



**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 Manager

Main Responsibilities

- ▲ Mentor direct reports in their daily responsibilities
- ▲ Identify, evaluate and facilitate process improvements as an agent of change
- ▲ Promote, facilitate, approve and maintain Quality procedures
- ▲ Maintain current knowledge of regulations required to carry out the company's activities
- ▲ Ensure the Quality Management System is defined, documented, implemented and participate in evaluating its effectiveness through management review
- ▲ Oversee internal and external audit program(s) ensuring adequate follow-up from previous audit(s) is completed, whenever applicable
- ▲ Responsible for overseeing the development and administration of the employee GMP Training Program
- ▲ Function as Quality department liaison and subject matter expert to other department representatives, customers and regulatory representatives
- ▲ Management of Deviations
- ▲ Ensuring meaningful and effective CAPAs
- ▲ Monthly trending and reporting of Deviations, Investigations and CAPAs

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



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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Education & Experience

- ▲ Bachelor's degree in Biology, Chemistry, Pharmacy or related experience with 5-8 years of experience ensuring Quality
- ▲ Working knowledge of GxPs, CFR, EU directives and ICH guidelines
- ▲ Experience in creating and implementing a Quality Management System

Skills

- ▲ Ability to assess departmental policies and procedures, and propose changes that yield the best quality improvement return for the time and effort invested
- ▲ Demonstrated ability to effectively collaborate and partner with all levels of management while maintaining an appropriate assertive style
- ▲ Ability to train and mentor others in continuous process improvements
- ▲ Excellent oral, written and interpersonal communication skills with active listening ability
- ▲ Self-motivated with exceptional time management skills to prioritize work and efficiently react to change in a fast-paced environment
- ▲ Maintain a high regard of confidentiality while dealing with all clients, proprietary and pharmaceutical related information
- ▲ Knowledge of computers and Microsoft Office products is a must

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