

# IMPLEMENTING BEST PRACTICE MEDICAL DEVICE CHANGE CONTROL PROCESSES (WHILE AVOIDING COMMON PITFALLS)



Jon Speer,  
Co-founder & VP of QA/RA at Greenlight Guru

# ABOUT THE PRESENTER

**Jon D. Speer**

Founder and VP of QA/RA of Greenlight Guru



- **20+** years in medical device industry
- Product development engineer, quality manager, regulatory specialist
- **40+** products to market
- Expert at QMS implementations
- Dozens of ISO audits & FDA inspections

***Greenlight Guru produces beautifully simple quality, design control and risk management software exclusively for medical device manufacturers.***

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# MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

75

years industry experience

275k

podcast listeners

#1

blog and podcast in the industry

90k

look to us for the latest in medical device quality



## FEATURED IN

THE VERGE



Forbes

QUALITYDIGEST



Inc.

MedTech Intelligence



Medical Design & OUTSOURCING

TNW THE NEXT WEB

Entrepreneur.



“One stop shop for MD QMS”



“My QMS is world class”



“Greenlight Guru Software is the handrail for Medical Device Development and Documentation”



# What You'll Learn Today

- Best practices to an effective and efficient change control process
- The different types of change and how each should be managed by applying real use case examples
- How to assure a risk-based approach to change management and avoid the common pitfalls that lead to quality issues
- Key tips for managing changes that occur at different stages of a company's process maturity and throughout the product lifecycle
- How technology solutions can help streamline your ability to plan, control, document, and implement changes at your company

# WHAT IS CHANGE MANAGEMENT?

# CHANGE TRIGGERS

- New or modified **products** and any subsequent changes to those products
- New or modified **processes** for how you conduct business as you right-size and grow your QMS
- New or modified **controlled documents** (templates, work orders, forms, etc.) and any subsequent revisions made to those documents
- **Quality events** such as CAPA's, Non-conformances, audits, or customer feedback that initiates the need for product, process, or document changes

# CHANGE CONTROL PROCESS

To implement any change, you must:

- **Describe** the change you're making
- **Justify** the reason for the change
- **Identify** what business outcomes will be affected
- **Include** the right people who need to be involved to assess and implement the change

# QMS REQUIREMENTS FOR CHANGE MANAGEMENT

- **High level traceability within companies QMS**
  - Must assure traceability between the different stages of the change processes are document in the QMS
- **Careful documentation**
  - Ability to easily identify, share, and document the people involved in reviewing and approving changes



# WHAT DO THE REGULATIONS SAY?

## FDA & ISO REQUIREMENTS

### FDA 21 CFR 820.30(i) - Design Change Mgmt

- *Each manufacturer shall establish and maintain procedures for the identification, documentation, validation or where appropriate verification, review, and approval of design changes before their implementation.*

### 21 CFR 820.40(b) - Document Control Change Mgmt

- *Device manufacturers must identify a designated individual(s) to review and approve any change that occurs and must inform in a timely manner*

### ISO 13485:2016

- *Very similar to FDA - requires detailed documentation and traceability for every change within your QMS*

### Section 4.1.4

- *Dedicated specifically to managing changes to an organizations QMS processes and complying with regulatory change control requirements*

# WHAT DO THE REGULATIONS SAY?

- Part 820.30(i) *Design changes*. Manufacturers must establish and maintain procedures for the identification, documentation, validation, review and approval of design changes before they are implemented.
- Part 820.40(b) *Document changes*. Changes to documents shall be reviewed and approved by a designated individual. Each manufacturer shall maintain records of changes to documents.
- Part 820.70(b) *Production and process changes*. Manufacturers must establish and maintain procedures for changes to a specification, method, process or procedure. They should be verified, validated or approved when appropriate.
- Part 820.70(i) *Automated processes*. Software changes shall be validated before approval and issuance.
- Part 820.75(c) When changes or process deviations occur, the manufacturer shall review and evaluate the process and perform re-validation when required.
- Part 820.100(a)(5) Each manufacturer should establish procedures for [implementing CAPA](#), including procedures for implementing and recording changes in methods and procedures needed to correct and prevent quality problems.

# HOW TO CONTROL AND MANAGE CHANGE

# ASSESSING & DOCUMENTING CHANGES

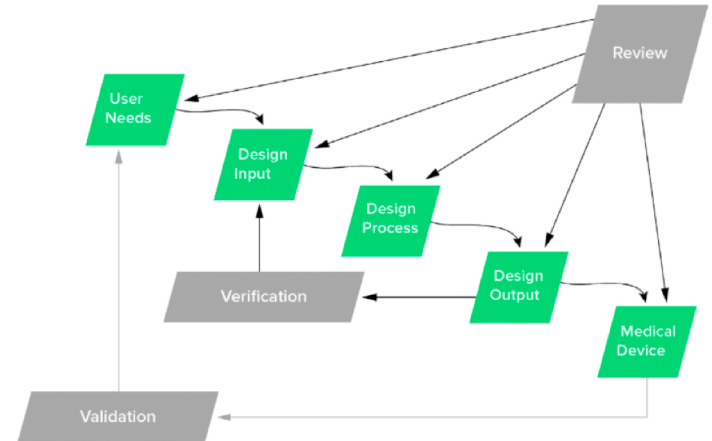
- **Assess** why you are making the change
  - Scope
  - Description
  - Justification
  - Impact
  - Risks
  - Regulatory implications
- **Document** the decisions & supporting evidence

# PRODUCT DESIGN CHANGES

# PREMARKET DESIGN CHANGES

## Key Factors to Consider:

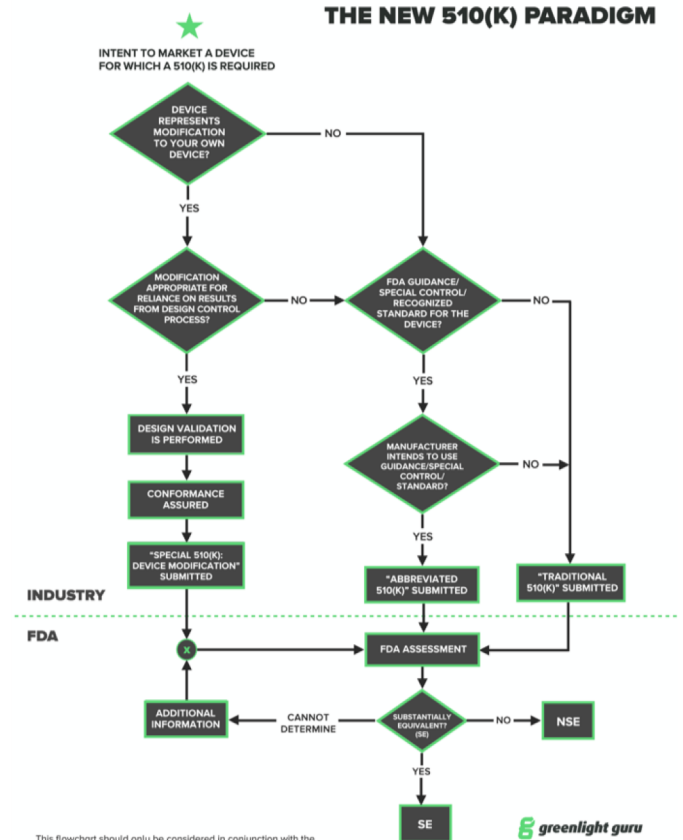
- Regulatory impact
- Documentation timeline uncertainty
- Design review checkpoints
- Verification & validation of changes
- Impact of changes on prior human or animal studies



# POSTMARKET DESIGN CHANGES

## Key Factors to Consider:

- Any impact to Form, Fit, or Function
- Necessary updates to device Design Controls
- Change impact on device risk matrix
- Regulatory Impact



# REGULATORY IMPACT OF CHANGES

## Assess Regulatory impact via standardized formats

- Deciding When to Submit a 510(k) for a Change to an Existing Device (Oct 25 2017)

AND

- 21 CFR Part 807.28 (Device Listing)





# PROCESS CHANGES

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## Things that may need to be updated or done:

- Process documentation, work instructions, or forms
- Device Master Record (if production process changes involved)
- Performing Risk Assessments associated with any manufacturing process changes
  - Hazards
  - Foreseeable Events
  - Hazardous Situations
  - Harms

# CHANGES TRIGGERED BY QUALITY EVENTS

# QUALITY EVENTS & CHANGE MANAGEMENT

- The need for product, process, and documentation changes could often time be triggered by different types of quality events
  - CAPA's
  - Non-conformances
  - Complaints (Holistic customer feedback)
  - Internal or external audits
  
- Change to regulatory requirements or standards

# **BENEFITS OF STREAMLINING CHANGE MANAGEMENT PROCESSES**

# Benefits of modernizing change processes

- **Simplify your team's ability to identify, assess, and track the items impacted by change orders** in a collaborative workspace
- **Easily review and approve the documents and records associated with change activities** through Part 11 compliant workflows and e-signatures
- **Assure connectivity and traceability to any sources or related items** that influenced design or process changes within your quality system (Complaints, CAPA's, NC's, Audits, etc.)
- **Track and trend the effectiveness of change activities** with analytics and KPI's
- **Be audit ready at a moment's notice by having full traceability into the history of change activities** with a single source of truth

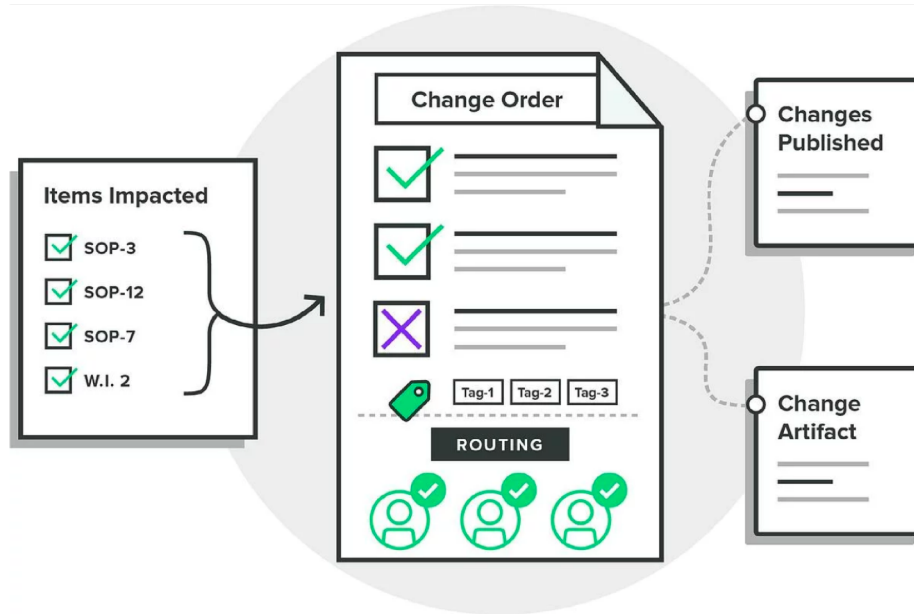
**ARE YOU CONFIDENT IN YOUR CHANGE  
MANAGEMENT PROCESSES?**

# MANAGING CHANGE IS HARD WITHOUT PURPOSE BUILT SOLUTIONS





# GREENLIGHT GURU'S CHANGE MANAGEMENT CAPABILITIES



**WEBINAR EXCLUSIVE:** Visit <https://www.greenlight.guru/change-webinar-offer> to access your FREE download!

# STREAMLINE AND CONTROL THE CHANGE MANAGEMENT PROCESS

The screenshot displays a software interface for managing change cases. The main title is "CO-1 Change Case Material". The interface is divided into several sections:

- Left Panel (Metadata):**
  - Description:** Praesent in felis eleifend, hendrerit felis ullamcorper, maximus libero. Aenean ut blandit diam, nec laoreet justo.
  - Justification:** Need to change the case material to resin to aid better sanitation.
  - Classification:** Record - Routed
  - Category:** Change Management
  - Due Date:** Oct 28, 2019
  - Priority:** Medium
  - Impact:** Major
  - Assigned To:** GG Tester
  - Initiated By:** GG Tester
  - Tags:** business, electrical, lab
  - Team:** Add Team Members
  - Related Items:** Document CAPA-7 Quality Review Ver. 0 in CAPA-7 (Testing Full CAPA Completion), CAPA-29 (Testing Capa Stage Locking), CAPA-29 (Testing Capa Stage Locking)
- Top Navigation:** View, Documents, Routing (active), Activity History
- Process Flow:** A horizontal timeline showing four stages: 1. Draft (checked), 2. Routing (active), 3. Approved, 4. Published.
- Reviewer Table:**

| Reviewer                            | Review Days | Review Status        | Status                  |
|-------------------------------------|-------------|----------------------|-------------------------|
| 2 Steve Jackson (Author)            | 2           | 4 / 4                | Approved (Jan 24, 2018) |
| 3 Parallel Track                    |             |                      |                         |
| Martha Lizel (Operations)           | 1           | 4 / 4                | Approved (Jan 25, 2018) |
| Kathy Miller (Operations)           | 1           | 3 / 4                | Approved (Jan 23, 2018) |
| Bobby Williams (Operations)         | 1           | 0 / 4 - Start Review | Reject, Approve         |
| 4 Rachel Swinner (Document Control) |             | 0 / 0                | Waiting                 |
- Bottom Right:** Cancel Routing, Edit Routing

# ELECTRONICALLY REVIEW AND APPROVE CHANGES IN PART 11 COMPLIANT WORKSPACE

The screenshot displays the 'Change + CD-1' interface. On the left, there is a sidebar with 'Edit Change Documents' and details for 'CD-1 Change Case Material', including a description, justification, classification (Record - Revised), category (Change Management), and tags (Business, Electrical, Lab). The main area shows a 'Documents' tab with a table of items:

| Name                       | ID       | Ver | Actions        |
|----------------------------|----------|-----|----------------|
| SOP-2 Verification Process | Doc12    | 0   | Check Out      |
| SOP-1 Quality Process      | Doc1     | 0   | Check Out      |
| SOP-10 Procedures          | Doc-2456 | 3   | Add to Routing |

Buttons for 'Add Document Order' and 'Add Document Order' are visible at the bottom of the table.

The screenshot shows the 'Add New Document' dialog box overlaid on the 'All Documents' list. The dialog has a green header and asks: 'Any related documents need to go through change. Would you like to add this document to an existing Change Order, or create a new one?'. It offers two options: 'Add to Existing Change' and 'Add New Change'. Below these are checkboxes for 'Do not add to change' and 'Add another after submitting'. A 'Select Change Order' dropdown menu is set to 'CD-1 Change Case Material'. A green 'Add Document to Change' button is at the bottom right.

# MDQMS PLATFORM CAPABILITIES

**Built-in controls** that align with 21 CFR Part 820 and ISO 13485:2016

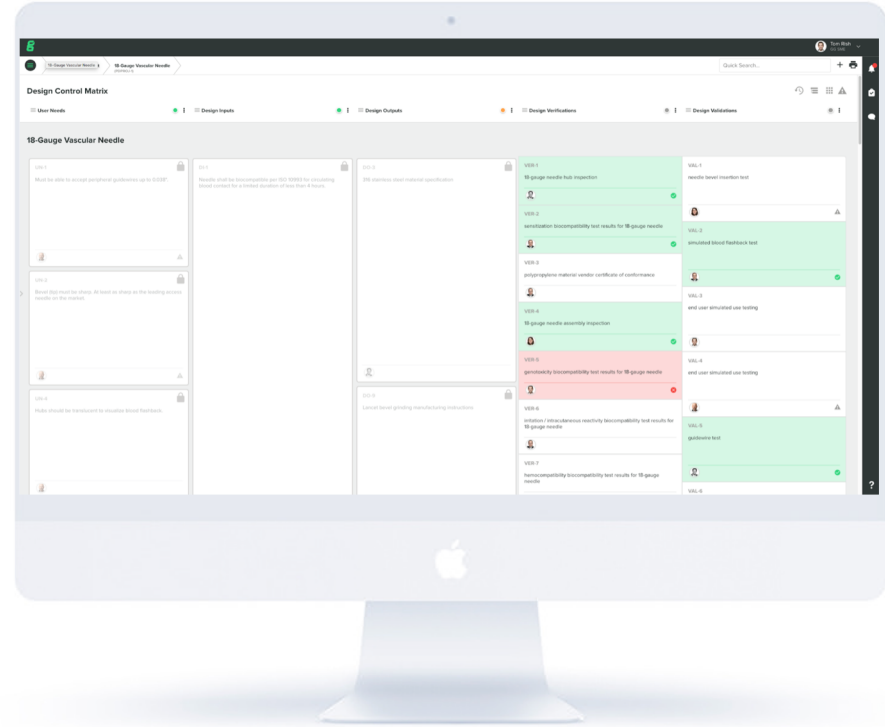
**Flexible review & approval workflows** with Part 11 compliant e-Signatures

**Fully integrated risk** aligned to ISO 14971

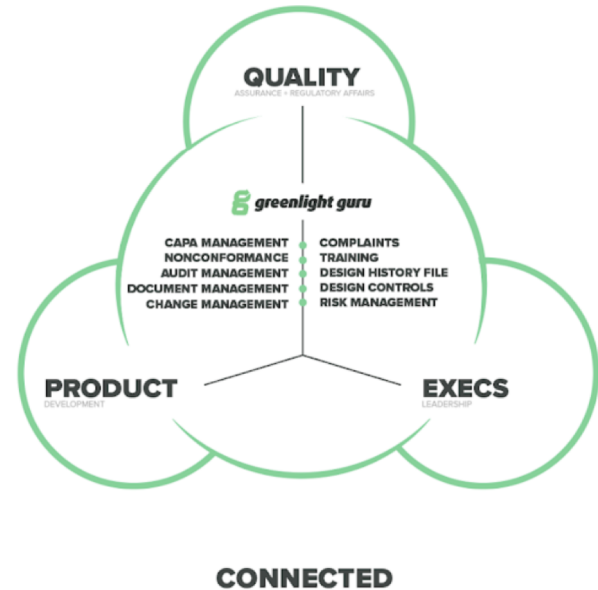
**LinkAnything** drives full lifecycle traceability

**Zero effort** system validation

**Drive collaboration** with task management, comments, and notifications



**A MODERN,  
CLOSED-LOOP QUALITY SYSTEM  
THAT GIVES YOUR TEAM FULL  
TRACEABILITY BETWEEN DESIGN  
CONTROLS, RISK, DOCUMENTS, AND  
QUALITY EVENTS  
AS CHANGES OCCUR**



**QUESTIONS?**



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