NEW CHALLENGES. NEW OPPORTUNITIES.

Our growing company is currently seeking a highly motivated and enthusiastic

QA OFFICER

Delivering First Class Clinical Packaging Solutions

CSM is a global company with five sites across the U.S. and Europe dedicated to clinical trial supplies and biomedical sample management. Our innovative solutions highlight our flexibility in managing our clients' clinical trials and allow us to efficiently and quickly deliver medicines to patients in need. Regardless of the size or complexity of the project, CSM will expertly manage the clinical supply chain.

CSM's only focus is clinical trial supplies, which means 100% of our infrastructure is dedicated to making sure our clients' investigational medical products are packaged, labeled, and shipped on time and with the highest regard for quality. CSM is designed to be agile, which for clients translates to confidence that CSM is ready to meet their clinical trial needs regardless of conditions.

We understand our work within the clinical trial process could not happen without our dedicated employees.

Main tasks and responsibilities

- Review and sign the CSM Batch record as QU representative to verify the conformity of GMP (before and after packaging).
- Review of provided batch certification documents of Investigational Medicinal Products and prepare the Conformity Assessment for Production or Distribution.
- Execute the Conformity Assessment.
- Review of the CTA approval, Ethic Committee approval and any other relevant approval (depending of country) and execute the release for use in clinical trial (regulatory release) as per Art 9 of EU Directive 2001/20/EC.
- Provide support to CSM Qualified Person.
- Coordinate and follow up on quality incidents, deviations and customer complaints.
- Define and follow up of corrective actions and preventive actions (CAPA) if any .
- Coordinate and follow up relevant Change Control.
- Stimulate continuous improvement of the CSM QMS.
- Perform internal audits to evaluate the effectiveness of the QMS and perform supplier and subcontractor audits. Assists in customer quality audits.
- Coordinate information collection via "quality questionnaires" sent to suppliers and subcontractors in collaboration with the departmental heads.

Skills

- **Industrial Pharmacist**
- **Belgian Registration number as Industrial Pharmacist is an asset.**
- High organizational and planning skills.
- French and English; any additional language is an asset.
- Relevant industry experience as Qualified Person is an asset.
- Good dose of assertiveness.
- Customer oriented.
- Eagle eye for details.

This position is based in Mont-Saint-Guibert (Belgium)

CSM®
Clinical Supplies Management, Inc.

At CSM, we provide competitive compensation and a complete benefits package. If you have the desire to work hard and play your part in making a difference in the lives of patients participating in clinical trials, we want you to apply today by submitting your resume to : ibertaggia@csmondemand.com