Celyad Oncology is looking for a **Specialist in Raw Material (CDD of 6 months, from September 2021 to March 2022), focused on the scientific & quality management of raw material**. The successful candidate will be based in Belgium in our office at Mont-Saint-Guibert and/or home-based and will report into the **Cell Therapy Manufacturing Unit Director** in Mont-Saint-Guibert.

Based in our office at Mont-Saint-Guibert and/or home-based, you will join a collaborative team of passionate specialists and hands-on operators.

As our Raw material specialist, you work across department boundaries, and in close collaboration with regulatory, R&D, Quality, QC, production, Supply Chain & Procurement, Business and CROs.

Scientific and GMP knowledge are essential in this role.

Role & Responsibilities

- Define, coordinate, plan and control the qualification and validation strategy in accordance with regulatory requirement and cGMP. This includes the strategic and operational Management of projects related to qualification & validation of Raw material in close collaboration with R&D (IND enabling, Process dev), CTMU operational unit and QA.
- Management of CMOs/CROs for the qualification of Raw Material
- Scientific Coordination and point of contact for all matters related to raw material with external partners, CROs and internally (R&D, CTMU operational unit), in collaboration with the Supply chain & Procurement Manager
- Follow-up on deadlines and raw material project objectives
- Define, coordinate, write and revise qualification and validation protocols/reports and other documentation related to the qualification and validation strategy (URS, QRM, CCR,…).
- Manage specifications, SOPs, and SOPs associated documents (incl. batch records, work files, checklists) related to raw materials, viral vector and start material in line with GMP and regulatory requirements;
- Provide scientific support to CMC submissions;
- Budget Management and Control for qualification/validation and Tech Transfer associated projects under your responsibility
- Work in a constructive and flexible way in a team

Qualifications & Experience

- Education: PhD Biology or equivalent relevant science or working experience
- Strong Knowledge and min 5 years experience of pharmaceutical GMP or ATMP
- Min 3 years experience in Quality Assurance, bio-analytical or raw material qualification / validation
- Experience with project and CRO/CMO management
- Scientific background with an in-depth understanding of viral vectors, including regulatory requirements and GMP operational constraints, are a nice-to-have
- Immunology / Cell & Gene Therapy background is a nice-to-have

Skills & Competencies

- Strong project management and organizational skills
- Strong interaction & communication skills, required to work across dept, with CROs and management levels
- Highly developed writing skills
- Good analytical and problem-solving mindset. Creative and innovative.
- Leadership attitude
- Work precisely according to procedures, rules and regulations
- Flexible mindset capable to deal with ambiguity and to respond quickly, energetically, and enthusiastically to changes.
- Self-motivated, enthusiastic personality, team player, with a desire to learn new skills
- Tenacity to drive issues until resolved and deliver results
- Languages: excellent level of English (oral and written)
- Proficient user of Microsoft Office applications
- Flexibility in schedule and for traveling (max 20%) when necessary

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**.