PHASE 5 ~ QUALIFICATION

Deliverable 23 ~ Assembly Process Validation Plan Presentation & Report

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable23

INSTRUCTIONS. Create an assembly process validation plan for potential, future mass production. Your plan is due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

Purpose

Assembly is where medical devices literally come together. An assembly process validation plan is necessary to confirm that chosen processes will consistently yield a product meeting its predefined quality criteria. Medical device manufacturers and the U.S. Food and Drug Administration (FDA) require adequate validation of the assembly process.

Critical Information

Assembly is a critical part of the design process because—perhaps more so than many other steps—it impacts production costs, speed to market and quality. Knowledge gained from development is the foundation for process validation.

A *process validation* is a methodology providing objective evidence that a process consistently results in a product or outcome that meets specifications.

An assembly process validation plan is a written protocol stating how validation will be conducted, including test parameters, product characteristics, production equipment, and decision points on what constitutes acceptable test results.

For the FDA, it is important that the manufacturer prepare *a written validation protocol which specifies the procedures (and tests) to be conducted and the data to be collected*. The FDA considers the following acceptable elements of process validation:

1. *Prospective Validation*. Considerations that should be made before an entirely new product is introduced by a firm or when there is a change in the manufacturing process which may affect the product's characteristics.
    a. *Equipment and Processes*. The equipment and processes should be designed and/or selected so that product specifications are consistently achieved.
        i. *Equipment: Installation Qualification*. Establish confidence that the process equipment and ancillary systems are capable of consistently operating within established limits and tolerances.
        ii. *Process: Performance Qualification*. Provide rigorous testing to demonstrate the effectiveness and reproducibility of the process.

b. *System to Assure Timely Revalidation*. A quality assurance system in place which requires revalidation whenever there are changes in packaging, formulation, equipment, or processes.
c. *Documentation*. Approval and release of the process for use in routine manufacturing should be based upon a review of all the validation documentation, including data from the equipment qualification, process performance qualification, and product/package testing to ensure compatibility with the process.

2. *Retrospective Validation*. Retrospective validation can be useful to augment insufficient initial premarket prospective validation for new products or changed processes.

Assembly Process Validation Plan: General Principles from the FDA

The FDA defines process validation as follows:

> *Process validation is 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 characteristics.*

You must carefully *design a validation plan of both the process and process controls* to establish a high degree of confidence that all manufactured units from successive lots will be acceptable.

You must *specify in your plan what procedures, tests, and data you will collect*. The purpose for which data are collected must be clear, the data must reflect facts and be collected carefully and accurately. The protocol should specify a sufficient number of replicate process runs to demonstrate reproducibility and provide an accurate measure of variability among successive runs. The test conditions for these runs should encompass upper and lower processing limits and circumstances. Validation documentation should include evidence of the suitability of materials and the performance and reliability of equipment and systems.

Your plan must *describe how key process variables should be monitored and documented*. Analysis of the data collected from monitoring will establish the variability of process parameters for individual runs and will establish whether or not the equipment and process controls are adequate to assure that product specifications are met.