MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

QUALITY CONTROL PROJECT LEADER

Full-time | Webster, TX - USA

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

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JOB OFFER

Quality Control Project Leader

RESPONSIBILITIES

The Quality Control (QC) Project Leader is responsible for leading and managing one (1) or several specific projects in the QC Department, in addition to the team members involved in the projects.

Communication

- Act as the interface between the Quality Control (QC) Department and all other Masthercell Departments and clients for QC aspects linked to the project(s) you are leading.
- Act as the interface between your project team and the other members of the QC Department. Alert the Head of QC of all problems.
- Maintain open and effective communication with all other departments.
- Participate in audits/prospects when required.
- Determine the impacts of a project scope change related to resources and timelines of the project(s) and report conclusions to Head of QC/Project Manager/Business team.

Planning/Team Management

- Plan the QC tests related to specific project(s) and organize the work of the team.
- Manage the action log related to the project(s) and respect the timelines.
- Ensure key performance indicators (KPIs) are met.
- Organize and manage weekly QC back-end meetings to ensure the follow-up of all tasks of the team.

Documentation

- Manage, set up and lead change management initiative of project specific documents for QC department.

- Draft/review QC documents related to project(s) (procedures, forms, instructions, ...).
- Double check project specific forms completed by operators.
- Draft/review stability protocols.
- Draft product specification form and sampling plan.
- Draft/review validation/transfer protocols of analytical methods.
- Interpret analytical results and draft/review analytical methods validation/transfer reports.

Release

- Ensure that certificates of analysis (CoA) are generated in a timely manner according to release planning.
- Review CoAs and ensures that a drug product will only be released if its quality responds to the current product specifications.
- Manage Out of Specifications (OOS), Deviation (DEV), Change Control (CHC), Curative and Preventive Actions (CAPA) linked to your project(s).

Trends

- Perform trends analyses based on batches data and interprets results.

Budget

- Ensure that all unexpected testing(s) related to your project(s) are properly communicated to the Head of QC.
- Identify specific needs related to equipment for your project(s) and training for your team and report to the Head of QC.

Training and Tech Transfer

- Ensure that operators are trained according to Masthercell and client quality requirements for the specific project(s).
- Manage the technology transfer of QC tests related to the project(s).
- Manage the setup of new QC tests related to the project(s).
- Suggest new technologies to implement and qualify.

SKILLS/QUALIFICATIONS

- Effective Communicator.
- Sense of Ethics.
- Demonstrated Leadership.
- Cross-Functional Team Spirit.
- Technical Expertise
- Quality-Minded.
- Rigorous.
- Customer Oriented.
- Team/People Management.

EDUCATION/EXPERIENCE

- Master's Degree in Engineering or PhD in Biology, Biomedical Sciences, Biochemistry, Clinical Chemistry, or Pharmacology; or relevant experience in the fields of Biotech/Pharma/Cell Therapy.
- Experience in cell therapy or quality control of cells from human tissue origin preferred.
- Experience in project management and/or people management preferred.
- Experience in a current Good Manufacturing Practice (cGMP) environment preferred.

REPORTING RELATIONSHIP

Direct line reporting to the Director of QC.

- APPLY TO: jobs-us@masthercell.com.
- Please be sure to include your salary requirements.
- NO TELEPHONE CALLS PLEASE!