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

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Tara Burnett
VP Regulatory Affairs & Compliance

Monarch Medical Technologies

Connie Space
Quality Assurance Specialist

MICRO-TECH ENDOSCOPY

Brittani Smith
Medical Device Guru

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WHAT WE KNOW

Bringing a Medical Device to Market is **Complex** and **Challenging**

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

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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.

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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

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

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"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

Monarch Medical Technologies

Connie Space

Quality Assurance Associate

MICRO-TECH™ ENDOSCOPY

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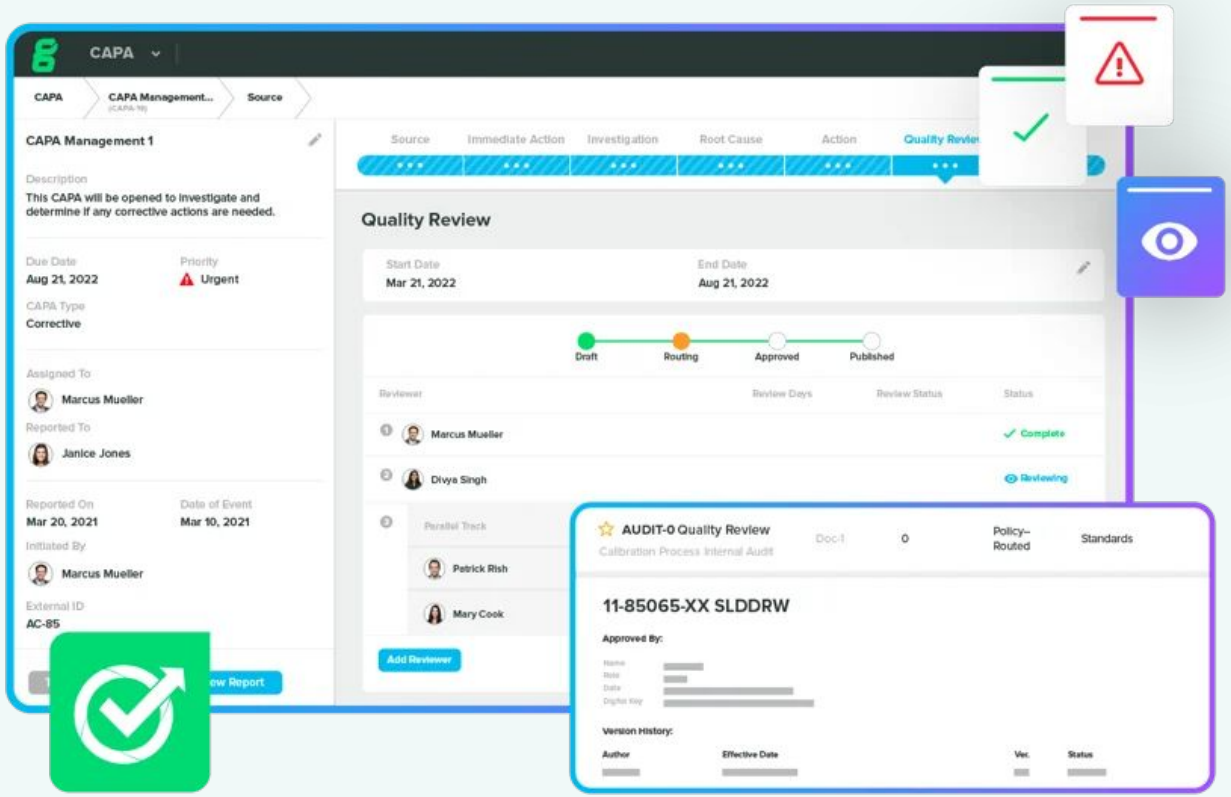
Rethink What Your QMS Can Do.
We Can Help.



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