CMC Project Manager for Minerva Imaging

Join Minerva Imaging as a CMC Project Manager and be a part of driving projects forward in a collaborative environment.

Minerva Imaging is seeking a Project Manager who is driven by the collaborative environment which is key to succeed with our sponsor projects. As a CMC Project Manager, you will be responsible for leading sponsor projects in our CDMO unit, managing internal and external stakeholders, and cross-functional cooperation. You will lead projects from tech transfer from sponsor or the contract research organization to clinical supply of product.

We are looking for an experienced CMC Project Manager with a strong background in managing and leading CMC developing and manufacturing projects with a extensive regulatory understanding. The ideal candidate has experience as project manager from the CRO, biotech, or pharma industry.

If you are eager to join an innovative company that has been recognized with six Gazelle awards for our exceptional growth, we want to hear from you.

About the Role

The ideal candidate will demonstrate extensive experience in the management and leadership of CMC projects, possess a comprehensive understanding of the late-stage pharmaceutical value chain, and bring substantial regulatory expertise. Furthermore, you demonstrate excellent communication and collaboration skills, which are indispensable in this role. Your ability to effectively set direction, drive performance, and maintain a balance between quality and speed, all while being pragmatic, is highly valued. Respecting and incorporating others' opinions and viewpoints, even when they differ from your own, is crucial.

You will join the Project Management Office and a team of 4 colleagues all dedicated to drive projects forward for the CRO and CDMO. Moreover, we are continuously working on optimizing and streamlining the way we work in projects across the organization.

Your key responsibilities will include:

- Ensuring efficient process and knowledge transfer from sponsor or the CRO to CDMO.
- Leading project teams in the late development and optimization of radiopharmaceutical formulations and manufacturing processes and ensure the team is focused on the right tasks.
- Collaborating with internal and external partners to ensure project timelines, budgets, and quality standards are met.
- Managing CMC-related documentation, including regulatory submissions and compliance across late-stage development and commercialization activities.
- Interpreting and implementing relevant regulatory guidelines (FDA, EMA, ICH) into project strategies and execution.
- Be an integral part of developing the project management framework within Minerva and develop project management processes and tools.

Qualifications:

- A master’s degree or PhD degree combined with relevant working experience from the biotech or pharma industry.
- A minimum of 3 years of project management experience (CMC projects).
- Strong understanding of CMC regulatory requirements and guidelines (e.g., FDA, EMA, ICH) and experience with GMP and CMC-related documentation.
- Experience with late-stage development and manufacture in the field of oncology and targeted radiopharmaceutical therapy. This is not a prerequisite but an advantage.
- Broad expertise in utilizing various project tools, coupled with a systematic and methodical approach to work and tasks.
- Proven capability in managing and driving multiple projects simultaneously.
- Strong written and verbal communication skills in English.

Minerva offers:

We believe in creating an agile working environment, so we have flexible working options including the option of working from home. We care about our employees’ well-being and offer health insurance and a quality conscious lunch scheme and monthly social activities.

We are an informal organization with a strong focus on open and honest communication. We value humour and a natural care for one another.

Application:
The application must include a motivated cover letter and a CV addressing the listed qualifications. Applications through LinkedIn are not accepted and will not get a response. Applications will be evaluated continuously. If you have questions regarding the position, please contact Trine Skovlund Neerup at tsn@minervaimaging.com

About Minerva Imaging:
Minerva Imaging is a scientifically driven and integrated CRO and CDMO specialized in targeted radionuclide therapies. We focus on the use of advanced animal models within oncology, cardiovascular diseases, and in vivo molecular imaging for translational research and drug development.

We engage with our sponsors to understand their scientific questions and discuss how our methods and capabilities can provide answers. Our facility located in Ølstykke, Denmark offers best–in–industry fully integrated radiopharmaceutical research, drug development, and manufacturing services.

As part of Minerva Imaging's recruitment policy we expect all candidates to provide their personal criminal record.

Minerva Imaging is an equal opportunity employer, and we encourage candidates of all backgrounds and experiences to apply.

Follow us on LinkedIn for the latest news updates or visit www.minervaimaging.com for more information.