

MaSTherCell

The global cell and gene therapy CDMO partner



We are currently looking for a:

QUALITY CONTROL SPECIALIST

Full-time

Webster, TX - USA

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

Quality Control Specialist

RESPONSIBILITIES

- Perform QC assays to evaluate the quality of the cell therapy products with a Good Manufacturing Practice (GMP) quality grade in an efficient way.
- Maintain open and effective communication with all other QC team members.
- Actively participate in weekly QC team meeting.
- Participate in technology transfer from the client under the supervision of QC Project Leader (may include meetings and observation of QC test on the customer's premises).
- Participate in implementation/improvement of new tests under the supervision of QC Project Leader/ QC supervisor
- Participate in analytical method validation under the supervision of QC Project Leader or QC Supervisor.
- Ensure the availability of reagents, consumables at the appropriate time.
- Double check data generated by other operators, as approved.
- Draft QC documents (Instruction (INS), Procedure (PRO), Form (FORM), General Specification (GSPE)).
- Draft technology transfer (TT), development, validation reports under the supervision of QC Project Leader or QC Supervisor.
- Perform QC tests in accordance with instructions given by the QC Supervisor or QC Project Leader.
- Perform daily responsibilities and document work according to Mastercell's current procedures and GMP rules.
- Interpret the obtained results and immediately alert the QC Project Leader or QC Supervisor in case of unusual event/result/out of specifications (OOS).
- Initiate deviation, OOS, change control (CHC) in connection with your work and perform necessary investigation.
- Implement curative and preventive actions (CAPA).
- Fill the certificates of analyses.
- Respect the safety rules within the laboratory.
- Immediately alert the Head of QC, QC Supervisor and/or QC Project Leader in case

of problem, failure or security issue.

- Participate in audits when required.
- Participate in daily maintenance of the laboratory (bench and floor cleaning, waste evacuation, general aspect...)
- Participate in routine and planned maintenance, calibration, and qualification of equipment when required.
- Ensure routine QC reagents are in stock.
- Serve as back-up for QC support.

SKILLS/QUALIFICATIONS

- Quality-Minded.
- Rigorous.
- Technical Expertise.
- Good Communication Skills.

EDUCATION/EXPERIENCE

- Bachelor's Degree in Chemistry, Biochemistry, Clinical Chemistry, or Biology; or relevant experience in the fields of Biotech/Pharma/Cell Therapy.
- Experience in quality control of cells from human tissue origin preferred.
- Experience in current Good Manufacturing Practice (cGMP) environment preferred.

REPORTING RELATIONSHIP

Direct line reporting to the QC Supervisor. However, communicate with the QC Project Leader for all things project related.

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