**RESUME**

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| **MR. DEVANAND C. BARAIYA**  “VIDHYANAGAR SOCIETY ”,  M-12/149, Near Keshwbag Party Plote,132 Feet Road, Setellite, Vastrapur- AHMEDABAD-15.,  Mobile: + 919879120818.  Email: baraiya\_devanand@yahoo.com. |  | **E:\Photos\IMG_20190310_125005.jpg** |

# SUBJECT: APPLICATION FOR THE POST OF QUALITY---AGM/DGM/GM

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## Personal Profile:

# M.Sc. (Organic Chemistry), DBM, & 26.0 YEARS EXPERIENCE IN QUALITY SECTION.

Born on 27th May 1968, having good communication skill, logical thinking, ability to work as a team leader, well versed with various aspects of QUALITY MANAGEMENT.

* Evaluation of Audit observation and write compliance response of different regulatory with respect to guidelines, Operation justification, hypothesis study and Corrective and Preventive Action.
* Audit management, Team management, coordination and tasking and delegation.
* Involvement in route of synthesis of new product of API, impurities and Intermediate stages. Method development of Unknown substances and its method validation.
* Effective communicator with strong analytical, problem solving and organizational abilities.
* Handle various wings of Quality control and Quality assurance departments like Formulation, Active Pharmaceutical Ingredient, Stability, Sterile lab and Process development.
* To evaluate the Nitroso and Nitrosamine impurity in API, KSM, Intermediates, Solvents (fresh and Recovered) and different stage of water by GCMS.
* My leadership skill, communication capabilities and analytical skills makes me a good team leader.
* My energy levels, self-motivation abilities, pressure handling abilities and self-exertion abilities make me an ideal candidate for Quality management team member in your organization.

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**Current Employment:**

* Presently, working as Quality (Sr. Manager-QC) at Glenmark Life Sciences, Dahej since December, 2016. (A USFDA. EUGMP, PMDA approved facility)

**Achievements:**

* Recently, USFDA, EDQM, Russia audits are successfully comply without 483. (Year-2018)
* Successfully audits complies like USFDA, TGA, MHRA, WHO, BSC and other customer audit like NOVO NORDISK, TEVA are clear without 483.
* Control the impurity generation during the reaction mass, this was carried out from KSM. Revised specification with control limit of impurity RRT.
* Using advance technology optimizes man and machine..
* With optimum resources handling day to day activities under compliance environment.
* Successfully handled the activity of Method Validation (Assay, Related substance, Dissolution), Method Transfer and Method verification of other countries.
* Developed new analytical method of different intermediate stages and finished drugs to control impurities, reduce time cycle and increase yields up to 20% to 50%.
* Timely analyzed, evaluated and provided the impurities standards to user department (National and international) for routine analysis to save NDP, cost and timely launch the product.

**Carrier Work Profile:**

**Quality Control and Analytical Development:**

* Overall responsibilities over the Quality control activities of the site, managing and leading the department. The role is a member of the Site Leadership Team and reports solid line into the Head of Quality
* Compliance of 21CFR part 10 and part 11 and data integrity in Quality control.
* Wide Knowledge of Analytical Method development of API, intermediate stage, solid and liquid doges form on different instrument like HPLC, GC, UV etc.
* Knowledge of Method transfer and Method Verification from ADL to Plant and other Countries.
* Exposures in validation like Method validation, Cleaning Validation, Retrospective validation, Prospective validation, Concurrent Validation, Water System Validation and Process validation.
* Handled the Documentation activity for preparation of Standard Operating Procedure, preparation of specification, Method of analysis, Protocol preparation of RM, FP, control of protocol and distribution of protocols.
* Resolve trouble shooting in Analytical method, route of synthesis etc.
* Knowledge of Calibration and operation with modern instrument like HPLC, GC-HSGC, FTIR, IR, UV spectrophotometer, Particle size analyzer, Auto Karl fisher, Polarimeter and Dissolution Apparatus.
* Qualification Exposure like URS (User requirement system), Design Qualification, Factory Acceptance test (FAT), Site Acceptance Test (SAT), Installation Qualification, Operational Qualification, Performance Qualification and Safety Qualification.
* Interpretation of MASS and XRDP histograms.
* Exposure in Chemical and HPLC analysis of Raw Material, Intermediate, Drug substance and Drug Product. Controlled the activity of sampling, testing and release of Raw Material.
* Controlled the activity of distribution and release of in-process sample, validation sample, Semi Finished Goods and Finished Goods.
* Knowledge of different formulation product in form of solid and liquid Dosage, Coated and ER/PR tablets, Hard and soft Gelatin capsule, Syrup, Injection and dry powder.
* Knowledge of different Drug Substance like Dounorubicine Hydrochloride, Sertraline Hydrochloride, Carbamazepine, Oxcarbazepine, Carbapenem Group, Cephalosporin group, ect.
* Practically do the maintenance work of HPLC, GC and other Laboratory Instruments.
* Investigation of details of Incident and Discrepancy of during analysis and reporting.
* To control data management and Maintain audit trail of different instruments.
* Exposure in Stability sample study analysis as per ICH guidelines and maintain its records.

**Quality Assurance:**

* The role plays a critical part in establishing the quality functions, labs & equipment at the site and its preparedness for cGMP product development to commercial production. The role ensures establishment of procedures, policies and practices in full compliance and consistency with company's global quality standards and national cGMP requirements.
* Responsible to prepare a strategic long-term plan to further strengthen the Quality system in the organization.
* Responsible for Leading and directing the QA leadership team.
* Provide technical leadership and expertise within the field of Quality Assurance and Quality Control.
* Responsible to build a strong team of professionals and ability to lead them to ensure that all facets of Quality like Assurance, control, documentation, Vendor Audits, Customer Audits are handled with required rigor.
* Knowledge of Risk Management, Risk Identification and Risked Based Testing.
* Review Quality Management system (QMS) as per current guideline and related implementation in verious department.
* Responsible for Review and approval of the Standard Operating Procedures (SOPs), Master Batch Record to meet the cGMP & regulatory requirements.
* Responsible to Ensure critical Deviations/Incidents are investigated and resolved.
* To evaluate and approval of the changes proposed through Change Controls management (Like Process, Equipments, Facility, Engg, Specification/STP etc )with complete risk assessments
* Investigating Out of specification (OOS) and find out actual root cause.
* Investigating Market Complaint, addressing root cause and prepared compliance report.
* Review and approval of the Annual Product Quality Review.
* Co-ordination with RA, CQA for ANDA and DMF submission project, timely fulfilled its requirements.
* Review the Product LDR (Laboratory Development Records) or Technology Transfer Document (TTD) and give the training to concern personnel
* Responsible for review and approval of Internal Audit Schedule and to conduct (Planned and Execution) Internal Audit as per schedule and also responsible to close the Non-Conformities
* Responsible for release batch and Document and Data control records activities.
* Review and approval of Qualification and Validation related documents of Sterile API, Non sterile API, and Dry Powder Injectable.
* Conduct the training of Production, QC, QA person regarding ICH guideline, regulatory updates and GMP/GLP compliance.
* To review and approval of the stability study data and significant changes during stability study.
* Approval of validation Master Plan/SMF, Quality Manual.
* To perform the vendor audits for approval of Raw Material/Packing material.
* Co-ordination with local FDA for various drug approvals.
* Responsible for corporate Quality related all the activities.
* Lead the team during several Regulatory/Customer audits.
* Review of details of OOS, OOT, Incident and Discrepancy and its CAPA.
* Review stability compilation and significant changes.
* Monitoring of all the QA activities, test results, defects, root cause analysis and identifying areas of improvement.

**EMPLOYMENT HISTORY**

* Worked at Amoli Organics Limited as DGM-QA/QC (Analytical Compliances) from March, 2016 to December, 2016 at Vadodara, Gujarat. (Independently faced USFDA and MHRA, WHO audit for QC Lab. No 483 observation.
* Worked at Unimark Remedies Limited, Baval. Ahmedabad as DGN -Quality from March 2013 to SEPT-2016.Independently faced USFDA audit for Cephalosporin plant. No Critical Observation.
* Worked at Unique Pharmaceutical Limited (JBCPL).Ankleshwar. as Sr. Manger -Quality control Head from October-2012 to Feb-203.Independently faced different customer audit for formulation plant. No Critical Observation.
* Worked at Torrent Pharmaceutical Limited, Indrad. as Manger -Quality control May-2006 to August-2012.Independently faced three times USFDA , MHRA audit and TGA audit for formulation and API plant, No 483 and Major observation.
* Worked at Amoli Organics Limited as Assit. Manager-QA/QC from May-2001 to December, May-2006 at Vadodara, Gujarat. Independently faced different customer audit for API plant. No Critical Observation.
* Worked at RPG Life Sciences Limited as Trainee to Officer-QA/QC from April-1994 to May-2001 at Aknleshwar, Gujarat in formulation unit.

#### MANAGEMENT SKILLS

Communication Skill, Problem Solving Skill, Leadership Skill, Team building and leading Skill.

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##### **Educational Information:**

* M.Sc. Organic Chemistry with Second class from Chemistry Bhavan , Bhavanagar

University, Bhavanagar, Gujarat in May-1993.

* B.Sc. Chemistry with First class from ShriK.V.Parekh Science Collage Mahuva. Bhavanager University, Gujarat in May-1991.
* DBM with First class from National Institute of Labour Education & Management, Chennai in April-1999.
* Diploma in Quality Control & ISO-9000 with First class from National Institute of Labour Education & Management, Chennai in Oct-1999.
* Have FDA approval for Tech. & Physiochemical from FDA, Gandhinagar, Gujarat.

**Total Experience: 26 Year in API and Formulation.**

⮚ In Formulation 14 years.

⮚ In API 12 years.

**Present Salary**: CTC 32.54 Lac ++.

**Reference:**

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| 1. Dr.P.C. Shekar (CEO),   Koras Pharmaceuticals Pvt. Limited.  Mumbai. (Mobile No.: 09821029547) | 2. Dr.R.K.Nanda (General Manager R&D)  Hindustan Antibiotic Ltd.  Pimpri-PUNE. |

(Devanand C. Baraiya)