

QA MANAGER

Cellaïon SA is a global innovator in liver therapeutics whose mission is to bring life-saving treatments to reduce the need for liver transplantation. Our lead clinical program, derived from our patented cell technology platform HepaStem®, is designed to benefit from its immune-modulatory and anti-fibrotic properties.

We are currently hiring a **QA Manager**, responsible for the QA Department.

YOUR RESPONSIBILITIES:

- Ensure adequate quality level in compliance with GMP, GCP, GDP and GLP rules and responsible for managing related authorizations/certificates and inspections.
- Achieve quality assurance operational objectives for Cellaïon by contributing information and analysis to strategic plans and reviews; preparing and completing action plans; implementing quality standards; identifying and resolving problems.
- Organize and take part in suppliers' and service providers' qualification / auditing; determining system improvements; implementing changes.
- Develop quality assurance plans by conducting hazard analyses; identifying critical control points and preventive measures; establishing monitoring procedures, corrective/preventive actions, and verification procedures.
- Validate quality processes by establishing product specifications; guaranteeing that GMP are respected during operations; documenting evidence; making sure maintenances, installation, operational and performance qualifications are performed on due time.
- Maintain and improve product quality and ensure continuous improvements by completing internal audits; investigating customer complaints; managing change controls, deviations, OOS, CAPA, Quality risk assessment.
- Prepare quality documentation and reports by collecting, analyzing and summarizing information and trends.
- Review manufacturing and QC batch records prior to release of clinical batches.
- Assure quality oversight of research and development activities within the Company, including the oversight of the Biobank, destined to control Human Body Material samples for research purposes.
- Manage the QA Department.

YOUR QUALIFICATIONS / SKILLS:

- Master's degree in sciences with relevant experience (min. 5 years) in a similar position in the sector of Biotech/Pharma, preferably Cell-or Gene therapy.
- Fluent in French and professional proficiency in English.
- People Manager and excellent communicator.
- Flexible and quality oriented.
- Rigor and respect for procedures, analytical mind.
- Autonomous and organized.
- Good knowledge of cGMP and other relevant guidelines.

If you want to join our team, you may apply for this position by sending your CV and application to hr@cellaion.com.

For information, resumes and application letters received will be retained as long as the employment's offer is valid and will be destroyed as soon as the position is filled. We will contact you in case we wish to keep your CV after the recruitment period.