Discover the world's leader in pharmaceutical and biotechnology manufacturing. Jump-start your career at an exciting and growing company where your skills will continuously develop. Your new colleagues are looking forward to welcoming you as the newest team member!

Senior Quality Operations Analyst Ref.-Nr: 27243
Contract: Full Time
Working hours: two-shift operation

Vetter is an international specialist in the production of aseptically prefilled syringe systems, cartridges and vials. We are a family-owned, independent company and do not manufacture our own drugs. Our focus is on providing highly skilled support and state-of-the-art manufacturing resources - we are a Contract Development and Manufacturing Organization (CDMO) supporting our customers from the initial phases of clinical development and regulatory approval process through successful product launch, commercial manufacturing, and life cycle management.

The company has production sites in Germany and the U.S., as well as sales offices in Singapore and Japan.

Responsibilities:

Quality Oversight and support for pharmaceutical aseptic manufacturing processes and the Microbiological and Chemical Analysis Quality Control Laboratories. Implementation of Quality Management Systems under the adherence of due dates.

Tasks:

- Primary Quality Operations Support of Audits or Inspections
- Primary Responsibility for the Training and Development of Quality Operations Analysts
- Primary Responsibility for the scheduling of Oversight Activities and ensuring appropriate adherence to published schedules
- Collaborates in monitoring Quality Management Systems including TrackWise
- Responsible for monitoring of the electronic Training Systems
- Responsible for conducting awareness and GMP training for the manufacturing personnel
- Responsible for conducting training for the manufacturing personnel such as Batch Record Review Training
- Quality contact for Manufacturing
- Processing of Deviations, Complaints, CAPAs and Change Control processes under adherence to the relevant due dates, using the appropriate Quality Management Tool
- Conduct, coordinate and write Root Cause Investigations
- Issue of interim and final reports for complaints and deviations
- Performance of Quality Oversight of pharmaceutical manufacturing processes
- Performance of process observations (routine process observations and media fills) and their documentation
- Performance of Quality Oversight of the Quality Control Laboratories
- Review and Approval of Laboratory Protocols/Reports and Laboratory Investigations
- Collaborates and supports in defining procedures with regard to cGMP production
- Responsible for creation, review and approval of Standard Operating Procedures (SOPs)
- Issuance of approved Standard Operating Procedures
- Responsible for issuance of Batch Records for production
- Responsible for review and approval of executed batch records
- Responsible for Media Fill Observations, Documentation and Reports
- Performance of risk analyses and associated documentation
- Responsible for documentation archival

Minimum Requirements:

Bachelor's degree in an applied science or engineering field or the equivalent work experience.

3 years experience working in pharmaceutical industry.

Knowledge of Quality Systems.

Knowledge of Regulatory Bodies & Associated Requirements.

Ability to work 2nd shift (3pm-11:30pm, with first 6 months training during 1st shift)

Start date: 3/1/19
Contact:
Location: Skokie (Chicago), Illinois

Are you ambitious and future-focused? In short, are you ready to be a part of Vetter?
If your answer is yes, we are looking forward to receiving your application. All you have to do is apply online. Be sure to indicate the job ID with your application.

Vetter Development Services USA, Inc.

Vetter Development Services USA, Inc.
Illinois Science+Technology Park
8025 Lamon Avenue
Skokie, IL 60077
USA
For further information please use our contact form on our website.

VETTER