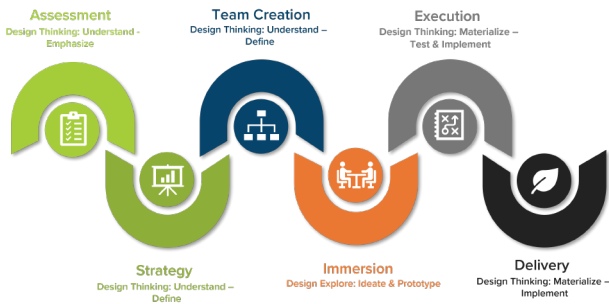




BeanStock Ventures is proud to be an Illumina Implementation Partner for Illumina Connected Analytics

## Our Signature Process



### Key Areas of Expertise

- Medical, Life Science and Healthcare
- Software as a Medical Device (SaMD)
- Clinical Decision Support (CDS) Software
- Cybersecurity in Medical Devices
- Artificial Intelligence
- Digital Health
- Machine Learning
- Instrument control
- Diagnostics
- Automation
- Analytics



Learn More

Contact Us



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WE ARE  
**MEDICAL  
DEVICE  
DEVELOPMENT**  
EXPERTS

Product Portfolio



## Software Product Development



Expedite time to market with the only all-in-one cloud-based software analysis platform that focuses on the end user.



**Safety Classification**  
**SaMD** ✓ I-IV  
**FDA** ✓ minor-major  
**IEC 62304** ✓ A-C

- 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
- Cybersecurity
- End user focused
- Custom branding

## Regulatory Compliance

### (diy) Regulatory Kit

**Required. Affordable. Easy to use.**

Save \$200k and 10 months in preparation with our SaMD/SiMD regulatory kit.

This do-it-yourself kit includes a full set of design templates required by the FDA for your submission or technical file, along with associated processes and training that provides you with guidance and best practices for a successful FDA submission.



### 3P510(k)

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

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



**FDA Clearance**  
**in as little as**  
**47 days**

Eileen Heller  
 VP of Operations



## SOAR® Training

The Software Online/Onsite Agile Regulatory (SOAR®) Training will assist the organization, team and engineer in implementing the right strategy for their Agile software teams.



Kelly Weyrauch  
 Owner, Agile Quality  
 Systems & a Principal

Shawnnah Monterrey  
 Chief Executive Officer,  
 BeanStock Ventures

This is a 15 course training program that has been designed to maintain the team's agility while:

- Aligning quality and software to efficiently integrate Agile into the regulatory landscape
- Advancing regulatory knowledge for real world application
- Establishing regulatory background and review requirements
- Creating confidence in meeting aggressive product launches
- Increasing ease in passing internal and external audits and inspections

