



About AM-Pharma

AM-Pharma is a clinical-stage biopharmaceutical company developing proprietary recombinant human Alkaline Phosphatase (AP) therapeutics. Its most advanced asset, known as recAP, is a fully human recombinant form of AP. In 2018, the company successfully completed a Phase IIb trial in sepsis-associated acute kidney injury patients (SA-AKI). The focus has since been on funding and preparing to launch the Phase III / registration trial. The company is gearing up to build the organization that will deliver on the next phase of evolution.

The new AM-Pharma organization will involve several new key positions with large pharma / biotech Phase III experience. The focus will be on Operational Excellence and flawless execution of pivotal studies with the objective to deliver a quality market authorization submission package. The bandwidth of the organization will allow for expanding the pipeline and/or accommodating new strategic opportunities.

To support the expansion of AM-Pharma's business, we are currently looking for a

VP Manufacturing & Supply Chain Management

About the role

The VP Manufacturing & SCM will be responsible for overseeing the overall CMC development, manufacturing and (clinical/market) supply of drug substance, drug product and IMP. He/she determines operations and manufacturing strategies to ensure attainment of financial and strategic goals, translating strategy into tactics, priorities and resource requirements. In addition, he/she oversees the execution of manufacturing, quality assurance and control, materials, procurement and logistics and manages the production from early stage product development to eventually full on-market manufacturing. The VP will also be responsible for outsourcing strategies and partnership management to achieve successful outcomes. The VP will have overall responsibility for the company's logistics strategy and oversight of supply chain management activities to deliver products to clinical trials and/or market within defined regulatory, legal, quality and cost standards.

What we expect

We expect our VP Manufacturing & Supply Chain Management to:

- Have a minimum of 15 years of experience in manufacturing of novel critical care therapeutics, in a GMP/FDA regulated pharmaceutical company; have experience in supporting Phase-III programs.
- Have experience in the production of (complex) compounds from planning through procurement, negotiation and execution.
- Have extensive experience in technical transfers, qualification, validation, trouble shooting, BLA's, FDA inspections, process scale-up, and commercial operations support.
- Have experience with managing contract manufacturing organizations and be familiar with international supply chain architectures including vendor selection, qualification, and contracting; understand the inbound quality control for materials and components.
- Keep a track-record of successful deployment of research and commercial compounds into high-volume production with fast time-to-market and cost-sensitivity requirements.

- Provide excellent guidance to compliance matters.
- Have outstanding written and verbal communication/listening and presentation skills; keep demonstrated problem solving abilities and strong organizational skills.
- Bring a history of great collaboration/teamwork; have a reputation for successful partnering with internal and external stakeholders.
- Have the ability to work successfully in a small organization.
- Be pragmatic, solution-oriented thinker who possesses a “can do” and “whatever it takes” attitude, coupled with excellent organizational and communication skills (verbal, written, listening, conveying messages).
- Have strong interpersonal skills with the ability to motivate and influence others, negotiate during situational conflict, and establish the best forward path in the face of competing points of view.
- Be willing to travel to achieve successful outcomes.

AM-Pharma company culture

The company culture of AM-Pharma is built on four important competences: Collaboration, Quality orientation, Accountability and Resilience. At AM-Pharma we work together in a constructive, collaborative and team-oriented way, towards achieving the company objectives without losing sight of our own objectives. We put the common interest of the company above our own individual interest. We set high standards regarding the quality of our materials, processes, documentation and collaborations, the staff are motivated to deliver excellence whilst also working to continually improve the quality of our work. We are fully accountable for the things that are in our power and control while working on the goals of the organization. We have an obligation to proactively report, explain and justify the things we do. We accept responsibility for our performance and we are transparent about the results of our work. Finally, we understand how to cope effectively with setbacks and obstacles and overcome hurdles on our way to reach our common goal. We stay committed to agreed objectives and company culture despite resistance while having the strength to adjust our plans when necessary. We are tolerant to stress and we deal effectively with criticism and resistance, building on our own strength.

Remuneration

At market level.

Start date

We expect the candidate to start its employment latest as of Q4 2019.

Location

The future organization will be based in the Netherlands along the A2 corridor between Amsterdam and Den Bosch, preferably located close to a major train station connected directly with Schiphol Amsterdam Airport with maximum travel distance of 1 hour nominally.

To apply

Please send your CV and cover letter, stating the title of the position you are applying for, to hr@am-pharma.com