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

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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.

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years industry experience

275k
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90k
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G2 CROWD

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"One stop shop for MD QMS"

★★★★★

"My QMS is world class"

★★★★★

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

★★★★★

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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

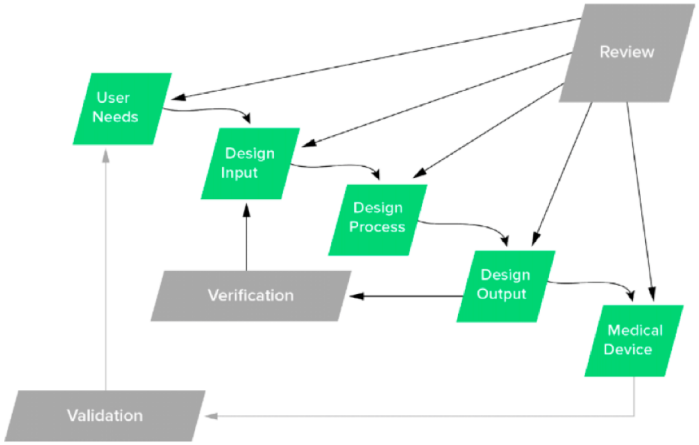
- ***Assess*** why you are making the change
  - Scope
  - Description
  - Justification
  - Impact
  - Risks
  - Regulatory implications
- ***Document*** the decisions & supporting evidence

PRODUCT DESIGN CHANGES

PREMARKET DESIGN CHANGES

Key Factors to Consider:

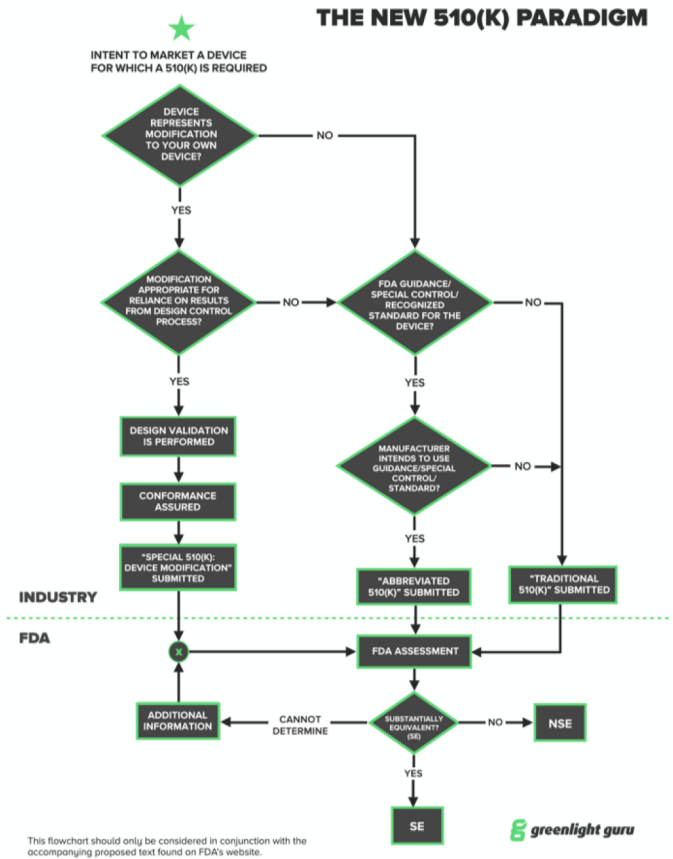
- Regulatory impact
- Documentation timeline uncertainty
- Design review checkpoints
- Verification & validation of changes
- Impact of changes on prior human or animal studies



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

PROCESS CHANGES

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

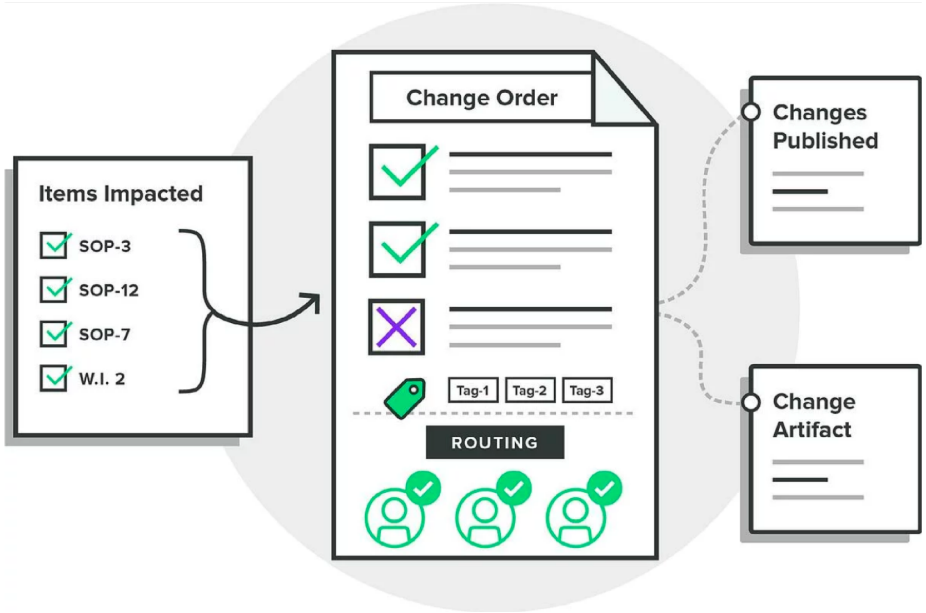
Benefits of modernizing change processes

- **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



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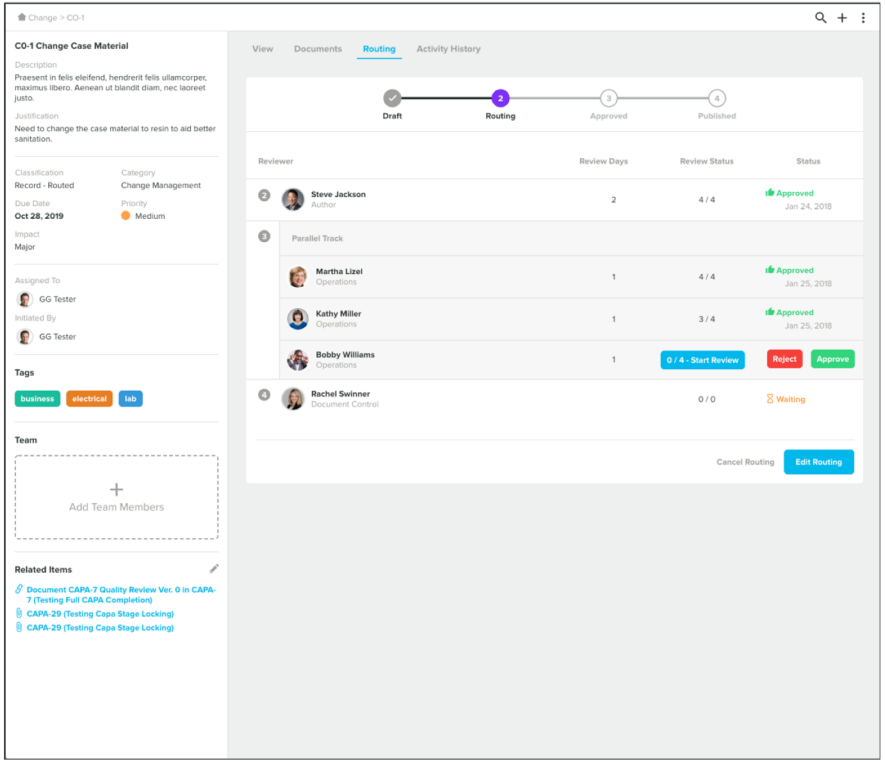
STREAMLINE AND CONTROL THE CHANGE MANAGEMENT PROCESS



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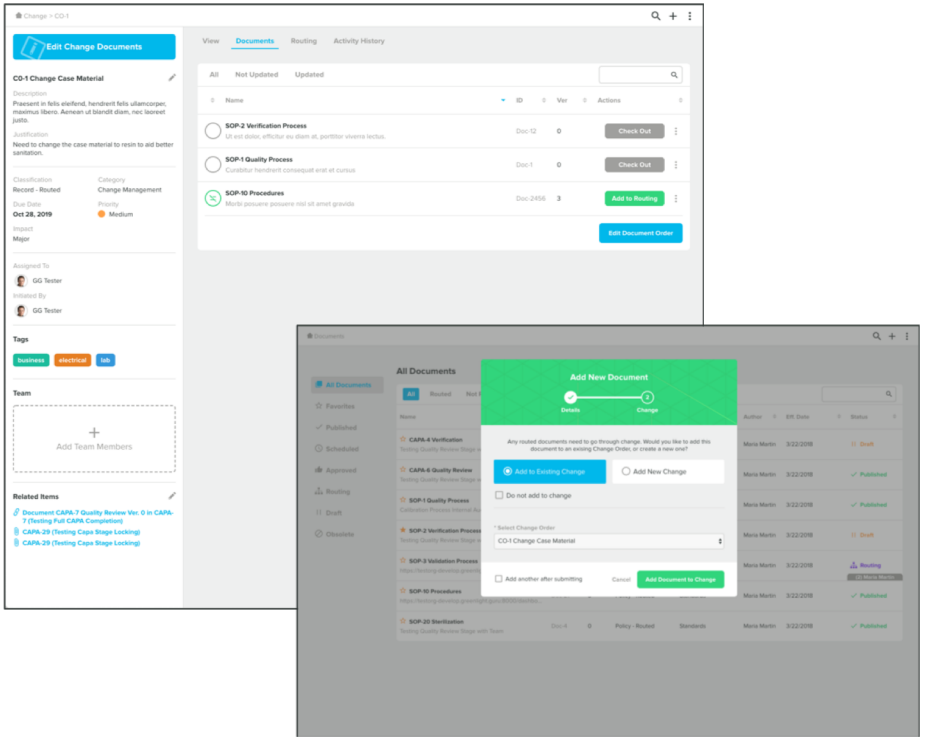
ELECTRONICALLY REVIEW AND APPROVE CHANGES IN PART 11 COMPLIANT WORKSPACE



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MDQMS PLATFORM CAPABILITIES

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

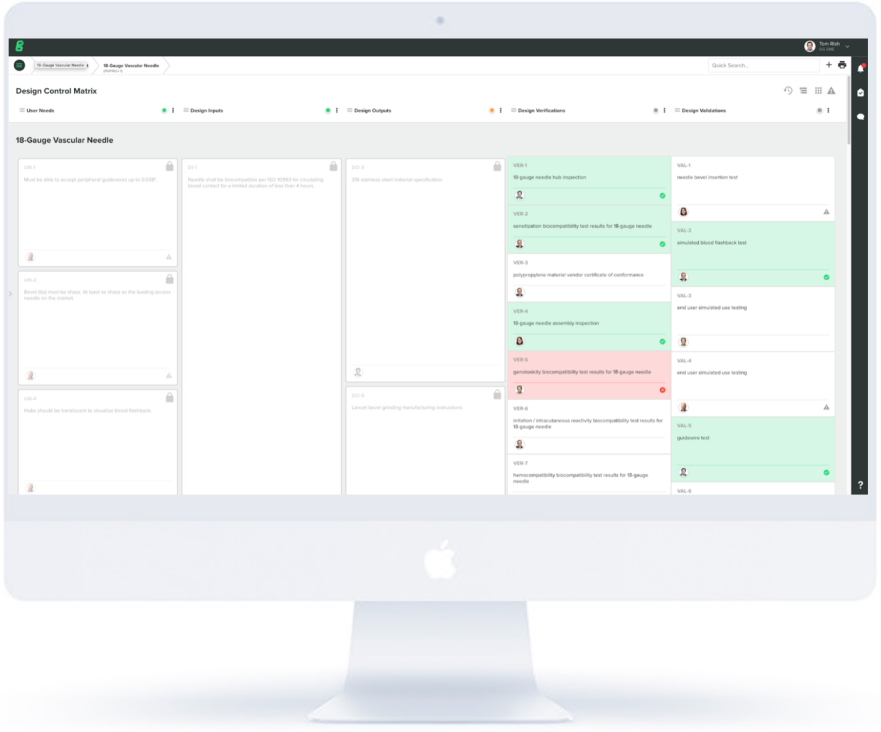
Flexible review & approval workflows with Part 11 compliant e-Signatures

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

CONNECTED

QUESTIONS?

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