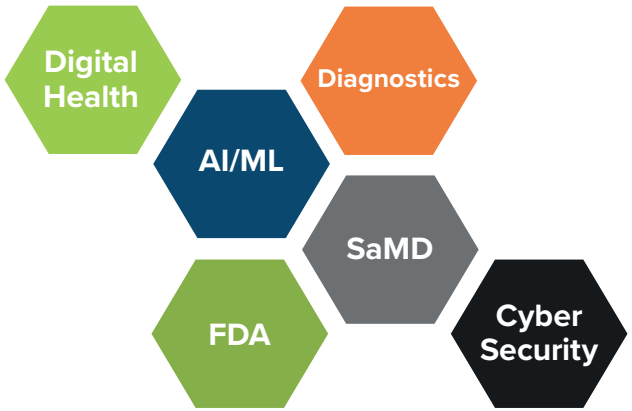
Reduce cost.

Reduce time to market.

Reduce regulatory complexity.



Learn More

Contact Us

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beanstockventures.com

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BEANSTOCK VENTURES

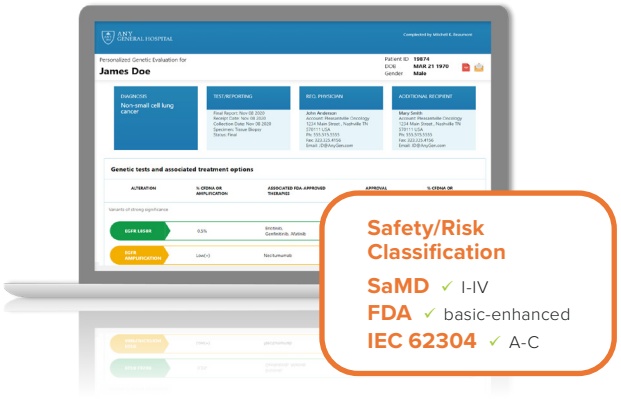
WE ARE DIGITAL HEALTH EXPERTS

Company Portfolio

Bedrock™

powered by BeanStock Ventures

The only all-in-one SaaS cloud-based clinical analysis platform that focuses on usability and regulatory compliance.



Platform Benefits

- Increased patient access
- Improved laboratory workflow
- Decreased test turn-around time
- Decreased need for technical personnel
- Decreased development costs
- Decreased time to market

BeanStock Consulting

a beanstock ventures company

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

Regulatory Strategy

Obtain clarity and align your team by working with our regulatory experts to help you define your regulatory pathway with a formal plan that aligns regulatory and product development activities to your business strategy and supports bringing your new or modified medical device product to market.

Technical Design

Reduce FDA additional information requests (AI) by developing a sound technical (design history file DHF).

Our technical and quality experts ensure your design specifications (DHF) are complete and compliant with services such as **DHF assessment**, **DHF artifact creation or remediation**, **Design Reviews**, and **DHF audit**.

FDA Submission

BeanStock Consulting

a beanstock ventures company

FDA Clearance in as little as 47 days

Eileen Heller
VP of Operations

Submission & Post-Market Support

Reduce regulatory complexity by allowing us to support you throughout the entire FDA submission process with services such as: **FDA Readiness reviews**, **FDA submission preparation and support**, **post-market registrations**, and **QMS (Quality Management System) support**.

3P510(k)

Saves time and money by allowing you to clear your devices faster than the typical FDA processing time. Our experts can review over 250 510(k) Product Codes on behalf of the FDA in as little as 47 days.

grassrootsDX

a beanstock ventures company

Digitial health platform focused on enabling market innovation by providing a community of resources & training.

Grassroots Dx

Community

Grow your software regulatory knowledge and engage in a community of your software medical device peers with features such as:

- Ask me anything social feed
- Curated & up to date regulatory information
- Relevant news feeds
- Free resources, training, templates and webinars

Software Regulatory Kits

Streamline your regulatory submission.

Our do-it-yourself kits pairs required design templates and SOAR® Training courses along with monthly Q&A sessions with industry experts that provide you with guidance and best practices to help you complete your own regulatory submission.

Our full design SaMD and SiMD templates and training are designed by medical software experts and comply with FDA guidances and recognized consensus standards.

SOAR® (Software Online Agile Regulatory) Training

This is a 16 course on-demand training program that has been designed to maintain the team's agility while:

- Establishing regulatory background and understanding of requirements
- Advancing regulatory knowledge for real world application
- Creating confidence in meeting aggressive product launches
- Increasing ease in FDA clearance and passing audits and inspections
- Aligning regulatory, quality and software teams to efficiently integrate Agile into the regulatory landscape