MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

DIRECTOR OF QUALITY CONTROL

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

Director of Quality Control

RESPONSIBILITIES

The Director of Quality Control (QC) is responsible for sampling, specifications and testing, as well as organization, documentation and release procedures, which ensure that necessary and relevant tests are carried out, and that materials are not released for use, nor products released for sale or supply, until their quality has been judged satisfactory. The Director of QC is not confined to laboratory operations but is required to be involved in all decisions which concern the quality of the product.

Building & Equipment

- Ensure that the required equipment is purchased, qualified and calibrated in accordance with the validation master plan.
- Ensure that Production and QC premises are conformed to Good Manufacturing Practice (GMP) requirements for clinical or commercial production.
- Ensure that QC laboratories are correctly maintained and operational.
- Conduct monthly environmental monitoring meeting to ensure maintenance of building and equipment is appropriate to preserve environment quality.

Quality

- Ensure that all necessary testing is carried out and the associated records evaluated.
- Ensure GMP compliance and implementation of Masthercell's Quality Management System (QMS), product quality and team driven by patient safety.
- Maintain license to operate and ensure implementation of remarks from any audits.
- Prepare for and participate in audits.
- Develop a fit for purpose approach based on risk assessment for QMS appropriate to clinical phase project advancement (ph I, II, III) or to commercial.
- Ensure continuous improvement with quality assurance (QA) through GMP watchfulness.
- Ensure that all department documents are available, and operators perform their duties according to existing procedures.
- Responsible for QC GMP compliance.
- Audit subcontractors in charge of QC tests in collaboration with quality assurance.

- Audit suppliers (raw materials...) in collaboration with quality assurance.
- Ensure that required validations are performed.
- Responsible for specification form, out of specifications (OOS), certificate of analysis, raw materials/consumables certificate of release (when QC testing is required), stability protocols and certificates, sampling plans, and all generic QC documents (procedures, validation protocols and reports, transfer protocols and reports, ...).
- Establish, validate and implement all quality control procedures, oversee the control of the reference and/or retention samples of materials and products when applicable, ensure the correct labelling of containers of materials and products, ensure the monitoring of the stability of the products, participate in the investigation of complaints related to the quality of the product, etc.
- Approve or reject (as necessary) starting materials, packaging materials, intermediate, bulk and finished products.

Continuous Improvement

- Identify and lead continuous improvement projects.
- Implement pertinent tools of operational excellence “lean culture.”
- Implement Key Performance Indicators (KPIs).
- Implement trends indicators.
- Recommend new technologies to implement and qualify in order to develop Masthercell’s QC activities.
- Participate in management reviews of process performance, product quality and the QMS.

GMP Clinical/Commercial Production

- Ensure appropriated resources, time and competencies in QC for Production projects.
- Ensure QC planning is aligned with quality, milestones, and resources.
- Ensure the team is focused on client expectations.
- Ensure documentation is prepared and supports Regulatory Affairs filing (clinical or commercial).

Budget

Responsible for the QC Department budget.

SKILLS/QUALIFICATIONS

- Confirmed Team Player.
- Effective Communicator.
- Demonstrated Leadership.
- Passionate.
- Cheerful.
- Quality-Minded.
- Rigorous.
- Customer Oriented.

EDUCATION/EXPERIENCE

- Bachelor's degree in Bioengineering or Advanced Degree (MS) in Biology, Pharmacy, Chemistry; or relevant experience in the fields of Biotech/Pharma/Cell Therapy.
- At least ten (10) years' experience in a current Good Manufacturing Practice (cGMP) biopharmaceutical environment, including at least three (3) years of people management.
- Minimum five (5) years' experience in QC of a pharmaceutical company.
- Team leader and excellent communicator, quality minded and customer oriented.
- Familiarity with Operational Excellence principles.
- Confirmed experience in QC techniques (environmental testing, sterility testing, LAL, mycoplasma, Polymerase Chain Reaction (PCR), various potency testing, cell characterization testing, etc.)
- Experience in QC equipment qualification.
- Experience in analytical methods validation and statistics.
- Experience in cell therapy or quality control of cells from human tissue origin preferred.

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