

## BASICS OF VALIDATION

The U.S. Food and Drug Administration (FDA) has defined validation as:

"Establishing documented evidence which provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes." (Guidelines on General Principles of Process Validation. FDA-1986)

Current Good Manufacturing Practices (CGMPs) defines the minimum regulatory requirements manufacturers must follow for finished pharmaceuticals. Creating a validated facility to CGMP compliance is mandatory if finished pharmaceuticals are the end product.

Validation is basically data collection and evaluation of the process and all its variables. In general, the validation effort typically consists of various elements, namely, master plan, protocols and reports, specifications, procedures, and instrument calibrations. The validation protocol is typically set up in four phases:

- ◆ Installation Qualification (IQ) - Verifies that the equipment is suitable for the purpose and meets the manufacturing specifications.
- ◆ Operation Qualification (OQ) - Verifies that the equipment operates within the defined system tolerances.
- ◆ Performance Qualification (PQ) - Challenges the system function and confirms that system specifications are met.
- ◆ Process Validation - Confirms the system capabilities and limitations.

The validation methodology performed for a project will affect the cost of the project, the schedule and ultimately the success of the project. Validation should not be done in discrete and unrelated phases. An integrated approach consisting of all team members, (i.e., vendors, designers, operating and maintenance personnel, contractors and owners) must all be involved throughout all design and construction phases to assure that the correct protocol is integrated into the design process.

Many of the problems encountered during the validation process can be eliminated in purchasing specifications by requiring the necessary quality control. This can be accomplished by specifying ISO 9000 certificates for appropriate equipment and requiring IQ/OQ packages for equipment. IQ/OQ requirements can include items such as checklist sheets for components and source code listings.

In summary, validation is a method of assuring that the intent of the user and their design teams are met, that the system operates as expected, and that the equipment and various components perform as expected. This ensures that the release of drug products will not endanger the public because of poor quality attributes.