

REGULATORY AFFAIRS MANAGER (M/F)

Cellaion 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 **Regulatory Affairs Manager**.

YOUR RESPONSIBILITIES:

- Obtain, maintain and update existing regulatory authorizations (such as Clinical Trial Applications (CTA) for Cellaion's products
- Communicate and advise the Company on general ICH regulatory requirements in support of Cellaion's products (advanced therapy medicinal products (ATMPs))
- Compile and submit, in a timely manner, regulatory documents according to regulatory requirements (such as ODD, PIP, Scientific Advice/Pre-IND packages),
- Establish and maintain Regulatory documentation (submission planning tools and trackers, archive correspondence, etc).
- Write Regulatory affairs SOPs & quality assurance system documents and Prepare, review, and approve labeling and SOP's,
- Provide responses to regulatory authorities regarding product information or issues
- involved in interactions with various external partners (academic institutions, CRO, suppliers, notified bodies, consultants).

YOUR PROFILE:

- Master degree in (Life) Sciences, min. of 5 years of experience in a similar position in Pharma/Biotech, preferably in Cell or Gene Therapy.
- Experience in ATMPs with a preference to Stem Cells/cell cultures would be an advantage.
- Good negotiation skills and some experience in interacting with regulatory authorities,
- Flexible and quality oriented.
- Rigorous and respect for procedures, analytical mind.
- Ability to identify compliance risks and escalate when necessary,
- Real problem solver always looking for solutions Excellent organizational skills "can do pull-the-sleeves-up" attitude and a real team player.
- Fluent in English (any additional language is an asset)

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.