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| |  |  | | --- | --- | | **First Name of Application CV No1624110**  Whatsapp Mobile: +971504753686  New_logo.gif  To get contact details of this candidate Purchase our CV Database Access on this link.  <http://www.gulfjobseeker.com/employer/services/buycvdatabase.php3> | | |  | **SENIOR PROFESSIONAL - PROCESS VALIDATION AND NEW PRODUCT LAUNCH** | | M. Pharmacy (Pharmaceutics) with expertise in Scale up & Process Validations and  Transfer of products from R & D scale to Commercial scale and Site Transfers,  Process Improvements and Troubleshooting of the Commercial Products. | |  | |
| **CAREER HIGHLIGHTS**   * Played a Critical role in supporting the New Product Launches for Regulated Markets by providing the Timely support during the Manufacturing of Pre validation and Validation batches. * Successful in Technology Transfer from R & D scale to Commercial Scale Manufacturing for Regulated markets like USA, Europe, Australia and Canada for many products (Tablets and Capsules - Immediate Release, Modified Release & Delayed Release) * Site Transfers (Transfers from One site to another site and in between sites)   -Visited to Toronto, Canada for site Transfer products.   * Performed Technical Risk Assessments (Scale up Risk Assessment) of the various Products before Process Validation by reviewing the product development reports and executed submission batch documents, Exhibit summary reports and Product history. * Succeeded in Resolving problems faced during Scale up (during Process validation batch manufacturing) and Addressed Many of the Market Complaints related to manufacturing process. * Qualified Trainer for the Process Validation Life Cycle Management-Validator Software used for reviewing the Process validation and Commercial batches analytical data. * Prepared Equipment Equivalency Reports for showing equivalency of the equipment’s at various scales (R &D and Commercial Scale). |
| **REWARDS AND RECOGNITION**   * + Received PAID award in Apotex Research Pvt Ltd, for resolving the Market complaint in time   + Received an Achievement award in ANVESHAN II for resolving the process issues in DR Reddys Labs Pvt Ltd.   + Received an "BEST PERFORMANCE TEAM" Achievement award in IPDO UTSAV- 2011.   + Winner of the Chairman's Gold medal for the best meritorious student, M. Pharm, 2006   **PROFESSIONAL EXPERIENCE** |

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| **KEY RESPONSIBILITIES**   |  |  | | --- | --- | | **Technology Transfer / Process validation** | * Technology Transfer of products from R& D to Commercial scale by performing the Technical Risk Evaluation and Execution Process Validations for New Product launches, Market Extensions, PLCM- Manufacturing Process Changes & Process Improvements & API Source Change | | **Technical Risk Evaluation (Scale up risk assessment)** | * Performing Technical Risk Evaluation (Scale up risk assessment) for the products Prior to start of Process Validation batch/First time commercial batch manufacturing by reviewing the Product development history, process development data, review of executed submission batch documents and submission batch report and related Incidents and Deviations, Past Product History. | | **Submission batch executions** | * Execution of Submission Batches New Products, Site Transfer products, Products with manufacturing process changes | | **Site transfers** | * Reviewing of the product history at the other site and Comparison of the manufacturing process between sites and Execution of Feasibility Trail batches, Process Optimization batches & Submission batches/ Process Validation | | **PLCM** | * Product Life Cycle Management Feasibility Trail batches, Process Optimization batches, Submission batches | | **Product Development** | * Formulation development of solid Oral dosage forms viz. Modified release dosage forms (Matrix systems, Multi-particulate systems, Bilayer systems, Delayed Release) and Immediate release dosage forms for US/ Europe and Australia. Preparation of Strategies for formulation development, literature and related patents search |  * Design of the Experimental plan for trouble shooting of the products for addressing the risks involved in the Scale Up and Validation Batch Manufacturing. * Review of the Process Validation Protocols and Process Validation Reports for various markets * Performing Technical Investigation and reporting the same for Problems faced during Commercial batch manufacturing. * Planning and Management of Submission batch execution/Process Validation batches execution/Process Demonstration batches execution. * Addressing the Formulation and Process development related CMC deficiencies from regulated agencies * Preparation and Review of the documents (Master Formula Records, Master Production Documents, Sampling protocols, Stability protocols and Hold study protocols, Process Demonstration protocols & Process demonstration summary reports * Applying for Test and Manufacturing licenses for new products and site transfer products * Reviewing all the Documents related to Technology transfer for Regulatory audits.  |  |  |  | | --- | --- | --- | | **EDUCATIONAL QUALIFICATIONS** | | **ADD. QUALIFICATIONS** | | **Master of Pharmacy (Pharmaceutics)** | Vinayaka Missions College of Pharmacy, (VMDU) Salem with 75% aggregate- **2004-2006** | Pursuing Part Time Course in **Statistical Quality Control and Six Sigma –Green Belt** from Indian Statistical Institute, Bangalore | | **Bachelor of Pharmacy** | G. Pulla Reddy College of Pharmacy, Hyderabad (OU university) with 70% aggregate-**2000-2004** | | **Board of Intermediate (M.P.C)** | Ideal Jr. College, Hyderabad with aggregate of 84%- **1997-1999** | | **Project Work** | Project title: Formulation Development of Fast Dissolving Tablets of Aceclofenac from Karnataka Antibiotics and Pharmaceuticals Ltd, Bangalore | |   **Personnel strengths**  Good Communication skills, Trouble shooting skills, Self-motivated, Report wiring  Data compilation and Data Interpretation  **Personnel details**  Age : 35 years  Date of Birth: 10-Jan-1981  Gender: Male  Nationality: Indian  .  Marital Status: Married  Religion: Hindu  Languages Known: English, Telugu, Hindi & Kannada  Hobbies: Reading |