

MaSTherCell

The global cell and gene therapy CDMO partner



We are currently looking for a:

QC Project Leader

Interested to work with us? Send your resume and a cover letter at job@masthercell.com

QC Project Leader

RESPONSABILITIES

The QC Project Leader main role is to lead and manage one or several specific project in the Quality Control department. In order to fulfill his/her role, the QC project leader is focused on the following topics:

Communication:

- The QC Project Leader is an active member of QC management team.
- He is the interface between the QC department and all others Masthercell's departments and client for QC aspect linked to the project he/she is leading.
- Warns the Head of QC in case of problem; Report weekly to the Head of QC
- Maintains open and effective communication with all other departments
- Vehicles MTC and QC chart values, and QC department vision and mission
- Takes part to audits when necessary

Planning/team management:

- Plans the QC tests related to his/her specific projects
- Manages the action log related to his project and respects the timelines
- Ensures respect of KPI

Documentation:

- Manages set up and leads change management initiative of project specific documents for QC department
- Reviews QC documents related to his/her projects (procedures, forms, instructions, ...)
- Double checks project specific form filled by operators
- Drafts stability protocols
- Drafts products specification form
- Drafts sampling plan
- Drafts validation/transfer protocols of analytical methods
- Interprets results and draft of analytical methods validation/transfer reports

Release:

- Ensures that COA are generated in a timely manner according to release planning
- Reviews certificates of analysis and ensures that a drug product will only be released if its quality responds to the current specifications
- Reviews OOS, DEV, CHC, CAPA linked to his project

Trends:

- Performs trends analyses based on batches data and interprets results

Budget:

- Mentions each budget deviation to MTC business

Training and Tech transfer:

- Ensures that operators are trained according to Masthercell and client quality requirements for his/her specific projects
- Manages the technology transfer of QC tests related to his/her projects
- Manages the setup of new QC tests related to his/her projects
- Suggests new technologies to implement and qualify

Back-up:

- The QC project leader is the back-up of QC specialist in performing QC tests linked to his project
- The QC project leader is the back-up of the Head of QC for project aspect

QUALIFICATIONS & EXPERIENCE

- Master, engineer or PhD degree in biology, chemistry, biochemistry, clinical chemistry or relevant experience in a similar position in the sector of biotech/pharma/cell therapy
- Experience in cell therapy or quality control of cells from human tissue origin is a plus
- At least 2 years of experience in cGMP environment

SKILLS & COMPETENCIES

- Efficient communicator and sense of ethic
- Demonstrated leadership and cross functional team spirit
- Technical expertise

- Quality minded, rigorous
- Customer oriented
- Fluency in French and English is a must
- Computer skills : Microsoft office, ERP system

WE OFFER

- Full-time position (40h/week);
- An Indeterminate contract;w
- Attractive salary packing including additional benefits as company car, full health insurance, group insurance, lunch-voucher, etc
- A human-sized working environment with a convivial atmosphere