Resume - Awadhesh Kumar

Awadhesh2007@outlook.com, 8892576206

OBJECTIVE

An ASQ certified and detail-oriented quality auditor with more than 10 years of experience in auditing and 14 years of experience in quality management of Pharmaceuticals and medical device manufacturing, compliance, quality assurance as per relevant industry regulations (USFDA, ISO, Health Canada, EU, ANVISA, TGA, WHO, CDSCO etc.). Skilled in GMP/GLP/GCP/GPV Quality audit & compliance, quality management, Project management, Process improvement, Validation & Qualification, Clearing validation, quality culture, laboratory management, investigations, data reliability, simplification, standard operating procedure, training, response writing, remediation etc. Also skilled in assessment of Sterile products manufacturing facility by Aseptic processing and terminal sterilization with emphasis on sterility assurance. Adept at ensuring adherence to industry regulations, mitigating risk, and enhancing operational efficiency through precise audits. Seeking to contribute expertise in medical device audits to support the quality and safety standards.

PROFESSIONAL EXPERIENCE

GxP Auditor & Quality Professional

- Lead and manage audits of medical device and pharma manufacturing facilities to assess compliance with relevant FDA regulations, ISO 13485, and other relevant standards.
- Review and assess quality management systems (QMS) for compliance with industry best practices and regulatory requirements.
- Conduct audits of design control, risk management, and post-market surveillance systems to ensure continuous compliance.
- Perform gap analyses and provide recommendations for improvement in policies, processes, and product documentation.
- Draft detailed audit reports, summarizing findings, non-conformances, and corrective actions for senior management.
- Facilitate corrective and preventive actions (CAPA) processes and track progress to ensure closure.
- Collaborate with cross-functional teams including regulatory affairs, product development, and quality assurance to ensure ongoing compliance.
- Stay updated on evolving regulatory changes and industry trends, providing guidance to internal teams.
- Conduct internal and supplier audits, monitoring performance and identifying areas for improvement.

- Performance of Gap Assessment of Formulation & API facilities (Sterile and non-sterile) including Quality control laboratories to evaluate the compliance as per Regulatory requirements of USFDA, HC, MHRA, EU etc.
- Conduct GMP audits of Quality Systems to assess compliance with internal SOPs, standards and regulatory requirements (US, HC, EU, MHRA, PICS, WHO, ICH Q7 etc.) of the manufacturing facilities of APIs, Excipients, Primary packing materials, Critical consumables, Finished products (Sterile & non-sterile) etc.
- Timely submission of audit report & review of Compliance Report submitted by vendor.
- Conduct GLP audits of analytical Laboratories with respect to analytical sample management, quality control laboratory management, incident/OOS/OOT investigations, reference/working standards & consumables management, documentation management, analyst qualification etc. with emphasis on data integrity and data reliability.
- Development of responses to Inspections, FDA 483s, Warning Letters and other regulatory findings
- Perform GMP, GCP, Compliance, Due diligence and Quality Systems audits and CAPA management and training on GMP matters.
- Validation/Qualification of Facility, equipment, processes, utilities & personal including engineering compliance.
- Technical writing (protocols, reports, specifications, policies, procedures, master documents).
- Perform risk analyses of manufacturing processes; Incorporation of risk assessment components with technical and scientific rationale
- Perform quality reviews of sterilization and aseptic validation and revalidation protocols, including media fills
- Conduct investigations into process deviations/incidents/OOS/OOT/market complaint/product failures etc., and determine appropriate corrective and preventive actions to prevent recurrences, including laboratory and positive sterility investigations
- Compliance GAP Assessments, Regulatory Inspection preparation, remediation, floor compliance, mitigation of Quality Systems and manufacturing process GAPS, Non-Conformance Investigations, Batch Records Review, QA and Manufacturing Process data for metrics evaluation.
- Participation in US FDA, HC, EU, MHRA, TGA, ANVISA, WHO and other worldwide regulatory agency pharmaceutical inspections as subject matter expert; manage teams to support record / information requests during regulatory inspections and subsequent compliance submission.

Key Achievements:

- Successfully led over 10 medical device audits and over 150 pharma audits resulting in a 90% compliance rate and mitigating potential regulatory risks.
- Developed audit protocols that reduced audit duration by 30% while increasing audit effectiveness.
- Identified key non-conformities that led to the revision of critical processes, improving overall product quality and compliance.

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EDUCATION

Master of Science in Pharmaceutical Technology,

Vinayaka Mission University, Salem

Bachelor of Pharmacy

Bangalore University

CERTIFICATIONS & TRAININGS

- **Certified Quality Auditor (CQA)**, ASQ
- **ISO 13485:2016 Lead Auditor** Training
- **Medical Device Regulations (MDR) Auditor Training**
- **ISO 9001 Auditor** Training
- **FDA 21 CFR 820 Compliance** Training

SKILLS

- **Auditing & Compliance:** Knowledge of FDA regulations - 21 CFR Part 820, 801, 803, 806, ISO 13485, 9001, 14971, 19011, etc., GMP, MDR, CMDR, TGA, ANVISA and other medical device relevant regulations, 21 CFR Part 210, 211, 11, EUGMP Annex 4, ICH Q7, Q9, Q10 and relevant guidelines.
- **Quality Management Systems:** Strong understanding of QMS implementation and evaluation in medical device environments.
- **Root Cause Analysis & CAPA:** Expertise in conducting root cause analysis and implementing corrective and preventive actions (CAPA).
- **Regulatory Knowledge:** Extensive knowledge of international medical device regulations (FDA, CE Mark, Health Canada, etc.).
- **Document Control:** Proficient in managing device master records (DMR), device history records (DHR), and other regulatory documents.
- **Audit Tools & Techniques:** Experience with audit planning, checklists, interviews, observation techniques, and data analysis.
- **Technical Writing:** Ability to produce comprehensive and actionable audit reports.
- **Problem-Solving:** Excellent problem-solving skills, with the ability to find solutions to complex regulatory issues.
- **Communication:** Strong written and verbal communication skills; effective in cross-functional team collaborations.

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PROJECTS

- **Audit Automation Project:** Spearheaded an initiative to automate audit tracking and reporting, resulting in a 30% improvement in audit processing efficiency.
- **Vendor Compliance Monitoring:** Developed and implemented a vendor audit program that improved vendor performance and reduced non-conformance incidents by 25%.

PROFESSIONAL DEVELOPMENT

- Attended training on medical device regulations, FDA guidelines, and ISO 13485 updates.

LANGUAGES

- English (Fluent)
- Hindi (Fluent)

EXPERIENCE

- Working as Freelance GxP Consultant and auditor (Since Aug. 2022).
- Worked as Site Quality Head (QA, QC and Compliance) at Emcure Pharmaceuticals Ltd. (From Apr. 2018 to Jul. 2022).
- Worked as Corporate Quality Auditor and compliance in-charge at Sun Pharmaceutical Industries Ltd. (From May 2016 to Mar. 2018).
- Worked as Corporate Quality Auditor and compliance in-charge at Viatris, Injectable Vertical (From Jul. 2012 to May 2016).
- Worked as Quality Assurance Manager at Fresenius Kabi Oncology Ltd. (From Jul. 2009 to Jul. 2012).
- Worked as Validation/Qualification In-charge at Sentiss Pharma Pvt. Ltd. (From Jan. 2007 to Jul. 2009).
- Worked in Quality Control at Dr. Reddy's Laboratories Ltd. (Apr. 2004 to Jan. 2007).
- Worked in Quality Control at Cipla Ltd. (Oct. 1999 to Mar. 2004).

EDUCATION

- Master of Science in Pharmaceutical Technology
- Bachelor of Pharmacy

CONTACT

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