



**Quality Systems Specialist
Location: Rochester MI**

Position Summary:

JHP is currently seeking a dynamic individual to fill our Quality Systems Specialist position. The candidate would work in a team environment in the Quality Documentation department.

Essential Functions / Key Results Areas:

- Maintains the Change Management System and provides metrics reporting; provides documentation assessments for Change Controls.
- Coordinates and designs clerical tasks related to controlled documentation processes for increased efficiency, cost reduction, and metric reporting.
- Establishes, develops and executes QA Documentation or Site projects.
- Develops departmental Standard Operating Procedures with management.
- Analyzes controlled documentation for concurrence with department methods, company procedures; governmental regulations, license, and compendia requirements.
- Assists manufacturing personnel and laboratory analysts developing controlled documentation that reduces misunderstanding, increases usability, and provide appropriate detail for training needs.
- Participates in FDA, CBER, and Contract Customer audits as required; responds to audit items specifically related to controlled documentation.
- Assists department management in review and approval of controlled documents.
- Changes controlled documentation; assures completeness of history, properties, and format.
- Collaborates with Operations, Pharmaceutical/Analytical Technology, Regulatory Affairs, Compliance, Quality and Contract Customers on technical problems and/or requirements and recommends systems, procedures, and documentation for control.
- Handle assignments as necessary to meet company objectives and contract customer.

Assist department management in the overall direction, coordination, preparation and approval of controlled documentation that results in the effective, quality manufacturing and control of products at JHP AND complies with manufacturing/laboratory practices, NDA/license commitments, current compendia and industry regulations. This person will be Responsible for maintaining the Change Management System, Retention Procedures, responsible for working with site management in the development of project work in collaboration with Operations, Quality, and Regulatory personnel. Also responsible for coordinating and developing clerical task processes, developing metrics for department management, and for providing technical writing support. Proficient with Microsoft® Office suite, including Access or other equivalent database systems. Good Writing Skills, Technical Writing, and Project Management experience preferred. If you possess experience in the above areas, and you are interested in being a team member of this growing company, please submit your resume and a cover letter on or before March 31, 2010 at <https://home.eease.com/recruit/?id=477520>

No relocation package offered with this position.

Requirements:**Education / Qualifications / Certifications**

BS/BA in Chemistry/Biology, or equivalent sciences. Related experience in QA/QC, Regulatory, and/or Manufacturing in the pharmaceutical industry or equivalent experience and training.

Experience / Knowledge

Knowledge of cGMPs, CFR Regulations, USP/NF/EP/BP, and FDA requirements. Proficient with Microsoft® Office suite, including Access or other equivalent database systems. Good Writing Skills, Technical Writing, and Project Management experience preferred. Knowledge of company policies and procedures and departmental SOPs as well as the site's organizational structure.

About JHP Pharmaceuticals, LLC:

JHP Pharmaceuticals is an integrated specialty healthcare company that specializes in sterile injectable products. JHP manufactures and sells brand aseptic injectable pharmaceuticals in hospital and clinical settings and provides contract manufacturing services for global pharmaceutical companies. JHP's own product portfolio includes leading diagnostic, women's health and anesthesia products. All products have a long track record of "gold standard" service and are at or near the front line of treatment in their therapeutic indications. Contract manufactured products include some of the leading global biologic products which involve liquid, lyophilized and suspension presentations.