# CMC analytical leader

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 an experienced **Analytical development leader** to support the development of our investigational drug programs. The analytical development leader will play an essential role in cross-functional teams and will be responsible for supporting /driving CMC activities related to analytical development for both API and drug products. This position will report to the Hea of CMC.

**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?**

- You will work collaboratively with internal stakeholder functions as such as drug substance leader, drug product leader, toxicologist, clinical, project management and regulatory to meet program goals
- You will ensure all analytical development & stability activities for both drug substance and drug product are aligned with AgomAb projects goals and timelines
- You will manage analytical development related activities at external vendors, including oversight of method development & validation and stability programs (protocol design, data review, …)
- You will ensure stability studies support clinical development and regulatory objectives & timelines
- You will take an active role and apply subject matter expertise in establishing phase-appropriate analytical methods & validation
- You will oversee qualification of reference materials and management of their inventory & supply across testing sites
- You will review and approve the analytical related technical documents, including methods development reports, method validation protocols, reports, test methods
- You will serve as an analytical SME for technical input

In collaboration with the drug substance leader and drug product leader:

- You will determine the retest period & shelf life and specifications of API and drug product
- You will oversee CDMO analytical deviation & event investigation, and resolution of OOS and OOT testing results

- You will support analytical in aspects of technology transfer, process scale up, process validation activities at contract organizations
- You will ensure the integrity of the CoAs
- You will ensure that all work is conducted in accordance with applicable policies and procedures, cGMP and regulatory standards & guidelines, maintain an understanding of global l laws & regulations applicable to the pharmaceutical industry
- You will prepare pharmaceutical development reports and other technical documentation required of regulatory submissions including authoring, review and approval of the requisite sections of IND, CTA, IMPD, NDA, MAA or other filings
- You will assist in the response to health authority questions
- You will lead and participate in initiatives for improving functional processes and technical operations within CMC

**Who are you?**

- You have a degree in a scientific discipline with demonstration subject matter expertise in analytical development with at least 10 years of experience working in CMC/analytical development in biopharmaceutical or pharmaceutical organizations
- You have extensive experience in small molecule NCE drugs (experience in mAb is a plus)
- You have expertise in a wide variety of analytical methodology and instrumentation used in testing and characterization of raw materials, excipients, drug substances, drug product analytical chemistry, specifically in method development and validation, troubleshooting an CRO/CDMOs management
- You have computer literacy in MS office applications as well as the ability to generate presentations
- You are comfortable with electronic records & digital workflows
- You are capable of working well independently under minimal supervision as well as in a team
- You are flexible and able to multitask, prioritize, meet deadlines in a fast-paced environment
- You are an open-minded individual with interpersonal abilities
- You speak and write English fluently
- You are willing to travel occasionally

**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