

- **Quality Customer Projects Expert**

Acts as Quality Subject Matter Expert for the Quality Unit matters in different multidisciplinary customer project teams, and as a liaison among customers and other departments.

Leads, as applicable, meetings focused on quality items, product-related projects, test method transfers and validations, annual product review, continued process verification and customer related topics.

Key responsibilities:

Quality representative in the different multidisciplinary teams for customer projects being responsible for the actions follow-up and any deliverable for the project team.

- Provide specific technical knowledge for the Quality Unit organization (participating on investigations, studies and trending evaluation as well as innovation and improvements projects).
- Collaborate to ensure that tasks are prioritized, completed on time, and communicated in an effective and timely manner.
- Perform, review, approve (as applicable) and follow up tech transfers and methods validation documentations related to the different customer's projects.
- Prepare and execute specific protocol studies requested by customers and present data and reports (internally and in front of customers).
- Perform the monitoring of the process from the quality perspective.
- Lot Disposition for the batch release.
- CPV (continued process verification) management.
- APR (annual product review) management.
- Creation, review and approval (as applicable) of Stability Protocols and Reports.
- CCRs (Customer Change Requests) management.
- Create, review and approval of product specifications for each specific customer as applicable.
- Review and approve process sampling plans and process descriptions.
- Product compliant approval and product recall.
- Ensure regulatory and customer inspection readiness and represent the department and participate in audits as required.
- Perform other duties as assigned.

Key requirements:

- Relevant University Degree in Life Sciences
- Solid experience in the pharmaceutical/biotech industry in the Quality field (ideally in Quality Assurance and Quality Control), 5-10 years
- Good knowledge of GMP regulations.
- Business fluent Spanish and English
- Strong written and oral communication skills including public speaking. Able to clearly express ideas and point of view both verbally and in writing.
- Experience leading conversations with customers (internal and external).
- Strong organizational and time management skills. Prioritization and problem solving skills.
- Strong knowledge of Quality procedures, processes and guidelines. Recognized by colleagues as a source of expertise.
- Able to interpret data.
- Perform assigned, complex and/or varied tasks.

Send your CV to susagna.sastremagem@valesta.com

