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Manager, QC Lead

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Company: Thermo Fisher Scientific

Location: St. Louis

Category: other-general

The job will be responsible for Quality Control Project Leads Department and will support of Commercial and Clinical Biopharmaceutical Manufacturing. They will be responsible for following Current Good Manufacturing Practices (cGMP). Functions may include, but are not limited to: Managing QC needs for clients, developing timelines and schedules for QC needs for complex projects, communication with both internal and client facing customers, and managing change controls and revision of documents per ICH guidelines for Biopharmaceutical Drug Substance (such as product specifications, validation protocols and reports).

What will you do?

Ensures the successful operations of the QC Leads team, providing support and setting team priorities

Establish meaningful goals and manage the performance of assigned personnel to those goals

Participates in troubleshooting, technical discussions, teleconferences, and client visits, as required

Proactively develops, manages, tracks and improves team’s performance. Set targets and monitors critical metrics for efficiency, compliance, and delivery.

Liaise between internal and client teams to drive QC projects and process solutions.

Manage client needs related to QC scheduling and visits in support of site departments

(Program Management, Operations, QA)

Interface directly with program management for scheduling and forecasting of QC specific scheduling and workflow

Facilitate and manage QC analytical meetings between client and designated internal SMEs to ensure completion of project prior to agreed timelines.

Monitor QC qualification, transfers, validation and release activities in progress. Provides risk mitigation strategies to ensure on time completion of activities.

Coordinate and communicate with Program Managers and clients for project related needs and issues.

Carries out duties in compliance with all local, state and federal regulations and guidelines including FDA, EPA, and OSHA.

Actively champions process improvement initiatives in the Project lead group, QC analytical group and inter-site collaboration (for co-validation, co-transfers etc)

Actively involved in scientific discussions with the Analytical Formulation Sciences team

Other duties as assigned

How will you get here?

Bachelor's Degree in a Biological Science related field and 5+ years related experience in biopharmaceutical or pharmaceutical industry.

Experience

At least 2 years supervisory/ team lead experience within the pharmaceutical industry.

Extensive knowledge of GMP regulations in cGMP manufacturing environment.

Working Knowledge of scientific principles for wide range of analytical techniques (HPLC, ELISA, Cell-Based Assay, Capillary Electrophoresis, etc.) strongly preferred.

Knowledge, Skills, Abilities

Ability to understand customer requirements related to Quality control, including processes and equipment.

Outstanding technical writing skills.

Strong social skills including actively listening, conflict resolution and the ability to effectively influence diverse customers for positive outcome.

Ability to build strong relationships with client while instilling trust and confidence

Highly organized with attention to detail, excellent interpersonal skills

Familiar with standard project management concepts, tools and responsibilities (objectives, scope, deliverables)

Advanced knowledge of FDA guidance for industry for Analytical Procedures and Methods Validation for Drugs and Biologics

Ability to drive functional, technical and operational excellence.

Ability to inspire and foster innovation, collaboration, transparency and team effectiveness.

Routine use of MS Excel, MS PowerPoint, and MS Word is crucial

Solid understanding of cGMPs and Quality Control regulatory requirements

Our Mission is to enable our customers to make the world healthier, cleaner and safer. Watch as our colleagues explain . As one team of 100,000+ colleagues, we share a common set of values - Integrity, Intensity, Innovation and Involvement - working together to accelerate research, solve complex scientific challenges, drive technological innovation and support patients in need. #StartYourStory at Thermo Fisher Scientific, where diverse experiences, backgrounds and perspectives are valued.

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