MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

PRODUCTION SUPERVISOR, CELL THERAPY

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

Production Supervisor, Cell Therapy

RESPONSIBILITIES

The Production Supervisor, Cell Therapy is responsible, coordinates and is actively involved in Shared Service activities as follows:

Training

- Ensure training plan/matrix for Production staff is adequate, effective and updated.
- Ensure completion of all training of Production staff.
- Ensure efficient training tools and adequate trainings are delivered.
- Implement the “Train the Trainer” system.
- Ensure gowning qualification and requalification for grades B/A personnel.
- Ensure generic Aseptic Process Simulation (APS) for grade A personnel is completed.
- Ensure the implementation and follow-up of a training record system.
- Create a training key performance indicator (KPI).

Logistic and Environmental Monitoring

- Ensure environmental monitoring (EM) and cleaning conformities, and respect of frequencies for all grades.
- Ensure grades C/D Environmental Deviation (Dev) and Curative and Preventive Actions (CAPA) are well managed and followed.
- Ensure to provide sufficient support to production for realization of grades B/A major cleaning and monitoring (monthly, quarterly, yearly).
- Ensure production daily checks of environmental monitoring system (EMS) reports.
- Ensure that EM trends are analyzed for production matters and that actions are taken for parts under your scope.
- Ensure rooms & projects’ inter-campaigns are realized in time with the scheduled needs of production and that documentation is well completed.
- Ensure Vaporized Hydrogen Peroxide (VHP) is realized and reports are reviewed.
- Ensure consumables are ordered for production, in addition to all other generic furniture.
- Ensure effective material transfer in classified rooms (grades D or C) and generic consumables stock level in common rooms.

- Ensure good interactions with quality control (QC) regarding EM and with technical service (TS) concerning logistics.

Facilities and Equipment

- Act as the interface between Production and Technical Service (TS)
- Guarantee production equipment management in partnership with TS and Production.
- Approves user requirement specification (URS) for generic equipment.
- Ensure equipment (re)qualification protocol writing under Shared Service responsibility.
- Responsible for or consulted about equipment ordering and selection.
- Ensure adequate qualification of equipment for Shared Service responsibility.
- Follow-up of curative maintenance on defective equipment.
- Responsible for production equipment logbook management.
- Responsible for furniture and utilities management in clean rooms.
- Ensure modification and improvement of current areas, and requalification if needed.
- Ensure production input for new facilities design is well implemented and new facilities qualification.
- Ensure URS writing for transversal and generic processes (as electronic samples storage management) and selection of these systems.
- Ensure transversal and generic process is validated (as Vaporized Hydrogen Peroxide (VHP)).
- Ensure Liquid Nitrogen (LN2) and -80°C freezer occupation, inventory and cleaning status management.

Quality

- Ensure efficient transversal documents are available and followed, with the support of adequate tools and training.
- Ensure current Good Manufacturing Practice (cGMP) implementation through Mastercell's quality system.
- Ensure continuous improvement by dedicating appropriate time in Production area to ensure all duties to produce in accordance to quality system and defined plan are implemented.
- Create, finalize and/or approve generic and transversal documentation as policies/

procedures/instructions/forms/protocols which could be eventually approved by any relevant stakeholder.
- Create and track KPIs to continuously feed quality and efficacy improvement. Ensure a system is in place to follow trends and anticipate proactive actions.
- Coordinate preparation and execution of any audits/inspections.
- Establishes in collaboration with QA L1 audit universe, planning for prod and performs some audits.
- Ensure execution and follow-up of any/all Deviation (Dev) and Curative and Preventive Actions (CAPA).
- Responsible for GMP watchfulness.

SKILLS/QUALIFICATIONS

- Effective Communicator.
- Sense of Ethics.
- Demonstrated Leadership.
- Team Management.
- Cross-Functional Team Spirit.
- Team Development.
- Technical Know How.
- 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 Good Manufacturing Practice (GMP) environment, aseptic production, team and/or project management.

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!