Celyad Oncology is looking for a **Regulatory Affairs Specialist**. The successful candidate will be based in Mont-Saint-Guibert and will report into the **Regulatory Affairs Senior Manager**.

Role & Responsibilities

- Manage documentation of regulatory interactions in compliance all applicable regulatory requirements and organizational policies.
- Manage the preparation and submission of global regulatory applications and notifications for assigned projects.
- Provide regional and global strategic and operational CMC expertise in cross-functional teams, as required.
- Manage CMC aspects of routine and non-routine regional Health Authority interactions including issue resolution and negotiation of approvals, as delegated.
- Writing and / or Review of regional and global CMC submission documents and responses to Health Authority questions.
- Manage Change Control requests, Coordinating and completing regulatory assessments of CMC changes in the designated systems. Prepare and submit CTA amendments as appropriate.
- Manage planning, preparation, and submission of documentation for IND Module 3, CTAs and IMPDs for cell therapy product.
- Establish and maintain Regulatory documentation (submission planning tools and trackers, archive correspondence, etc.).
- Write and prepare well-organized and scientifically sound regulatory documents including eCTD-compliant regulatory submissions.
- Ensure adherence to applicable requirements, accuracy, consistency, completeness of regulatory documents, as needed to meet global business objectives.
- Support RA team in various activities, communications and documentation as needed, including research, writing, proof-reading, and QC review.
- Support Cell Therapy Manufacturing Unit to ensure that CMC practices are carried out in accordance with the requirements of regulatory bodies, such as the FDA (US Food and Drug Administration) and EMA (European Medicines Agency).
- Support Regulatory team meetings including agenda, minutes and logistics.

Qualifications & Experience

- Master in Pharmaceutical Sciences, Life Sciences or equivalent with at least 2 years in pharmaceutical industry is required; a PhD is a plus.
- Regulatory affairs experience is strongly preferred; experience in eCTD-compliant regulatory submissions is a plus.
- Experience with clinical development and associated regulatory CMC submissions (IND/IMPD/CTAs).
- Experience of working within a quality management system (e.g. GMP, GCP, GLP) is strongly preferred.
- Knowledge of European, US and International laws, regulations and guidelines for pharmaceuticals, biologics, medical devices, human cells and tissues strongly preferred.
- Experience in Immuno-oncology and/or advanced therapy medicinal products is preferred.

Skills & Competencies

- Outstanding written and verbal communication skills, including excellent organization and attention to detail.
- Successful authoring and contribution to delivering CMC submission documents of development products, specifically cell therapies.
- Good team player, used to working in multifunctional environments.
- Ability to build and maintain excellent working relations at all levels with strong professional integrity.
- Ability to take initiative and work independently on assigned activities.
- Ability to manage complex projects and organize heavy workloads effectively.
- Flexibility to adapt to rapidly-evolving business needs in fast-paced environment.
- Creative thinking.
- Excellent computer literacy, Microsoft Office Suite applications strongly preferred.
- Languages: Fluent English (written and spoken), additional languages are a plus.

For more information about this position or about the Company, please contact us by email at job@celyad.com

About Celyad Oncology

Celyad Oncology is a clinical-stage biotechnology company focused on the discovery and development of chimeric antigen receptor T cell (CAR T) therapies for cancer. The Company is developing a pipeline of allogeneic (off-the-shelf) and autologous (personalized) CAR T cell therapy candidates for the treatment of both hematological malignancies and solid tumors. Celyad Oncology was founded in 2007 and is based in Mont-Saint-Guibert, Belgium and New York, NY. The Company has received funding from the Walloon Region (Belgium) to support the advancement of its CAR T cell therapy programs. For more information, please visit www.celyad.com.