NEW CHALLENGES.
NEW OPPORTUNITES.

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.

Our growing company is currently seeking a highly motivated and enthusiastic

Quality Assurance Specialist

Main Responsibilities

- Responsible for the review and approval of operational documents, ensuring compliance to cGMP and company SOPs
- Responsible for the final review and disposition of Clinical Trial Material prior to distribution from CSM
- Ensure the application and compliance of quality systems within operational functions.
- Responsible for the quality oversight of assigned client projects
- Assist the Quality Assurance Manager with QA governance and quality related client meetings for assigned client projects
- Interact with the Quality Control group to resolve review observations
- Assist the QA Manager and the QA Specialist II in all Quality Assurance tasks
- Develop and review quality process related Standard Operating Procedures (SOPs) and controlled forms
- Conduct as needed, company-wide in-service trainings on newly implemented quality related SOPs
- Assist the Quality Systems department to identify and implement quality enhancements and resolve deviations
- Maintain current knowledge of quality assurance-related and regulatory-related government and industry standards as they pertain to the company's mission statement, values statement and results statement
- Communicate operational and personal concerns, and opportunities for improvement to the department leadership.
- Take responsibility for personal skill development in continuing to learn current trends in pharmaceutical standards and best practices of cGMP
- Know, understand and comply with the company's standard operating procedures and policies.
- Perform other related job duties or responsibilities as assigned.

This position is based in Fargo, ND

CSM®

At CSM, we provide competitive compensation and a compete 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 by submitting your resume today through **Indeed.**

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Education and Experience

- 2-3 years in Quality Assurance/Quality Control.
- Working knowledge of GMPs, GCPs, CFR, EU directives and ICH guidelines is essential.
- Knowledge of pharmaceutical manufacturing/packaging operations or principles and practices involved in clinical trials preferred.
- Four-year degree (preferred)

Skills

- Drive to grow and learn more within the HR field
- Ability to develop and maintain effective working relationships with clients and work associates at all levels of the organization is critical in this position.
- Ability to work well independently or in a team and to be self-motivated in taking initiative along with a strong work ethic is required.
- Excellent oral and written communication skills and active listening ability along with excellent time management skills for working within a fast paced, ever-changing environment is necessary.
- All Microsoft Office Products: Word, Excel, Outlook, PowerPoint,
- Office Equipment: Telephone, calculator, photocopier, fax and scanning machines
- Other company proprietary software

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