

DRUG PRODUCT MANAGER

NH TherAguix is a French biotech start-up 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 through a single 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 managing the subcontractors in order to design, develop, produce and control Drug Product for the clinical needs, up to registration / commercialization of our product(s). The job position is located at Lyon area.

Responsibilities:

- Define and develop project scopes, deliverables, budget, milestones, resources, and timelines with CMC team members to deliver successful CMC package
- Manage CDMO and CROs in charge of Drug Product development, manufacturing and release, in particular :
 - production / labelling / packaging / distribution of NHT Drug Product to clinical centres
 - leachable / delamination / extractable studies
 - analytical method development and validation
- Participate in identification, selection and contracting of subcontractors; Organize and manage meetings with subcontractors.
- Collaborate with other CMC team members to ensure appropriate resolution of critical issues related to NHT products development
- Provides onsite support during CMC activities to ensure overall compliance, appropriate resolution to critical issues, and timely progress updates
- Author/review CMC development reports and related sections in IND/IMPd and NDA filing
- Participate in the review of master batch records, change control process, technical manufacturing deviation investigations, and review of executed batch records
- Work closely with all other functional areas of the company to deliver high performance products

Profile:

Engineer or MSc with an experience in a similar position with a strong background ideally in the field of nanomedicine or in chemistry and/or pharmacy (3 to 5 years).

You wish to join a meaningful project in a dynamic growing start-up.

You like to work in a team, managing frequent internal and external interactions. You are an organized and structured person with proven ability to work autonomously and take initiatives. You have shown strong capabilities to write and review scientific and regulatory CMC documentation in depth.

English : B2 level

Please submit your application to : recrutement@nhtheraguix.com