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:

QA System Officer (m/f)

Responsabilities

In life cycle phase, the QA System Officer is focus in the maintenance of the following system:

- Pharmaceutical Quality System: updates, the QA quality system documents, establishes annually the Annual Quality Review (AQR);
- People: has the appropriate training before realizing an activity, maintains opened and effective communication with all other department, updates QA training related to his activity, gives QA training related to his activity to the site;
- Production, Area, Premise and Equipment: realizes periodical check in production (e.i.: EM), updates, analyzes the process of deviation, CAPA, change control, risk analysis with KPI, proposes and realizes adapted action, updates the process of preventive maintenance with KPI;
- Outsourced activities, supplier, cell banks;
- Self Inspection: updates the Self Inspection quality system documents, updates and take adapted action to ensure the CAPA follow up;
- Computerized Systems: maintains organized, updated and validated the document management system (Verse, Quality System server, Quality Registration server);

- Qualification, validation & calibration: updates qualification, validation and calibration quality system documents, reviews the protocols emitted to give the assurance they are compliance with the current regulation, reviews and approves the reports emitted to give the assurance they are compliant to the protocols;
- Quality Risk Management: updates and takes adapted action to maintain the Risk Management quality system documents;
- Continuous improvement.

Qualifications & Experience

- At least Graduate level in Sciences;
- Experience in quality assurance is a plus.

Skills & Competencies

- Rigorous, conscientious, versatile, Open mind, Quality mind;
- Good communication skills and willing to bring new challenges;
- Fluency in French and good speaking, reading comprehension and writing skills in English.

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