Are my Design and Development Changes Documented Adequately – Let's Check!

A design change is typically a modification to a device's raw materials, constituents, labels, intended use, manufacturing process, dimension, mechanism of action, operation or other. Understanding when a change qualifies as a significant design change is crucial because in most cases, such changes necessitate notifying the regulatory authorities and notified bodies and re-authorizing the device. So it is imperative to make sure the design changes continue to be compliant with the intended usage without compromising the device's safety and effectiveness.

This checklist will help you in understanding the basic design change requirements.

S .NO.	CRITERIA	FINDINGS	REMARKS
1	To control design and development changes, the organisation has established and documented procedure(s).	☐ Compliant ☐ Non-Compliant	
2	The organization determines the significance of the change to function, performance, usability, safety and applicable regulatory requirements for the medical device and its intended use.	☐ Compliant ☐ Non-Compliant	
3	Design and development changes are identified by the organization at regular or periodic intervals during each stage of design and development activities.	☐ Compliant ☐ Non-Compliant	
4	Design changes are controlled, reviewed, verified, validated, documented as appropriate, and approved prior to implementation.	☐ Compliant ☐ Non-Compliant	
5	At every stage, the organization identifies new risks related to design changes and mitigates to the extent possible.	☐ Compliant ☐ Non-Compliant	
6	Changes in design and development are assessed for their effects on key components, products currently being manufactured or delivered, risk management inputs or outputs, and the process of realising the product.	☐ Compliant ☐ Non-Compliant	
7	The organization maintains records of changes, their review and necessary actions.	☐ Compliant ☐ Non-Compliant	

Implementing a compliant and comprehensive product design process that accounts for every part, requirement, design, input and user need can be both challenging and time consuming. One small change can lead to a series of changes, tests, reviews and validations which are impossible to keep track of with spreadsheets or disparate systems.

ComplianceQuest's Product Design Management solution offers a unified repository for all design information offering teams full visibility and 100% traceability to keep teams in-sync. This solution is fully integrated with the rest of the CQ EQMS, providing full access to risk management, document management and change control solutions among others, for a complete and compliant approach to bringing high quality products to market.

Request A Demo

REFERENCE:

A. TITLE 21 CFR -Food and Drugs CHAPTER I-Food and Drug Administration, Department of Health and Human Services, SUBCHAPTER H - MEDICAL DEVICES, PART 820 -- QUALITY SYSTEM REGULATION, Subpart C - Design Controls, Sec. 820.30 Design controls.
B. MDSAP AUDIT APPROACH, Document No: MDSAP AU P0002.007 Revision Date:2022-04-15, Chapter 5 - Design and Development
C. ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes, Clause 7.3 Design and development

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About ComplianceQuest

Transform to a fully connected business with a next-generation AI-Powered Product, Quality and Safety management platform, built on Salesforce. Our connected suite of solutions helps businesses of all sizes increase quality, safety and efficiency as they bring their products from concept to customer success. Our intelligent data-driven platform comes with best-in-class integrated processes to mitigate risks, protecting your employees, suppliers and brand reputation, and to increase innovation, compliance, profit and customer loyalty. ComplianceQuest is pre-validated and easy to implement, use, and maintain, allowing for streamlined communication and collaboration across the product value chain.

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