Head of Quality

Job ID
REQ-10002668
Sep 03, 2024
USA

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.

Role Requirements

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Business Unit
Innovative Medicines
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Site

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Functional Area
Quality
Job Type
Full time
Employment Type
Regular
Shift Work
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Head of Quality

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