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

## Role & Responsibilities

As a Regulatory Affairs Assistant, you will support all assigned regulatory affairs activities from adequate documentation, tracking and filing to agenda organization and management:

- Support regulatory submission:
  - Assist in collection of essential documentation required for regulatory submissions and assist in ongoing collection of essential documents throughout submission processes,
  - Assist in documentation formatting,
  - Create printed binders of ongoing submissions when required.
  - Perform Quality Check of submission dossier,
  - Assist with publishing coordination and follow-up.
- Manage filling and maintenance of regulatory tracking tools.
- Manage department's Archiving:
  - Assist with regulatory e-mails archiving and tracking,
  - Ensure regulatory data is correctly stored in the company's data warehouse,
  - Assist with periodic review of regulatory files for accuracy and completeness.
  - Perform an overall housekeeping and inventory to ensure all necessary regulatory documents are properly stored.
- Manage regulatory documentation in compliance with international/national regulations and relevant Standard Operating Procedures (SOPs).
- Support regulatory team with different tasks like scanning, storing of training documents, final contracts, logs, etc.
- Support organization of regulatory meetings (internal and external) including agenda, minutes and logistics.
- Support department's SOPs and Policies creation, review and update e.g., create historical, prepare initial draft, review formatting, coordinate review rounds, support comments implementation.
- May act as regulatory affairs' team central contact for assigned activities
- Other regulatory activities as directed by Regulatory Affairs Management e.g. study tracking invoices
- Support on Process Improvement initiatives related to the department.
- Assist in making travel arrangements for regulatory staff.

## Qualifications & Experience

- Bachelor's Degree in health care, life sciences or related field with demonstrable related experience in pharmaceutical / biotechnology industry including documentation management experience in a highly regulated environment. Oncology field experience is an advantage.
- Minimum of 2 years of regulatory affairs administration experience.
- Solid experience of electronic and paper document management systems.

- Proficient in common office technology e.g. Microsoft Office Suite tools, teleconferencing, etc.
- Knowledge of international and national (US & Belgium) regulations/guidelines and of the auditing process and compliance requirements in relation to regulatory submissions.

## Skills & Competencies

- Strong general administrative skills
- Excellent planning, communication (written and verbal) and organizational skills.
- Ability to handle multiple complex tasks within a given timeline.
- Ability to work in an international team environment as well as independently.
- Hands-on attitude and can-do mentality
- Fluent in English and French and/or Dutch

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.