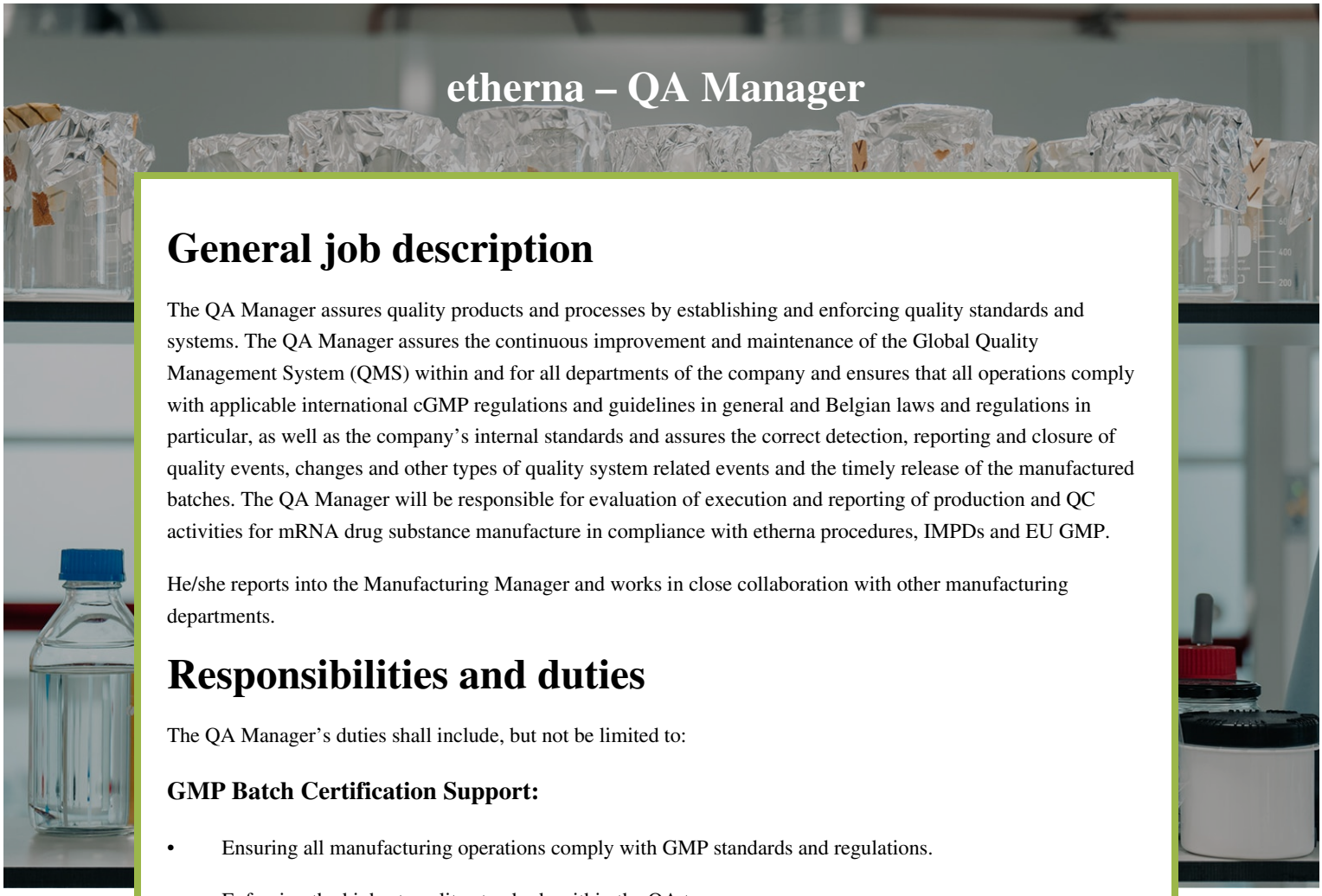

etherna – QA Manager

General job description

The QA Manager assures quality products and processes by establishing and enforcing quality standards and systems. The QA Manager assures the continuous improvement and maintenance of the Global Quality Management System (QMS) within and for all departments of the company and ensures that all operations comply with applicable international cGMP regulations and guidelines in general and Belgian laws and regulations in particular, as well as the company's internal standards and assures the correct detection, reporting and closure of quality events, changes and other types of quality system related events and the timely release of the manufactured batches. The QA Manager will be responsible for evaluation of execution and reporting of production and QC activities for mRNA drug substance manufacture in compliance with etherna procedures, IMPDs and EU GMP.

He/she reports into the Manufacturing Manager and works in close collaboration with other manufacturing departments.

Responsibilities and duties

The QA Manager's duties shall include, but not be limited to:

GMP Batch Certification Support:

- Ensuring all manufacturing operations comply with GMP standards and regulations.
- Enforcing the highest quality standards within the QA team.
- Building strong relationships with internal stakeholders to address deviations, change controls, investigations, complaints, and product releases.
- Supporting the QP in certifying each IMP batch, overseeing drug substance release, and managing complaints, recalls, and returns.
- Authorizing retesting, rework, and reprocessing of products, where permitted by applicable requirements and supported by a documented investigation.
- Approving master batch records and product specification files.
- Reviewing and authorizing regulatory documents when necessary.
- Installing lean quality management system

Global Quality Management System

- Establishing, implementing, maintaining, and overseeing a robust Global Quality Management System.
- Overseeing deviations, investigations, CAPA and change controls, including effectiveness checks and trend review.
- Maintaining document control, data integrity and QA oversight of computerised systems, qualification and validation.
- Coordinating quality management reviews and product quality reviews, where required.
- Overseeing supplier qualification and maintaining generic and client/project-specific quality agreements.

- Involving the QP in all QP certification matters and QP representation, including quality agreement negotiations and supplier qualification.

Product quality and release:

- Ensuring product quality by enforcing quality policies and procedures in line with government requirements and international guidelines.
- Efficiently preparing and reviewing batches for QP certification and coordinating release within agreed timelines, subject to meeting applicable quality and regulatory requirements.
- Leading the evaluation of production and QC documentation up to QP release
- Overseeing stability, samples, traceability, storage and transport conditions, and contamination controls relevant to product quality and release.

Personnel

- Managing and developing your team, ensuring they are well-equipped to meet quality operational requirements.
- Participating in the selection, orientation, and training of employees and consultants.
- Maintaining staff job results through coaching, supporting and performance appraisals
- Prioritizing workload, delegating tasks and working hands-on where needed, with suitable QA and QP cover.

Financial objectives

- Preparing and managing the quality assurance budget as part of the manufacturing budget.
- Analyzing variances and initiating corrective actions as necessary

Regulatory, audits, inspections and compliance

- Leading efforts during regulatory inspections and customer audits, showcasing our commitment to compliance.
- Coordinating self-inspections and following up audit and inspection findings through effective closure.
- Ensuring manufacturing aligns with IMPD or other regulatory documentation from customers or collaborators.
- Collaborating closely with Production, Product Development and QC teams to streamline operations and maintain efficiency.

Job requirements

Education:

Master’s degree in Pharmaceutical Sciences, Life Sciences (or equivalent)

Experience:

- Minimum of 7 years of relevant experience in pharma/biotech industry in a similar function.
- Experience in managing a QA team and priorities in a biotech company.

Other Qualifications, Skills and Abilities:

- Qualifications: Proactive, detail-oriented, excellent problem-solving skills, strong management and organizational abilities, exceptional interpersonal skills, knowledge of manufacturing methods, proficiency in process improvement, and detailed documentation practices
- Abilities: Collaborative, result-focused, well-organized, and adaptable. Strong initiative, fluency in English, and expertise in MS Office tools (Excel, Word, PowerPoint, Outlook)

https://www.etherna.be/