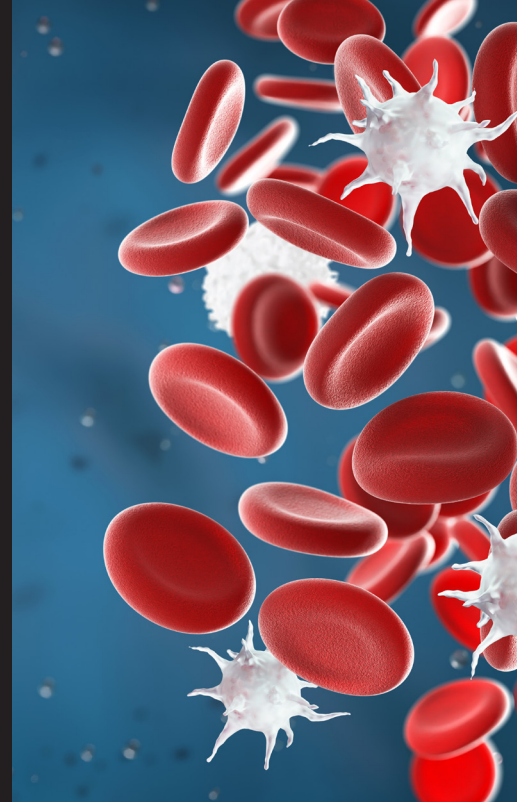


CASE STUDY

Turning a medical device concept into software ready for clinical trials

How Firefinch delivered compliant, integrated software for a first medical device



The challenge

Hart Biologicals is a leading reagent manufacturer and supplier that set out to expand their offering with IMPACT, their first medical device. With no internal software team, they faced the challenge of building a user-friendly, compliant system while navigating complex, country-specific regulations.

Firefinch joined as an embedded partner, bringing a structured, collaborative approach to develop software from the ground up. The solution integrates with custom hardware, supports HL7 connectivity, and prioritises usability, delivering a user-focused platform aligned with global regulatory standards and ready for clinical trials.

Key takeaways

- Delivered a trial-ready software platform, fully aligned with IEC 62304 and guided by AAMI TIR45, reducing regulatory risk from the outset
- Applied agile, sprint-based delivery to maintain momentum and adapt to evolving requirements
- Designed an intuitive, user-focused interface through collaborative UX workshops, reflecting real-world use
- Built a secure, maintainable OS optimised for long-term performance and medical-grade stability
- Supported regulatory readiness with robust documentation, traceability, and QMS alignment throughout the project lifecycle

Results



TRIAL-READY PLATFORM

Fully prepared for clinical use



COMPLIANT BY DESIGN

Aligned with IEC 62304



BUILT TO SCALE

Flexible for future growth

About Hart Biologicals

Hart Biologicals is a UK-based manufacturer and global supplier of reagents for haemostasis and platelet function analysis. With a strong foundation in laboratory diagnostics, the company is expanding its capabilities through the development of IMPACT, its first internally designed medical device. Drawing on deep customer insight and a commitment to innovation, Hart Biologicals aims to drive the future of point-of-care with user-friendly medical software to support future growth.

"Firefinch has been a critical partner, helping us build compliant, user-friendly software for our first medical device. Their collaborative approach, technical strength, and clear communication made the process smooth and enjoyable, and ultimately helped to deliver a great product."

Alexander Ebinger

MANAGING DIRECTOR, HART BIOLOGICALS

Our approach

1. Collaborated with internal teams with structured discovery workshops to define user roles, needs, and priorities
2. Created and refined UI prototypes in partnership with internal stakeholders
3. Developed compliant architecture using agile sprints aligned with IEC 62304 and AAMI TIR45
4. Integrated hardware and software, including pipette, printer, PC, and HL7 messaging for LIS
5. Delivered a custom OS optimised for medical device use and long-term updates
6. Supported QMS alignment to help structure documentation to meet submission needs

About Firefinch

Navigating the regulatory landscape for medical devices

Firefinch helped Hart Biologicals bring their first medical device to life by combining strategic guidance with practical execution, all while navigating the complexities of regulated software development. Whether you're launching your first product or expanding an established portfolio, Firefinch provides the expertise, collaborative mindset, and regulatory know-how to get it right the first time.

Get in touch

Bringing your medical device to market?

We offer the regulatory fluency, technical depth, and collaborative approach you need to build safe, user-friendly software — faster and with less risk.

 www.firefinch.io

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 Firefinch Software