Senior Manager (Head of), Quality Control

Link to Apply: https://jobs.vibrantm.com/job-invite/249472/

A career with MilliporeSigma is an ongoing journey of discovery: our 60,300 people are shaping how the world lives, works and plays through next generation advancements in Healthcare, Life Science and Electronics. For more than 350 years and across the world we have passionately pursued our curiosity to find novel and vibrant ways of enhancing the lives of others. MilliporeSigma is a business of Merck KGaA, Darmstadt, Germany.

Your role:

As the Head of Quality Control (QC), you will be accountable for management of a GMP Quality Control Operations Department supporting custom starting materials, excipients and API manufacturing testing according to IPEC, ICH guidelines and applicable FDA's 21 CFRs.

The 24/7 QC operations group consists of 6 QC supervisors and a total of approx. 40 employees. This is a great opportunity to lead a dedicated team!

You will lead all aspects of the QC activities associated with material testing (finished product, intermediates, in process samples and raw materials), stability, equipment cleaning verification samples and environment monitoring and will be solely responsible for all quality staff which conduct these quality control activities within a Contract Development and Manufacturing (CDMO) Site.

Responsibilities:

- Ensure that all materials and products that require testing and release in the laboratory are done so according to agreed specifications and procedures in a cGMP environment.
- Liaise with planning and project teams (internal and external) to build, maintain, and communicate the QC schedule.
- Responsible for the safety of the quality control areas and operations.
- Implement and run a structured business process to ensure all QC work is captured and up to date.
- Ensures laboratory documentation and computerized systems comply with data integrity policies and regulatory requirements. The QC Manager will prepare, review and approve documents as needed.
- Understands Regulations and business processes required to maintain Laboratory Data Integrity; Represents QC matters during regulatory agency and customer inspections.
- Manage laboratory resources (instruments and personnel) to provide a comprehensive analytical service for testing of all QC and microbiological samples.
- Leads the QC workstream of technology transfer as part of the CDMO business assuring the milestones of the projects are reached.

- Manage the investigation into any non-conformance, instrument malfunction, accident or other abnormal occurrence. Ensure that any Out of Specification (OOS) or Out of Trend (OOT) analytical results are captured as per standard operating procedures (SOP).
- Responsible for monitoring, statistically analyzing, trending and reporting of QC data/metrics to evaluate performance and risks
- Effectively engages with the Laboratory management teams to implement and maintain a system for capacity planning and demand forecasts.
- Compiles data and develop analysis to support QC Investigations, KPIs and other QC Reports as requested.
- Develop and manage the department budget and capital expenditure budget
- Lead and coach team members in Continuous improvement across planning, metrics and scheduling activities.

Who you are:

Minimum Requirements:

- Bachelor's degree in Chemistry, Chemistry Engineering, Pharmacy, Biochemistry, Biology or a related science.
- Minimum 8 years' of applicable experience in cGMP pharmaceutical quality control operations
- Experience leading a team of direct reports
- Knowledge of Good Manufacturing Practices for pharmaceutical manufacturing (21 CFR 210, 211 and 820) and ICHQ7 Good Manufacturing Practice Guidance for APIs.
- Knowledge in 21 CFR Part 11 and Data Integrity Guidelines for pharmaceutical manufacturing

Preferred Qualifications:

- Pharmaceutical quality control operations experience in CDMO business
- Proficient knowledge of and ability to use Microsoft Word, Excel and Access.
- Excellent interpersonal, written and verbal communication skills
- Results driven, team player, able to balance multiple projects/tasks

What we offer: We are curious minds that come from a broad range of backgrounds, perspectives, and life experiences. We celebrate all dimensions of diversity. We believe that it drives excellence, innovation, and human progress. We care about our customers, patients, and our rich mix of people. This diversity strengthens our ability to lead in science and technology. We are committed to creating access and opportunities for all and empower you to fulfil your ambitions. Our diverse businesses offer various career moves to seek new horizons. Join us in building a culture of inclusion and belonging that impacts millions and empowers everyone to bring their curiosity to life!

Curious? Chat with one of our curious minds on our interactive Q&A platform and catch a glimpse of our people, values, and culture. You can also apply and find more information at https://jobs.vibrantm.com

If you would like to know more about what diversity, equity, and inclusion means to us, please visit https://www.emdgroup.com/en/company/press-positions.html

If you are a resident of NYC, Connecticut or Colorado, you are eligible to receive additional information about the compensation and benefits, which we will provide upon request. You may contact 855 444 5678 from 8:00am to 5:30pm ET Monday through Friday, for assistance.

The Company is an Equal Employment Opportunity employer. No employee or applicant for employment will be discriminated against on the basis of race, color, religion, age, sex, sexual orientation, national origin, ancestry, disability, military or veteran status, genetic information, gender identity, transgender status, marital status, or any other classification protected by applicable federal, state, or local law. This policy of Equal Employment Opportunity applies to all policies and programs relating to recruitment and hiring, promotion, compensation, benefits, discipline, termination, and all other terms and conditions of employment. Any applicant or employee who believes they have been discriminated against by the Company or anyone acting on behalf of the Company must report any concerns to their Human Resources Business Partner, Legal, or Compliance immediately. The Company will not retaliate against any individual because they made a good faith report of discrimination.

As an employee of the Company, you will be required to comply with all of the Company's COVID-19 safety protocols and policies. The organization has currently suspended enforcement of its COVID-19 Vaccination Policy, but that policy may be reinstated by the Company in its discretion.