MaSTherCell

The global cell and gene therapy CDMO partner

We are currently looking for a:

QC Manager Raw Material

Full-time | CDI | Gosselies

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

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JOB OFFER

QC Manager Raw Material

RESPONSABILITIES

The QC Manager RM main role is to develop, optimize and perform generic activities P00 in the Quality Control department. In order to fulfill his/her role, the Quality Control Expert P00:

- Evaluates the risk level associated to each raw material based on COA and contact the supplier/manufacturer in order to obtain the missing/unclear information needed to have a well understanding of the material and its control strategy;
- Takes part in analytical method validation under the supervision of QC Project Leader/ QC Supervisor (computerized validation);
- Defines the needs in additional mitigation activities (supplier on site audit, additional documentation about the material qualification documentation obtained from the supplier, additional testing performed during the material qualification or for each material release, alternative supplier or material reference, etc.....);
- Follows the needed training on due time; QC RM expert train people of MTC involved in RM strategy (Prod, QA, Technical service, QC,...);
- When a project shift from one clinical phase to another, the material risk analysis must be repeated, to assess the quality level of the materials against the new requirements. A new qualification plan, with associated mitigation activities and testing plan is also issued.
- Performs his/her duties and documents his/her work according to MTC's current procedures and GMP rules;
- Drafts generic QC documents (INS, PRO, FORM, and SPEC);
- Initiates Deviation, OOS, CHC linked to his/her work, performs investigations and implements CAPA;
- Takes part in new tests implementation/improvement under the supervision of QC Project Leader/ QC Supervisor;
- Takes part to internal and/or external audits, if necessary;

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- For project already covered by an approved IMPD, the raw material control strategy will be aligned, at least, on the IMPD. Additional tests may be performed and will be discussed in the Material Qualification Plan.
- Assures a consistent approach across all the projects;
- Follows regulatory updates and adapt the RM strategy accordingly.

QUALIFICATIONS & EXPERIENCE

- At least Graduate level in chemistry, biochemistry, clinical chemistry, biology, etc.;
- 10 years experience in cGMP environment;
- Experience in quality control of cells from human tissue origin is an asset;
- Experience in microbiological testing is a plus.

SKILLS & COMPETENCIES

- Organization skills, multitasking;
- Quality minded, autonomous, rigorous, attentive to details, persevering and pro-active;
- Technical expertise;
- Teamwork and teaching skills;
- Good communication skills and cheerful;
- Strong communication skills and fluent in English and French.

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

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