Quality Assurance Specialist

Location: Tuscaloosa, AL

To Apply: Send Resume and Cover Letter to careers@gaylordchem.com

The Quality Assurance (QA) Specialist is responsible for supporting the QA Manager with all quality assurance functions within Gaylord Chemical Company, LLC for Procipient® (Dimethyl Sulfoxide USP, PhEur).

This role assists with oversight of the maintenance of product quality and compliance for Procipient through the QA function as well as supporting the management of the GMP Quality Management System and compliance processes. The QA Specialist will interact with all departments within Gaylord and may interact with regulatory agencies, customers, consultants and vendors as related to Procipient.

1.1 QA responsibilities to support Procipient production and distribution.

The QA Specialist will work with the QA Manager and other staff to establish procedures and quality standards and to monitor these against agreed targets. The QA Specialist must have experience in the production of pharmaceutical products. In this role the QA Specialist must support the QA Manager to lead the company's quality efforts such that it is prepared to adapt to changes in the regulatory landscape. Specific responsibilities include:

- Maintain document control for GMP procedures, methods, and records.
- Maintain documentation for GMP function specific training of all areas.
- Completion of customer document requests associated with the GMP Quality Management System.
- Maintain GMP quality issue(s) and investigations.
- Maintain of the customer complaint system associated with the company's GMP products.
- Maintain internal audits of the GMP quality system.
- Batch record review of products made under GMPs, prior to QA Manager disposition.
- Participate in customer audits and inspections by regulatory agencies.
- Review of analytical chemistry data to support Procipient product disposition.
- Review of Procipient stability data.
- Assist with GMP training.
- Monitoring performance of GMP products through annual product review(s).
- Familiarization of USP and EP monograph methods and monitors for monograph changes.
- Support QA Manager, as needed, with maintenance of regulatory filings and reporting requirements.

Other responsibilities as assigned.

2.0 REQUIREMENTS

2.1 Education

- B.S. degree in Chemistry or similar field.

2.2 Experience

- A minimum of 5 years of experience in a pharmaceutical Quality position is required. The successful candidate must have working knowledge of pharmaceutical manufacturing in an ICH Q7 GMP environment.

2.3 Skills and Abilities

- Strong understanding of analytical chemistry methods and practices.
- Understanding of chemical manufacturing processes.
- Excellent communication skills and a proven ability to manage customer and agency audits.

3.0 PHYSICAL AND SAFETY REQUIREMENTS

- Squatting, sitting, bending, pushing, walking 8-10 hours per day.
- Able to lift 25lbs.
- Daily exposure to production environment.

4.0 OTHERS

- Attention to detail
- Self-starter
- Works with minimal supervision
- Innovative/creative
- Flexible/ adaptable