**AJAYPAL SHARMA**

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**OBJECTIVE**

* Seeking challenging assignments for a career encompassing personal & professional enhancement.
* A recognized position in the field of Regulatory affairs, which utilizes the subject knowledge, communication and documentation skills as a proactive member of organization.
* My long term career goal is to hone my regulatory knowledge and management skills towards a leadership position in Regulatory and Business development.

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**CAREER HIGHLIGHTS**

* **PRESENT**

**NOVARTIS HEALTHCARE PVT. LIMITED, HYDERBAD March 2012– till –Present**

**Post held: Documentation Specialist-II in OTC GPD Division**

**Responsibilities handled**

* Writes/reviews high-quality CMC documentation during development and product registration, respecting agreed CMC regulatory strategies, assuring technical congruency and regulatory compliance, meeting agreed upon timelines and e-publishing requirements
* Assists with providing information for responses to health authority questions during development and registration
* Identifies the required documentation for submissions and negotiates the delivery of approved technical source documents in accordance with project timelines
* Partners closely with Global regulatory affairs CMC associate responsible for project for review and approval of CMC documents
* Writes high quality internal analytical documentation for GPD in conjunction with technical experts.
* Writes product monograph and raw material monographs. Assists with writing of analytical method validation documents including protocols and reports. Assists with writing of analytical instrumentation documents, including qualification and re-qualification protocols and reports.
* Assures timely delivery of all documents to customers.
* Applies systems (EDMS, Novstyle, Access, Sharepoint) and procedures necessary to maintain proper records and documentation management.
* Acts as training administrator for eSOP, QMs for India and Switzerland Site.
* Control and distribution of internal technical documents for GPD, India
* **PREVIOUS**

**RANBAXY LABORATORIES LIMITED GURAGON Feburary 2011 – till –March 2012**

***Post Held:* Regulatory Research Scientist**

***Responsibilities Handled:***

* Prepared CMC documentation for drug product registration through National Procedure/ Mutual Recognition Procedure and Decentralised Procedure in EU.
* Responded queries (Quality) raised by various EU Regulatory Agency while the assessment of dossier through National Procedure/ Mutual Recognition Procedure/ Decentralized Procedure.
* Working knowledge of Type I (A&B) and Type II complex variation based on the requirement of manufacturing and compliance and responded to the queries raised during their assessment procedure in EU.
* Identify the required documentation for submissions and arrange approved technical source documents from the concerned department in accordance with project timelines.
* Compilation of marketing authorization approval status/ details and ensure for future manufacturing and supply of finished product as per approved MA details.
* Experience of working in close liaison with cross functional teams including those of Product development, Manufacturing, Licensing and Corporate affairs.
* Maintenance of filed dossier, archival of Response to query, Variation and Renewal.
* Actively involved in the preparation of SOP and regulatory guidance
* Review of change control and their evaluation
* Review of Safety update and their compliance in commercial supply.
* Provided necessary feedback to team developing drug products using regulatory guidelines and practices.
* Communicated with regional regulatory counterparts on requirements /clarifications arising during product development.
* Additional support to regulatory affairs based at region with respect to module 1 (administrative) information in MAA.
* Evaluate regulatory filing impact of OOS, variations, change controls, deviations etc.
* Ensure reposition of comprehensive product information into central repository

**CORE COMPETENCIES**

* Communication in technical matters.
* Regulatory requirements.

**Analytical Research (Ranbaxy Research Laboratories, Gurgaon) April 2006 – Jan 2011**

Worked on HPLC method development and method validation for assay, related substances and dissolution method development studies of drug products and drug substances

***Responsibilities Handled:***

* Prominently involved in the Analytical Method transfer at sites in the United States for the settlement of FDA queries.
* HPLC analytical method development.
* Validation of HPLC analytical methods fulfilling ICH and USFDA guidelines.
* Development of analytical methods and validating the same for formulations for Para IV and EU submission.
* Technology transfer of Analytical methods to various sites and locations across the globe from R & D.
* Scale up co-ordination for Validation batches
* Trouble shooting handling during analysis.
* Calibration of HPLC instruments (Waters-Alliance & Agilent)
* Literature search.
* Preparation and execution of SOP’s.
* Providing support to regulatory department in responding to different analytical related queries.
* Industrial instruments handled: -with HPLC system (Waters, Agilent, Merck), UV spectrophotometer (Shimadzu, Perkin Elmer), IR spectrophotometer (Perkin Elmer), Dissolution tester (Distek and Pharma test), Electrolab Disintegration apparatus.
* Software Knowledge: Empower HPLC software built 1154, Shimadzu HPLC software, Agilent Chemstation software.

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**ACADEMIA**

**Master of Pharmacy (Quality Assurance)** from Lachoo Memorial College of Science & technology, Jodhpur, India.

**Bachelors in pharmacy** from Guru Nanak Dev University, Amritsar, Punjab, India.

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**PROFESSIONAL ACHIEVEMENTS**

* Recipient of 2012 OTC Global Excellence Award at Novartis Consumer Health.
* Qualified GATE (Graduate Aptitude Test in Engineering) Exam with 80.34 percentile.
* Received Scholarship from AICTE (All India Council for Technical Education) for higher studies.

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**IT Expertise**

* Basic understanding of Track wise IT system, SharePoint, and Global Variation Management System.
* Proficient in managing *NeeS and EURS validator tools* for all post-approval submissions.
* Proficient in managing Adobe 8 & above reader/writer tools for handling of all regulatory submissions.
* EUDRALINK

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**PERSONAL INFORMATION**

**Date of Birth:** July 29th 1979

**References:** Available on Request

**Marital Status:** Married