Block 1. General Skills

Module 1. Documentation

1.1. Hardware Documentation

Documenting hardware medical devices is essential for regulatory compliance, traceability, and patient safety. It ensures consistent manufacturing and proper use,x and facilitates troubleshooting by providing clear records of design, testing, and production. Documentation also supports knowledge transfer, legal protection, and innovation, enabling improvements and adherence to industry standards.

ISO 13485 is an international standard that outlines quality management system (QMS) requirements for medical device manufacturers.

Task: Read this article and answer some questions.

What is the primary purpose of design controls in medical device development?
a) Speeding up product development
b) Ensuring safety, effectiveness, and compliance
c) Reducing manufacturing costs
d) Simplifying documentation

Which phase in the design control process ensures that the final product meets user needs and intended uses?
a) Design verification
b) Design validation
c) Risk analysis
d) Design transfer

What document outlines the general requirements and framework for design controls in medical device development?
a) ISO 14971
b) ISO 13485
c) FDA 510(k)
d) CE Mark Certification

Why is traceability crucial in design controls?
a) To reduce manufacturing time
b) To link requirements, design, and testing activities
c) To eliminate the need for risk assessments
d) To ensure faster market approval

Which of the following is NOT a part of the design control process?
a) Design planning
b) Design output
c) Post-market surveillance
d) Design verification

Task: Read this document to understand "Requirement Specification"documentation. Now, read this document to understand "Design Specification" documentation. There are no required questions for these documents, but here are some things to look out for.

- Formatting (look at the order of the titles, the numbering, etc.)
- Writing tone
- The way the information is presented (read through both of them and understand how this serves as an example of proper documentation)

1.2. OneNote
Task: Make sure you have access to the OneNote. Look at this example of the Weekly Meeting template, and complete the following.

1. Open OneNote
2. Click "SOP"
3. Click "Weekly Meeting Example"
4. Make a copy of it and move it to "Onboarding"
5. Rename the page to your first and last name.
6. Find the contact information of your subsystem lead or director. Send a message/email asking for access to Jira.
7. Go back to OneNote, and at the bottom of your personal page, type "I have requested access to Jira by contacting [who you contacted]."

Module 2. Introductory Digital Design
2.1. Fusion 360 (CAD)
Fusion 360 is a powerful all-in-one CAD tool that combines design, engineering, simulation, and manufacturing into a seamless platform. With its ability to create detailed 3D models, perform stress and thermal simulations, and integrate directly with CNC machining processes, Fusion 360 is an essential tool for modern design and prototyping. Its parametric design capabilities make it easy to refine and adjust models, while cloud-based storage enables real-time collaboration and access from anywhere.

Task: Use this link to download Fusion. If you don't have an account, use your UT credentials to make one. Next, watch the videos below and follow the tutorials.

1. Lesson 1

2. Lesson 2
3. Lesson 3

Module 3. Introductory Circuitry

3.1. Basics (Ohm's Law, Components, Schematics, Breadboard)

Ohm's Law states the relationship between voltage (V), current (I), and resistance (R) in an electrical circuit: V = I x R

Voltage (V) is the electrical potential difference, measured in volts (V).
Current (I) is the flow of electric charge, measured in amperes (A).
Resistance (R) is the opposition to current flow, measured in ohms (Ω).

Common components in circuits include:

- Resistor: Limits the flow of current.
- Capacitor: Stores and releases electrical energy.
- Inductor: Resists changes in current.
- Diode: Allows current to flow in one direction only.
- Transistor: Acts as a switch or amplifier.
- Battery: Provides the power (voltage) for the circuit.

Schematics are graphical representations of circuits. They use symbols for each component (e.g., a zigzag line for resistors, a triangle for transistors) to show how components are connected. These diagrams help engineers and technicians design, analyze, and troubleshoot circuits.

A breadboard is a tool used for prototyping electronic circuits without soldering. It consists of a grid of holes that are electrically connected in rows and columns, allowing components to be placed and connected easily. Components are inserted into the breadboard to create temporary circuits for testing.

3.2. Electronic Systems

A PCB (Printed Circuit Board) schematic is a diagram that represents the electrical components and their connections in a circuit design, specifically for a PCB. It visually shows how each component, such as resistors, capacitors, diodes, transistors, etc., is interconnected through electrical traces (wires) and how the circuit functions.

Task: Watch this video and follow the steps to design a PCB schematic using Fusion.