How Investors Can Encourage Startups to Work Constructively with the FDA

Armen A. Vidian, Partner, DCVC

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Who We Are: A Venture Firm Investing at the Intersection of AI and Challenging Problems

- Artificial Intelligence
- Proprietary Data
- Robotics & Real-world Systems
- Huge Compute

We call this “Deep Tech”

- $1.7B under management across 8 funds
- Average check size for first money in ~$2–5M
- Series Seed, Series A
- Investors in Caption Health, Subtle Medical, Freenome, many others!
Why Is This Topic Important?

- Tech entrepreneurs have much to give.
- The world of regulated devices for healthcare is often new and intimidating.
- It’s important that entrepreneurs and investors alike understand the regulatory process.
Direct Entrepreneurs to Understand How Regulations Help Strengthen the Business

- It’s not just a requirement. Companies benefit from strong clinical evidence. Credibility is key!
- Guide entrepreneurs to define what they should want to demonstrate and why it’s important to clinicians and patients.
- The FDA regulates *claims* about the safety and effectiveness of technology – so knowing what you want to say to your customers is critical. The process gives you a chance to provide *evidence*!
Understand the Regulations Early

➢ Learn what Class I, Class II, Class III, 510(k), *de novo* 510(k) classifications are and why they’re important!

➢ Encourage entrepreneurs to hire a regulatory affairs expert EARLY in the company’s history.

➢ Understand how the regulatory pathway may impact product requirements.

*Strong Product – RA collaboration is key!!*
Be Transparent!

- Encourage a dialog between Investors / Board and the entrepreneurs early in the life of the company about claims and the likely path to those claims.
- Instill a value that building a solid relationship with the FDA reviewer and being candid is critical to success.
- Be up front and open about challenges, always.
Understand What Regulations Mean for Your Fundraising Timeline and Goals

➤ Understand what personnel a company will need to hire to support a successful study:

➤ VP/Director of Regulatory & Clinical Affairs and Field Specialists?

➤ Develop a timeline for these hires well ahead of when a study starts!

➤ Incorporate this information into the entrepreneur’s projected cash needs.

➤ Work to integrate the entrepreneur’s regulatory strategy into the narrative of your company’s story for investors, partners, potential board members – everyone!