5 CHALLENGES in Digital Health Solution Development

Accelerate innovation for software development in digital health solutions, while maintaining quality standards. Modern requirements management can help you respond quickly to new regulations, reduce uncertainty, and bring more cost-effective digital health and software as a medical device (SaMD) solutions to market.

1 THE RISE IN DEMAND FOR DIGITAL HEALTH SOLUTIONS

This increased market demand has cast a spotlight on the need for organizations to adopt greater agility and better management across the software development lifecycle (SDLC) to bring new solutions to market at an accelerated pace.

Increased Demand = Need for Efficiency and Quality at Speed

In 2018, only 29% of healthcare solution providers said their development and launch cycles for digital health solutions were less than 18 months. Today, this number has increased to 44%.[1]

The virtual health market in the United States is projected to reach $100 billion by 2025.[2]

2 AN INCREASE IN BIOSENSORS AND WEARABLES

As software complexity evolves with growing trends in biosensors and wearables become more prevalent, organizations developing digital health solutions are realizing that real-time data collection and communication are critical to their digital health initiatives.

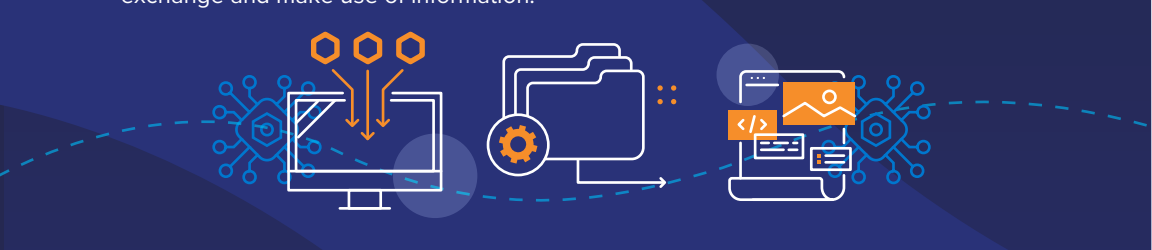
Wearable Technology Necessitates Real-time Data & Communication

88% of executives predicted wearable devices will be integrated with care delivery.[2]

52% of survey respondents said they are currently developing or planning to develop wearables as part of their strategy... another 33% said the same for patient-monitoring solutions.[3]

3 BALANCING INTEROPERABILITY WITH QUALITY & SAFETY ASSURANCE

Whether responding to regulations or market innovation, companies must be prepared to demonstrate their products are safe. Bringing a digital health solution to market requires more than the expertise of a single solution provider; it must permit different service providers to combine their expertise and allow for various systems and software to exchange and make use of information.



At the Forefront: Standardization of Data Across Providers

93% agree that digital healthcare's collection and purposing of data should be standardized to enable interoperability.[3]

Indirect quality costs can reach as much as $1 Billion and market-cap impact as much as $2 Billion for individual companies.[4]

4 THE HIGH COST OF PRODUCT DEVELOPMENT

In this ever-changing digital health industry, the high cost of development, like SDLC, can be addressed by adopting modern technology solutions for improved nimbleness and flexibility.

Advancing Health Technology = Increased Investment

It takes 3-7 years for a new medical device to come to market[5]

...and a cost between $31 - 94 Million to get there.[6]

5 REGULATORY DISRUPTION

The medical device landscape is in a constant state of flux thanks to ongoing technological innovation and evolving regulation. An evolving regulatory environment means it is no longer feasible for development teams to have disparate content without central access.

Medical Device Innovation = Expanding Regulations

FDA in September 2020 launched the Digital Health Center of Excellence to better coordinate policy & regulatory approaches tailored for the fast-growing technologies.[7]

The first mandates in 3 Decades - The EU MDR took effect in May 2021 and the IVDR took effect in May 2022, and both serve to diminish the adverse health impacts associated with medical device development.[8]

Meet Complex Industry Challenges with Jama Software's Solution

Jama Software can help you stay market competitive and accelerate device development, while improving product quality and meeting industry regulations with Jama Connect® for Digital Health. In one powerful platform, you can better manage requirements, risks, and design controls, making regulatory submissions and audit preparations a straightforward process while adhering to FDA, EU (MDR and IVDR), and ISO regulations.

Jama Connect for Digital Health was designed to help teams:

- Align tests and requirements, run test cases, and instantly log connected defects when tests fail to mitigate hazards earlier in the development process, saving costly late-stage changes.
- Manage and verify complex systems requirements while eliminating the risks and inefficiencies associated with documents-based and legacy systems.
- Keep track of Software of Unknown Provinance (SOUP) / Off the Shelf (OTS) components and manage risk in alignment with ISO 14971.
- Accelerate adoption and improve compliance using frameworks aligned to aligned to key industry regulations: ISO 13485:2016, 21 CFR 820.30, ISO 62304:2016, and ISO 14971.
- Support the SDLC process with export templates and risk reports designed specifically for the medical device industry.
- Prioritize critical decisions and align stakeholders to improve response times.
- Visually track relationships across projects and identify potentially problematic links when changes are made.
- Create catalogs of reusable requirements to get your products to market faster.
- Easily provide auditors reporting to demonstrate connections between regulations, requirements and tests.
- Manage cybersecurity risks and trace them to your risk controls.

OUR CUSTOMERS' EXPERIENCE

80% of planning time saved that previously would have been wasted on meetings, sorting through versioned documents and emails, and consolidating feedback in review cycles.

RBC Medical Innovations **saves $150,000 per project** by upgrading their semi-manual processes to exceptional team collaboration and outstanding workflow efficiencies using Jama Connect.

Grifols **saves 80 hours or more per project** in medical device development using Jama Connect's Review Center.

Are you looking to optimize your digital health solutions development processes?

To learn more, visit jamasoftware.com/solutions/medical-device/

SOURCES:

1) The rise of digital health solutions in a post COVID world, The Scalers, October 2020
2) The Future of Virtual Health, Deloitte, April 2020
3) Top five digital health technology trends, MDDI Qmed, June 2020
4) Capturing the Value of Good Quality in Medical Devices, Mckinsey & Company, February 2017
5) Part One: Medical Device Classification in the United States, IMARC Research, 6 September 2019
6) Exploring FDA approval pathways for medical devices, Mass Device, 12 September 2019
7) 5 things medtech can expect from FDA in 2021 , Medtechdive, March 2021
8) What New EU MDR Legislation Means for the Medical Devices Market , SRG, January 2021