Gadigyappa Patath

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Industry Preference: Pharma Area: Quality Assurance/CQA
Location Preference: PAN India, Overseas

OBJECTIVE

Seeking a challenging career to excel my performance. Looking forward for an opportunity to work in a well-projected environment where my knowledge can be shared and enriched.

CORE COMPETENCIES

- Validation
- Qualification
- Computer System Validation (CSV)
- Cleaning Validation
- Vendor Management
- Quality Management Systems
- Quality Risk Management
- Audits Management
- Training & Development
- Expert in Manufacturing Investigation
- SOP Preparation & Implementation
- Continuous process verification

PROFILE SUMMARY

- Competent professional with 17 years of experience in Quality Assurance
- Presently associated with **Marksans pharm India Ltd., Goa, India as Manager QA (Divested plant of Teva pharma India Pvt Ltd)**
- Handling of Validation related to process validation, cleaning validation computer system validation and qualification.
- Take a lead role and demonstrated leadership skills in various functions such as Process validation, cleaning validation, CSV, manufacturing investigation and In process quality assurance.
- Holds the merit of working with various renowned companies like FDC Ltd. Dr Reddys Labotatory Ltd., Teva pharma India, Marksans pharma Ltd.
- Demonstrated excellent leadership in applying Quality Management tools / approaches in quality assurance & reporting processes in business unit; skilful in formulating & maintaining Quality objectives complementary to corporate policies / customer demands.
- Abilities in establishing cGMP Compliance & SOPs, streamlining workflow and creating work environment to enhance productivity innovatively.
- Demonstrated leadership proficiency for the preparedness of various regulatory audits and take a lead role to address deficiency arise by regulatory agency during the review process.
- Proven track record on handling of Market complaint, OOS, Incidence & Investigation, CAPA, Deviation management, and other quality management system.
- Ability to generate ideas and use technical expertise to bring them to fruition.
- Strong communication and coordination skills with ability to lead teams effectively.

- Organized and methodical capable of planning and prioritizing work to utilize resources optimally.
- Faced regulatory audit like USFDA, MHRA, WHO, PMDA and local FDA.
- Support and co-ordination with corporate Q.A/Regulatory department for Technology transfer, preparation of ANDA submission and Variation filing and response of regulatory queries raised by authorities.
- Preparation of validation master plan. Periodic validation of laboratory instruments / equipment used in manufacturing process and analytical process (IQ, OQ, PQ).
- Experience in conducting internal/self-inspection/vendor/supplier/ CMO/CRO audits in compliance with global and local standards; merit of successfully leading teams
- Excellent Knowledge of quality aspects of development of products from initial development stage to final approval.
- Review of product development reports and supporting CMC documents intended for dossier submission for US and Europe country.
- Review and approval of MFC, BMR, BPR and analytical reports.
- Well versed with **Trackwise Harmony & MaxiQ for QMS, SAP, Training software studium E-learning system, and Glorya (EDMS)**
- Well versed with relevant ICH, 21CFR, WHO, GXP, ISO(13485:2016/ 9001:2015), CSV GAMP, PIC/S and EU regulatory requirements for GMP and GCP

PROFESSIONAL EXPERIENCE

- **Marksans Pharma Ltd. Verna, Goa (Divested plant of Teva pharma India Pvt Ltd) Verna, Goa. as Manager QA** **Since – Aril '2023**
- **Tevapharm India Pvt. Ltd. Verna, Goa. as Group leader QA** **Dec'2017-April'2023**

Job Profile in Marksans Pharma and Teva Pharm:

- Validation team lead and Digitization projects implementation in compliance with GAMP5, 21 CFR and EU annex 11.
- Comprehensive experience in full validation life cycle – SDLC Validation approach (Concept, Project, Operation and Retirement phases) and validation deliverables as per GAMP 5 and EU Annex-11.
- Develop and continuous improve expertise linked to validation activities.

- Ensure implementation of validation related commitments towards internal and external authorities and organize the follow-up.
- Be a strong advocate for validation approaches of HVAC, facility and Microbiology lab equipment's.
- Reviewed high level documents related to validation activity like URS, FAT, SAT, IQ/OQ/PQ, QRA, RTM, VSR for New facility, Utilities (HVAC, Water systems and compressed air).
- Reviewed qualification documents of Environmental Building Management System (EBMS), Electronic Document Management System (EDMS), Electronic Quality Management System – Trackwise.
- Good knowledge on Risk based approach to GxP Computerized systems.
- Authored critical common utility validation approach policy.
- Involved in continuous improvement, data gathering, performance improvement as per principles of operation excellence
- Preparation, Review and Execution of SDLC documents as per based on GAMP5 Guidelines.
- (Validation Plan, User Requirement Specification, Design Qualification (DQ), Risk Assessment (RA), OQ, PQ, Traceability Matrix (TM), & Validation Report (VR)).
- Validate the Computerized Systems as per the in-house policies like Global VMP, GAMP 5 guidance and Part 11 regulations to ensure that the Computerized Systems are functioning as intended to meet business requirements and as per the predetermined specifications.
- Conducted GxP review of validation deliverables like User requirement specifications, Validation plan, Functional design specifications, configuration documents, test scripts, test results and Validation summary report.
- Active team member for validation analysis, preparing test protocols, test summary reports and validation summary reports in accordance with Global and local regulatory bodies
- Handling of QA team of 15 members and ensuring the in-process QA check conducted during manufacturing and packing operations, laboratory as per standards and compliance to GMP and GLP norms.
- Reviewing and approving Validation (Process validation, cleaning validation and computer system validation) Qualification/Technology transfer protocols and reports.
- Assessing risk with respect to different procedures; assigning change control to other departments for review.
- Reviewing and approving of Exhibit/Commercial Batch Summary Report, Hold Study Report and Stability Report
- Conducting GAP Analysis (Procedure vs. Practice/Procedure vs. Regulatory Requirement); leading audit compliance.
- Ensuring adherence to SOPs and Corporate standards/regulatory guidelines at all times.
- Preparation of regulatory audit response reports by coordinating with cross functional teams.
- Vendor/Supplier Audit and Qualification, Evaluation of vendor Questionnaire forms and supporting documents and Vendor Audit for Raw and Packaging material.
- Auditing CMO/CRO for GMP/GCP compliance.
- Reviewing and approving analytical data, investigation for lab failure related to OOS,OOT and questionable results

IT EXPOSURE(PHARMA DOMAIN)

- Technical exposure document development and execution of end-to-end validation management life cycle of the GxP compliance software system with GAMP5, FDA 21 CFR & EU Annex11 approach.
- Well versed in CSV with experience in FDA (GxP,21 CFR Part 11, Data Integrity), EU Annex 11, GAMP5, and other regulatory compliance and adherence. Experience in core pharma industry and IT compliance of Life Science domain with validation and quality compliance.

PREVIOUS EXPERIENCE

Marksans Pharma Ltd. Verna, Goa as Assistant Manager **Feb'2016 – Dec'2017**

- Handling of QA team of 30 members and ensuring the in-process QA check conducted during manufacturing and packing operations, laboratory as per standards and compliance to GMP and GLP norms.
- Allocating day-to-day work to team members and facilitate knowledge transfer; motivating the team continuously
- Reviewing analytical data of Exhibit/Commercial Batch Summary Report, Hold Study Report and Stability Report
- Preparation of regulatory audit response reports by coordinating with cross functional teams
- Vendor/Supplier Audit and Qualification, Evaluation of vendor Questionnaire forms and supporting documents and Vendor Audit for Raw and Packaging material.

Kemwell Biopharmaceuticals Pvt. Ltd., Bangalore as Senior executive DQA **Mar'2013 – Feb'2016**

- Implementation of QMS in R&D unit (Product Development Unit)
- Preparation and review of Batch records for Exhibit and validation batches and intended batch records for commercial Batches for filing including review of executed exhibit batch records
- Responsible for to involve day to day activities of Formulation development and analytical development functions
- Preparation and review of write ups for filing of ANDA as per CMC Module (module 3 and Module 4)
- Involving in Query response for ANDA application and correspondence received from US FDA
- Review of Product Development Report (PDR) and Process Characterization report
- Review and approve of various documents, including product specification, batch documentation, test method, analytical validation report, method transfer, equipment qualification and packaging material documentation (Container closure system)
- Responsible of handling all stability studies for the exhibit and validation batches
- Preparation and review stability, Process validation Hold time study protocol and report for Exhibit batches.
- Review of executed Pilot and pivotal batch records and associated documentation for release of batches for clinical studies or BA/BE studies.
- Support clinical supplies activities, including providing formal approval and release for clinical supplies and registration sample

Bluefish pharmaceuticals, India Pvt. Ltd., as Senior executive Q.A. **Jun'2011– Mar'2013**

- Maintain and develop the quality system in accordance with EU and national requirements.
- Responsible for the audit of suppliers and API manufacturers as required
- Maintenance of the quality systems by holding responsibility to follow up with the Complaints, deviation, change controls and any other with CMO.
- Co-ordination with suppliers on technical matters.
- Review of Artworks for primary and secondary packaging components of products.
- Responsible for the second sourcing activities/Technology transfer.
- Responsible for updating the annual quality reviews from different manufacturers.
- Coordinating with R A team for notification to regulatory authorities.

Dr. Reddy's Laboratories Ltd., Hyderabad as Junior Manager Q.A **Mar'2009 – May'2011**

- Performing IPQA activities in manufacturing and packing areas
- Preparation of samples (content uniformity, Pooled and finished product) for QC analysis at different stages of validations, commercial and Exhibit batches

FDC Pharmaceuticals Ltd. Verna, Goa as Q.A. Officer **Jun'2008 – Feb'2009**

- Review of batch records (BMR, BPR).
- Monitoring of Shop floor activities.
- Carrying out in-process checks during different stages of manufacturing for tablets and capsules.

TRAININGS/ CERTIFICATIONS

• GMP Auditor
• Reviewer Skill test

ACADEMIC DETAILS

Professional Qualification	College	University	Percentage Secured
Masters in Pharmacy	K.L.E.'S College of Pharmacy, Hubli. Karnataka.	Rajiv Gandhi University of Health Sciences, Bangalore, Karnataka.	(Distinction) 77%
Bachelor in Pharmacy	S.C.S College of Pharmacy, Harapanahalli. Karnataka.		First Division 68.86%

PERSONAL DETAILS

Date of Birth: 25th March 1981

Address: H. No. 197/1/47, Bottle palm road, Palm Estate, Zuari Nagar, Goa- India 403726

Languages Known: English, Kannada, Telagu, Konkani, Hindi & Marathi.

Hobbies: Playing cricket and Reading article and scientific journals.

Passport: B6544158

DECLERATION

I hereby declare that the above-mentioned details all are true to the best of my knowledge and concerns.

Place:

Yours faithfully

Gadigyappa Patath

Date: