SHIVA KUMAR JAGIRDAAR

Result-oriented and creative professional with M.Pharmacy+13 Years Pharma-AR&D and MST-Analytical Experience +LSSGB +Project management +Business Analytics & Intelligence -IIM-R

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shiva-kumar-jagirdaar

PROFILE SUMMARY

13+ years of functional experience in Pharmaceuticals industry especially in Analytical Science activities, well versed with product filing requirements and Method Life cycle management. Expertise in Analytical method development/expertise in Method validation/Method verification/Method Transfer of analytical methods for drug substance and drug products, expertise in analytical trouble shootings ,exposure in drafting Specifications and Analytical test procedure, Sound knowledge of regulatory guidelines/filing requirements, expertise in preparing(designing) and reviewing protocols and reports as per regulatory guideline, Exposure in Preparing Risk assessment Reports for Residual solvents/Elemental impurities/Genotoxic impurities/Nitrosamine impurities/NDSRI, Compendial updations handling, Quality review, functional knowledge of QMS, Statistical (Data Science) Analysis and Data Visualizations.

WORK EXPERIENCE

Jul'2023 – Nov'2024

Graviti Pharmaceuticals Pvt. Ltd, Hyderabad, Telangana, India| Senior Manager (Senior Scientist) - Formulation-Analytical R&D

Key Result Areas:

- Group Leader- analytical R&D initiatives for drug products, excipients, and drug substances, ensuring alignment with regulatory filing requirements and industry standards.
- Conducted comprehensive risk assessments for residual solvents, elemental impurities, genotoxic impurities, and nitrosamines, contributing to enhanced product safety profiles.
- Oversaw the meticulous review of specifications, test procedures, and analytical reports, ensuring data integrity and compliance with regulatory expectations.
- Managed the evaluation of DMF and vendor documentation to ascertain data adequacy and compliance with regulatory standards.
- Addressed and resolved complex queries from the US FDA, including Information Requests (IR), Discipline Review Letters (DRL), & Complete Response Letters (CRL), enhancing the organization's regulatory standing.
- Implemented a comprehensive training program for junior scientists, enhancing their proficiency in analytical methodologies and regulatory compliance, which is crucial for maintaining high standards in the laboratory.

Jan'2022 – Jun'2022

Szhaveri Pharmakem Pvt. Ltd., Mumbai, India | Senior Manager – MST –Tech Transfer

Key Result Areas:

- Worked as the Senior Technical Scientist, providing critical support for analytical method co-validations, verifications, and transfers within a GLP-compliant laboratory environment.
- Conducted thorough reviews of method development activities, ensuring analytical methods were finalized and ready for validation and transfer processes.
- Designed and reviewed analytical method validation, verification, and transfer protocols, ensuring adherence to regulatory guidelines and industry best practices.
- Managed incidents, deviations, and investigation reports through the QMS, ensuring timely resolution of analytical discrepancies and compliance with quality standards.

Jan'2021 – Jan'2022

Abryl Laboratories, Chandigarh, India | Manager (MST - Method Validation/Verification/Transfer)

Key Result Areas:

- Led the technical team in delivering analytical method validations, verifications, and transfers for regulatory filings across US, EU, and emerging markets.
- Responsible for the initiation, planning, execution, monitoring, and closure of analytical method validation projects, ensuring alignment with regulatory timelines.
- Conducted comprehensive reviews of method development reports, analytical reports, SOPs, and specifications, ensuring compliance with industry standards.
- Designed and finalized analytical method validation, verification, and transfer protocols, ensuring rigorous adherence to regulatory guidelines.
- Championed initiatives that enhanced project management and documentation practices, leading to improved compliance and operational effectiveness in analytical method validation

Sep'2017 – Jun'2020

Asymchem Labs, Tianjin, China | Senior Scientist (Associate Director - Solids & Injectables)|

Key Result Areas:

- Prepared and reviewed technical proposals for analytical segments based on customer requests, coordinating closely with business development and project management teams.
- Executed and managed technical work with teams to deliver pre-formulation and formulation projects for solid orals and injectable, adhering to strict timelines.
- Developed and reviewed protocols, Certificates of Analysis (COAs), SOPs, specifications, and stability reports, ensuring compliance with regulatory standards.
- Conducted analytical method development, validation, and transfer for APIs and formulations, utilizing advanced techniques such as HPLC, GC, and LC-MS.

Nov'2016 – Aug'2017

Fresenius-Kabi Ltd, Delhi-NCR, India | Senior Research Scientist-II (Injectables)|

Key Result Areas:

- Executed analytical method development for solid orals and injectable by using HPLC, GC and GC-MS.
- Executed analytical Method transfers to QC. (to different GMP plants)
- Executed analytical support for formulation development.
- Prepared of Specifications, Test Methods, analytical protocols and reports.

Oct'2015 – Nov'2016

Apotex.Pvt. Ltd, Bangalore, India | Senior Research Scientist-I (Solid orals)|

Key Result Areas:

- Handled Analytical development team (Team of 5 scientists) along with critical task execution to deliver analytical method development, support analysis and developmental stability studies.
- Planned and monitored experimentation for method development and formulation development analytical activities to report to Group Leader.
- Prepared and reviewed of Test methods, COA, method development, stability protocols.

Feb'2010 –Sep'2015

Dr Reddy's Lab Ltd, Hyderabad, India | Scientist-R1B (Proprietary Products-ARD & Generics-Tech Transfer)|

Key Result Areas:

- Performed analytical Method Development for API & formulations (Assay, RS, CU, and Dissolution) based on QBD principles.
- Performed Residual solvents method development and validation by GC.
- Performed Analytical method validations for 505b (2) and SUPAC projects.
- Monitored Analytical Method transfers to QC. (to different GMP plants)
- Investigation of root cause analysis through Quality risk assessment approach.
- Reviewed of Instrument qualification and calibration data.
- Formulation Support analysis executed for 505b (2) & SUPAC projects.
- Prepared Test methods, AMD, AMV protocols and reports.
- Handled Analytical development team (Team of 5 scientists) along with critical task execution to deliver analytical method development, support analysis and developmental stability studies.

PROJECTS & TRAININGS

Trident Life Sciences| Jul'2009 – Jan'2010
Trainee Research Associate - Bio-analytical Department

- Supported senior scientists in conducting experiments and analyzing data, contributing to the successful completion of research projects.

M.Pharmacy-Industrial Project| Sept'2008 – Jul'2009
Industrial Project work at Dr.Reddy's Lab- Process Validation and Stability studies of Rivastigmine Capsules

- Participated in the Process validation and Stability studies of Rivastigmine capsules, gaining valuable insights into pharmaceutical manufacturing processes.
- Collaborated with cross-functional teams to ensure compliance with regulatory standards and quality assurance protocols.

LSSGB-Lean Six Sigma Green Belt|Aug'2021 – Oct'2021

- Attended 30 hours contact sessions, 30 Practice sessions and 2 hands-on Project assignments to apply DMAIC strategy to solve problems.

Business analytics and Intelligence from IIM-R|Jul'2024 – Dec'2024
(Indian Institute of Management-Rohtak)

- Attended 50 hours Weekend sessions from reputed IIM faculty on Data analytical tools –Descriptive analytics, exploratory analytics, Supervised and Unsupervised Learning, Data Visualizations by using Excel Pivotal charts, Tableau and Power BI.
- Successfully presented Project on "Impact of Covid-19 on different sectors of India" by using Descriptive statistics, Excel Pivotal charts and Tableau.

ACHIEVEMENTS

Prathiba Award by Chief Minister, Andhra Pradesh for best performance at Secondary school level.

Awarded GATE fellowship in M.Pharmacy based on All-India GATE score 97.6%.

State 7th Rank in E-CET entrance to get into B.Pharmacy.

SKILLS

- Expertise in designing and preparing protocols & reports for various formulation analytical activities for regulatory submission.
- Good at People management, Communication, Presentational skills and good at Written& Oral English.
- Good at Analytics to Solve Problems and Predict future failures.
- Typing Skill with Speed more than 35 words per minute.

EDUCATION

1999 — S.S.C., ZPHS, Yedpally, Nizamabad, Andhra Pradesh with 89.6% (First Class with Distinction)

1999 – 2001 — Intermediate (M.P.C), Ushodaya Junior College, Bodhan, Andhra Pradesh Board of intermediate with 91.8% (First Class with Distinction)

2002 – 2004 — D. Pharmacy, Govt. Polytechnic, Masab tank, Hyderabad with 82.5% (First Class with Distinction)

2004 – 2007 — B. Pharmacy, Kakatiya University Campus, K.U.Warangal with 76.1%(First Class with Distinction)

2007 – 2009 — Master of Pharmacy (Pharma Analysis & Quality Assurance), Center for Pharmacy, JNTU Campus, Andhra Pradesh, Hyderabad with 81.8%(First Class with Distinction)

PROFESSIONAL CERTIFICATION

Jul'2024 – Dec'2024 — Executive Certification Programme in Business Analytics and Intelligence, Indian Institute of Management, Rohtak (Credential ID: IIM-R/2024/eMDP/BAI-IV/26)

Jul'2022 – Nov'2022 — PMP Certified , Simplilearn (Credential ID: 3765334)

Aug'2021 – Oct'2021 — Lean six sigma Green Belt, OTIFAS International Pvt. Ltd. with 86.0% (Credential ID: 100641 & B100311)

INSTRUMENTS HANDLED

HPLC, GC, ICP-MS, UPLC, DISSOLUYION APPARTAUS, UV-VISIBLE Spectrophotometer, GC-MS, LC-MS, Particle size Analyzers, pKa-Sinus T3, DVS-Intrinsic, BET Surface area, SCM-Phenom pure, TGA, DSC, XRD, Osmomat-033 and related Instruments.

PERSONAL DETAILS

Father Name: DIL SUKH RAM
Date of Birth: 03-04-1984
Gender: Male
Nationality: Indian
Current Residential Address: Bachupally- Hyderabad, Telangana-India.