Associate Director, Regulatory Affairs – Europe

About AzurBio Group

AzurBio Group is a fast-growing company offering strategic advice, tailored services and innovative solutions to companies in the life sciences sector.
We specialize in supporting organizations throughout the lifecycle of their healthcare products, with a focus on European regulatory challenges—particularly in the areas of rare diseases and innovative therapies.

As part of our continued expansion and organizational development, we are seeking a **motivated and rigorous Regulatory Affairs Associate Director (M/F)** to join our European Operating Unit.
You will directly report to the Chief Operating Officer, Europe.
This position does not involve team management responsibilities but offers significant opportunities for cross-functional collaboration and strategic influence.

Position overview

The Associate Director, Regulatory Affairs – Europe will provide expert regulatory insight and operational support across client projects, ensuring high-quality service delivery in their area of expertise.
This role involves maintaining strong client relationships, guiding consulting teams, resolving complex regulatory challenges, and contributing to commercial proposals.
The incumbent must demonstrate leadership, adaptability, and strong interpersonal and analytical skills, while representing AzurBio Group through clear, effective communication and a strong understanding of the company's mission and values.

Key Responsibilities

- Provide expert regulatory guidance and strategic insight throughout the lifecycle of client projects, ensuring high-quality and timely service delivery.
- Develop and lead regulatory strategies for drugs and biologics, including orphan designation, pediatric plans, clinical trial applications, and interactions with health authorities.
- Oversee European and international registration activities, including regulatory roadmaps, dossier reviews (CTD), and coordination with clients and authorities.
- Act as global launch coordinator, advising on and supporting early access programs and local regulatory operations across Europe, the UK, and Switzerland.
- Maintain strong client relationships by identifying needs, resolving regulatory challenges, and ensuring high client satisfaction.
- Contribute to commercial activities by preparing technical sections of proposals, timelines, and marketing content in collaboration with business development.
- Represent clients in meetings with regulatory agencies and provide regulatory due diligence for partnerships, acquisitions, or submissions.
- Mentor and support consulting teams, ensuring skill development, efficient task execution, and alignment with project objectives.
- Act as an ambassador for AzurBio Group through clear, effective communication and a strong understanding of internal processes and values.

Profile

- 10+ years of experience in the pharmaceutical, clinical-stage biotech, regulatory consultancy, or health authority environment.
- Deep expertise in regulatory affairs with a strong track record in CTD submissions, major filings, and regulatory interactions.
- Solid experience preparing and leading Health Authority meetings, including strategic planning and regulatory risk mitigation.
- Life Sciences degree, PharmD, or equivalent qualification required.
- Proven ability to communicate regulatory strategy effectively across cross-functional teams and senior stakeholders.
- Demonstrated experience working in fast-paced, dynamic environments; prior consulting experience is a plus.
- Strong interpersonal, leadership, and team development skills, with the ability to mentor and guide teams.
- Experienced managing multiple complex projects in a matrixed, multicultural environment.
- Decisive, proactive, and hands-on, with a practical and adaptable mindset suited to entrepreneurial settings.
- Full professional proficiency in English; proficiency in another European language is an asset.

Why join us?

- Be part of a fast-growing, innovative company that is making a significant impact, particularly in the field of rare diseases and advanced therapies.
- Work in a dynamic and collaborative environment with a passionate team dedicated to improving patient outcomes.
- Competitive salary package with opportunities for professional growth and development. Flexible working conditions, including flexible hours and location arrangements.

This is a **full-time position** based in France, with the option to work from either Paris 8th arrondissement or Sophia-Antipolis.

Please send your CV in English to RH@azurbio-pharma.com