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| **[RESUME : YOGESH GHULE](https://www.slideshare.net/ShreyKOTHARI5/resume-pramesh-kothari" \l "1)**  • Address : E-mail: ghuley504@gmail.com • Phone: +91 7384615658, 7384616350,  • Flat No. B-208, Mayur Geminus, Hadapdar, Pune, India. Passport No. : V5498363. |
| **Summary :**  • An eminently successful Quality Control professional with more than 20 years of comprehensive analytical expertise in complex formulations including Sold-Oral, Aerosol, Nasal, MDIs, DPIs, Injectable, transdermal in the pharmaceutical industry.  • More than 5 years of experience as Head of quality control leading the QC laboratories of growing multinational pharmaceutical companies, including one year in Africa.  • Adept at developing, enhancing, monitoring sustainable quality practices, compliant with global regulatory standards.  • Skilled in developing and enhancing Quality Control standards, Compliance, Method Validations and Transfers, Stability, and Timely executions.  • Competent with conducting quality audits for on-site labs, contract labs, API, and formulation manufacturing.  • Adroit at managing multiple chemistry and microbiology labs with various functions.  • Skilled at developing new laboratories (Greenfield Projects) and compliance standards establishment.  • Able to cultivate strategic relationships with employees, peers, managers, and stakeholders.  • Expert in writing technical reports like analytical method development, method transfer, deviation, change controls, audit compliance .  • Skilled at providing technical support for RA for CMC query of ANDA products.  •Focused and methodical Director offering expertise in testing scheduling and quality monitoring of multiple labs.  • Successfully faced USFDA, MHRA, ANVISA, WHO, PICs, Health Canada, and other regulatory audits. |
| **Key Skills/Expertise :**  • Have expertise and experience in all the latest tools and techniques of the laboratory.  • Analytical expertise for sophisticated analytical techniques like HPLC, GC, Dissolution, Malvern, Spreytech, Breath simulator, NGI, Cascade Impactor, etc.  • Established the analytical laboratory for complex formulation like MDI/DPI.  • Have specialization and exposure of OSD, aerosol / Nasal / MDIs / DPIs / Injectable / products analysis / product characterization and BA/BE studies.  • For specializing formulations like Tablets, Hard gelatin capsules, soft gelatin capsules, Aerosols, Nasal, Transdermal, Injectable, Medical devices.  • Have great analytical / investigation skills for the root cause identification.  • Have successfully transferred and validated many analytical methods for complex formulations like Tablet, capsule, Injection / Nasal / Aerosols / Nebulizer / MDIs / DPIs.  • Excellent communication and presentation skills for effective communications.  • Have excellent management skills and mentored to develop skilled analysts, executives, and managers.  •Trend evaluation of OOS / OOT / Laboratory Incidences to derive the CAPA and reduce the errors. |
| **Other competencies :**  • Designing Service Level Agreement  • GLP  • Internal and External Audits  • Trending and Analytics  • Investigation, Root Cause Analysis and CAPA of OOS/OOT/Deviations  • Technology Transfers  • Troubleshooting  • Analytical Method Validation  • Trackwise /Documentum /LMS /LIMS /Chromeleone /Lab Solution.  • Management skills  • PAT / NIR  • Regulatory Impact and Risk Assessment of the Proposed Changes.  • Microbiology  • CMO activities and Stability studies  • Strong work ethic  • Employee training/ Mentoring /Coaching  • Budget preparation and cost monitoring  • Recruiting and Hiring  • Composing Corporate policies and procedures  • Worked with MCKINSEY for Quality culture improvement and productivity enhancement  • Greenfield Laboratory project establishment Education. |
| **Education :**  • Bachelor of Science- (Pune University).  • Master of Science in Chemistry- (Pune University). |
| **Selected Achievements :**  • Successfully cleared USFDA audit resulted as VAI 2 times at Cipla Ltd, Goa at Verna.  • Successfully cleared USFDA (3 times), MHRA, ANVISA, Brazil audit leading QC team at Cadila Healthcare Ltd (Zydus).  • Three consecutive USFDA audits cleared without any 483 at Zydus Cadila.  • Have successfully managed multiple laboratories consisting of about 100 employees at Cadila Healthcare Ltd (Zydus). Ahmedabad, Zydus Healthcare Ltd Sikkim.  • Successfully cleared USFDA audit by supporting manufacturing site as Corporate Quality representative at Aurobindo Pharma, (All API Units : Aurobindo Sangareddy, Aurobindo Pashamyalaram, Aurobindo Isnapur, Aurobindo Gaddapotaram, Aurobindo Vizag & |
| •Successfully cleared USFDA audit Formulations : Aurobindo Bolaram, Aurobindo Pashamylaram, Aurobindo Isnapur, Aurobindo Jadcherla, Miyapur unit.  • Successfully cleared USFDA (22 times), MHRA (3 times), ANVISA, Brazil audit leading QC team at Aurobindo Pharmaceuticals Ltd, Hyderabad.  • Successfully cleared MHRA (3 times), ANVISA (2 times), ROW (Uganda, Taiwan, Srilanka) audit leading QC team at Pinnacle Life Science Ltd, Baddi.  • Have validated more than 100 methods for ANDA and DMF products under my supervision.  • Resolved analytical issue at Bodycote laboratory, United Kingdom and saved batches worth of 20 million USD.  • Honored with the Best mentor award by Quest. |
| **• Professional Work Experience (Starting with current position) :**  **Gary Pharmaceuticals LTD. (Ludhania), India Plant Quality Control Head (From Setember’2023 to Nov’2024) The plant is a green-field project and is still under qualification stage. It is large scale OSD product manufacturing plant with market target is USA.**  It is OSD manufacturing plant including manufacturer of Dermatology products and Cosmaceutical for all sorts of skin problems in the form of Tablets Capsules, Creams, Ointments, Gels, Lotions, Shampoos, Powders, etc. manufacturing capability. It is also engaged in CMO activities. The QC has about 35 employees with chemistry and microbiology labs.  • **ESSENTIAL DUTIES AND RESPONSIBILITIES**:  • Monitoring of laboratory establishment activities.  • Review and approve of instrument/equipment URS and purchasing.  • Responsible for preparation of the QC Capex.  • Review and approve of qualification protocols.  • Hiring quality professionals  • Involved in method development of PAT for blend uniformity testing and successfully implemented.  • Responsible for the establishment of the new laboratory, SOPs, instrument qualifications, and employee training.  • Evaluating equipment and process of laboratory, including automated systems that may be required to maintain performance levels for reproducible, reliable and efficiency improvement.  • Having expertise of Investigation tools, technical narration of Quality Management Systems (Change Control, Deviation, OOS ,OOT, Root Cause, Impact assessment, CAPA, Risk Assessment Protocol Reports).  • Develop and maintain robust SOP’s for QC activities and ensure their adherence.  • Responsible for laboratory operations.  • Monitoring of the GMP compliance within the Laboratory as per the SOP and guidance.  • Analysis planning with PPC, delegate and monitor the progress of work daily for timely deliveries.  • Review and approve of SOP’s, change controls, specifications, protocols, and reports.  • Troubleshooting to analyse for the Instrumental and Compliance problems.  • Set up the laboratory for the regulatory environment (USFDA and MHRA) from local FDA by training, teamwork, skill development.  • Timely submission of ANDA documents and CMC query-related response.  • Implementation of the quality system provided by CQ.  • Instrument qualification review and approval.  • Budgeting and purchasing of laboratory instruments and consumables.  • Handling of OOS/OOC/Repeat analysis and deviations.  • Improve productivity of analysts by monthly report monitoring and discussion.  • Lead QC team during regulatory audits. |
| **Pinnacle Life Sciences Ltd, Baddi. Head Quality Control May’ 2020 to Sept 2023.**  It is OSD, Sterile manufacturing plant including Anti-Diabetic, Anti-Cancer, Gastrointestinal and Analgesics products manufacturing capability having dosage forms OSD *- Tablets, Capsules*, Liquid Syrups, Creams, Gels.t is also engaged in CMO activities. It is UK-MHRA, EU-GMP, US FDA, and ANVISA approved plant. The QC has about 45 employees with chemistry, and microbiology labs.  **[SUMMARY](https://www.slideshare.net/ShreyKOTHARI5/resume-pramesh-kothari" \l "4)**  • Release targets and stability oversight. Overseeing and investigating OOS, OOT, deviations, Change controls, CAPA and laboratory incidents. Working with SME auditors like LACHMAN for compliance improvements. Composing QC budget and overlooking resource management. Managing FDA audits and compliance of GMP and PAI audits. Responsible for interviewing potential candidates and collaborating with HR for hiring QC professionals. Responsible for timely launch of new products. Actively participating in the business and compliance meetings. Designing more efficient processes to improve Quality and efficiency.  **ESSENTIAL DUTIES AND RESPONSIBILITIES**  • FDA compliance, efficiency, and output for targeted deliveries & Determining laboratory (Chemistry & Microbiology) capacity and resources needed to maintain QC turnaround time for finished goods and raw materials.  • Representing QC during audits. Faced FDA successfully two times in 2020.  • Review and approval of specifications and test methods for finished goods and raw materials methods in an accurate, timely manner.  • Successfully retrospective review of deviations, CAPA and stability program under compliance commitment to FDA.  • Ensuring the method transfer of finished goods and raw material occurs in a timely manner from R&D or any other sources. & Monitoring of CMO activities and participate for troubleshooting.  • Providing comprehensive formal and informal leadership to promote a positive work environment and communicates overall business expectations to the QC groups.  • Directing the daily operations of the QC Lab to maintain a high degree of performance, Cgm. |
| **Cadila Healthcare Limited (Zydus), Ahmedabad, India Site Quality Control Associate Manager (Since December’2011 to April’ 2020) Joined as Deputy Manager.**  It is OSD, sterile and transdermal manufacturing plant including vaccine manufacturing capability. It is also engaged in CMO activities. The QC has about 300 employees with chemistry, vaccine, and microbiology labs. The product supply to USA, EU and ROW Markets.  **SUMMARY**  Directing 10 managers and more than 100 Quality Control professionals and managing two QC laboratories. Developing the Quality culture by QUEST movement. Responsible for reviewing and approving the documents including SOPs, OOS, OOT, OOC, Lab incidences, Change Controls, CAPAs, and deviations. Work with SME auditors like 5W, LACHMAN for compliance improvements. To support the investigation team for hypothesis plan and root cause analysis of OOS/OOT/OOC and laboratory incidences. Responsible for installing and maintaining CFR compliant instruments. Accountable to upgrade quality system as per corporate guidance. Supporting managers for troubleshooting for testing and compliance. Responsible for achieving the release target and updating the supply chain. Monitoring and maintaining laboratory expanses per allotted budget. Responsible for timely commercialization of ANDA products.  **ESSENTIAL DUTIES AND RESPONSIBILITIES**  • Managing laboratory operations (Including vaccine lab.) and about 100 employees.  • Managing about 10 managers as the second line to maintain QC operations.  • Monitoring of the GMP compliance of the Laboratory for business continuity.  • Implementation of the quality system provided by corporate quality.  • Lead QC team during regulatory audits.  • Develop the quality culture by QUEST movement.  • Successful audits SMEs like 5WS, Lachman.  • Review and approve of QMS documents like SOP’s, OOS, OOT, Lab. Incidences, change controls, CAPA, Deviations.  • Analysis planning with GDSO for release of raw materials and finished products to achieve the business targets.  • Developing the team for various skill levels including complex analysis, review, investigation, and leadership.  • Troubleshooting for the Instrumental and chemical analysis.  • Submission of ANDA documents and CMC query-related response.  • Budgeting and purchasing laboratory consumables and instruments.  • Review and approve of QMS documents like SOP’s, OOS, OOT, Lab. Incidences, change controls, CAPA, Deviations.  • Attending business meetings for future products development • Initiative to improve laboratory productivity, infrastructure.  • Reviewing and approves investigations in a timely manner to ensure adequacy of investigations by directing the team with investigation strategies.  • Ensuring all analysts/microbiologists are properly trained and training is maintained at the highest level for compliance and deliverable.  • Reviewing and ensures timely revisions and implementation of compendia changes for monograph. Reviewing and updates SOPs as per regulatory guidance.  • Participating in company meetings as needed for business and compliance needs.  • Evaluating equipment and process of laboratory, including automated systems that may be required to maintain performance levels for reproducible, reliable and efficiency improvement.  • Working cross-functionally for deviations and system improvement.  • Quality systems in the plant.  • Responsible for setting up the laboratory and plant for the regulatory environment, by re-arrangement of resources, training, teamwork, skill development.  • Handling of OOS/OOC/Repeat analysis and deviations.  • Review and approval of change control, SOPs, Protocols, etc…  • Develop the skilled person for all sections of the lab. Like raw-material, final products, stability, review.  • Set up the method validation laboratory to support the ANDA registration of other locations. .  • Implementation of the quality system provided by CQ and monthly discussion of QRM for quality system improvement. |
| **Aurobindo Pharmaceuticals Ltd., Hyderabad, India Research Associate-IV, Corporate Quality Department. (November’2007 – November’2011) Joined as Research Associate-III.**  It was the corporate laboratory of Aurobindo Pharmaceuticals Ltd. It provides services for Quality control, Stability, method validation and transfers for all Bulk, OSD, sterile units. It has also, laboratory for MDI/DPI [and Nasal for](https://www.slideshare.net/ShreyKOTHARI5/resume-pramesh-kothari" \l "6)method validation/transfer and commercial testing with 50 employees. The primary market was USA, EU and ROW.  ESSENTIAL DUTIES AND RESPONSIBILITIES  •Method validation/transfer and commercial testing to all units with co-ordination to RnD, Regulatory, Units.  • Validated and transferred about 100 methods.  • Hold full responsibility for the timely delivery of ANDA/NDA projects through successful coordination of all tasks associated with analytical testing like method validation, method transfer, dissolution studies, BA/BE studies.  • Investigation of technical issues/failures, developing CAPAs and its implementation scientifically, thorough, and timely manner by supporting investigator in setting investigation strategies.  • Providing support to the plant QC for successful transfer of methods and remedial of methods on the analytical issue.  • Defining Key Performance Objectives (KPOs) for all personal and specific projects.  • Continuous development, update, and strengthen GLP requirements by reviewing regulatory guidance, events, deviations, trends, warning letters.  • Continuous improving productivity by updating instruments, introducing new instruments, trending of analyst productivity, methods review.  • To ensure adherence to QMS document closure/completion timelines,  • Directing staff in troubleshooting of methods and instruments.  • To review of Raw data, Laboratory incidents, Out of Trends, Out of Specifications for API and Formulations and ensure closure of same as per SOP.  • Review of qualification, validation & calibration of lab instruments, stability chambers.  • Audit products data review, internal audits & audit preparations in units.  •Responsible for QC-related activities including guidelines, directives, and CAPA preparation.  • Guideline preparation base on regulatory guidance, pharmacopeia, lab. Practices  • Review of plant monthly report for OOS / OOC / Repeat/productivity.  • Visit to plant for GLP system Gap analysis.  • Technical discussion for specification finalization with ADD / FDD / OS / RA.  • Handling of analytical issues notifies by the plant QC with the help of ADD.  • Monitoring of analytical and stability failures of the plant.  • Visit to plant for audit preparation.  • Budgeting of instruments and manpower for location QC.  • Monitoring of LIMS related development activities. |
| **Cipla Limited , Goa, India, Quality Control Department, From June’ 2004 to November’ 2007. (Analyst).**  It is OSD, Oral suspensions, MDI/DPI/Nasal manufacturing plant including manufacturing capability. It has also a manufacturing facility for the cytotoxic drug with a separate QC lab. The QC has about 150 employees with chemistry and microbiology labs. The product supply to USA, EU, and ROW markets.  **ESSENTIAL DUTIES AND RESPONSIBILITES :**  • Analysis of Finished product, In-Process samples, Process Validation, Cleaning validation,  samples.  • Analysis of Stability samples Exhibit, Commercial, Validation samples (Bu, Cu, Pv samples etc).  • Sampling and analysis of Raw materials as per approved standard testing procedures. (IP, BP, USP Pharmacopiea).  • Samples analysis for Antiretroviral drugs (ARVs), products (e.g LNS, LNZ, Lopinavir & Ritonavir, Didanosine, Tenofovir Dispersible Fumarate, Abacavir & Lamivudine, Atorvastatin, Warfarin sodium, Doxazosin Mesylate, Alfuzosin HCl, Tamsulosin HCL).  • Analytical Method Validation of oral suspensions, Forced degradation studies etc.  • Preparation of cleaning validation protocols & Validating the Analytical method for Cleaning validation. Analysis of Stability samples, and its documentation.  • Troubleshooting to analyse for the Instrumental and Compliance problems.  • Calibration of Instruments HPLC (Agilent, Perkin Elmer), UV Spectrophotometer, FTIR, GC Chromatography, UPLC etc.  ***Mr. Yogesh Ghule*** |