Pharmaceutical Development Specialist

Agomab is a young and dynamic biotech company developing medicine for patients with inflammatory and fibrotic diseases, including Crohn's disease. We are headquartered in Gent with offices in Antwerp and Barcelona; and laboratory facilities in Turin and Touro.

We are looking for a **Pharmaceutical Development Specialist** to expand our CMC team. The role will provide support in formulation development, clinical trial supplies (from manufacturing to product release and logistics), through high involvement in vendor management and authoring of regulatory submission documents, in close coordination with other departments within Agomab.

Who are we?

We are a highly motivated team, valuing ownership, trust, humility and courage in everything we do. We focus on pioneering science and getting results within an environment of continuous self-improvement.

What will you do?

- Collaborate in Vendor selection (from preparation of RFP, evaluation of candidates) to contract (in collaboration with Legal and QA)
- Manage Vendor activities, including communication (meetings, minutes), planning (timelines and cost), cost tracking (in collaboration with Project Management and Controlling) and participating in vendor audits.
- Technical monitoring of outsourced activities, reviewing the scope of work and results from Drug Product and Pharmaceutical Process Development activities
- Manage the technical information related to formulation and product development and manufacturing tasks, including the tracking of the batch/product/project history along the different development stages and suggesting alternatives or improvements when optimization may be necessary.
- Review and approve master manufacturing batch records, manufacturing protocols, analytical method protocols, the corresponding reports and product specifications.
- Review/author Drug Product development reports, manufacturing protocols for development and for GMP batches.
- Lead the Drug Product method transfers (manufacturing process and analytical methods).
- Review MBR, PBR, in process specifications, release specifications and sampling plans needed for GMP manufacturing and facilitate change controls when necessary.
- Coordinate the labelling of the CTS according to the clinical study
- Review executed records and CoA/CoC for compliance before batch release, review and approve stability protocols.
- Provide CMC Drug Product support for Regulatory purposes, including the organization and compilation of the project specific supporting data, the authoring the CMC Drug Product

sections in regulatory submission documents, and the participation in interactions with regulatory authorities.

Who are you?

- You have a bachelor's degree in Pharmaceutical Sciences or equivalent with 10+ years pharmaceutical industry experience or Pharmaceutical Scientist, Master's degree or Ph.D. with 5+ years of pharmaceutical industry experience.
- You have working knowledge of scale-up processes and industrialization of Pharmaceutical Drug Products, and in the interpretation of analytical results for pharmaceutical products characterization.
- You have a demonstrated understanding of the entire supply chain logistics, warehousing, distribution logistics and associated cost drivers
- You have writing skills focused on technical and regulatory documents
- You have knowledge and experience in cGMP and GCP requirements, in international regulations and in their application in CMC documents.
- Your regulatory and/or project management experience will be very valuable. Experience in drug product development for inhalation will be a plus
- You have the ability to execute activities on multiple projects running in parallel under challenges of time and workload.
- You are flexible to adapt to change, pay attention to detail without losing sight of overall objectives.
- You are able to work in a multi-cultural environment, supporting a multi-national matrix organized project team, and to interact with international CRO/CDMOs.
- You speak and write English fluently, and have a sound experience in using MS Office applications (Word, Excel, PowerPoint).
- You are most of all a motivated and self-driven person, independently managing your time and projects

What we offer

- The opportunity to develop **pioneering science in a young biotech company**
- Challenging and innovative work environment as part of a driven team
- **Flexibility and responsibility** based in Barcelona or Antwerp, with remote working options that can be tailored for you
- Competitive salary and benefits
- An agile and fast paced environment

Interested in having a high-impact contribution in a growing company? **Send your application to HR@agomab.com** to the attention of Paul van der Horst, Chief Business Officer and join the team! Please be aware, Agomab is not working with any recruitment agencies so please reach out directly.

Visit us at: www.agomab.com