MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

DIRECTOR OF PRODUCTION

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 Production

RESPONSIBILITIES

The Director of Production is responsible for all activities performed in the Production Department as follows:

- Ensure that products are produced and stored according to the appropriate documentation in order to obtain the required quality.
- Ensure a process is in place to approve instructions relating to production operations and ensure their strict implementation.
- Ensure that the production records are evaluated and signed by an authorized person.
- Ensure the qualification and maintenance of the Production Department, premises and equipment.
- Ensure that the appropriate validations are prepared.
- Ensure that the required initial and continuing training of the Production Department team is carried out and adapted according to needs.

General

- Responsible for the Production team management and production deliverables.
- Ensure quality processes implementation guaranteeing that Good Manufacturing Practice (GMP) is followed during operations, documenting evidence, and making sure maintenance, installation, operational and performance qualifications are performed in the appropriate amount of time.
- Ensure continuous improvement by completing product, company, system, compliance, and internal audits, investigating customer complaints, collaborating with other members of Masthercell's management to develop new engineering designs, and manufacturing and training methods by managing change controls, deviations, out of specifications (OOS), Curative and Preventive Actions (CAPA), and Quality Risk assessment.

Building and Equipment

- Ensure that the required equipment is purchased, validated and calibrated in accordance with the validation master plan to guarantee product quality.

- Ensure that Production premises are conformed to GMP requirements for clinical or commercial production.
- Ensure maintenance of building and equipment is appropriate to preserve environment quality.

Quality

- Ensure GMP compliance and implementation of Masthercell's Quality Management System (QMS), product quality and team driven by patient safety.
- Preserve license to operate and ensure implementation of remarks from any audits.
- Prepare and participate in audits with authorities and customers.
- Ensure appropriate training systems for staff.
- 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.
- Identify and implement quality key performance indicators (KPIs).
- Ensure continuous improvement with quality assurance (QA) through GMP watchfulness.

Prospect Evaluation and Production Process Acquisition

- Ensure appropriated resources, time and competencies to prospects/projects technical evaluation (Front End Leader) and Transfer Team to manage technology transfer.
- Support formalized technical evaluation and transfer (standardizes processes in place) and integration of GMP constraints in production process.
- Ensure single point of contact (SPOC) effectively interacts with client to prevent direct interference from client with the Production Department Team.
- Dedicate resources (i.e., Experts, Specialists) to Process Development Team.

GMP Clinical/Commercial Production

- Ensure appropriated resources, time and competencies to Production projects.
- Ensure production planning is aligned with quality, milestones, and resources.
- Ensure Production Department team is focused on client expectations.
- Ensure documentation is prepared to support regulatory affairs (RA) filing (clinical or commercial).

Budget

- Responsible for the budget of the Production Department.
- Ensure best productivity and cost control on all projects.
- Responsible for implementation of tools to prioritize investments (equipment, technology and people development) to fit with resources (budget and team).

SKILLS/QUALIFICATIONS

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

EDUCATION/EXPERIENCE

- Master's Degree in Biology, Chemistry, Bioengineering, Pharmacy or relevant experience in the fields of Biotech/Pharma/Cell Therapy.
- Minimum of five (5) to ten (10) years in current Good Manufacturing Practice (cGMP) environment.
- Minimum of five (5) years in cell culture production.
- Team leading.
- Experience in cell therapy or cultivation of cells from human tissue origin preferred.

REPORTING RELATIONSHIP

Direct line reporting to the Chief Executive Officer.

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