



Upgrading Your QMS Solution

Practical Tips & Tricks for a Seamless Transition

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Housekeeping



Questions



Recording

Today's Panelists



Lisa Van Ryn

Medical Device Guru



Tara Burnett

*VP Regulatory Affairs &
Compliance*



Connie Space

Quality Assurance Specialist



Brittani Smith

Medical Device Guru



WHAT WE KNOW

Bringing a Medical Device to Market is
Complex and Challenging

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For pre-market device companies, **ineffective systems pose a serious threat**

30%

of pre-market companies say they are “very confident” their current quality system can handle projected growth over the next 12 months



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Tech Complexity Breeds Inefficiency

9

Number of distinct platforms
and tools post-market
companies use.

68%

Pre-market companies not
using purpose built tools

74%

Post-market companies not
using purpose built tools

Companies using purpose-built tools say they are:

- ✓ **50% more likely** to say they'll meet their quality objectives in 2023.
- ✓ Nearly **2x more likely** to say they'll meet their product development objectives in 2023.
- ✓ Almost 3x more likely to say employee training oversight is fully automated.
- ✓ **1.8x more likely** to say employees have “high visibility” to access data and details about quality problems.

Greenlight Guru Creates:

75%

*reduction in time
needed to set up a
QMS*

40%

*reduction in number of
audit findings*

50%

*reduction in time spent
on development &
design documentation*

35%

*reduction in time to
market*

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Organizations that switch to Greenlight Guru get:

- ✓ 1:1 Relationship with a Guru that has medical-device industry experience
- ✓ Onboarding customized to their unique milestones
- ✓ Access to on-demand system training materials via Greenlight Guru Academy

"Resistance to change" is the most common obstacle to improving quality

Q What are your biggest challenges when it comes to improving quality management processes?

	Post-market	Pre-market
Resistance to change efforts	37%	25%
Cost/ effort of validating new tools or processes	33%	35%
Confusion about regulatory compliance guidelines	33%	34%
Insufficient budget	28%	35%
Underinvestment in education/ training	27%	20%
Underinvestment in tools/ solutions	26%	15%
Lack of management buy-in	23%	18%
Not measuring results	21%	18%
Not aware of better solutions/ tools	20%	16%
None of the above	5%	10%
Not applicable	4%	7%



Tara Burnett
VP Regulatory & Compliance



Connie Space
Quality Assurance Associate



Rethink What Your QMS Can Do.

We Can Help.

The screenshot displays the Greenlight Guru software interface for CAPA (Corrective and Preventive Action) and Quality Review. The main window is titled 'CAPA Management 1' and shows a detailed view of a CAPA record. The record includes a description, due date (Aug 21, 2022), priority (Urgent), and CAPA type (Corrective). It also lists assigned personnel (Marcus Mueller, Janice Jones) and the date of the event (Mar 10, 2021). A 'Show Report' button is visible at the bottom left. The 'Quality Review' section shows a progress bar with stages: Draft, Routing, Approved, and Published. A table lists reviewers: Marcus Mueller (Complete), Divya Singh (Reviewing), and a Parallel Track with Petrick Rish and Mary Cook. A pop-up window titled 'AUDIT-0 Quality Review' shows a document ID '11-85065-XX SLDDRW' and an 'Approved By' section with fields for Name, Role, Date, and Digital Sign. A 'Version History' table is also present. A green checkmark icon is overlaid on the bottom left, and a red warning triangle icon is overlaid on the top right.

CAPA Management 1

Description
This CAPA will be opened to investigate and determine if any corrective actions are needed.

Due Date: Aug 21, 2022
Priority: Urgent
CAPA Type: Corrective

Assigned To: Marcus Mueller
Reported To: Janice Jones

Reported On: Mar 20, 2021
Date of Event: Mar 10, 2021
Initiated By: Marcus Mueller
External ID: AC-85

Quality Review

Start Date: Mar 21, 2022
End Date: Aug 21, 2022

Progress: Draft → Routing → Approved → Published

Reviewer	Review Days	Review Status	Status
1. Marcus Mueller			Complete
2. Divya Singh			Reviewing
3. Parallel Track			
Petrick Rish			
Mary Cook			

AUDIT-0 Quality Review
Calibration Process Internal Audit
Doc: 1 | 0 | Policy-Routed | Standards

11-85065-XX SLDDRW

Approved By:

Name: _____
Role: _____
Date: _____
Digital Sign: _____

Version History:

Author	Effective Date	Ver.	Status
_____	_____	_____	_____

Get a free demo today at
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