

Aseptic and Qualification Project Specialist

Job ID
REQ-10064838

10月 23, 2025

USA

摘要

The Aseptic and Qualification Project Lead is accountable for leading and coordinating all technical training initiatives across the operations organization with a key specialized focus on production qualification projects. As a vital member of the team, the Lead will oversee the development and implementation of training programs, facilitate the creation of high-quality training materials, procedures, protocols, records, actively support the training plan by engaging with various stakeholders within a classroom for aseptic training environments and new technologies. With a focus on optimizing employee skillsets and knowledge, Aseptic and Qualification Project Lead will play a crucial role in elevating the organization's technical capabilities and fostering a culture of continuous learning and growth.

About the Role

Major Accountabilities

- Develop and implement comprehensive technical training programs and curricula to address the learning needs of employees.
- Site point of contact for planning, orchestrating, executing, and closing all activities linked to production operator qualifications
- Primary liaison between the project team and production operations to ensure all qualification/tech transfer initiatives are successfully implemented by seamlessly integrating the training and process learning into the existing training program and applicable personnel
- Support in defining and planning agendas, delivering content and lead preparation for key site management engagements and governance meetings for assigned projects
- Establish Project Change Management & manage changes successfully throughout a complex multifunctional organization
- Manage and design engaging and effective training materials, presentations, and hands-on activities to facilitate learning in a classroom and more importantly aseptic production environment.
- Coordinate and conduct technical training sessions for employees at all levels.
- Collaborate with subject matter experts and stakeholders to identify training requirements and ensure training content aligns with business objectives.
- Evaluate and assess the effectiveness of training programs through feedback, surveys, and performance metrics.
- Continuously update and improve training materials and methodologies-based shop floor best practices and industry trends.
- Monitor and track the progress of trainees, providing additional support or resources as needed to ensure successful outcomes.
- Establish and maintain training documentation, including manuals, guides, operator training records and online resources for easy access and reference.
- Act as a mentor and coach to employees, assisting them in their technical development and career growth.
- Liaise with other departments and teams to address cross-functional training needs and ensure a cohesive learning experience.
- Collaborate with external training providers, if necessary, to source specialized technical training programs.
- Stay abreast of advancements in technology and industry standards to incorporate relevant updates into training content.
- Champion a culture of continuous learning and professional development throughout the organization.
- Provide regular progress reports and updates to management and stakeholders on the effectiveness and impact of technical training initiatives development.

Key Requirements:

- Bachelor ' s degree in education, science or related field or equivalent experience
- 4 years ' relevant experience required with aseptic pharmaceutical manufacturing
- Direct experience working in a cGMP and aseptic environment is highly desired.
- Prior experience or training in radiochemistry or radio pharmacy desired
- Strong leadership, communication and analytical/problem solving skills
- Demonstrated history of working collaboratively across functions and sites.
- Knowledge and understanding of cGMP requirements and the application of continuous improvement in a regulated environment.
- 5-10% travel

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U469 (FCRS = US469) AAA USA Inc.

Functional Area
Technical Operations

Job Type
Full time

Employment Type
Regular

Shift Work
No

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