MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

CELL THERAPY PRODUCTION SUPERVISOR

Full-time | Webster, TX - USA

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

MaSTherCell
The global cell and gene therapy CDMO partner

JOB OFFER

Cell Therapy Production Supervisor

RESPONSIBILITIES

The Cell Therapy Production Supervisor is responsible for global management of one (1) or several specific projects to be transferred in the Production Department and production of the first series of clinical batches, followed by transfer of the project to a Production Supervisor.

Phase I

Once contract is concluded with the client, responsible for early phases of technology transfer from client to Masthercell which entails meetings with client, set up of quality with Front End colleagues, and observation of production at the customer's premises.

Phase II

- Build dedicated team. Review appropriateness of dedicated staff training matrix and adapt according to needs (including technology and environmental health and safety (EHS).
- Fine tune timing (process/budget/resources).
- Evaluate equipment needs, user requirement specification (URS), supplier selection, ordering, Factory Acceptance Testing (FAT), reception, Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ) in collaboration with Shared Service Supervisor.
- Select raw materials and disposable supplier (Raw materials/Consumables (RM/CP/CC)).
- Set of bill of material (BOM).
- Identify establishment for raw material, disposable and starting material.
- Implement the project on Masthercell's premises.
- Execute lab tech transfer/reproducibility runs.
- Establish all documentation and qualification/validation protocols/runs/reports specific to the project for process and equipment (Specific Master Batch Record (MBR) and Aseptic Process Simulation (APS) included).
- Manage according to change control and risk assessment.

Phase III

- Finalize all specific Good Manufacturing Practice (GMP) documentation.
- Run and release of first clinical batches and apply all GMP requirements.
- Transition project to the Production Supervisor.
- Prepare reports for client and internal.

SKILLS/QUALIFICATIONS

- Efficient Communicator.
- Sense of Ethics.
- Demonstrated Leadership.
- Cross Functional Team Spirit.
- Project Driving Management
- Technical Expertise.
- Quality Minded.
- Rigorous.
- Customer Oriented.

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) years' experience in GMP, cell culture production and/or human cells cultivation.

REPORTING RELATIONSHIP

Direct line reporting to the Director of Production.

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