

# Facility & Process Validation

According to the Quality System Regulation Definitions 21 CFR 820.3(z)(1), the process validation means establishing by objective evidence that a process consistently produces a result or product meeting its predetermined specifications. Manufacturing facilities and processes can be a primary source of product contamination. Facility and Process Validation is a process used to evaluate the manufacturing environmental conditions, as well as water system validations, raw material screening, and residual manufacturing material tests under specification guided by EP, USP, or ISO. This test is applied to monitor and eliminate the source of product contamination.

"Process Validation: General Principles and Practices", the FDA guidance document for industry, gives out the general considerations that FDA considers should be taken into account when evaluating the process validation of a medical device. It outlines the principles and approaches that appropriate elements of process validation for the manufacture of human and animal drug and biological products.

**STEMart** offers comprehensive facility and process validation for your medical devices. With extensive expertise in Microbiology & Sterility testing, STEMart can provide a full-service experience, support manufacturers to meet the regulatory goals, and minimize the compliance risks.