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 Systems Specialist

Main Responsibilities

- Supporting the Quality Systems Manager by ensuring effective implementation of quality systems
- Assist with processing and coordinating activities related to the Deviation, Complaint and CAPA program(s)
- Conducting in-service trainings for Standard Operating Procedures and current Good Manufacturing Practices, as required
- Updating and maintaining Standard Operating Procedures and Controlled Form active manual(s) and employee training file(s)
- Assisting with client audit/visits by: coordinating and scheduling the visits; tracking the audit report(s) and response(s); preparing the audit agenda(s) and audit/visit binder(s)
- Assisting with internal and external audit(s), as required
- Reviewing/approving and generating reports on documents, as needed
- Maintaining, storing and coordinating archiving of documents

This position is based in Fargo, ND or Malvern, PA

CSM®

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: apply@csmondemand.com

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Quality Systems Specialist

Education & Experience

- Associates degree or equivalent from two-year college or technical school; or equivalent combination of education and experience

Skills

- Working knowledge of Good Manufacturing Practices, Good Clinical Practices, Code of Federal Regulation, EU directives and International Conference of Harmonization
- Ability to read and interpret documents, such as Standard Operating Procedures and policies
- Ability to think critically and be innovative to incorporate process improvements
- Must demonstrate a high level of initiative to work independently or within a team setting
- Must be self-motivated with exceptional time management skills to prioritize work and efficiently react to change in a fast-paced environment
- Ability to think critically and be innovative to incorporate process improvements
- Excellent oral, written, and interpersonal communication with active listening skills
- Maintain a high level of confidentiality while dealing with all clients, proprietary and pharmaceutical related information
- Knowledge of computers and Microsoft Office products is required

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