MaSTherCell
Manufacturing Synergies for Therapeutic Cells

MaSTherCell is a dynamic and global Contract Development and Manufacturing Organization (CDMO) on a mission to deliver optimized process industrialization capacities to cell therapy organizations, and speed up the arrival of their therapies onto the market. From technology selection to business modeling, through GMP manufacturing, process development, quality services, MaSTherCell's teams are fully committed to helping their clients fulfill their objective of providing sustainable and affordable therapies to their patients.

To lead its increasing number of development and manufacturing projects, MaSTherCell is looking for a highly motivated:

Production Cell Culture Expert (m/f)

Responsabilities

Expert's responsibilities need to be adapted according to the development phase of the project from early process development, technical transfer or GMP production. The supervisor could delegate activities to the Expert. The below list is not exhaustive.

General:

- Can be involved in all stages of production process maturity (from development or acquisition to continuous commercial GMP production) and follow up of closed projects;
- Deals with technology, productions and team management;
- Generates (responsible) and/or ensures finalization (accountable/owner) and/or approves documentation (procedures/instructions/forms/protocols) to perform specific production, or generic documentation which could be eventually approved by Supervisor and relevant stakeholder prior to production start;
- Respects EHS rules in working area;
- Compiles KPIs of his/her team and feed continuous improvement of the production team;
- Masters critical parameters of production process;
- Plans, coordinates and performs daily production;
- Organizes production campaigns;
- Dedicates appropriate time in production area to ensure all duties to produce according quality system and defined plan and to perform production activities to support Specialists. Due to administrative tasks, the Cell Culture Expert dedicates more time to office than the Cell Culture Specialist;
- Is highly trained/qualified to work in A/B environment and is a referent to train colleagues;
- Generates (responsible) and/or ensures finalization (accountable/owner) and/or approves of all GMP documentation related to performed production for final approval by hierarchy/certified reviewer;

- Upon specific request will represent the project he/she manages to internal/external meetings.

Building & Equipments:

- Could be responsible for one or several production area out of dedicated project (daily double checks of area parameters);
- Plans, in partnership with Shared Service team, and guarantees realization of grades A/B major cleaning (monthly, quarterly, yearly);
- Coordinates, in partnership with Shared Service team / Technical Service, VHP realization.

Quality:

- For his/her direct responsibility, ensures cGMP implementation through MTC's quality system and feeds continuous quality improvement;
- Ensures his/her team is adequately staffed, trained, equipped (premises, equipment and any material) to execute required work. Shares appropriately work between team members according to their competencies and workload;
- Takes a special care to continuously train colleagues working in aseptic environment and manages all A/B area monitoring;
- Support to change control preparation and derogation;
- Finalizes Deviations (Owner role) and CAPA for hierarchy approval. When transversal (on top of the specific project) actions to close Deviations or CAPA are identified, the Expert is able to evaluate impacts across MTC on top of its own project;
- Generate product investigations related to OOS opened by QC;
- Involved in preparation and execution of any audits/inspection.

People:

- Set up project specific team with supervisor;
- Lead a team of Cell Culture Specialists for a specific project and direct reporting;
- Ensures planning is built to restrict to the minimum extra hours. Can justify to hierarchy additional hours (out of normal day) when required. Regularly challenge resources over time based on the learning experience curve of the project;
- Is responsible of the training matrix (appropriated matrix and effectively trained staff) of his/her team, under his/her responsibility for the specific project;
- Centralizes Time Sheet for Production Specialists and manages leave or absence request of his/her functional team in alignment with other Experts/Supervisors when needed;
- Could delegate activities to Specialist.

Skills & competencies

- Master degree in biology, pharmacy, clinical chemistry, bioengineering or relevant experience in a similar position in the sector of Biotech/Pharma/Cell therapy. Experts in cell culture and GMP aseptic environment, mastering the cell therapy specific context;

- Quality minded, rigorous, customer oriented and continuous improvement driven;
- Demonstrated team management capabilities and cross functional team spirit. Dedicates time to team development;
- Organization skills, multitasking, flexibility and autonomous;
- Good communicator.

We offer

- Full-time position (40h/week);
- An Indeterminate contract;
- The opportunity to take part in a growing dynamic biotech company;
- A human-sized working environment with a convivial atmosphere.

Interested?

Please send your detailed CV and your application letter to Mrs Elodie Noël, HR Manager: job@masthercell.com