driving quality system initiatives to ensure strict conformance to laid-down quality parameters. Structuring validation protocol to ensure execution of validation process as per schedule.
* Developing and implementing various quality assurance system, generating related documents in tune with national and international guidelines.
* Review of reformulation of based on SUPAC criteria.
* Conducting quality audits and ensuring in process QA check are conducted in formulation development laboratory to confirm that all activities are performed as per standards and compliances to GLP & GMP norms.
* Ensuring cGMP compliance followed for pilot bio batch/submission batch manufacturing taken at R&D center & review of BMR, BPR for the same.
* Review of calibration records, preventing maintenance reports and IQ/OQ/PQ protocols and reports for equipments/instruments.
* Preparation and review of departmental SOPs and review of SOP of the department.
* Evaluation of stability data of development batches and identifying, justifying and informing risk for the products based on the devlopment batch data for technology transfer of products to manufacturing locations.
* Preparation of monthly reports on departmental activity.
* Review of dossier for regulatory submission.

**♦Previous Employer: Astra Life Care (India) Private Limited,Ahmedabad**

**♦Designation:Trainee Q.A Chemist**

**♦ Duration: Aug’05-Jan’06**

* SOP preparation, review and its distribution
* Review of MFC,BMR,BPR,Specification and MOA.
* Review of calibration reports, IQ/OQ/PQ protocol and report for equipments/instruments.
* Review of process validation protocol and report.
* Review of filled BMR,BPR and analytical reports of the batches manufactured for release of the batch.
* Preparation of Quality documents like Quality Manual, Site Master File,Validation Master Plan.
* Review of dossier for regulatory submission.

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**EDUCATIONAL CREDENTIALS**

**Master in Business Administration (Operation Management), 2010**

IGNOU; 59.30%

**Bachelor of Pharmacy, 2004**

L.M College of Pharmacy, Ahmedabad; 64%

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**PERSONAL DETAILS**

**Date of Birth:** 20th February1983

**Marital Status:**Married

**Languages Known:** English, Hindi and Gujarati

**Hobbies:**Music, Shopping