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Current Address: H. No 479, sector No 3. Shivbasavnagar Belgaum- 590010

Mr. Shivprasad Sanikop

Asst. Manager in Quality Assurances

PERSONAL PROFILE

Mr. Shivprasad Sanikop

DOB- June 12th, 1984

Gender-Male

Marital Status- Married

Permanent Address- H. No 479, sector No 3. Shivbasavnagar Belgaum- 590010

SOFT SKILL

SOFWARE EXPOSURE

- ERP
- SAP
- TRACKWISE

QUALIFICATION

Bachelor of Pharmacy
Rajiv Gandhi University of Health Science Bangalore
2006-2010

Diploma in Pharmacy
KLE Pharmacy College, Karnataka
2005-2007

summary PROFESSIONAL

- Total 12+ years of experience in Quality Assurance department of formulation plant like Injectable, Tablets, capsules, dry powders etc.
- Presently working with Ray Life Science Limited, Hubballi, Karnataka as Assistant Manager in Quality Assurances, responsible for the role of Team Leader.
- Previously worked with Shree Anand Life Science Ltd., Belgaum, Karnataka, Micro Labs limited. Goa, Lupin limited. Goa, Indoco Remedies ltd. Goa, from trainee officer to Asst. Manger role.
- Experience of handling multiple dosage forms like, Injectable, Tablets, capsules, dry powders etc.
- Experience in handling the Regulatory audits & documentation.
- Well conversant in below activities with various kinds of validation activities, In process activities, QMS, Deviation Change control, Market Complaint and Recall Handling, BMR/BPR Review, Vendor Qualification etc.
- **IN Process Activities-** Handled activities like Line Clearance, Sampling, proof checking and process Monitoring in Tablets, Capsules, liquid Injectable like ampoules, vials, PFS, lyophilized products during Manufacturing and Packing to ensure the Quality of products.
- **QUALITY MANAGEMENT SYSTEM:** overall maintenance of Quality related aspects of the company to ensure the quality and safety of the product and people along with the consistency of the product.
- **CHANGE Control and Deviation Management:** Initiate change control, review and assessment and check the effectiveness of the change, Conduct investigations of deviations upon reporting. Provide appropriate corrective and preventive actions (CAPA) to avoid recurrences and potential occurrences of deviations.
- **MARKET Complaint and Recall Handling:** Conduct investigation upon receipt of complaints from market. Propose and implement Corrective and Preventive action to avoid recurrence. Preparing report and replying to the complaint
- **Document Management:** Preparation, review, arrangement and retrieval of documents related to manufacturing, complaints deviations and Risk Management
- **STANDARD Operating Procedure/Batch Manufacturing Record:** Prepare, Review and implement standard operating procedures. Preparation of BMR of exhibit and commercial batch with the help of MFR and BOM.
- **VENDOR Qualification:** Review of Vendor Qualification documents like Vendor suitability report, Vendor Audit Report

Achievements- ***Successfully commission of Dry powder injectable line in Anand life science***
Successfully introducing and validation of ERP software in Shree Anand life science

WORK EXPERIANCE

RAY LIFE SCIENCES LTD, Hubballi, Karnataka — Since March 2023

Manufacturing unit is engaged in Manufacturing of Pharmaceuticals parenteral dosage form (ampoules and vials) and approved by WHO.

Designation- Asst. Manager (QMS- Production)

- Responsible for ensuring the control and maintenance of documents including the pharmaceutical quality system as per the requirements of regulatory authorities which involves raw data, sops, documentation exhibits, protocols, training charts etc. For Production department.
- To ensure that the execution of GMP, cGMP and good documentation practices (GDP) at Production department.
- Reviewing the standard operating procedures and updating in accordance with current guidelines.
- Review and Assessment of Change controls, deviations, incidents and Participate in the investigation of deviation.
- Root cause analysis with implementation of Corrective and preventive action.
- Risk Assessment of the impacts with respect to the changes on the subject and classifying the changes.
- Coordinating with the Audit compliance team for responding the audit observation and effective closure of observation with implementation of CAPA.
- Participate in the scheduled media fill programme and ensuring 100 % aseptic practices and GMP.
- Rejection trend Analysis and preparation of report.
- Review of Qualification documents and Execution of routine validation and Qualification activities in accordance with the Validation master plan.
- Organize and conduct practical and theoretical training programs to enhance skills and motivational Levels.
- Review and approve the validation documents like process validation etc.
- Review of batch yield statement, production achievement report, and WIP report,
- Lead Auditor for Internal Audits.
- Review of Batch Manufacturing Records and packaging records.
- To provide specific trainings to personnel.

M/s SHREE ANAND LIFESCIENCE LTD. BELGAUM, KARNATAKA — From Dec 2018 to March 2023

Manufacturing unit is engaged in Manufacturing of Pharmaceuticals parenteral dosage form (Ampoules, Vials and dry powder injection, and Lyophilized injection and approved by , WHO, Kenya, Tanzania, Yemen and Brazil etc.

Designation: Asst.Manager Quality Assurances

Job Responsibilities

- Preparation of Process validation protocol with respect to MFR and execution, compilation of process validation report.
- Review of APQR and ongoing verification reports.
- Reviewing the standard operating procedures and updating with accordance with current guidelines.
- Assessment of Change controls, deviations, incidents and Participate in the investigation of deviation.
- Root cause analysis with implementation of Corrective and preventive action.
- Risk Assessment of the impacts with respect to the changes on the subject and classifying the changes.
- Post approval review of the change control with respect to the implementation of the changes and closure of change control.
- Co-ordinating with the Audit compliance team for responding the audit observation and effective closure of observation with implementation of CAPA.
- Assessment of Nitrosamine Impurities and coordinating for testing requirement.

- Review and Preparation of Qualification documents like PQ, and participating in the scheduled Qualification of HVAC, and equipment revalidation.
- Development and review of Site master file, Quality manual, Validation master plan.
- Lead Auditor for Vendor Audit and Internal Audits.

M/s MICRO LABS LIMITED. Goa From June 2014 to November 2018

Manufacturing unit is engaged in Manufacturing of Pharmaceuticals solid oral dosage form (Tablets, Capsules) and approved by 100 % EOU unit, USFDA, MHRA (UK), EMEA (EU), WHO etc.

Designation: Executive officer Quality Assurances

Job Responsibilities

- Preparation of BMR of exhibit and commercial batch with the help of MFR and BOM.
- Review of Vendor Qualification documents like Vendor suitability report, Vendor Audit Report and conducting vendor audit for excipients and packing materials as per the audit schedule.
- Yearly vendor evaluation for approved vendors of raw materials and packing materials.
- Review of the Change Controls related to Document, System, Facility and Product.
- Deviation-Participate in the investigation of deviation, Route causes analysis and Handling and effective Implementation of CAPA.
- Risk Assessment of the impacts with respect to the changes on the subject and classifying the changes.
- Post approval review of the change control with respect to the implementation of the changes and closure of change control.
- Handling of Online Rejection and Batch Rejections and their Destructions.
- Updation and review of Rejection Logs, Destruction logs.
- Review and Approval of Artworks related to cartons, leaflets, foil etc.

M/s LUPIN LIMITED. Goa From April 2013 to April 2014

Manufacturing unit is engaged in Manufacturing of Pharmaceuticals solid oral dosage form (Tablets, Capsules) and Injection Lyophilized injection and approved by 100 % EOU unit, USFDA, MHRA (UK), EMEA (EU), PMDA (Japan), WHO etc.

Designation: Executive officer Quality Assurances

Job Responsibilities

- Finalization of process parameter as per PV recommendation and co-ordination with R & D.
- Co-ordinating with the regulatory affairs for Change control proceedings and handling of the queries related to products.
- Co-ordinating with the Audit compliance team for responding the audit observation.
- Preparation and review of QMS-related QAPs and SOPs.

M/s INDOCO REMEDIES LTD. Goa From Feb 2011 to March 2013

Manufacturing unit is engaged in Manufacturing of Pharmaceuticals solid oral dosage form (Tablets, Capsules) ann and approved by 100 % EOU unit, USFDA, MHRA (UK), EMEA (EU), WHO etc.

Designation: Junior officer Quality Assurances

Job Responsibilities

- To ensure the timely calibration of the Instruments on shop floor.
- Performing unit operation study and rejection analysis in packing.
- Preparation and Compilation of process/product/equipment wise validation protocols, reports and summary.
- Withdrawal of samples according to process validation protocol.

AUDIT EXPOSURE

- Active participation in the successfully cleared USFDA, MHRA, TGA and WHO Audits.

TRAINING

- IPA workshop data integrity and remote/ virtual audits.
- Workshop handling of investigation in track wise system.

PERSONAL STRENGTH

- Equally effective in working independently and collaboratively in team effort.
- Enthusiastic and optimistic
- Team Leadership
- Ability to establish strong rapport with teams, and management with a down to earth approach, can judge and adjust quickly to dynamic conditions.
- Systematic Approach: Thorough planner, self-starter and prolific learner

Declaration

- I consider myself familiar with Management aspect. I am also confident of my ability to work in a team. I hereby declare that the information furnished above is true to the best of my knowledge.

Place:

Date: **Mr. Shivprasad Sanikop**