CSM®

Clinical Supplies Management, Inc.

IS RECRUITING!

INNOVATION / QUALITY / TEAMWORK / RESPECT

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. 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 approve the CSM Batch records as QU representative to confirm if the packaging will be/has been done in accordance with GMP and customer requirement (pre & post approval).
- Provide support to CSM Qualified Person (review of batch documentation provided for EU batch certification, preparation of batch certification…).
- Coordinate and follow up on quality incidents, deviations and customer complaints.
- Define and follow up on corrective actions and preventive actions (CAPA).
- Coordinate and follow up on any relevant Change Control.
- Stimulate continuous improvement of the CSM QMS and participate in the writing of Quality documents.
- If required, participate to inspections of Belgian competent authorities at CSM.
- Perform internal audits to evaluate the effectiveness of CSM QMS.
- Perform external supplier and subcontractor audits (offsite).
- Assists in customer quality audits.
- Coordinate information collection via "quality questionnaires" sent to suppliers and subcontractors.

Skills

- **3-5 years' experience**
- High organizational and planning skills.
- French and English; any additional language is an asset.
- Good dose of assertiveness.
- Customer oriented.
- Eagle eye for details.
- Good computer skills : Word, Excel, Outlook, PowerPoint...
- Excellent communication and intercultural skills.
- Team worker and team spirit.
- Customer oriented.

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

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: gsmal@csmondemand.com

NEW CHALLENGES. NEW OPPORTUNITIES.

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Junior QP Back-up

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Main tasks and responsibilities

QP Activities

- Batch certification & release of medicinal products as Back-up QP.
- Provide support to CSM Qualified Person (e.g. preparation of Batch Certification, Technical Agreement).
- If required, participate to inspections of Belgian Competent Authorities.
- Verify/evaluate GMP manufacturing documentation.
- If applicable, perform GMP audits to proof that the medicinal products have been manufactured and tested according to EU GMP.
- Take part in the overall improvements of internal processes and systems.

Quality Assurance Activities

- Review and sign the CSM Batch record as QU representative to confirm if the packaging has been done in accordance with GMP and customer requirement.
- Execute the Conformity Assessment for the Products released by other Qualified Person in Europe.
- Execute the release for use in clinical trial (regulatory release) as per Art 9 of EU Directive 2001/20/EC.
- Contribute to the quality department's activities to ensure continuity of operation.
- Coordinate and follow up on quality incidents, deviations and customer complaints.
- Define and follow up of corrective actions and preventive actions (CAPA).
- Coordinate and follow up on any relevant Change

Skills

- Qualification as Qualified Person (recently).
- Experience in manufacturing, packaging & labelling and/or supply chain is an asset.
- GMP-GDP-GCP knowledge.
- French & English.
- Good computer skills : Word, Excel, Outlook, PowerPoint...
- Assertiveness and diplomacy.
- High organizational and planning skills.
- Excellent verbal and written communication skills.
- Team worker and team spirit.
- Customer oriented.
- Eagle eye for details.

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