Essential Design and Development Review and Approval Criteria

A formal review by the design team and any other important parties, including Quality, Regulatory, Production, Laboratory, Planning and Operations, HR, Information Technology, Sales, Marketing, etc. is not just essential, but mandatory. The outcomes, date, participants, version/revision under review, and documentation of such review meetings should all be maintained and shall be included in the product's Design History File (DHF).

This checklist will assist you in comprehending the basic requirements of design and development review and approval.

S .NO.	CRITERIA	FINDINGS	REMARKS
1	As per the design and development plan, the organization conducts documented reviews of design and development at appropriate levels	☐ Compliant ☐ Non-Compliant	
2	Design and development reviews should be conducted to assess the design and development outputs to meet requirements.	☐ Compliant ☐ Non-Compliant	
3	The organization performs design and development reviews to identify and recommend appropriate actions/CAPA.	☐ Compliant ☐ Non-Compliant	
4	Participants in design review are the representatives of all functions concerned with the design stage.	☐ Compliant ☐ Non-Compliant	
5	Individual(s) involve in design review stage must be independent and shall not review their own work.	☐ Compliant ☐ Non-Compliant	
6	Design review stage should involve specialists when needed.	☐ Compliant ☐ Non-Compliant	
7	The verification and validation review shall include review of test reports, verification and validation studies, clinical evidences, etc.	☐ Compliant ☐ Non-Compliant	
8	Records of the outcomes of design reviews and appropriate actions including identity of the design, people engaged and review date are documented.	☐ Compliant ☐ Non-Compliant	
9	Design review and approval are electronically maintained (e-copies)	☐ Compliant ☐ Non-Compliant ☐ Not applicable	
10	Design review and approval are printed copies maintained (printed copies)	☐ Compliant ☐ Non-Compliant ☐ Not applicable	
11	In general, each phase of design and development including change is reviewed, approved and documented.	☐ Compliant ☐ Non-Compliant	

It is essential to perform Design Review where the results of the design process are going to be reviewed and decisions are taken in order to move forward according to the Design Plan. However, conducting meeting reviews that are not only compliant, but also effective and convenient for everyone involved is not as straightforward.

A cloud-based Product Design Management Solution from ComplianceQuest can help you better manage design reviews better and overcome collaboration hurdles. With CQ you can schedule and manage design review meetings in one place. You can assess project progress, assign, and easily track assigned actions during the meeting, all while meeting minutes are automatically documented for full traceability.

CQ's Product Design Management 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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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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