PHASE 4 ~ MANUFACTURING

Deliverable 20 ~ Product Qualification Protocol

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable20

INSTRUCTIONS. Create a qualification protocol, or test plan, for your working prototype. Your plan is due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

Purpose

Every product must be qualified with a number of tests and quality checks to be sure it is being made to the manufacturing specifications (Phase 3), fulfills the design requirements to properly function as planned (Phase 2), and meets the assessed stakeholder needs (Phase 1). Product qualification and testing is a critical step in the product development life cycle. The qualification protocol is used to understand, quantify, and improve the manufactured product, or your working prototype at this point.

Critical Information

You must have a plan in place for product qualification (an act or process to guarantee compliance with some condition) to verify the design outputs (performance aspects) of the product you have designed are confirmed as meeting design inputs (functions and requirements) set out in the earlier phases of the design process. This planning encompasses functions and requirements for component-level verifications through system-level verifications of your prototype(s).

The FDA requires that each manufacturer shall establish and maintain procedures for verifying the device design. Design verification shall confirm that the design output meets the design input requirements. The results of the design verification, including identification of the design, method(s), the date, and the individual(s) performing the verification, shall be documented in the design history file.

Product Qualification Protocol: A Prototype Testing Plan

A detailed document that describes the system under consideration, testing plans, and acceptance criteria for test results (these results generated later in Phase 5) that ensure the system is manufactured properly and operates in accordance with predetermined specifications. A qualification plan (later implemented as a qualification report deliverable in Phase 5) may include the following columns:

Qualification Plan

1. *Test #*. The number of the test that needs to be performed.
2. *Test Identifier (Name).* A short name for the test that needs to be performed.
3. *Test/Specification Method*. A short description of the test that needs to be performed.
4. *Acceptance Criteria*. The criteria that must be met in order to pass the test.

5. *Requirement Source*. The source of the requirement that must be met in order to pass the test.
6. *Requirement*. The requirement that must be met in order to pass the test.
7. *Specification Type*. The type of specification that must be met in order to pass the test.
8. *Classification*. The special characteristic classification (e.g., stakeholder-specific symbols).
9. *Planned Test Location*. The location where the test will be performed.
10. *Planned Test Phase*. The phase of development in which the test will be performed.
11. *Planned Sample Size*. The sample size that is planned for the test. *Note, a sample size of 1 does not yield robust results and an average result of several tests should be generated.*
12. *Planned Sample Type*. The type of sample that is planned to be used for the test.
13. *Planned Test Duration*. The planned duration of the test.
14. *Planned Start*. The planned start date for the test.
15. *Planned End*. The planned end date for the test.
16. *Assigned To*. The person or group responsible for performing the test.
17. *Notes (Plan)*. Any notes related to the planned test.

Qualification Report (*to be completed in Phase 5*)

18. *Test Report #*. The number of the report for the completed test.
19. *Test Report Identifier*. A short name for the report for the completed test.
20. *Status*. The status of the test report (e.g., "active" or "replaced by test YYY," etc.).
21. *Actual Start*. The actual start date for the test.
22. *Actual End*. The actual end date for the test.
23. *Actual Sample Size*. The actual sample size that was used in the test.
24. *Test Results*. The results of the test.
25. *Completed By*. The person or group who completed the test.
26. *Notes (Results)*. Any notes related to the completed test.