MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

QA Release Project Leader, Human Body Material

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

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JOB OFFER

QA Release Project Leader, Human Body Material

RESPONSABILITIES

The QA Release Project Leader main role is to lead and manage the launch of new projects in the Quality Assurance department. In order to fulfill his/her role, the QA Release Project Leader is focused on the following topics :

Pharmaceutical Quality System:

- He/she is the Subject Matter Expert covering QA questions related to QA Release project launch activities, by customers or internal teams.

Communication:

- He/she is the interface between the QA department and all other MaSTherCell's departments and customer for QA aspects related to projects he/she is leading;
- He/she communicates and interacts effectively with the colleagues of QA department for QA aspects related to projects he/she is leading;
- Takes part to audits when necessary.

Documentation & release:

- He/she manages set up and leads change management initiative of project launch specific documents for QA department;
- He/she reviews and challenges, in compliance with the IMPD and the current regulations, the Deviations, CAPA's, Changes Controls and Risk Analysis related to projects he/she is leading;
- He/she reviews and challenges Gowning qualification and Aseptic Process Simulation related to projects he/she is leading.

Training and Tech Transfer:

- He/she manages the QA aspects of technology transfer related to his/her projects;
- He/she manages the QA activities related to his/her projects he/she is leading.

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The Deputy Responsible Person main role is to ensure the overall quality, safety and traceability of tissues and cells as starting material for Advanced Therapy Medicinal Products (ATMPs) in the Production Establishment/Intermediate Structure.

In order to fulfill his/her role, the Deputy Responsible Person is focused on the following topics :

- Ensure the activities of the Responsible Person when he is unavailable;
- He supervises all the operation related to the bank of Human Body Material.

QUALIFICATIONS & EXPERIENCE

- Experience of minimum 5 years in quality assurance is required;
- Bioengineering degree or Master degree in biology, pharmacy, clinical chemistry, etc., or relevant an actual experience in a similar position in the sector of Bank of Human Body Material;
- At least 5 years of practical experience in the management of human tissues and cells, more specifically in the fields of quality, safety and traceability;
- Excellent written and verbal communication skills in English and French.

SKILLS & COMPETENCIES

- Efficient communicator and willing to bring new challenges;
- Demonstrated leadership and cross functional team spirit;
- Rigorous, conscientious, versatile, open-minded & quality-minded;
- Customer oriented;
- Demonstrated ability to manage multiple tasks/projects/priorities and complex issues;
- Team-player with a sound understanding of the pharmaceutical/biotech business-environment;
- Demonstrated attitude of reliability, confidentiality and attention to detail;
- Demonstrated professional attitude towards external and internal contacts;
- Diplomatic attitude with excellent negotiation skills allowing to reach a consensus between different stakeholders.

WE OFFER

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

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