

# Computerized system validation

The purpose of the validation process is to provide a high degree of assurance that a specific process will consistently produce a product which meets predetermined specification and quality attributes.

1. It is a process of achieving and maintaining compliance with applicable GxP regulations and fitness for intended use of computerized system.
2. Computerized system validation is the process of testing/validating/qualifying a regulated (E.g., FDA 21CFR11) computerized system to ensure that it does exactly what it is designed to do in a consistent and reproducible manner that is as safe, secure, reliable and traceable
3. The process used to ensure and document that a computer based system will operate according to predefined requirements.
4. Systems meet the business needs of their users.

# A Study Of Computerized System Validation Method For Plc

**John Fitzgerald, Cliff B. Jones, Peter Lucas**

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