



Monetize Software: The Challenges of Commercialization and How to Overcome Them

*presented by Greenlight Guru in partnership with BeanStock Ventures,
an FDA accredited 510(k) Third Party Review Organization*

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

1.5M

years industry
experience

522k

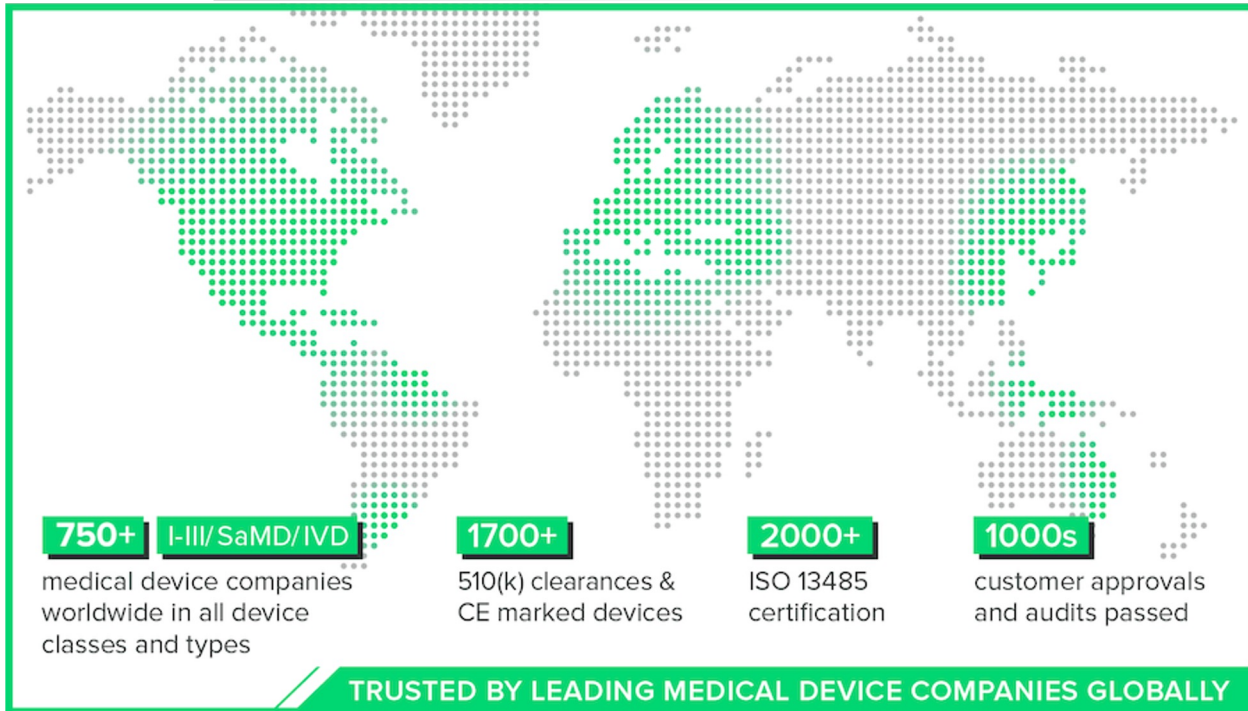
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in the industry



**“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”



Presented By



Niki Price

Medical Device Guru



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*Senior Software
Product Manager*



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CEO





An FDA® Accredited 510(k) 3rd Party Review Organization

BeanStock Ventures is 1 of 9 FDA-accredited Third Party Review Organizations globally which provides software development and regulatory compliance products and services to minimize complexity, and reduce cost and time to market of innovative medical devices.

BeanStock Ventures has over 140 years of combined experience in software development for the healthcare and life science space. [Product Portfolio](#)

“I would highly recommend partnering with BeanStock Ventures on innovation and software product development in life sciences, biotechnology, or medical devices.” - Mimi Healy, Former CEO, Lasergen, Inc.

“BeanStock Ventures deep understanding of the medical device industry and regulatory landscape helped deliver a professional, thorough software process and thereby a finished product for submission.”
- Paul DiPerna, CEO, Modular Medical and Founder of Tandem Diabetes

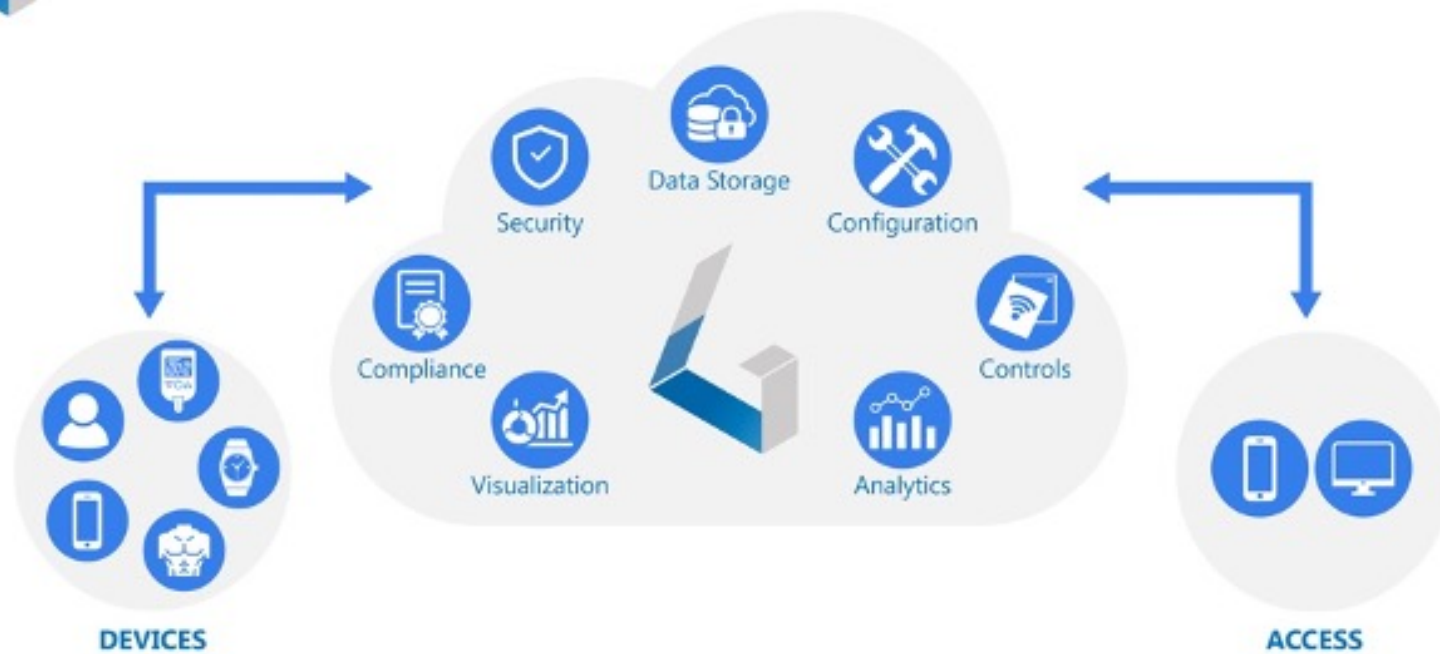


Galen Cloud™

Secure, Compliant, Turnkey Cloud Connectivity Platform



The Galen Cloud™




- Purpose-built platform for medical devices
- Compatible with all cloud infrastructures (AWS, Azure, etc.)
- ISO 13485:2016 certified
- *HITRUST* Certified: Galen Cloud hosted on AWS
- FDA, HIPAA, GDPR compliant
- Highly configurable interface for data access/display, levels of access, alerts, more

The background features a dark, semi-transparent overlay on a light-colored background. The overlay contains a stethoscope on the left, a tablet in the center displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 bpm, and a pulse oximeter showing 96%. The dashboard also includes various charts and icons. The background itself shows a faint ECG waveform and a pen on the right side.

Is the medical device industry moving towards the monetization of software?

The background is a dark, semi-transparent overlay on a light-colored image. The image shows a stethoscope, a pen, and a tablet displaying medical data. The tablet screen features a DNA double helix, a heart rate monitor showing 78 bpm, and a bar chart. The text is centered over the tablet area.

What are corporate challenges that hinder companies from monetizing software?

A tablet displaying a medical software interface with a DNA helix, heart rate (78 bpm), and other health metrics. The background features a stethoscope, a pen, and an ECG tracing on a grid.

From a software engineering perspective: what hinders the monetization of medical device software?

The background features a dark, semi-transparent overlay on a light-colored surface. It includes a stethoscope on the left, a tablet in the center displaying a medical dashboard with a heart rate of 78 BPM and a DNA helix, and a pen on the right. ECG waveforms are visible across the entire background.

What are a few ways organizations have successfully increased revenues by monetizing their software?

A tablet displaying medical software with a DNA helix, heart rate (78 bpm), and other health metrics. The background features a stethoscope, a pen, and an ECG tracing on a grid.

Who in medical device has been successful in monetizing software and how did they achieve?

The background features a dark, semi-transparent overlay on a medical-themed image. It includes an ECG (heart rate) line, a stethoscope, and a tablet displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 bpm, and a pulse oximeter showing 96%. The text is centered over the tablet area.

How much influence does software have in product development?

The background is a dark, semi-transparent overlay on a medical-themed image. It features a stethoscope, a tablet displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 BPM, and a blood pressure monitor showing 76 BPM. The dashboard also includes a bar chart and a location pin icon. The overall aesthetic is professional and tech-oriented.

What are ways companies can start to structure themselves towards software monetization?

The background is a dark, semi-transparent overlay on a medical-themed image. It features a stethoscope, a pen, and a tablet displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 bpm, and a bar chart. The text is centered over the tablet area.

How to increase customer adoption, especially when customers are used to getting software for 'free'?

The background is a dark, semi-transparent overlay on a medical-themed image. It features a stethoscope, a tablet displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 bpm, and a blood pressure monitor showing 76 BPM. The entire scene is overlaid with a faint ECG (heart rate) line.

How to align the culture and corporate capability to support software as a revenue generator?

The background is a dark, semi-transparent overlay on a medical-themed image. It features a stethoscope, a pen, and a tablet displaying a medical dashboard with a DNA helix, a heart rate monitor showing 78 bpm, and a bar chart. The text is centered and framed by two horizontal green lines.

How can investing in infrastructure such as people, process and tools be the catalyst behind driving up software valuations?

Questions? Contact Us



[San Diego, CA](#)



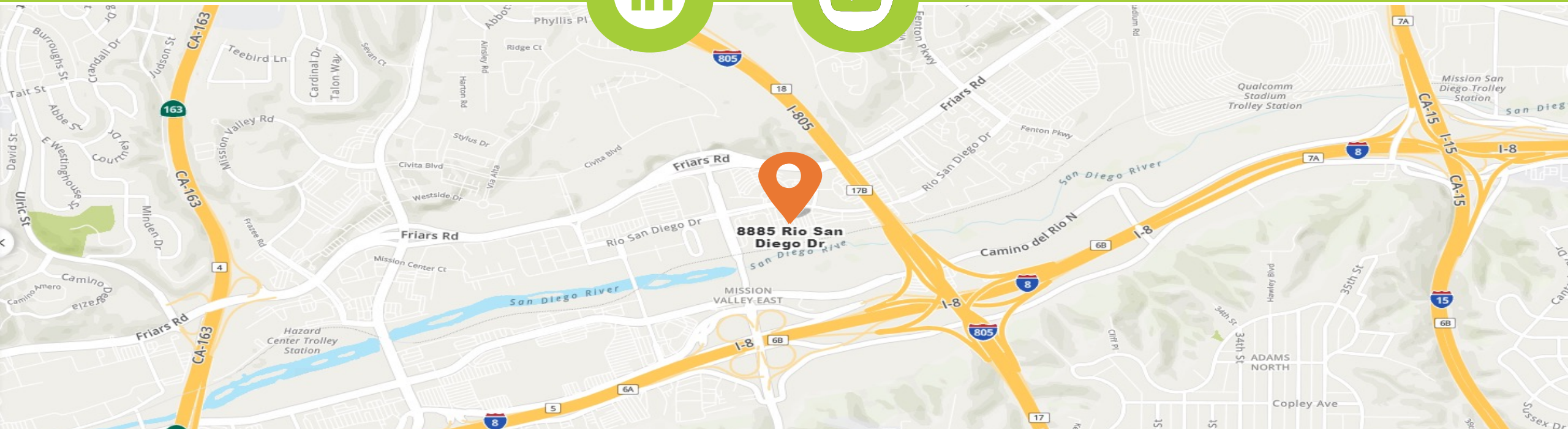
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www.beanstockventures.com





Appendix

Resources

Product

DIY Regulatory Kits

Streamline your FDA or EU submission with our SaMD/SiMD regulatory kit.

*This (diy) kit includes a full set of design history file (DHF) templates **required by the FDA**, along with training that provides regulatory guidance aligned with best practices.*

[Product flyer here.](#)



BeanStock Ventures

3P510K

BeanStock Ventures is 1 of only 9 FDA-Recognized 510(k) Third Party Review Organizations globally.

Our experts save time and money by clearing devices from over 250 product codes in less than 60 days.

510(k) Third Party Review Process Infographic



We are 98% faster to FDA approval – 47 days compared to 31 months



In most cases, we can shave over a year off traditional FDA processing times for class 2 devices.



Ideal for the multitude of emerging digital health startups and established powerhouses alike.



BEANSTOCK
VENTURES

FDA Clearance
in as little as
47 days



Eileen Heller
VP of Operations



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The infographic features the BeanStock Ventures logo at the top left. The main headline reads 'FDA Clearance in as little as 47 days' in a mix of bold green and black text. Below this is a red YouTube play button icon. To the right of the text is a portrait of Eileen Heller, VP of Operations, a woman with blonde hair and glasses wearing a black patterned top. At the bottom left of the infographic is a small copyright notice: '© 2022 BeanStock Ventures'.

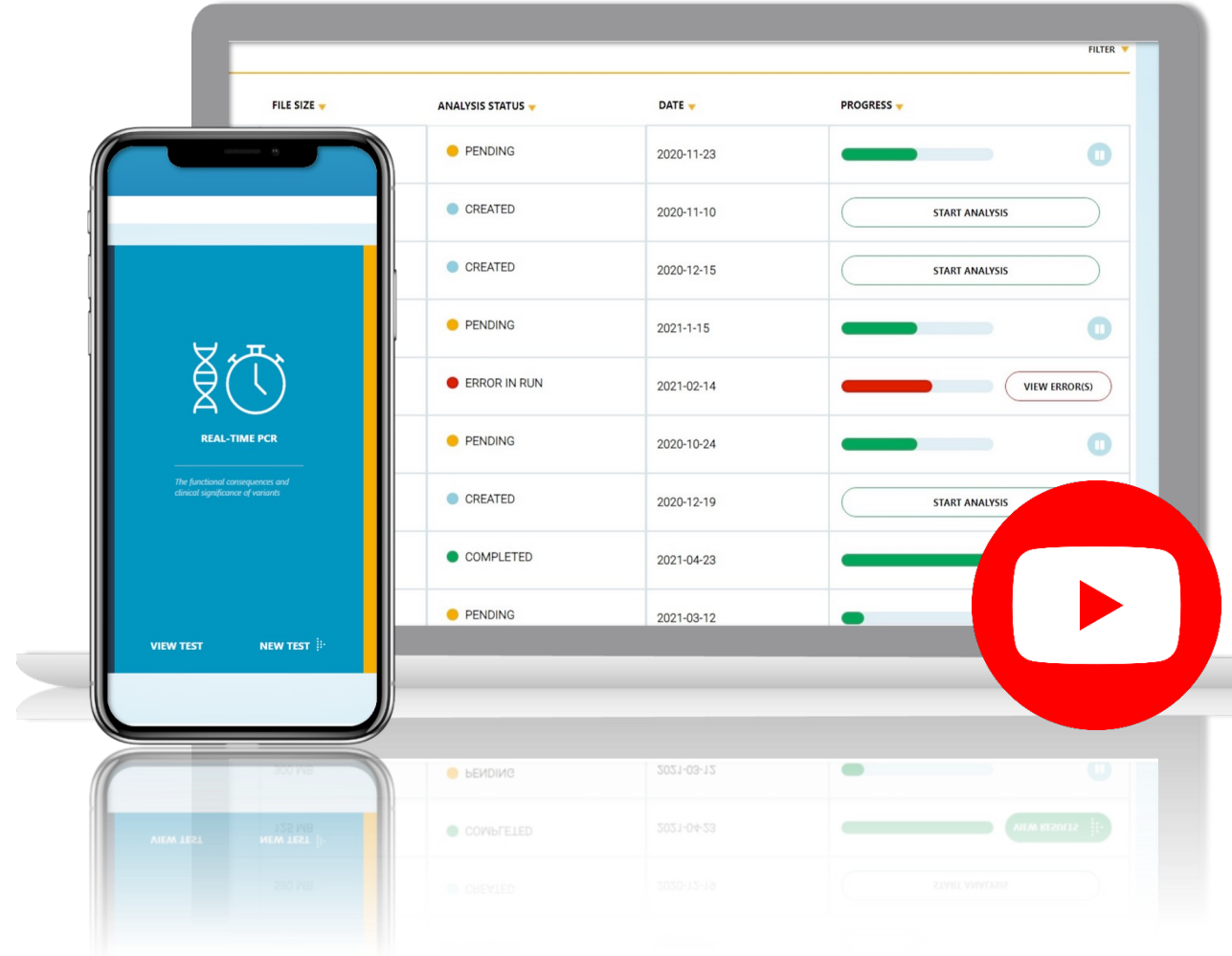
BeanStock Ventures

Bedrock

Expedite time to market with the only all-in-one cloud-based clinical diagnostics (CDx) software platform that focuses on reuse and compliance.

[Product flyer here](#)

- Cloud-based analysis platform
- End-to-end integration of devices
- Data and computation management
- Integrates with existing frameworks
- Cohesive intuitive clinical application
- Automated system self-validation
- Scalable platform and infrastructure
- Custom workflows
- Regulatory compliant
- Cybersecure
- End user focused
- Custom branding



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