**BHAKTI**

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| **MSc Formulation Science**  **University of Greenwich(UK)**  [**Bhakti.331934@2freemail.com**](mailto:Bhakti.331934@2freemail.com) | bhakti |

Executive Summary

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| *Western Post-Graduate from Greenwich University (UK) with over 10 years of broad experience in allopathic and ayurvedic drug formulation with respect to development and validation of robust analytical test methods to support formulation development, stability testing and quality control testing of new pharmaceutical formulations, ensuring delivery in accordance with project timescales and deadlines. Experience in analytical investigations and analytical problem solving, in support of formulation development activities. Experience in supervising the day to day analytical development activities and analytical development team.*  **MSc. In Formulation Science from University of Greenwich (UK).**  Presently working as **Senior Analytical Development And QC Manager with Arihant Siddha Lab. Pvt.** **Ltd. India** |

**Career Objective**

To seek a challenging job which is in tune with my ability and aptitude in a reputed organization, where I can integrate my management, technical, analytical and entrepreneurial skills for the organization as well as adding growth and value to both the organization and my own professional development.

## **Skills**

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| * Leadership in analytical development | * Strong manager and communicator |
| * 10+ years of lab management experience | * Strategic thinker that sees the bigger picture |
| * Deep knowledge of FDA guidance related to method development and validation | * Focus on business process optimization |
| * Project management expertise | * Technology Transfer |
| * GLP/GMP experience | * Successful Motivator |

Professional Experience

**Arihant Siddhaa Laboratories Pvt Ltd. (2006 to till date)**

***Job Responsibilities:***

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| Senior Analytical Development and QC MANAGER | **From: Oct.2014 to Dec.2016** |

* Developing and validating analytical test methods to release drug substance, drug product and intermediates followed by Good Manufacturing Practice (GMP).
* Established regulatory specifications for drug substances, drug products and successfully filed numerous filings with the FDA.
* Transferring new analytical techniques to the Quality Control (QC) laboratory.
* Ensured that all lab operations meet all compliance and regulatory guidelines.
* Purchasing, validating and maintaining equipment for analytical development activities.
* Controlling laboratory chemicals required for analytical development activities.
* Planning and organizing stability testing.
* Stability testing for products for new formulations.
* Writing/reviewing specifications and methods of analysis.
* Writing/reviewing of Standard Operating Procedures (SOPs).
* Using laboratory chemicals in accordance with Health and Safety and Home Office requirements.
* Observing and complying with Good Manufacturing Practice (GMP) and Good Distribution Practice (GDP).
* Observing and complying with company Health and Safety Policies.
* Observing and complying with company Standard Operating Procedures (SOPs).
* Working with all members of staff to maintain and develop the positive progressive culture within the organization.
* Undertaking any other duties, either for this department or any other department within the business, which may be requested by the Line Manager, for which training and/or an explanation has been provided and understood.

***Job Responsibilities:***

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| Quality Control And Quality Assurance Head | From: Apr.2013 to Sept.2014 |

* Manage, plan and direct the Quality Control and Microbiology laboratories to ensure lab testing provide the highest quality analytical support for manufacturing while ensuring compliance with protocols, cGMP and safety regulations.
* Provide QA leadership and technical support to external suppliers in order to ensure commercial products are manufactured and tested in compliance of GMP/GDP.
* Direct the work activities of the finished products / raw material and microbiology work groups to ensure that testing is executed in a timely and compliant manner.
* Execute and approve all laboratory investigations.
* Review and investigate all laboratory data outside of trend.
* Review and approve protocols and reports such as method validation, method transfer, process validation and stability.
* Provide leadership, management, evaluation and training to all laboratory employees.
* Ensure all vendors have been qualified and adhere to vendor qualification standards with the aim of optimal utilization of the reduced testing procedure.
* Establish and implement a standard structure to ensure optimal test / cost ratio.

***Job Responsibilities:***

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| Sr .Microbiologist Quality Control Dept.And Lab QA | From: Apr 2012 to Apr 2013 |

* To maintain work flow in Microbiology section by communicating and coordinating with other functional department such as Production, Quality Assurance, Store and Engineering departments coordinating with them and to improve the good quality work.
* To perform Environmental Monitoring of Production Areas by settle plate, Air Sampling and Surface Swab method.
* To perform and prepare Microbial Culture Media and its Sterilization as per approved loading pattern system.
* To perform Growth Promotion Test (GPT) and Growth inhibitory test of microbial culture media prepared.
* Water sampling and analysis: Purified water and Potable water.
* Microbial Limit Test (MLT) for in process samples, Finished Products, Bulk Samples and Raw materials.
* Bio-burden testing of In-process samples.
* Documentation managements: To maintain routine and non-routine log books records and Reports.
* Culture Preparation, dilution and sub-culturing of microbial standard culture and master Culture.
* Graphical Representation of data for environmental monitoring and water results.
* Perform surface monitoring in the production area by Swab sampling analysis /Testing.
* Participate in all documentation and reporting of result data.
* **Instrument knowledge**

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| * Laminar Air Flow unit | * Centrifuge |
| * pH meter | * Vacuum oven |
| * Air Sampler | * B.O.D Incubator |
| * Microscope | * Water bath |
| * Colony Counter | * Fumigator |
| * Vertical Autoclave |  |

***Job Responsibilities:***

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| Microbiologist Quality Control Dept. | From:  **Dec 2008 to Dec 2010** |

* Media preparation & sterilization.
* Water analysis and Environment monitoring.
* Swab testing*,* Growth promotion test of media.
* To perform Identification of cultures and sub culturing.
* To perform dry syrup assay.(Lactic Acid Bacillus Assay)
* Testing of load of Bioburend.
* Analysis of Raw materials, Bulk Samples, In-process samples, finished products.
* Calibration of Instruments and Maintaining calibration records.
* Sampling of Raw material & Bulk Samples.
* Preparation and review of SOP & SCP related to Micro.
* Review of analytical reports.
* Maintaining daily usage log books of instrument and related documents.
* Preparation Protocols and TDS.
* Checking the reports of Raw materials, bulk and finished products, packing material.
* **Instrument knowledge**

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| --- | --- |
| * Laminar Air Flow unit | * Microscope |
| * pH meter | * Autoclave |
| * Centrifuge | * Hot Air Oven |
| * Vacuum oven | * B.O.D Incubator |
| * Water bath |  |

***Job Responsibilities:***

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| Production Manager | From:  Oct2007 to Dec 2008 |

* Co-ordination with Formulation department for scaling up the production
* Production planning
* Ensuring actual production as per the plan
* Optimizing Batch Size to maintain a good balance between sales & manufacturing.
* Optimizing Initial stock & bulk requirement for new batch products.
* Optimizing Shelf Life for certain products by communicating to the R&D, the products for which the Shelf Life needs to be increased and thereby reduce stock expiry.
* Study packaging for Pharma products.

**Job Responsibilities:**

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| Assistant QC Manager | From: July 2006 to Oct 2007 |

* To ensure products to meet quality and efficiency standards set by company.
* Analysis of Raw materials, Bulk Samples, In-process samples, finished products.
* Using various laboratory instruments like High Performance Liquid Chromatography (HPLC), UV Visible Spectrometer, Polarimeterj, Refractometer, PH meter, Particle size analyzer, Melting Point apparatus, Muffle Furnace, Friability Apparatus, Disintegration Apparatus, Dissolution Apparatus.

Academic Background

**Master of Science:** Formulation Science Year Completed: 2012

University of Greenwich-London

**Masters Dissertation** in Preparation of New Microgel Polymers.

**Bachelor of Science**: Pharmacy Year Completed: 2006

Shivaji University-Kolhapur, India

Languages:

English, Hindi And Marathi

Personnel Information:

**Nationality:** Indian

**D.O.B.:** 15 Sep 1983

**Marital Status**: Married

References:

To be furnished promptly upon request with supporting documents.