Process Validation

Process validation is a regulatory requirement that verifies that a production process produces consistent results despite the variation the process may experience. A manufacturer can assure through careful design of the device and packaging, careful design and validation of processes, and process controls, that there is a high probability that all manufactured units will meet specifications and have uniform quality. As a result, the process output meets the predefined specifications. The FDA requires any process used to produce a pharmaceutical or medical device be validated. This provides the agency with the confidence that the process used to produce the medical device and pharmaceutical will be safe for the public to use.

Process validation may be applied to industries not regulated by the FDA.   A properly validated and controlled process will yield little scrap or rework, resulting in increased output. As a result, a validated process, in any industry, would be a valuable tool to improved productivity. When any of the conditions listed below exist, a process validation may be warranted:

- Final product testing is not sensitive enough to verify that the desired efficacy of the finished product
- Destructive testing would be required to show that the manufacturing process has produced the desired result or product.
- The process capability is unknown or it is suspected that the process is barely capable of meeting established specifications

Types of Process Validations

Prospective Validation: This validation is performed before the product is released for distribution. A concurrent validation is a type of prospective validation when the product produced during the validation is intended for distribution.

Retrospective Validation: This is the validation of a process based on accumulated historical production, testing, control and other information for a product that is already in production and distribution.