

PRODUCT WEBINAR

BUILDING YOUR BOM: 3 WAYS TO MANAGE YOUR PRODUCT INFORMATION WITH FULL TRACEABILITY

Presented by  *greenlight guru*

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

75

years industry
experience

275k

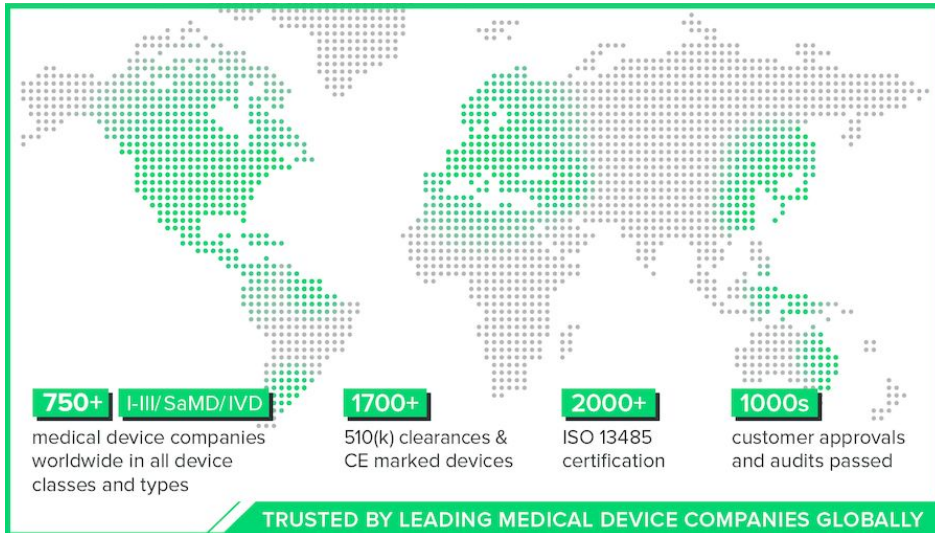
podcast listeners

#1

blog and podcast
in the industry

114k+

look to us for the
latest in quality



**“Best eQMS I have ever
used...”**

This is the easiest eQMS I have used in
the 20 years I have been in the Medical
Device Industry. ***It is simple, intuitive
and easy to use...*** We are successfully
implementing a Quality Culture.

- Director of Regulatory Affairs
& Quality Assurance

“Modern QMS Software and Outstanding Customer Service.”

★★★★★

“Demystifying QMS and Regulatory Requirements”

★★★★★

“Makes your QMS Simple and Effective”

BUILDING YOUR BOM:

3 Ways to Manage Your Product Information with Full Traceability

Today's Presenters:



Alex Butler

Sr. Product Manager,
Greenlight Guru



Jesseca Lyons

Operations and Enablement
Guru, Greenlight Guru

You will walk away knowing...

- ✓ How to overcome data silos and reduce the risk of communication gaps and common errors that increase costs, and delays during product development
- ✓ How to build and manage your items and multi-level bills of materials (BOMs) while you design your medical devices
- ✓ 3 proven strategies for streamlining engineering change and building traceability throughout the entire device lifecycle.
- ✓ How to leverage the capabilities of Medical Device Product Management to drive continuous, collaborative product development within your QMS

PRODUCT DEVELOPMENT V. **PRODUCT MANAGEMENT**

Product Development

The creation and ideation processes

Mostly pre-market

Product Management

The continuous upkeep of your products

Post-market and growing product lines

Example: While you are documenting your Design Control components, you will need to build out your BOM's. Items and components need to be organized into different product families that best suit your company needs - by location, process, product type, you name it.

WE SURVEYED 500+ MEDICAL DEVICE PROFESSIONALS

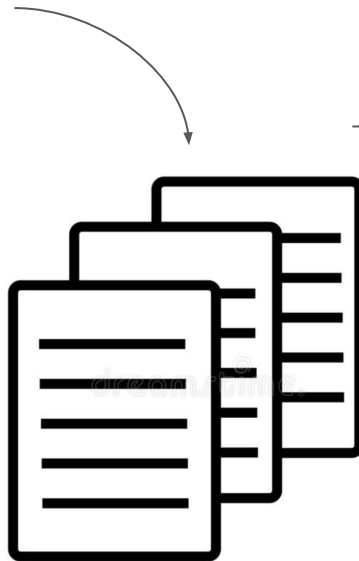
70%

of employees in development roles believe that innovation in the medical device field is **driven by investing in the right solutions and resources that support design and development.**

Medical device companies need to be able to **build, evolve, and innovate** upon their products without the worry of *siloes and disconnected data*.

INDUSTRY CHALLENGES AROUND **PRODUCT MANAGEMENT**

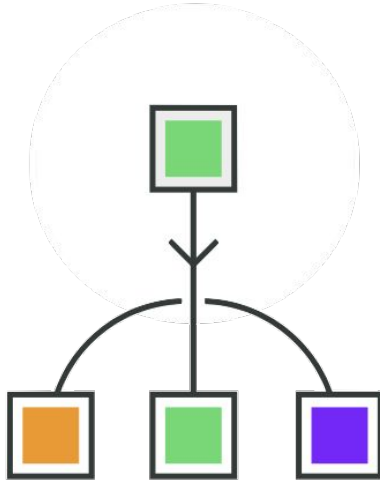
OLD WAY



Lack of visibility, control, structure, linking

THE NEW WAY

INTRODUCING GREENLIGHT GURU PRODUCTS

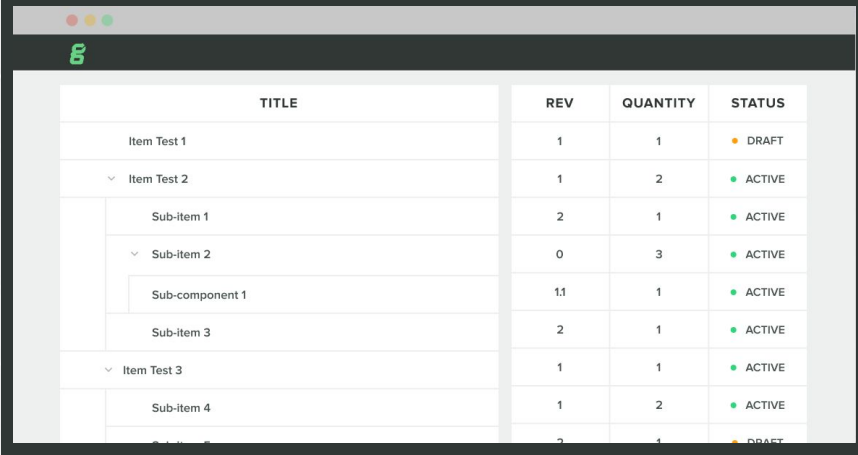


Build, control, and manage your product information

INTRODUCING GREENLIGHT GURU PRODUCTS

GREENLIGHT GURU PRODUCTS

- ✓ Build and manage your items and multi-level bills of materials (BOMs) while you design your medical devices
- ✓ Ensure everyone has access to latest product design
- ✓ Meet quality compliance requirements
- ✓ Leverage full traceability and easily link product data to other records and actions
- ✓ **Focus on innovation, not paperwork**



The screenshot displays a software window with a green 'G' logo in the top-left corner. The main content is a table with four columns: 'TITLE', 'REV', 'QUANTITY', and 'STATUS'. The table lists a hierarchy of items, including 'Item Test 1', 'Item Test 2', and 'Item Test 3', each with its own sub-items. The status of each item is indicated by a colored dot (orange for DRAFT, green for ACTIVE) and the text 'DRAFT' or 'ACTIVE'.

TITLE	REV	QUANTITY	STATUS
Item Test 1	1	1	DRAFT
Item Test 2	1	2	ACTIVE
Sub-item 1	2	1	ACTIVE
Sub-item 2	0	3	ACTIVE
Sub-component 1	1.1	1	ACTIVE
Sub-item 3	2	1	ACTIVE
Item Test 3	1	1	ACTIVE
Sub-item 4	1	2	ACTIVE
Sub-item 5	2	1	DRAFT

*“The fact that we can **create product families and use item types across products and into product families** is very useful.*

*Greenlight Guru Products will allow us to **keep track of our device components with traceability.***

*Having the ability to build out a BOM connected with Greenlight Guru **versus trying to manage it outside the system or in a word document/excel sheet** is wonderful.”*

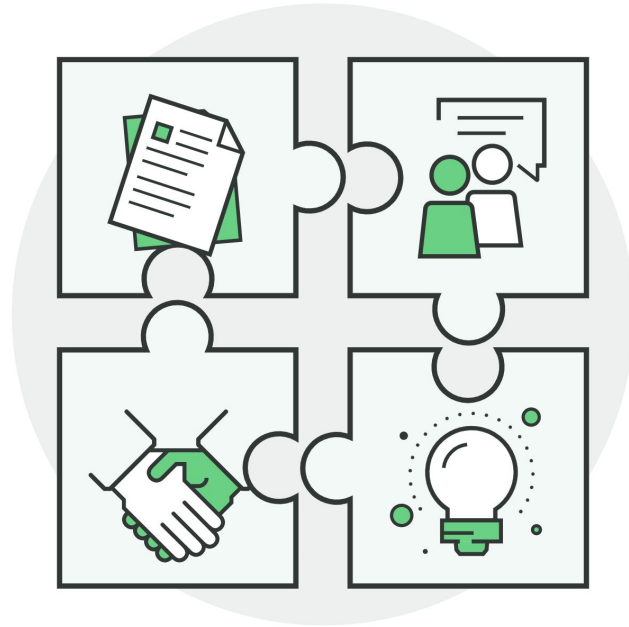
- Adam Cargill, Director of QA/RA/CA at MediView

3 WAYS TO MANAGE YOUR **PRODUCT** **INFORMATION WITH FULL TRACEABILITY**

1**Enhance your product development activities**

2

3



Critical device information living across multiple sources

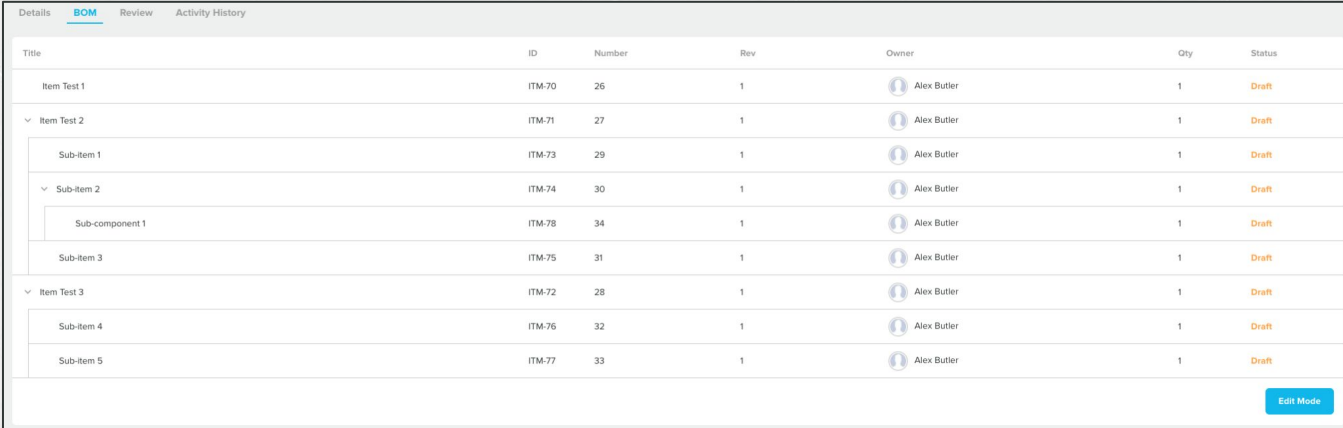
ENHANCE

PRODUCT DEVELOPMENT

Define your product families

Build and manage your items and multi-level BOMs while you design

Efficiently collaborate across your teams



The screenshot displays a software interface for managing a Bill of Materials (BOM). At the top, there are navigation tabs: 'Details', 'BOM' (which is selected and highlighted in blue), 'Review', and 'Activity History'. Below the tabs is a table with the following columns: 'Title', 'ID', 'Number', 'Rev', 'Owner', 'Qty', and 'Status'. The table contains a hierarchical list of items. 'Item Test 1' is the root item. It has three sub-items: 'Sub-item 1', 'Sub-item 2', and 'Sub-item 3'. 'Sub-item 2' further has a sub-component 'Sub-component 1'. 'Item Test 3' is another root item with sub-items 'Sub-item 4' and 'Sub-item 5'. All items are owned by 'Alex Butler' and are in a 'Draft' status. A blue 'Edit Mode' button is located in the bottom right corner of the table area.

Title	ID	Number	Rev	Owner	Qty	Status
Item Test 1	ITM-70	26	1	Alex Butler	1	Draft
Item Test 2	ITM-71	27	1	Alex Butler	1	Draft
Sub-item 1	ITM-73	29	1	Alex Butler	1	Draft
Sub-item 2	ITM-74	30	1	Alex Butler	1	Draft
Sub-component 1	ITM-78	34	1	Alex Butler	1	Draft
Sub-item 3	ITM-75	31	1	Alex Butler	1	Draft
Item Test 3	ITM-72	28	1	Alex Butler	1	Draft
Sub-item 4	ITM-76	32	1	Alex Butler	1	Draft
Sub-item 5	ITM-77	33	1	Alex Butler	1	Draft

1**Enhance your product development activities****2****Streamline engineering change management****3**



Designs change and evolve over time

STREAMLINE

ENGINEERING CHANGE

Electronic engineering
change process

Track revisions, conduct
reviews, route, and approve
changes

Ensure everyone has access
to latest product design

Details		BOM	Where Used	Review	Activity History
Reviewer	Reason	Status			
1 Alex Butler Owner	Approval of Circuit board (ITM-63) Rev. 1	✓ Approved			
2 Parallel Track					
Kevin Kidd Reviewer	Approval of Circuit board (ITM-63) Rev. 1	✓ Approved			
Radhika Pandya Product Development Manager	Approval of Circuit board (ITM-63) Rev. 1	✓ Approved			

1

Enhance your product development activities

2

Streamline engineering change management

3

Connect Product Development & Quality activities to support full lifecycle traceability



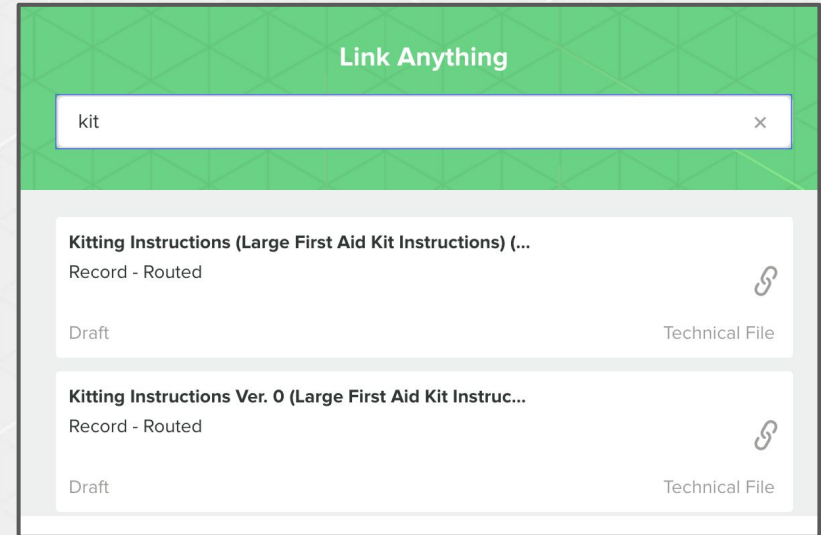
Lack of traceability leads to expensive mistakes

CONNECT

PRODUCT INFORMATION

Link product families, products, and items to...

- Product development projects
- Records and documentation
- Other aspects of your QMS



LET'S TAKE A LOOK

Products Demo - Saved to my Mac

Home Insert Draw Page Layout Formulas Data Review View Developer Acrobat Tell me

Calibri 11 A A

Conditional Formatting on: Tables Styles

Share Comments

Ready

Family	Products	Type	Second Level	Third Level	Fourth Level	Mfg P/N	PK	QTY - Each	Attribute	Supplier	Note
Frid Aids	Frid Aids - Small					FF 200	77	Inventory	n/A		
	Frid Aids - Medium					RS000	77	n/A	n/A	Greenlight Health - Brand	Retail over the counter Frid aid
	Frid Aids - Large					RS002	77	n/A	n/A	Greenlight Health - Brand	
Frid Aids Kit - Large FS	Manual					RS002LV	4	Purchased Good	n/A		
	Box					PK90-101	1	Non Inventory	n/A		Floor stock - printed
	Box					RS 6000	1	Kit Assembly	n/A		
	Small sterile gauze pads					SGP1	5	Purchased Part	Gu's/Procure of Cause		
	Medium sterile gauze pads					SGP2	5	Purchased Part	Gu's/Procure of Cause		
	Large sterile gauze pads					SGP3	5	Purchased Part	Gu's/Procure of Cause		
	Gauze Pads Box					SGS-100	5	Purchased Part	Box/Procure of Cause		
	Adhesive tape					ATLS	2	Purchased Part	Gu's/Procure of Cause		
	Band-Aid Kit Assembly					n/A	RS 001	1	Kit Assembly	n/A	
	Small Band Aid					SGP4	100	Purchased Part	Gu's/Procure of Cause		
Medium Band Aid					SGP5	100	Purchased Part	Gu's/Procure of Cause			
Large Band Aid					SGP6	100	Purchased Part	Gu's/Procure of Cause			
Band-Aid Box					SGS-015	100	Purchased Part	Box/Procure of Cause			
Elastic bandage						SGP7	4	Purchased Part	Gu's/Procure of Cause		
						CO000	5	Purchased Part	Medmart		
Antiseptic swabs						CO001	5	Purchased Part	Medmart		
						CO002	5	Purchased Part	Medmart		
Antiseptic solution						CO003	5	Purchased Part	Medmart		
						CO004	5	Purchased Part	Medmart		
Acetaminophen Packet						CO005	5	Purchased Part	Medmart		
						CO006	5	Purchased Part	Medmart		
Syringes						CO007	5	Purchased Part	Medmart		
						CO008	5	Purchased Part	Medmart		
Disposable instant cold pack						CO009	2	Purchased Part	Medmart		
						CO010	2	Purchased Part	Medmart		
First Aid Kit - Large Green						RS000	5	Purchased Part	Medmart		
						RS001	2	Purchased Part	Medmart		
First Aid Kit - Large Red						RS002	5	Purchased Part	Medmart		
						RS003	2	Purchased Part	Medmart		
Masks						RS004	1	Purchased Part	Medmart		
						RS005	1	Purchased Part	Medmart		
Gloves - Nitrile						RS006	5	Purchased Part	Medmart		
						RS007	5	Purchased Part	Medmart		
Digital Thermometer						RS008	1	Kit Assembly	n/A		
						RS009	1	Kit Assembly	n/A		
Digital Thermometer						RS010	1	Kit Assembly	n/A		
						RS011	1	Kit Assembly	n/A		
Digital Thermometer						RS012	1	Kit Assembly	n/A		
						RS013	1	Kit Assembly	n/A		
Digital Thermometer						RS014	1	Kit Assembly	n/A		
						RS015	1	Kit Assembly	n/A		
Digital Thermometer						RS016	1	Kit Assembly	n/A		
						RS017	1	Kit Assembly	n/A		
Digital Thermometer						RS018	1	Kit Assembly	n/A		
						RS019	1	Kit Assembly	n/A		
Digital Thermometer						RS020	1	Kit Assembly	n/A		
						RS021	1	Kit Assembly	n/A		
Digital Thermometer						RS022	1	Kit Assembly	n/A		
						RS023	1	Kit Assembly	n/A		
Digital Thermometer						RS024	1	Kit Assembly	n/A		
						RS025	1	Kit Assembly	n/A		
Digital Thermometer						RS026	1	Kit Assembly	n/A		
						RS027	1	Kit Assembly	n/A		
Digital Thermometer						RS028	1	Kit Assembly	n/A		
						RS029	1	Kit Assembly	n/A		
Digital Thermometer						RS030	1	Kit Assembly	n/A		
						RS031	1	Kit Assembly	n/A		
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Digital Thermometer						RS036	1	Kit Assembly	n/A		
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Digital Thermometer						RS038	1	Kit Assembly	n/A		
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Digital Thermometer						RS040	1	Kit Assembly	n/A		
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Digital Thermometer						RS046	1	Kit Assembly	n/A		
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Digital Thermometer						RS048	1	Kit Assembly	n/A		
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Digital Thermometer						RS052	1	Kit Assembly	n/A		
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Digital Thermometer						RS058	1	Kit Assembly	n/A		
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Digital Thermometer						RS060	1	Kit Assembly	n/A		
						RS061	1	Kit Assembly	n/A		
Digital Thermometer						RS062	1	Kit Assembly	n/A		
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Digital Thermometer						RS064	1	Kit Assembly	n/A		
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Digital Thermometer						RS066	1	Kit Assembly	n/A		
						RS067	1	Kit Assembly	n/A		
Digital Thermometer						RS068	1	Kit Assembly	n/A		
						RS069	1	Kit Assembly	n/A		
Digital Thermometer						RS070	1	Kit Assembly	n/A		
						RS071	1	Kit Assembly	n/A		
Digital Thermometer						RS072	1	Kit Assembly	n/A		
						RS073	1	Kit Assembly	n/A		
Digital Thermometer						RS074	1	Kit Assembly	n/A		
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Digital Thermometer						RS076	1	Kit Assembly	n/A		
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Digital Thermometer						RS098	1	Kit Assembly	n/A		
						RS099	1	Kit Assembly	n/A		
Digital Thermometer						RS100	1	Kit Assembly	n/A		
						RS101	1	Kit Assembly	n/A		

MANAGE YOUR PRODUCT INFORMATION WITH FULL TRACEABILITY

1

Enhance your product development activities

2

Streamline engineering change management

3

Create a connected ecosystem for your product development and quality activities

HOW TO BETTER MANAGE YOUR PRODUCT INFORMATION TODAY

3 THINGS YOU CAN DO TODAY:

1

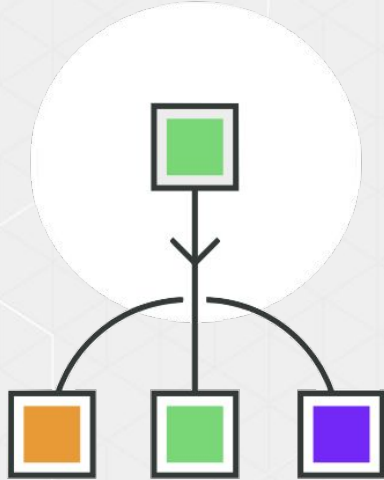
Establish ways to foster team alignment on injecting quality from the beginning

2

TBD

3

Invest in purpose-built tools to help you remove data silos and reduce risk of disconnected information



QUESTIONS?