Head of Quality

Job ID
REQ-10002668
Abr 26, 2024
Estados Unidos

Resumen

This position is responsible for leading the Quality team ensuring compliant process, team management, and oversight of the Quality compliance and Quality operations in support of EU, FDA, Clinical Trial, CLIA/CAP, state and ISO compliance requirements. Responsibilities include the management of personnel and compliance for assay validation, clinical study development and testing, IVD manufacturing, and overall Quality Systems (change control, CAPA, equipment, computerized systems, etc.).

About the Role

Major accountabilities:

- Works in a GCP/CLIA/GCLP/IVD GMP regulated environment and is responsible for oversight of all applicable regulations.
- Implement and maintain quality metrics, systems and documentation associated with clinical trials, including, but not limited to procedures, processes, tests, equipment, materials, regulatory requirements, and staffing proficiency.
- Develop and conduct GxP, CLIA, IVD Manufacturing, and GCLP training across all lab areas to ensure compliance to regulatory requirements.
- Manage, create and ensure appropriateness of procedures related to Clinical Trials and IVDs. Provide quality and regulatory assessment for laboratory policies and procedures.
- Serve as quality liaison with regulatory agencies and sponsors.
- Maintain appropriate state licenses for a CLIA medical laboratory and CAP and ISO accreditations.
- Manage staff to ensure timely deliverance of assigned responsibilities including product release, IVD design control and manufacturing, and compliance including that of partner laboratories
- Provide quality assessment for assay/product validations
- Establish and maintain Quality Systems to meet regulatory requirements, including IVD GMP, GCP, CLIA, and CAP.
- Oversee, host and/or lead regulatory, sponsor, external vendor and/or partner lab inspections/audits, and perform related internal GMP, GCLP and CLIA Regulatory Compliance Audits. Work with internal departments as needed to identify and resolve / complete corrective actions. Assist with other internal audits as needed.
- Identify, design and implement opportunities for improvement across all areas of responsibility.
- Develop metrics, reports, charts and/or related documentation as needed for Quality Management Review
- Ensure complete and compliant documentation in support of internal auditing, change control, and incident management

Key performance indicators:

- Provide successful strategic and managerial leadership for Navigate in all Quality related matters and ensure that all aspects of the operational business comply with applicable compliance and regulatory requirements.
- Successful oversight of Navigate's Quality Management System; Perform leadership and strategic responsibilities related to company objectives and changing regulatory requirements.
- Successful Quality partnership internally with all stakeholders, and externally with all Sponsors and Regulatory agencies.
- Successful oversight of all inspections/audits, management of deviations and incidents, and maintenance of applicable permits and licenses.

Minimum Requirements:
Work Experience:

- Minimum of twelve (12) years progressively responsible experience in a related Quality Assurance role in a regulated environment, preferably GCP.
- Minimum of seven (7) years specifically related experience with clinical trials supporting GCLP
- Minimum of five (5) years with leadership and direct supervisory experience
- CLS license desired
- IVD experience desired (Companion Diagnostics)

Skills:

- Detail and goal oriented with ability to manage multiple projects at one time
- People leadership across all areas of Quality
- Ability to contribute to Navigate leadership and partner with other leaders
- Strong agility, collaboration, and teamwork
- Clear understanding of Clinical Labs in support of drug development clinical trials (GCP / GCLP / CLIA)
- Strong experience in managing and hosting Sponsor and Regulatory audits
- Strong experience managing internal auditing for GCP studies (study monitoring)
- Decision making skills understanding risk, operational practices, and compliance
- Team development and leadership

Languages :

- English.

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The Novartis Group of Companies are committed to working with and providing reasonable accommodation to individuals with disabilities. If, because of a medical condition or disability, you need a reasonable accommodation for any part of the application process, or to perform the essential functions of a position, please send an e-mail to us.reasonableaccommodations@novartis.com or call +1(877)395-2339 and let us know the nature of your request and your contact information. Please include the job requisition number in your message.

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