

Celyad Oncology is looking for a **Regulatory Manager**. The successful candidate will be homebased in The United States (East Coast) and will report into the Regulatory Affairs Senior Manager in Belgium.

Role & Responsibilities

- Regulatory Lead for assigned Celyad Oncology CAR T cell pipeline projects
- Develop and implement innovative global regulatory strategies for assigned projects
- Provide guidance to team on Regulatory CMC, Nonclinical and Clinical topics
- Develop detailed regulatory project plans and timelines for assigned projects; identify critical path activities, risks, gaps and mitigations
- Organizing meetings, coordinate discussions and capture minutes as assigned
- Manage regulatory submissions and rapid responses to Health Authority questions according to required timelines; coordination with internal and external collaborators
- Effective communication of regulatory strategy and submission status to stakeholders
- Liaise with individual contributors and Subject Matter Experts to develop key messages and complete regulatory submission documents
- Write, prepare and review well-organized, scientifically sound regulatory documents
- Ensure accuracy, consistency, completeness and adherence to applicable requirements of regulatory submission documents
- Format submission-ready documents to meet eCTD publishing requirements
- Track submissions, archive correspondence, maintain regulatory documentation and ensure filling and maintenance of regulatory tracking tools
- Maintain knowledge of current regulatory landscape and competitive intelligence
- Review and interpret regulatory, clinical, scientific and other technical documents
- Represent Department at team meetings as assigned
- Represent Company as liaison with Health Authorities
- Mentor RA staff and cross-functional team members as needed
- Follow policies, procedures and checklists for submission processes and archiving
- Contribute to new internal documentation, SOPs and checklists as assigned
- Additional support with department and company objectives as assigned

Qualifications & Experience

- Masters in Pharmaceutical/Life Sciences with minimum 5 years in a biopharma regulatory role; or PhD in Pharmaceutical/Life Sciences with minimum 3 years in a biopharma regulatory role;
- Expertise in Immuno-Oncology and CMC CAR-T Cell Therapy ;
- Experience in eCTD-compliant regulatory submissions;
- Experience working within a Quality Management System (GxPs);
- Knowledge of European, US and International laws, regulations and guidelines for biologics and human cells and tissues

Skills & Competencies

- Outstanding written and verbal communication skills, excellent attention to detail;
- Good team player, experienced working in matrixed environments.
- Ability to build excellent working relations at all levels with high professional integrity;
- Strong motivation and ability to take initiative and work independently;
- Ability to manage complex projects and organize heavy workloads effectively;
- Flexibility to prioritize workload to meet evolving timelines in fast-paced environment;
- Computer and data processing skills, Microsoft Office Suite expertise;
- Languages: Fluent English (written and spoken), additional languages are an asset;

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.
