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| **Guru Kripa,1B701,**  **NG Suncity, Phase -1 opp to BMC hospital, Thakur Village** ARVIND GUPTA Kandivali E-400101, Mumbai. **Email– gupta2002gupta@rediffmail.com** Contact No., +919930613636 |
| **Introduction :**   * An experienced quality-led business manager with a proven track record of success within highly competitive manufacturing sectors. * Strong all-round leadership & operational management experience. * Results orientated & profit-focused, with quality, planning skills. * Experience of production operations with enrichment of quality, ISO 9001, MHRA, USFDA, productivity, quality focus & profitability initiatives within leading-edge markets.   **Highlight:**   * M.PHARM (PHARMACEUTICS) * Ten years experience in Quality Assurance (injectable, semisolids and solid dosage form ) * Well travelled abroad on official responsibilities, countries visited are Switzerland,England,Oman, France etc. as Auditee and Auditor. * **Present status**: Working as Quality Manager-Corporate Quality Assurance (CQA), Amdipharm Mercury Pharma company Ltd (AMCo),London, UK. Working at Mumbai office.  Specialties  * GMP Compliance, Regulatory Compliance, Stability Studies & documentation. * Process Validation & Qualification, Cleaning Validation, Computer System Validation (SAP Validation also) and Hold Time Studies. * GMP auditor (see appendix-I). * User Champion in SAP Development & Implementation Project (QM Module).   **Education, Qualification**:   * M. Pharma in Pharmaceutics from S.G.S.I.T.S, Indore in 2003. * B. Pharma from L.M. College of Science & Technology, Jodhpur (Rajas than) in 2001. * GATE 2001 qualified with 91.7 percentile.   **Employment:**   1. Working with Amdipharm Mercury Pharma company Ltd (AMCo), Mumbai. (A UK based MNC)   **Designation**: Quality Manager-CQA (injectable, Semisolids and solid dosage form).   * **Duration**: July, 2008 to till date. * **Job Profile**: responsible for * Coordination with third party manufacturers (TPMs) and testing laboratories to get the quality product as per MA and GMP regulations. * Overall responsible for products quality manufactured at external manufacturing site & monitoring of the sites for GMP compliance and communication with Central Quality of external manufacturing site. * Coordination with Qualified Person (QP) for product release in time for EU market. * Regulatory and QMS Compliance & Quality related issues leading to a threat to the Product or Patient Risk. * Review and follow up of documentation such as change control,deviation, investigation reports & implementation of CAPA. * Ensuring compliance with national and international standards and legislation. * Quality Risk Management * Management of Validation activities likes process validation and computer system validation. * To manage stability study with a view to ensure timely accomplishment of product targets to meet the regulatory requirements. * Responsible for preparation of response against regulatory queries. * To ensure that all the skills and knowledge gaps identified within the team is managed and delivered. * Liaise effectively with SCM\Regulatory Personnel to drive efficiency. * **Key achievements include** * Active host in MHRA audit four times, * Successfully completed SAP implementation project for quality module. * Participation as Manager in project “**Chrysalis- company name change**”. * Design and successfully implemented stability studies program for finished product. * Successfully establish profit making products by gap analysis and trouble soothing. * Implementation of risk assessment concept in change management system. * Currently participating as key member in project “**Gemini- Company Merger**”   (2) Worked with **Torrent Pharma Pvt Ltd, Indrad, Ahemdabad**   * **Designation:** Assistant Manager Quality Assurance (injectable and solid dosage form). * Duration: September, 2005 to July, 2008. * Job Profile: * Handling & review of ANDA before submission. * Review of following documents for dossier compilation * Master Formula Card, Sampling Protocol, Process Evaluation Report, Exhibit Batch Summary Report, Stability Protocol, Specification & STP of RM and Finished product * Preparation and Implementation of Validation Master plan (Process Validation, Cleaning Validation, Computer system validation) * Handling of Site Transfer Dossier. * Handling of Variation in Site Transfer Dossier. * To get prepared to face external GMP audits * Self inspection and auditing * Handling of OOS & Deviation. * Key achievements include * Active hosted in USFDA audit two times, * Design and implementation of Hold Time studies for intermediates and bulk pharmaceutical. * Successful technology transfer of 120 products from German dossiers (Company takeover). * Championed the development & implementation of cleaning validation and Process validation plans.   (3) Worked with **SUN Pharmaceutical Industries, Silvassa. (DNH)**   * **Duration**: August, 2004 to September 2005 * **Job Profile:** * BMR & BPR preparation and auditing * Change control & deviation handling * SOP Preparation and issuance * Process Validation Protocol preparation * Validation result handling and report preparation * Market complaints handling.     (4) Worked with **Nicholas Piramal India Limited, Pithampur (M.P)**   * Duration: July 2003 to July 2004. * Job Profile: (injectable and solid dosage form) * Batch Manufacturing Record Checking. * Assisting in Validation work. * SOP & Format review, and Issued   **Personal Details :**   * Father’s Name : Shri R.D. Gupta * Mother’s Name : Smt. S.D. Gupta * Date of Birth : 9th July, 1975 * Marital Status : Married * Gender : Male * Health : Excellent * Permanent Address : 46, Jawahar Nagar,   : Bazaria, Sawai Madhopur – Rajasthan   * Phone Number :+91 99 3061 3636, +91 99 3061 3637 * Present salary : 13.60 lacks (fixed) + Performance pays 15%-20% of fixed CTC (variable) per annum. * Expected salary : Negotiable at the time of interview * Notice period : 30 days   **References:**  **Dr. Alok Agarwal Mr. Sairam**  Executive Director, Executive Director, Quality  Nector Pharmaceutical Ltd Dr. Reddy laboratory Ltd  Hyderabad Hyderabad    **Place : Mumbai**  **[ARVIND GUPTA]** |
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**A p p e n d i x l**

**Site Visited**

1. Euro Caps Ltd, a manufacturer of softgel capsules based in South Wales,UK
2. Honeywood Limited, a contract packaging company operating in the pharmaceutical, healthcare and general sectors.UK
3. Bentley Laboratories Ltd, a manufacturer of pharmaceuticals, based in Edgware,UK.
4. Pharmapac UK Ltd. Wirral, United Kingdom.
5. Oman pharmaceutical ltd, Oman.
6. Custom pharmaceutical ltd , UK
7. Bristol Lab, UK.

**A p p e n d i x II:-Trainings attended**

**Work related trainings;**

1. Computer System Validation-21CFR Part11/Annex 11.
2. Preparation of dossier and Variation application procedure (EU Dossier) by RRG, UK.
3. New GMP regulations for dietary supplements
4. Cleaning validation technologies and GMP expectations
5. Process validation technologies and GMP requirements.
6. Basic principles & concept of SAP.
7. SUPAC guidelines for IR dosage forms.
8. Stability studies of new drug substances and new dosage forms.
9. Basic requirement for ANDA filing.
10. Basic aspect and rules for GMP audit.

**Personality development related trainings**;

1. Accent leadership Program
2. Work life balance skills
3. Goal setting & Planning skills
4. Presentation skills
5. Financial and Nonfinancial aspects
6. Conflict Management skills
7. Coaching and Feedback skills
8. Interpersonal skills
9. Prioritization and Problem solving skills
10. Work delegation and listening skills