

DRUG PRODUCT MANAGER

NH TherAguix is a late-stage biotech company developing innovative nanomedicine that improve radiation therapy benefits without modifying current clinical workflows. Our leading product, AGuIX® is a nanoparticle designed to improve the localization of solid tumors and the outcomes of radiation therapy by a unique intravenous injection. The company is pursuing its strategy ambitiously as it is currently focused on its clinical development in the USA and on the preclinical development of a second generation drug.

More about the company : nhtheraguix.com

To support our growth, we are recruiting a **Drug Product Manager** for our Chemistry Manufacturing Control Department.

Mission:

Under the supervision of the CMC Director you will be in charge of the design, development, production and control of Drug Product to support clinical needs up to registration / commercialization of our product(s). The job position is located at Lyon area.

Responsibilities:

- Act as technical interface both to guide CRO/CDMO to manufacture and release NHT Drug Product
- Manage CRO in charge of labeling / packaging / distribution of NHT finished product to clinical center
- Participate in the process of identification, qualifying, selection and contracting out with CRO in charge of leachable / delamination / extractable studies and back-up CDMO for Drug Product development and manufacturing according to specific project needs
- Manage CRO in charge of leachable / delamination / extractable studies
- Provides onsite support during production at Drug Product CMO to ensure overall compliance, appropriate resolution to critical issues, and timely progress updates
- Author/review Drug Product development reports and related sections in IND/IMPd and NDA filing
- Supports technology transfer, review of master batch records, change control process, technical manufacturing deviation investigations, and review of executed batch records
- Develop project scopes, deliverables, budget, milestones, resources, and timelines with CMC team members to deliver successful CMC package
- Close coordination with all others functional area of the company to deliver high performance Drug Product

Profile:

You have an experience in a similar position with a strong background ideally in nanoparticles fields or in chemistry and/or pharmacy. You are comfortable in English and have mastered the Office Pack and the usual office automation tools. You are an organized and structured person with proven ability to work independently and take initiatives. You like to work in a team and you have a sense of initiative as appropriate for a growing start-up with no routine. You are accurate, rigorous, and detail-oriented, with a proven, strong capability to review scientific and regulatory CMC documentation in depth. You have the capacity to handle multiple projects with multiple CDMOs/CROs simultaneously. You have strong interpersonal and teamwork skills, including the ability to communicate, collaborate and deliver results in a dynamic growing start-up.

Please address your application to : rh@nhtheraguix.com