Celyad Oncology is looking for a **Cell Therapy Development & Validation Lead**. The successful candidate will be based in Belgium and will report into the **Development & Validation Senior Manager** in Mont-Saint-Guibert.

Role

The Cell Therapy Development & Validation Lead acts as a reference expert at the level of the Company in all aspects surrounding the development, validation, and tech transfer of innovative allogeneic CAR-T cell therapies.

He/She independently designs, plans, and coordinates projects, mentors Scientists and Specialists and generates proposals to meet the corporate strategy.

Responsibilities

- Define, coordinate, plan and control the development, qualification, and validation strategy in accordance with regulatory requirements and cGMP. This includes the strategic and operational Management of projects related to the development, qualification & validation of :
    1) analytical methods for raw material, start material, in-process and drug substance/ drug product) testing,
    2) raw and starting material,
    3) Cell & Gene Therapy production processes,
    4) process and analytical equipment,

  in close collaboration with R&D and Cell Therapy Manufacturing operational units, Regulatory and Quality teams.
- Support to CAR-T cell product development plan, led by R&D.
- Provide scientific coaching of junior profiles within CTMU validation unit and R&D CMC & Process Development team.
- Provide scientific support to CMC submissions, including scientific writing and revision.
- Define, coordinate, plan, and control Tech Transfer; operational & Scientific Coordination and point of contact of Tech Transfer of Drug Substance / Drug Product manufacturing process & QC testing to external partners, CROs and internally (R&D, Cell Therapy Manufacturing operational units).
- Define, coordinate, plan, and control incremental Process optimizations without impact on the final product.
- Oversee raw & starting materials technical selection and any subsequent custom-made manufacturing at Third Parties.
- Data monitoring (analysis, interpretation, and reporting) of clinical manufacturing processes.
- Define, coordinate, plan and control drug product investigations (including batch failures).
- Define, coordinate, revise development, qualification and validation protocols/reports and other documentation related to the development, validation strategy (URS, QRM, CCR,…); active participation to Validation Master Plan.

- Manage SOPs, SOPs associated documents (incl. batch records, work files, checklists) and specifications related to manufacturing process, raw materials, analytical method and process and analytical equipment in line with cGMP.
- Budget Management and Control for projects under his/her responsibility.

Qualifications & Experience

- Education: PhD in Biological sciences or equivalent relevant working experience.
- Strong Knowledge and min 8 years' experience of pharmaceutical GMP and ATMP.
- Strong Knowledge and min 8 years' experience in ATMP / bio-analytical, process and raw material qualification / validation.
- Strong knowledge and hands-on experience in CMC submissions and technical transfer.
- Strong Experience with project management and/or management of external activities.
- Immunology or cellular biology background is highly preferred.

Skills & Competencies

- Highly developed project management and organizational skills.
- Excellent interaction & communication skills, required to work across dept and management levels.
- Leadership attitude, including coaching and mentorship.
- Highly developed writing skills.
- Good analytical and problem-solving mindset.
- Creative and innovative.
- 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), working knowledge of French would be an advantage.
- 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