

MaSTherCell is a dynamic and global Contract Development and Manufacturing Organization (CDMO) on a mission to deliver optimized process industrialization capacities to cell therapy organizations, and speed up the arrival of their therapies onto the market. From technology selection to business modeling, through GMP manufacturing, process development, quality services, MaSTherCell's teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients.

To lead its increasing number of development and manufacturing projects, MaSTherCell is looking for a highly motivated:

## Quality Control Engineer

### Responsibilities

The QC Engineer main role is to support the team of project leaders with their projects. He/she **will supervise the transfer of analytical methods** and **leads validation in the QC department**.

In order to fulfill his/her role, the QC Engineer:

#### Communication/Mindset

- The QC Engineer is an active member of the QC management team;
- Warns the Head of QC in case of problem;
- Maintains open and effective communication with all other departments;
- Vehicles MTC and QC chart values, and QC department vision and mission;
- Ensures respect of KPI.

#### Scientific support on Analytical Methods Transfer/Validation (AMT/AMV)

- Coaches QC members to AMV and transfer environment (concept of validation, protocols, design of experiments) and statistical analyses associated to QC (ANOVA, bridging, ...);
- Can take part in the design and review of AMT protocol & report depending on the need;
- Coordinates the different AMV of all the current projects in MTC;
- Is responsible of the AMV/planning and respect of projects deadlines;
- Ensures that the discussed strategy is translated into validation protocol and experimental plan and communicates with Project Leaders (PL) and QC specialists/experts in charge of the method;
- Develops a fit for purpose approach for AMV depending on clinical Phase of the study and requirements of the customer;
- Follows up of experiments related to AMT/AMV and support statistical data analysis
- Is responsible for the review of AMV protocols & reports;
- Ensures GMP compliance and implementation of MTC's QMS, product quality and team driven by patient safety;
- Sets up generic templates for all AMV activities and follow up for continuous improvement.

#### Budget

- Mentions each budget deviation to MTC business.

## Audits

- Prepares and participates to audits with authorities and customers.

## People Management

- Supervises and participates in individual development of N-1;
- Performs 1:1 throughout the year to discuss N-1 issues and achievements;
- Sets up annuals SMART objectives to his/her N-1 and perform annual performance review;
- Ensures human well-being by a good private/professional life balance while ;
- preserving team spirit and good work atmosphere;
- Approves timesheet and holidays.

## Back-up of this function

- The QC project leader of the related project where the QC engineer is involved, is the back-up of the QC Engineer.

## **Qualifications & Experience**

- At least Bioengineering degree or Master degree in biology, pharmacy, chemistry, etc.;
- At least 2 years experiences in a cGMP biopharmaceutical environment;
- Experience in analytical methods validation and statistics is a must;
- Experience in cell therapy or quality control of cells from human tissue origin is a plus.
- Fluency in French and English is a must;
- Computer skills: Microsoft office, ERP system Knowledge of a statistics software (e.g. JMP) is an asset.

## **Skills & Competencies**

- Confirmed team player
- Efficient communicator
- Demonstrated leadership
- Passionate and cheerful
- Hands-on mentality
- Quality minded, rigorous
- Customer oriented
- Can work in multi projects / multi departments environment
- Ability to switch easily and adapt to different projects requirements

## **We offer**

- Full-time position (40h/week)
- An Indeterminate contract
- The opportunity to take part in a growing dynamic biotech company
- A human-sized working environment with a convivial atmosphere

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## **Interested?**

Please send your detailed CV and your application letter to Mrs Elodie Noël, HR Manager : [job@masthercell.com](mailto:job@masthercell.com).