ASHVINS GROUP
TECHNOLOGY PROFESSIONALS

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SYSTEMS VALIDATION AND OPERATIONAL QUALIFICATION

Client Profile:

A pharmaceutical manufacturing company implementing laboratory automation instrumentation to support production operations.

Technologies Used:

FDA Regulations/Standards, IEEE Documentation Standards, Computer Related Systems Validation (CRSV) Methods, Project Management Techniques

Project Summary:

The pharmaceutical manufacturing client recently started production in a new plant. Part of the production process included automated ELISA testing using a TECAN Genesis System and components. The ASHVINS Group led the Operational Qualification (OQ) efforts for this important automation project. Operational Qualification is the process of demonstrating that an instrument system and associated software will function according to its specifications and requirements (including FDA regulations such as 21 CFR 11) in the selected environment. Working with the client, The ASHVINS Group prepared the OQ Validation Plan, assisted during the execution of the OQ protocols and prepared the Summary of Results. The client was able to capitalize on the ASHVINS' laboratory automation expertise, knowledge of FDA regulations and documentation skills to efficiently document and implement their new instrument system.