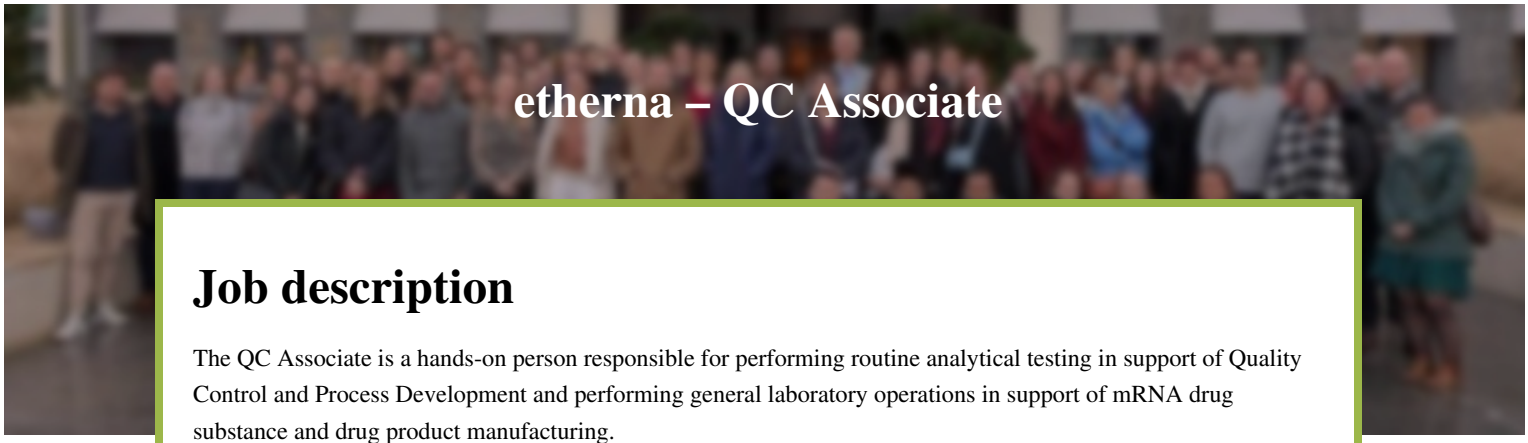

etherna – QC Associate

Job description

The QC Associate is a hands-on person responsible for performing routine analytical testing in support of Quality Control and Process Development and performing general laboratory operations in support of mRNA drug substance and drug product manufacturing.

He/she assists in the different aspects of the method lifecycle within QC to ensure that methods are fit for their intended purpose throughout the product lifecycle.

The QC Associate is a member of the QC department. This position reports into the QC Manager and will be based in Niel, Belgium.

Responsibilities and duties

The **QC Associate**'s duties shall include, but not be limited to:

- Primary responsibility will be performing general QC and Process Development routine characterization, release and stability testing and performing general laboratory operations including reagent preparation and qualification, sample/reagent/consumables stock management, equipment maintenance, lab housekeeping etc.
- Document and report data and results in accordance with the current procedures, protocols and cGMP regulations and interpret generated data for compliance towards method criteria and specifications.
- Report interim stability data, perform trending and write stability reports to determine the final product shelf-life and expiry date
- Assist in the phase-appropriate development, qualification/validation, implementation and transfer of QC methods (e.g., qPCR, Western Blot, SDSPAGE, Spectrophotometry, Fluorimetry, Capillary Gel Electrophoresis, Sequencing, ELISA, …) to support the manufacturing, characterization and release of DNA start material, raw materials, lipids, mRNA Drug Substance and Drug Product.
- Interact very closely with the Process Development department regarding analytical support in order to ensure that Process Development and QC activities are aligned with respect to process improvement.
- Write and revise procedures, protocols and reports to support the QC test method lifecycle.
- Assist in the planning, coordination and execution of required activities related to etherna's stability and environmental monitoring programs.
- Assist in on-time implementation of documentation in support of the Environmental Monitoring program.
- Report interim EM data, perform trending and write trend report reports to ensure manufacturing of mRNA Drug Substance and Drug Product in a controlled cGMP cleanroom environment
- Update and review of master batch records and QC-related documentation in support of GMP manufacturing.
- Monitor QC method performance and perform investigations under supervision related to QC method and equipment failures and non-conformance events and escalate accordingly.
- Initiate and write quality systems documents such as events, change controls and CAPAs

- Act as Subject Matter Expert for certain QC methods during internal and external data presentation and communication and as part of internal, customer and regulatory audits.
- Establish and maintain a safe laboratory working environment.

Job requirements

Education:

Master in biology, (bio)medicine or related discipline with a of minimum of 2 years of relevant cGMP laboratory experience in the biopharmaceutical industry, or a Bachelor with minimum of 5 years of experience.

Experience:

- Proven expertise of working in a QC role within a cGMP laboratory.
- Hands on experience with several QC laboratory techniques like qPCR, Slot Blot, Western Blot, SDS-PAGE, Spectrophotometry, Fluorimetry, Capillary Gel Electrophoresis, Sequencing, ELISA, Flow Cytometry, …
- Knowledge and understanding of relevant and current ICH and GMP guidelines, regulations and Pharmacopoeia.

Other Qualifications, Skills and Abilities:

- Detail-oriented and accurate in following instructions, record keeping and completion of reports
- Able to prioritize QC testing and work under stringent time lines in a highly independent manner.
- Affinity with working in a quality-oriented and fast-changing environment
- Able to perform experimental trouble-shooting and propose solutions
- Good organizational capacities and detailed documentation practices
- Excellent knowledge of English, both spoken and in writing • Well organized, well-structured, hands-on, problem solving, result focused with ability to pick up on important details
- Ability to foster teamwork and a collaborative atmosphere to meet project goals within the established timelines
- Enthusiastic and flexible
- Understanding of MS Office (Excel, Word, PowerPoint, Outlook)

Our offer

- An exciting job in a dynamic and entrepreneurial environment with room for personal development.
- Work within an innovative environment that will give you the resources to extend your knowledge.
- Employment contract of unlimited duration with a competitive salary package. (insurance package, meal vouchers, eco vouchers, possibility to lease a bike, benefits at work ...)
- Working in a fun team where collaboration, growth but above all fun are central.

While we appreciate the interest, we're not engaging with external recruiters for this position.

https://www.etherna.be/