



Quality Compliance Auditor

**Location: Rochester, MI**

Position Summary:

**JHP is currently seeking a dynamic individual to fill our Quality Compliance Auditor position. The candidate would work in a team environment in the Quality Operations group.** Assist Compliance management in assuring that the facility is in compliance with cGMP, and company policies and procedures; performs and/or assists with internal/self-improvement audits; evaluates suppliers through internal data and/or supplier audits; escorts regulatory and customer auditors; performs follow-up and maintains documentation of all audit activities; carries out essential functions of the position with a high degree of independence and stands in for department management when necessary.

**Essential Functions / Key Results Areas:**

The essential functions of the position include, but are not limited to:

- Maintains a working knowledge of government and industry quality assurance codes and standards. Assists management in monitoring regulatory and industry trends and evaluating company practices accordingly.
- Assists management in developing and evaluating departmental policies and procedures.
- Performs or assists with internal/self-audits to assess and improve the state of compliance of the facility to cGMPs and internal SOPs.
- Prepares for customer audits and verifies audit-readiness of the facility.
- Escorts and interacts with regulatory and other external auditors and keeps minutes of discussions.
- Ensures that management is kept informed of the progress and outcome of audits/inspections.
- Evaluates suppliers and makes recommendations regarding the need for a supplier audit; conducts supplier audits as determined necessary.
- Plans, schedules, perform, and documents audit activities in a timely manner. Issues written reports when required. Takes a lead role on difficult or complex audits or projects.
- Evaluates and tracks corrective action commitments resulting from audit observations to verify implementation and effectiveness.
- Identifies potential problems during compliance activities and reports them to department and/or facility management.

- Travels as needed to audit suppliers as required by the audit schedule.
- Assists Compliance management in training and directing other team members as appropriate.
- Consistently demonstrates good judgment and critical thinking in the performance of Compliance activities.
- Carries out essential management responsibilities when department management is absent.

**Minimum Requirements (Education, Knowledge, Qualifications, Certifications, Experience)**

Bachelor's degree in scientific discipline supplemented with ten years of related experience, or the equivalent combination of education and/or experience; must include at least six years experience in quality auditing, supplier auditing, or related QA function and at least three years pharmaceutical industry experience. Experience as a lead auditor on supplier and internal audits, and experience interacting with regulatory agencies are required. Auditor certification (ASQ CQA or similar) preferred.

If you possess the required background and are interested in being a member of the team, submit your resume and a cover letter to <https://home.eease.com/recruit/?id=477518>.

**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.