Amit Saxena

103, New MHADA Colony, Goregaon (E), Mumbai 65

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Pharmaceutical Quality Assurance Auditor

Certified GMP Compliance Auditor from “European Compliance Academy” Barcelona Spain in 2008.

GMP audits are a fundamental element of managing quality assurance in the pharmaceutical industry. The inclusion of suppliers in the quality assurance system of a pharmaceutical enterprise is addressed directly in Chapter 1 of the EU-GMP Guide. The EU-GMP Guide also specifies that self-inspections have to be carried out. The United States FDA also requires supplier audits and expects self-inspections

Professional Profile

* Performance-driven, entrepreneurial quality professional with 15+ year of continues advancement and expertise in international pharmaceutical quality,
* Proactive self-starter with track record of initiative, personal responsibility, ownership of work and reputation for removing obstacles and making things happen,
* Highly analytical thinker with demonstrated ability to scrutinize technical data,
* Strong leader who effectively motivates others,
* Superlative interpersonal communicator, presenter, and negotiator; delivered effective presentations to corporate senior executives,
* Creative, dependable, and enthusiastic change agent with proven track record in improving efficiencies,
* Skilled coalition-builder with multicultural experience

Area of Expertise

* Preparing and performing a GMP audit
* Audit program and planning
* Performing Internal and external (supplier) Audit of Quality System, Laboratory control, Production, Material Management, Facility & equipment, Packaging and labeling
* Audit reports and rating
* Response to the audit report
* Action plan and tracking major observations
* Re-audit and follow-up an Audit
* Investigation of Deviation, Failure and Market Complaints
* Review of Technical data
* CAPA planning and implementation
* Harmonization of Quality System
* Preparation of Quality System & Agreements
* Quality System for IND Products
* GMP & Quality Training

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Professional Experience

**Deputy General Manager – Global Quality (Audit & Compliances)**, *Glenmark Pharmaceuticals Limited, Mumbai, July 2007 to present*

* Internal Audit of all the Manufacturing Sites, Clinical Sites, R&D centers, Warehouses & Distributer’s Locations of Glenmark across the Globe,
* Supplier audit for API, excipients, and packaging material,
* Identify gaps in quality system evaluate risk associate & rate the audit observation. Suggest corrective & preventative action plans,
* Harmonies Quality System across the Glenmark in term of providing Quality Guidelines/Directives for Key quality area.
* Lead NCE/IND project team to meat Quality/Regulatory Requirement for Developing Molecule.
* Lead 29+ members Project Team – to implement SAP system across the Glenmark as Project SMART.
* Handle Regulatory inspections at different sites of Glenmark

**Sr. Manager – Site QA (Head QA),**

*Glenmark Pharmaceuticals Limited, Ankleshwar, July 2006 to July 2007.*

* Having created performance-driven culture that ensures accountability and personal responsibility. Lead, develop, coach, andmotivate team member in communications, administration, research & development, and engineering to accomplish Quality objectives.
* Supervise and lead creative team in developing and executing integrated Quality System at site,
* Review & approve Validation, Qualification, Calibration, Change Request, Deviations and other Quality documents i.e. Site Master File etc.
* Root Cause Analysis of “Out of Specification” / “Outlier observations” and “Market Complaints”.
* Effective Supplier evaluation and vendor Qualification.
* Handle successfully MHRA, US-FDA & WHO Regulatory Audit at site and Vendor Audits without any major concern.
* Provide extensive Support for Regulatory Submission (so far filed 30 DMF) to meet business requirement.
* Impart GMP awareness across the site through effective GMP Trainings.
* Capital investment recommendations & approvals.

**Manager – Corporate QA**

*Glenmark Pharmaceuticals Limited, Mumbai, July 2004 to July 2006.*

* Review Quality Documents & provide support to regulatory submission
* lead to commercial and Corporate procurement on quality matter
* Review of Monthly Report for Manufacturing Site & Prepare Monthly Quality Presentation
* Identify GAPs in Quality System and Ensure for compliance
* Support to Manufacturing Site for Regulatory Audits.
* Vendor Audit & Internal Audit.

**Sr. Executive Quality – Site QA**

*Lupin Limited, Mandideep (Bhopal), September 1994 to July 2004.*

* Working as emerging dynamic team member of Quality Team.
* Second line support to senior management for implementation of Quality System.
* Preparation & Execution of Qualification and Validation protocols, Validation of analytical methods.
* Preparation & Execution of stability protocols for Drug Substances & Drugs Products.

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Education

* Master of Science (Organic Chemistry) – from Vikram University Ujjain (M.P.) 1993
* Bachelor of Legislation (LLB) – Taxation – From Bhopal University Bhopal (M.P.) 2002.
* Post Graduation Diploma in Computer Application – Bhopal University Bhopal (M.P.) 1991.
* Certified Trainer for internal training in Glenmark
* Certified Value Coach for Glenmark

Professional Certification

Certified GMP Compliance Auditor from “European Compliance Academy” Barcelona Spain in 2008.

Personal

Full Name: Amit Saxena

Father’s Name: Dr. K. C. Saxena

Date of Birth: 16th June 1970

Nationality: Indian

Mother tongue: Hindi

Proficiency on other language: English