PHASE 5 ~ QUALIFICATION

Deliverable 25 ~ Design History File Audit

Due Date: http://rrg.utk.edu/resources/BME469/assignments.html#Deliverable25

INSTRUCTIONS. Complete an audit for your design history file. Your audit is due electronically to Dr. Jeff Reinbolt (reinbolt@utk.edu) and should be included in your design history file as well.

Purpose

The *design history file (DHF)* documents and describes the steps taken throughout the design process to create your medical device. The *DHF is a record of the process including all plans, specifications, verification and validation tests and results, design reviews and closing events, and changes to the design*. This file is necessary to ensure that standards of design, production, and quality control for medical device development have been met to prevent injury or death. The *DHF audit is a check that all elements of the DHF are complete and present in the file.*

Critical Information

For the purposes of this course, the DHF audit is a checklist of deliverables that have been assigned and you have completed throughout the academic year. In addition, *your DHF should have two forms: 1) a 3-ring binder with hardcopies of your deliverables*, where you simply print out what has already been completed *and 2) an electronic backup of this file as a single PDF document, not multiple deliverables PDF's*.

Design History File Audit: A Checklist for Your Design Process

Design Controls	Description	Deliverable	Complete
Design and development planning	Interfaces with different groups or activities that provide, or result in, input to the design and development process.	1. Assessment	☐
		2. Team contract	☐
		6. Project plan	☐
		7. Project schedule	☐
		8. Competitive landscape	☐
		9. Early risk assessment	☐
		19. Product risk analysis	☐
		20. Product qualification plan	☐
		26. Lessons learned	☐
Design input	Physical and performance requirements used for device design	3a. White paper proposal	☐
		4. Needs assessment	☐
		5. Functions and requirements	☐
		11. Manufacturing specifications	☐

Design Controls	Description	Deliverable	Complete
Design review	Examination of a design to evaluate the adequacy of the design requirements, to evaluate the capability of the design to meet these requirements, and to identify problems	3b. White paper slides and phase 1 meeting notes	☐
		10a. Interim design slides and phase 2 meeting notes	☐
		17a. Manufacturing plan slides and phase 3 meeting notes	☐
		22a. Manufacturing report slides and phase 4 meeting notes	☐
		27a. Final design slides and phase 5 meeting notes	☐
Design output	Documents and physical design elements that are either complete or are used to move the design effort into the next phase	10b. Interim design report	☐
		17b. Manufacturing plan report	☐
		22b. Manufacturing report	☐
		27b. Final design report	☐
Design verification and validation	Design verification confirms design output meets the design input requirements	14. Product feasibility	☐
	Design validation provides objective evidence that device specifications conform with user needs and intended use(s)	15. User evaluation	☐
		24. Product qualification report	☐
Design transfers	Procedures ensuring the device design is correctly translated into production	12. Biocompatibility	☐
		13. Supplier selection	☐
		18. Bill of materials	☐
		21. IP disclosure	☐
		23. Process validation plan	☐
Design changes	Procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation	16. Change management	☐
Design history file (DHF)	A compilation of records which describes the design history of a finished device	25. Design history file audit	☐
		• 3-ring binder version of DHF	☐
		• Single PDF file version of DHF	☐