How to Create Your DHF/TF & RMF for a Hardware or Software Medical Device

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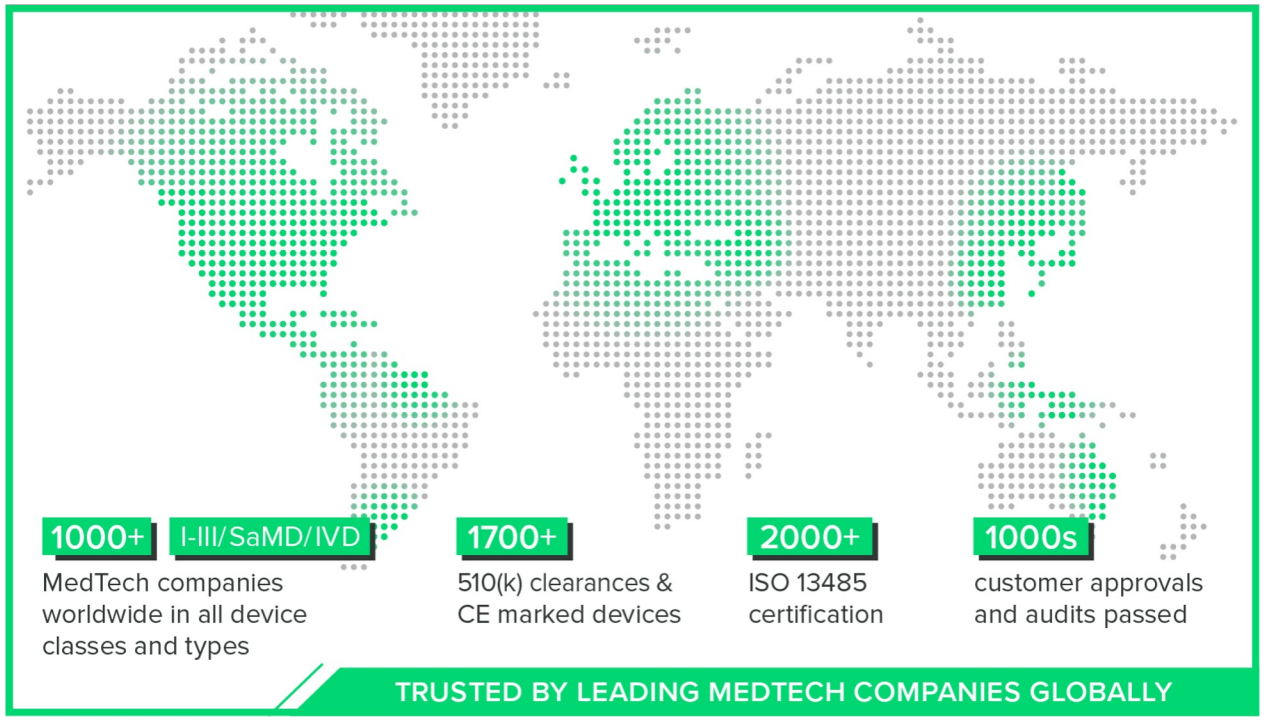

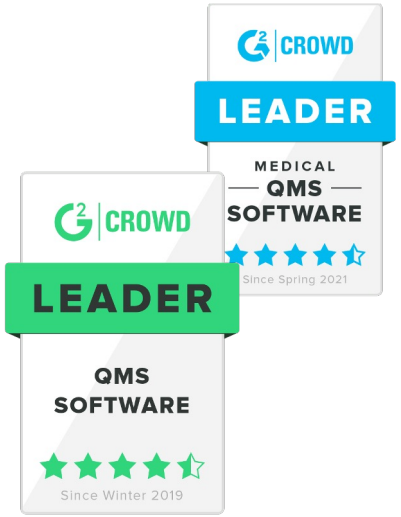

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- Director of Regulatory Affairs & Quality Assurance

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"Demystifying QMS and Regulatory Requirements"

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"Makes your QMS Simple and Effective"

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In This Webinar

- Medical Device Regulations Overview
- Starting DHF - Timeline
- Design Controls Timeline
- Risk Activities Timeline
- Design and Risk Plans
- PHA vs. FMEA
- Verification & Validation
- Risk Review
- How this relates to 510k
- Technical File Differences
- Software Devices

Definitions

DHF – Design History File

TF – Technical File

CER- Clinical Evaluation Report

RMF – Risk Management File

PHA/HA – Preliminary Hazard Analysis / Hazard Analysis

FMEA – Failure Modes and Effects Analysis

RMP/RMR – Risk Management Plan/Report

Medical Device Regulations Overview

FDA/ISO/MDR

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IRQS

Medical Device Regulations

- **FDA**
  - 21 CFR 820 – Outlines requirements for Quality Management System for Medical Device Manufacturers
- **ISO**
  - ISO 13485 – Quality Management Systems
  - ISO 14971 – Medical Devices – Applications of risk management
- **MDR**
  - EUMDR – European Union Medical Device Regulation
    - Outlines specifications for QMS, Technical File, and Risk Management

Medical Device Regulations Overview

FDA		ISO		MDR	
DHF* *(21 CFR 820)*	RMF	DHF *(ISO 13485)*	RMF *(ISO 14971)*	TF	RMF
Subpart C: Must maintain DHF for each device type. Includes: • Design and Development Planning • Design Inputs • Design Outputs • Design Reviews • Design V&V • Design Transfer • Design Changes	Defer to ISO 14971.	**Section 7.3**: Plan and control design and development of product. Includes: • Design and Development Planning • Design Inputs • Design Outputs • Design Reviews • Design V&V • Design Transfer • Design Changes	Includes: • Risk Management Plan • Risk Analysis • Risk Evaluation • Risk Controls • Residual Risk Evaluation • Risk Management Review • Production/post-production activities	**Annex II, #3:** • Info to allow design stages to be applied and understood • Complete specifications	**Annex I, Ch. I, #3-4:** Implement, document, and maintain risk management system Includes: • RMP for each device • Foreseeable hazard identification • Estimate and evaluate risks during use • Risk controls • Benefit/Risk Analysis • Post-market surveillance

Meets FDA requirements for DHF

Meets FDA and EUMDR requirements for RMF

*Class II, III, and some Class I devices.

DHF Overview

DESIGN CONTROLS TIMELINE AND PLANNING

(ISO 13485)

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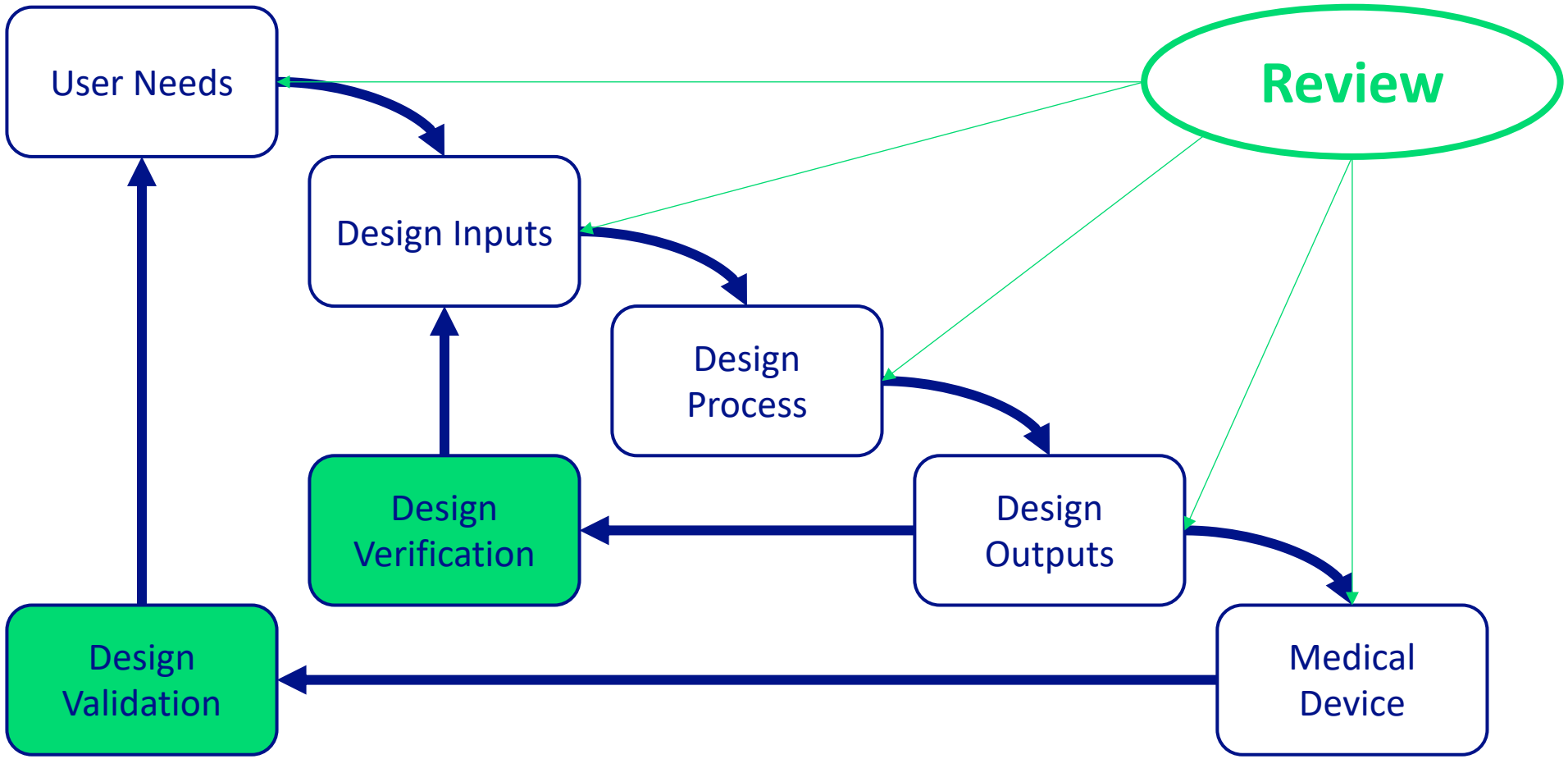
IRQS

Design Controls Timeline

Prior to or during design process	1	Design Plan
	2	User Needs and Design Inputs • User Needs – non-technical/layman's explanation of design needs • Design Input – directly related to UNs, technical and non-ambiguous, calls out specifications if necessary
Throughout the design process	3	Design Reviews
Post-design freeze	4	Design Outputs • Outputs of the device based on the design inputs (requirements). Can be drawings, work instructions, labeling, etc.
	5	Design V&V
	6	Design Transfer

FDA Design Controls Waterfall Diagram



Design Plans

- Per ISO 13485, during the design and development planning stage, the following shall be documented:
  - Assignment of responsibilities and authorities
  - Design and development stages
  - Reviews needed at each D&D stage
  - Verification, validation, and design transfer activities done at each stage
  - Traceability methods of D&D outputs to inputs
  - Necessary resources and personnel competencies

Design and Development Stages

Design and Development Planning	• Identify scope of project/device • Design Plan creation and approval
Design Input	• Define User Needs and Design Input (Design Controls Matrix) • Design Process and Design Freeze
Design Output	• Define Design Outputs and verification methods • Design Controls Matrix update
Design V&V	• Design Verification – show product meets DIs • Design Validation – show products meets UNs
Design Transfer	• Product Launch

Verification & Validation

Verification

Do the outputs meet the inputs?
Did we make the device we meant to?

Example Verification Activities:

- Bench Testing
- Animal Testing
- Inspections

Documentation shall include methods of verification (e.g. test methods).

Validation

Does our device meet the UNs and intended use?
Did we make the right device for what the need is?

- Must be performed using production units – i.e. units built following all production processes and with all materials intended to be released to market.

Validation Activities:

- Clinical evaluation – end-user testing of the device
- Muse be done under intended environmental conditions (actual or simulated)
- Usability Evaluation
- Packaging and labeling should be included

RMF Overview

RISK MANAGEMENT FILE AND REQUIREMENTS

(ISO 14971)

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IRQS

Risk Activities Creation Timelines

Prior to or during design process	1	Risk Management Plan
Throughout the design process	2	Risk Analysis – Based off intended use of device. • Hazard Analysis • dFMEA, uFMEA, sFMEA
	3	Risk Evaluation and Risk Control • Review risk acceptability and reduce risks to acceptable levels • Risk Acceptability Matrix (RAM) • Controls Considerations: Inherent Safety by Design, Protective Measures, Information for Safety
Post-design freeze	4	Risk Management Review/Report • Summarize risk activities and explain risk analysis and risk acceptability • Explain process/plans for evaluation production/post-production risks
	5	Production/Post-Production Activities • Process FMEA (pFMEA)

Risk Plans

- Per ISO 14971, the RMP shall include:
  - Scope of planned risk management activities
  - Assignment of responsibilities and authorities
  - Review requirements
  - Risk acceptability criteria
  - Residual risk evaluation method
  - Verification activities for implementation and effectiveness of risk controls
  - Collection/review activities for post-production risk information

Risk Analysis using PHA and FMEA

PHA vs. FMEA

PHA

focuses on harms and hazards to end users

- **Hazards –** Potential sources of harm
  - ISO 14971, Annex C – example list
- **Hazardous Situations –** Circumstance in which people, property, or the environment may be exposed to hazards
- **Harm –** the physical impact on people, property, or the environment
- **Foreseeable Event –** Event that leads to the hazardous situation

FMEA

focuses on device/process failure outcomes

- **Failure Mode –** how the device or process fails.
- **Potential Failure Effect –** Potential effect or outcome due to the failure mode
- **Potential Causes –** potential cause of the failure mode. Can be user error, design flaw, software bug, etc.

Types of FMEA

dFMEA
Design FMEA

Failure modes due to design and device specifications (hardware)

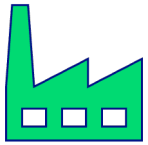
uFMEA
Use FMEA

Failure modes due to user error or human failure

sFMEA
Software FMEA

Failure modes due to software design and architecture

pFMEA
Process FMEA



Failure modes **in manufacturing process** leading to scrap units or device failures due to incorrect manufacturing.

Risk Review

To be completed **prior** to initial production release.

- Review execution of risk management plan to ensure:
  - Proper implementation
  - Overall residual risk is acceptable
  - Methods or production/post-production review are in place and appropriate
- Record results in Risk Management Report

Production/Post-Production Review

- Collect information generated in production, by the user, during installation, and throughout the supply chain.
- Review for relevance to safety
  - Unrecognized hazards or hazardous situations
  - Updated risk and residual risks
  - Whether generally accepted *state of the art* has changed

Software Devices

DHF/TF	Risk Management
FDA Additional Requirements	
• Software Development Plan • User Software Requirement Specifications (URS) • User Interface Wireframes • Software Configuration Management Plan • Software Architecture • Software Deployment Plan • SOUP Documentation	• Software Level of Concern • Software Safety Classification • Cybersecurity

Technical File

DIFFERENCES AND ADDITIONAL REQUIREMENTS

Technical File Requirements

General device description and specifications (Annex II 1.1)

Device labelling, packaging, and instructions for use (Annex II 1.2)

Detailed design and manufacturing documentation (Annex II 1.3)

General Safety and Performance Requirements (GSPR) (Annex II 1.4)

Risk Management and Risk-Benefit information (Annex II 1.5)

Product verification and validation information (Annex II 1.6)

Post-market surveillance information (Annex III)

Declaration of Conformity (Annex IV)

GSPR

General Safety and Performance Requirements (GSPR)

Annex I/Annex II #1.4

- Documented evidence needed for each element
  - May provide justification why element does not apply
- List harmonized standards

Clinical Evaluation Report

Manufacturers are also required to (per Annex XIV Part A):

- Identify available clinical data relevant to the device and its intended purpose and any gaps in clinical evidence through a systematic scientific literature review
- Appraise all relevant clinical data by evaluating their suitability for establishing the safety and performance of the device
- Generate any new or additional clinical data necessary to address outstanding issues through clinical investigations.
- Analyze all relevant clinical data in order to reach conclusions about the safety and clinical performance of the device including its clinical benefits.
- Have a depth an extent proportionate and appropriate to the nature, classification, intended purpose, risks, and manufacturer's claims of the device in question.
- Have results and clinical evidence documented in a clinical evaluation report.

PMCF

Post Market Clinical Follow Up (PMCF) Plan and Report

Annex XIV Part B

- Required unless manufacturer can justify non-applicability

Includes the following:

- General and specific methods and procedures to be applied (e.g. user feedback, PMCF studies)
- Rationale for methods and procedures
- References to relevant parts of clinical evaluation report and risk management, harmonized standards, and relevant guidance
- Specific objectives
- Evaluation of clinical date
- Time schedule

Post-Market Surveillance

Post Market Surveillance Plan and Report

Annex III

- Covers processes to collected market information, assess data, and provides threshold values used for benefit-risk analysis reassessment.
- Includes complaint evaluation methods, trend reporting, and reporting information.
- Includes Periodic Safety Update Report (PSUR)* to summarize PMCF and provide benefit-risk determination concluations
  - Minimum update: Annually (Class IIb and III) or every two years (Class IIa)
- PMS Report required for Class I

*Class IIa, IIb, and III devices

Declaration of Conformity

Declaration of Conformity

Annex IV

- Only signed *after* Notified Body approves conformity
  - Not required for Class I, single-use, non-measuring, non-sterile devices
- Details product name, catalogue number, SRN, sole responsibility statement, basic UDI, risk class, harmonized standards, NB identification, place of issue, and person who will sign.

Regulatory Submissions

HOW DHF AND RMF RELATES

How this relates to 510(k)

DHF

- Submission requires Intended Use, Design Inputs, and Design Verification information
- 510(k) can be submitted once Design Verification is completed, and **before** Design Validation.

RMF

- Only risk requirement for 510(k) is risk analysis for moderate/major-level risk software devices

eSTAR template makes 510(k) requirements for your device type clear and easier to understand compared to traditional filing methods.

How this relates to CE Mark

DHF

- Submission requires Intended Use, Design Inputs, Design Outputs, and Design V&V information
- Technical File for CE Mark can only be submitted after Design Verification **and** Validation
  - Requires Clinical Evaluation Report
- Specific format requirements for Technical File

RMF

- Submission requires Risk Assessment file with documented risk identification and mitigation
- GSPR requirements for risk file

Questions

www.RookQS.com
Make sure to visit our website to learn more about our services and consulting team.

Contact **info@rookqs.com** for more questions, comments, or to set up a meeting. One of our consultants will be sure to reach out to assist!

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