Streamlining Your Medical Device Development

Greenlight Guru QMS Live Software Demo

December 12th, 2023

Documenting the design of a safe product that meets user needs and requirements fuels the performance and success of your entire project.

Deep-dive into Greenlight Guru's Project Workspace

Today's Presenters:

Laura Court
Solutions Engineer

greenlight guru

greenlight guru

MedTechSuite

Moving MedTech Forward

100+ years of industry experience

522k podcast listeners

200k+ look to us for the latest in MedTech

#1 blog & podcast in the industry

TRUSTED BY LEADING MEDTECH COMPANIES GLOBALLY

"Best QMS I have ever used..."

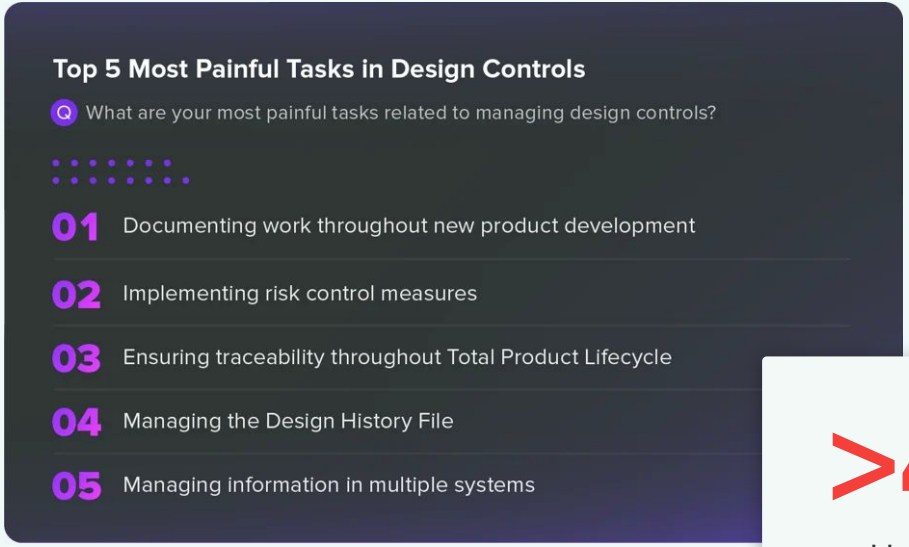
"User-friendly EDC and esponsive support team"

"This is the easiest eQMS I have used in the 20 years I have been in the Medical Device Industry."

"The whole experience of using Greenlight Guru Clinical is accessible and user-friendly"

"Makes your QMS Simple and Effective"

Where things can go wrong



>41%

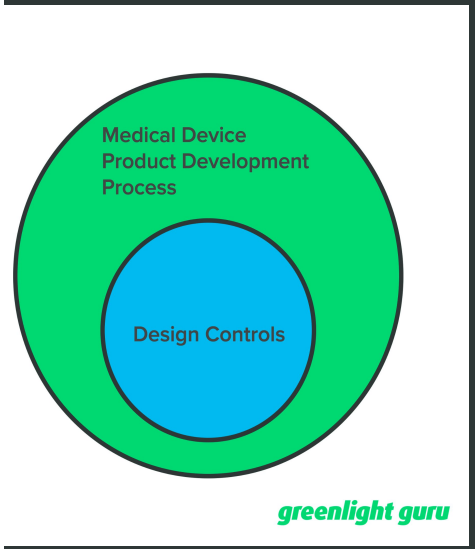
Use Excel for documenting Design Controls & Risk

Understand the Requirements

Design Controls FDA 820.30	Design & Development ISO 13485:2016
(a) General	7.3.1 General
(b) Design and development planning	7.3.2 Design and development planning
(c) Design input	7.3.3 Design and development inputs
(d) Design output	7.3.4 Design and development outputs
(e) Design review	7.3.5 Design and development review
(f) Design verifications	7.3.6 Design and development verification
(g) Design validation	7.3.7 Design and development validation
(h) Design transfer	7.3.8 Design and development transfer
(i) Design changes	7.3.9 Control of design and development changes
(j) Design history file	7.3.10 Design and development files

Product Development 🤝 Design Controls

Product Development Process Phase	Purpose
Planning	Identify scope of the project
User Need	Define user needs (requirements)
Design Input	Define and design inputs (product specifications)
Design Output	Identify and establish design outputs and verification methods
Design Verification	To demonstrate the product meets the design inputs
Design Validation	To demonstrate the product meets the user needs
Market Release	To launch product into manufacturing and marketplace



Enhance Collaboration & Efficiency

Expedite device clearance timelines, prepare for regulatory submission, and confidently navigate audits.

35% increase in development efficiency *and speed to launch*

Faster new-product and change approvals *with open access to data and records*

100s of hours saved *by automatically compiling records (DHF, design reviews, change orders, etc.)*

Digital Design Reviews

Record to prove that all Design Controls have been included as part of a Design Review.

When it comes to Design Review...

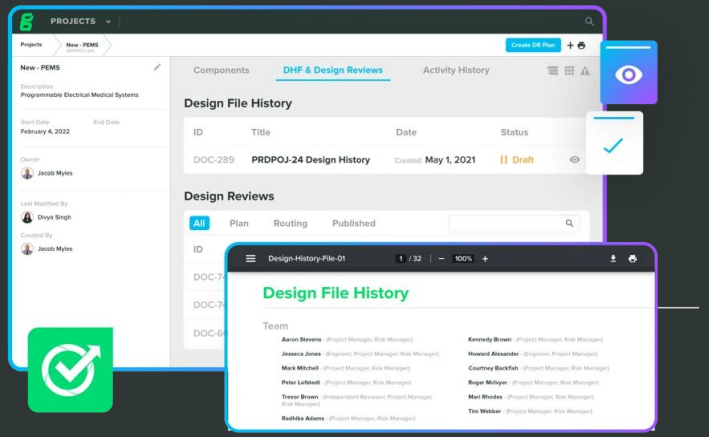
1. Design Verification can not happen until Design Outputs and Design Inputs are done.
2. Design Validation can not happen until User Needs are done.
3. Design Transfer can not happen until Design Outputs are done.

Linking Risk & Design Controls

- Hazards and hazardous situations ➜ Design Controls process in defining User Needs and Design Inputs.
- establish Risk Controls to mitigate and reduce risks. Design Outputs, Design Verifications, and Design Validations become these risk controls.
- Risk Controls should align with and include Design Verification and Design Validation activities.
- Will help you with Design Verification and Design Validation planning.

Maintain a Living DHF

Document device requirements and simplify traceability while you iterate through your design - with a DHF that generates and updates automatically.



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See it in action