Sr. Specialist Audit Mgt (GXP)

Job ID
REQ-10058097

7月 17, 2025

India

摘要

As a key resource within the Audit Management Office (AMO), this role ensures effective coordination and management of audits and inspections involving Data, Digital & IT (DD&IT) systems and processes. This includes supporting GxP audits (e.g., GMP, GCP) and regulatory inspections by authorities such as FDA, EMA, MHRA and Swissmedic. The associate acts as a liaison, ensuring that relevant DD&IT subject matter experts address audit queries and deliver required documentation in a timely and accurate manner. Additionally, the role involves monitoring audit findings, overseeing remediations, and driving continuous improvement in audit readiness.

About the Role

MAJOR ACCOUNTABILITIES

- Govern processes to effectively manage both internal and external audits across Data, Digital

& IT (DD&IT), focusing on GxP (e.g., GMP, GCP), quality, and regulatory-related audits, along with stakeholder management, remediation tracking, status reporting, and lessons-learned sharing. Act as the single point of contact (SPOC) for audit teams across DD&IT, coordinating audit and inspection activities, ensuring effective communication, and maintaining compliance throughout the process.

- Notify and mobilize relevant DD&IT stakeholders–such as application managers, system owners, QA, Information Security & Compliance (ISC), and SOP process owners–for audits and inspections, ensuring timely readiness. Coordinate globally with business teams to ensure audit support tickets are created, tracked, and resolved in alignment with Novartis policies and procedures.
- Conduct pre-audit meetings to clarify IT scope, agree on auditor pre-requests, align timelines, and ensure stakeholders understand expectations for audits and inspections.
- Provide advice and guidance to DD&IT teams on GxP and information systems compliance requirements to ensure alignment with regulatory standards such as FDA, EMA, MHRA and Swissmedic expectations. Track and proactively manage audit requests across different time zones, ensuring SMEs respond on time, identifying backups where needed, and escalating delays or deviations as appropriate.
- Guide DD&IT SMEs by clarifying audit process requirements and supporting them throughout the audit lifecycle, ensuring accurate delivery of requested information. Conduct training sessions on audit readiness, including proper inspection etiquette and effective collaboration during audits and inspections.
- Collaborate with internal teams to improve and standardize governance frameworks and processes, aiming to reduce audit findings and improve inspection readiness. Escalate compliance deviations and critical quality issues to senior management and coordinate resolution efforts, ensuring corrective and preventive actions (CAPAs) are implemented effectively.
- Manage relationships at a global level across divisions and functions, including ISC, e-Compliance, and DDIT teams, facilitating cross-functional alignment and collaboration on audit-related matters.
- Coordinate and participate in audit closing meetings, preparing summaries of findings, tracking observations, and supporting SMEs in addressing them. Partner with security, compliance, and quality experts to identify focus areas, evaluate industry trends, and recommend strategies to improve audit processes and outcomes.
- Monitor and report on audit findings, remediation actions, and related improvement activities, ensuring compliance, security, and quality gaps are addressed thoroughly. Drive and coordinate key Sarbanes-Oxley (SOX) activities in collaboration with application teams and external auditors, ensuring alignment to SOX IT controls and timely delivery of evidence while minimizing audit-related disruptions. Ensure adherence to security and compliance policies and procedures within the audit management governance framework, while aligning with internal and external quality standards.

Minimum Requirements

- University degree or equivalent. Master ' s degree in IT, Quality Management, Business Administration, or related fields.
- Overall 8-10 years of work experience in quality management, audit, and compliance within IT, preferably in a global organization.
- Experience in the pharmaceutical industry or other regulated industries, with knowledge of GxP processes and compliance requirements.

- In-depth understanding of pharma business processes and their interrelationship with IT systems and regulatory frameworks. Proven track record of managing audits, regulatory inspections, and remediation efforts in pharma or other highly regulated environments.
- Experince with Computer System Validation (CSV), system testing, and adherence to lifecycle validation processes (e.g., requirements gathering, system design, validation testing, implementation, and maintenance).

    - Knowledge of ITIL processes and best practices.
    - Demonstrated ability to work effectively in large, cross-functional, global organizations.
- Proficient in Excel, PowerPoint, and other productivity tools for reporting and presentation. Business-proficient in English (written and spoken).Strong communication skills–with the ability to articulate expectations and audit requirements clearly to diverse teams and stakeholders.
- Ability to manage multiple priorities and time-sensitive processes efficiently. ITIL-certified professional. Strong knowledge of validation practices, including GxP, Sarbanes-Oxley (SOX), and pharmaceutical quality compliance standards. understanding of CSV lifecycle processes, including risk assessment, traceability matrix development, protocol execution, and impact analysis.
- Business knowledge or experience in IT ' s role supporting audit and compliance functions within regulated industries. Expertise in Computer System Validation (CSV) testing methodologies and frameworks.

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部门
Operations

Business Unit
Universal Hierarchy Node

地点
India

站点
Hyderabad (Office)

Company / Legal Entity
IN10 (FCRS = IN010) Novartis Healthcare Private Limited

Functional Area
Technology Transformation

Job Type
Full time

Employment Type
Regular

Shift Work
No

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