A Greenlight Guru Webinar

TOP THINGS YOU SHOULD KNOW WHEN DEVELOPING SOFTWARE AS A MEDICAL DEVICE (SAMD)

Presented by BeanStock Ventures

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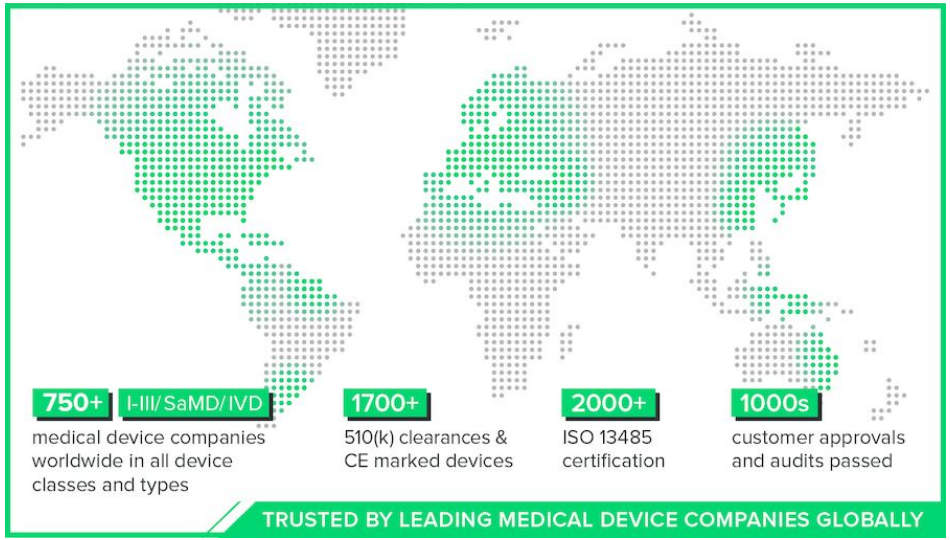
MEDICAL DEVICE QUALITY IS ALL WE DO, AND WE'RE ALWAYS AHEAD OF THE GAME.

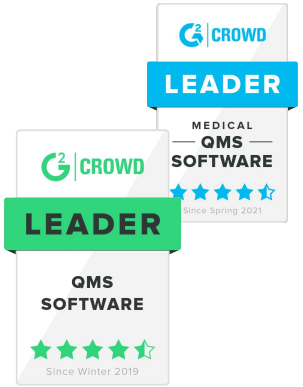
75
years industry experience

275k
podcast listeners

#1
blog and podcast in the industry

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"

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Top Things You Should Know When Developing Software as a Medical Device (SaMD)

Today's Presenter:

Shawnnah Monterrey
CEO
BeanStock Ventures

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BEANSTOCK VENTURES

BeanStock Ventures is a software development company and an FDA accredited third-part 510(k) approver. We are focused on improving lives by directly and indirectly supporting the development and delivery of innovative healthcare related products and services. BeanStock Ventures provides 20 years of regulatory and software development experience in various healthcare specific domains including but not limited to instrumentation, diagnostics, digital health, point of care, critical care, laboratory, automation, complex workflows, and connectivity. We believe that client collaboration is key to a successful product launch. Our signature program was developed to enable our clients to build the right product while meeting the demands of the meeting.

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SaMD BASICS

SaMD Basics

- ✓ Determine if a software product is a medical device
- ✓ Intended use statement

“Software intended to be used for one or more medical purposes that perform these purposes without being part of a hardware medical device”.

The International Medical Device Regulators Forum (IMDRF)

SAFETY, EFFECTIVITY, AND PERFORMANCE:
DETERMINING THE RISK CATEGORY

ADOPTING (OR ADAPTING) YOUR QMS FOR SaMD

PRACTICAL AND CONTINUAL STEPS TO MARKET

QUESTIONS?

Thank you!

Want More Information?

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Or Email: marketing@beanstockventures.com

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