Gaurav Katore

Assistant Manager – QA (GMP Compliance, Pharmaceuticals)

Contact

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Accomplishments

- Promoted from the manufacturing site to the headquarters QA team in recognition of strong performance in quality systems, customer complaint handling, and cross-functional coordination.
- Achieved two rapid career advancements—from Executive to Senior Executive to Assistant Manager within 2.5 years, driven by consistent high performance and successful execution of new product launch projects.
- Recognized for outstanding contributions to UK product launch initiatives and cross-

Accomplished Assistant Manager, Quality Assurance (GMP Compliance) with 8 years 7 months of experience in the pharmaceutical industry across sterile (parenteral) and solid oral dosage manufacturing environments.

- Strong expertise in cGMP compliance, global regulatory requirements, and Quality Management Systems (QMS) within regulated manufacturing operations in India and United Kingdom.
- Experienced in end-to-end QA leadership covering new product launches, technology transfer activities, validation lifecycle oversight, batch release, and regulatory compliance management.
- Exposure to international pharmaceutical operations, including UK assignments and product launch support aligned with global quality and regulatory standards.
- Skilled in deviation management, CAPA, change control, SOP governance, and batch record review (BMR/BPR/MFR).
- Proficient in validation lifecycle activities including process validation (PV), cleaning validation (CV), equipment qualification (EQ), stability studies, and hold time studies.
- Experienced in audit readiness programs, regulatory inspections, and ensuring continuous compliance.
- Strong capability in trend analysis, quality data evaluation, and driving continuous improvement initiatives for quality enhancement and operational efficiency.
- Active contributor to Management Review Meetings (MRM) for QMS performance evaluation and strategic quality decisions.
- Recognized for leadership, cross-functional coordination, mentoring QA professionals, and promoting a strong GMP compliance culture.
- cGMP & Global Regulatory Compliance (India & UK exposure)
- Quality Management System (QMS) Leadership & Governance
- End-to-End QA Operations Ownership
- New Product Launch & Technology Transfer Support
- Deviation, CAPA & Change Control Management
- Batch Record Review & Release (BMR / BPR / MFR)

functional project execution.

• Education

2017-07

Master of Science: Master of Pharmacy, Pharmaceutics

Savitribai Phule Pune University - Narayangaon, Pune (India)

- 8.340 GPA/CGPA
- Final Grade: A
- Final Grade: 67%

2015-03

Bachelor of Science: Bachelor of Pharmacy

Sant Gajanan Maharaj College of Pharmacy - Chinchewadi, Mahagaon (Maharashtra)

- Graduation with Distinction, 2015
- Final Grade: 67.55%

2011-02

Science

VIVA College of Science - Virar, Mumbai (Maharashtra)

- Final Grade: 54.50%

2009-03

S.S.C

Annasaheb Vartak Vidyamandir - Virar, Mumbai (Maharashtra)

- Final Grade: 81.53%

• Skills

- MS Office (Word, Excel, PowerPoint) with
- Validation Lifecycle Management (PV, CV, EQ, Stability, Hold Time)
- Audit Preparation & Regulatory Inspection Support
- Trend Analysis & Quality Performance Monitoring
- SOP Management & Documentation Control
- Cross-functional Leadership & Team Development
- Continuous Improvement & Quality Risk Management

• Work History

2022-12 - Current

Assistant Manager – QA (GMP Compliance)

Ipca Laboratories Ltd., 125, Charkop Industrial Estate, Kandivali, Mumbai

- Exposure to international pharmaceutical operations, including UK assignment and UK-based project support for product launch activities, ensuring alignment with global quality and compliance expectations
- Completed 1-month UK assignment (UK return experience) for new product launch support, coordination, and quality system alignment
- Participated in site visits in India and UK for product launch readiness, operational assessment, and compliance verification
- Involved in new product launch activities for UK market, including documentation readiness and regulatory compliance alignment
- Led cross-functional teams for product launch operations and technology transfer activities
- Actively participated in Management Review Meetings (MRM) for evaluation of Quality Management System (QMS) performance and continuous improvement initiatives
- Provided leadership and mentoring to junior QA team members, ensuring GMP awareness, compliance discipline, and skill development.
- Supervised day-to-day QA operations, ensuring compliance with GMP, quality, and regulatory standards.
- Experienced in the review and approval of Master Batch Manufacturing Records (BMR) and Batch Packing Records (BPR) prior to

documentation and reporting capability

- Strong knowledge of compliance, quality awareness, and basic regulatory understanding
- Excellent documentation, report preparation, and meeting notes handling
- Team leadership, team building, and cross-functional coordination
- Strong decision-making and problem-solving abilities
- Effective time management, workload prioritization, and multitasking skills
- Customer relations and customer service handling
- Meeting facilitation, operational coordination, and workflow management
- Business development awareness and product branding understanding
- Strong organizational skills with ability to manage multiple responsibilities
- Operational oversight and closing supervision
- Corporate Social Responsibility (CSR) participation

manufacturing and packaging activities, ensuring GMP compliance.

- Responsible for the review of executed batch records post-manufacturing, ensuring accuracy, completeness, and regulatory compliance.
- Review and approval of validation protocols and associated reports, including process validation, cleaning validation, equipment qualification, hold time studies, and stability studies, along with evaluation of lifecycle trend data to ensure product integrity, process compliance, and continuous quality monitoring.
- Performing trend analysis of product quality data across lifecycle stages to support continuous improvement initiatives.
- Handling and investigation of deviations, CAPA, market complaints, and customer inquiries with proper documentation and closure.
- Preparation, review, and implementation of SOPs in line with GMP requirements.
- Conducting and coordinating GMP training programs across departments.
- Ensuring coordination between QA, production, and management teams for smooth quality operations.
- Contributing to continuous improvement initiatives for enhancing product quality and operational efficiency.
- Ensuring adherence to SOPs, documentation accuracy, and regulatory compliance across operations.

2021-08 - 2022-12

Senior Quality Assurance Officer

IPCA LABORATORIES Ltd, Athal, Silvassa

- Managed responses to customer and regulatory authority queries in line with applicable GMP requirements.
- Reviewed and approved Deviations, CAPAs, and CCP records in TrackWise ensuring proper classification and closure.

- Positive attitude, adaptability, and continuous learning mindset

Personal Details

Date of Birth: 17/03/1993

Nationality: Indian

Marital Status: Married

Visa Status: Indian Citizen

Passport: X5197194

Professional Interest

Interested in exploring new informational sources and staying updated on emerging pharmaceutical technologies and industry trends.

Additional Information

Achieved recognition in 2009 as a member of the Japan Karate Association. Served as a Senpai (senior member), mentoring junior students (Kohai) and supporting discipline, training, and skill development.

Websites, Portfolios, Profiles

- www.linkedin.com/in/gaurav-katore-57b5b3b9

Languages

- Assessed investigation reports with detailed evaluation of root cause and probable cause findings.
- Reviewed and approved GMP documents including SOPs, BMRs, BPRs, and MFRs, ensuring regulatory compliance and data integrity.
- Verified executed BMRs and BPRs for compliance with approved manufacturing and packaging procedures.
- Prepared regulatory compliance documentation such as COM, TSCA declarations, and TSE/BSE certificates as per customer requirements.
- Escalated critical compliance risks to management for timely corrective action and risk mitigation.
- Conducted deviation investigations and documented technical justifications with supporting evidence.
- Monitored retention sample records and performed periodic review for ongoing quality assurance.
- Conducted training sessions for junior QA staff to improve compliance awareness and documentation practices.
- Supported internal and external audits, including USFDA, MHRA, and WHO inspections, and contributed to successful closure of observations.

Senior Quality Assurance Officer

2021-03 - 2021-08

UMEDICA LABORATORIES Pvt. Ltd, Vapi

- Reviewed and approved GMP documentation, including SOPs, BMRs, BPRs, and MFRs, ensuring full regulatory compliance and data integrity.
- Verified executed BMRs and BPRs to confirm adherence to approved manufacturing and packaging procedures and regulatory requirements.

Senior Quality Assurance Officer (Shift incharge)

2019-03 - 2021-03

INTAS PHARMACEUTICALS LTD, Ahmedabad

English, Hindi, Marathi & Gujarati

- Utilized ProcessXE software for GMP documentation control, ensuring accurate, timely entries and maintaining high standards of data integrity and regulatory compliance.
- Performed SAP transactions to support production activities, ensuring smooth workflow execution, and real-time system accuracy.
- Ensured compliance with Current Good Manufacturing Practices (cGMP) in General Parenteral (injection manufacturing) manufacturing and packaging areas, maintaining strict quality and regulatory standards.
- Performed in-process control checks during manufacturing and packaging operations to ensure product quality and process consistency.
- Provided line clearance for manufacturing and packing operations after verifying compliance with approved procedures.
- Verified that all equipment used remained within valid qualification status prior to and during operations.
- Managed sampling activities, including retained samples, QP stability study samples, and other regulatory samples during packaging operations.
- Raised vendor complaints for material discrepancies, conducted preliminary investigations, and forwarded reports to CQA for further action.

2017-09 - 2019-02

Quality Assurance Officer

SAMRUDH PHARMACEUTICALS Pvt. Ltd, Boisar, Mumbai

- Strong experience in regulatory compliance and GMP documentation, including review of batch manufacturing and packing records for ROW markets
- Hands-on involvement in validation activities, including process validation, packing validation, and execution/review of media fill studies

- Proficient in quality assurance operations such as in-process checks, sampling activities, and verification of product quality during manufacturing and packing stages
- Skilled in line clearance activities during product-to-product and batch-to-batch changeovers in manufacturing and packing areas
- Experienced in review and monitoring of environmental monitoring reports to ensure compliance with quality standards
- Ensured documentation integrity and compliance through systematic review of batch records, logbooks, and associated quality documents
- Conducted proof checks during packing start-up activities to ensure correctness and regulatory adherence
- Managed controlled destruction of expired raw materials, packing materials, finished goods, and semi-finished goods as per SOPs
- Reviewed critical quality and compliance records including calibration logs, equipment and area cleaning records, and stereo issuance/destruction logs
- Well-versed in ensuring adherence to GMP practices and maintaining audit-ready documentation systems