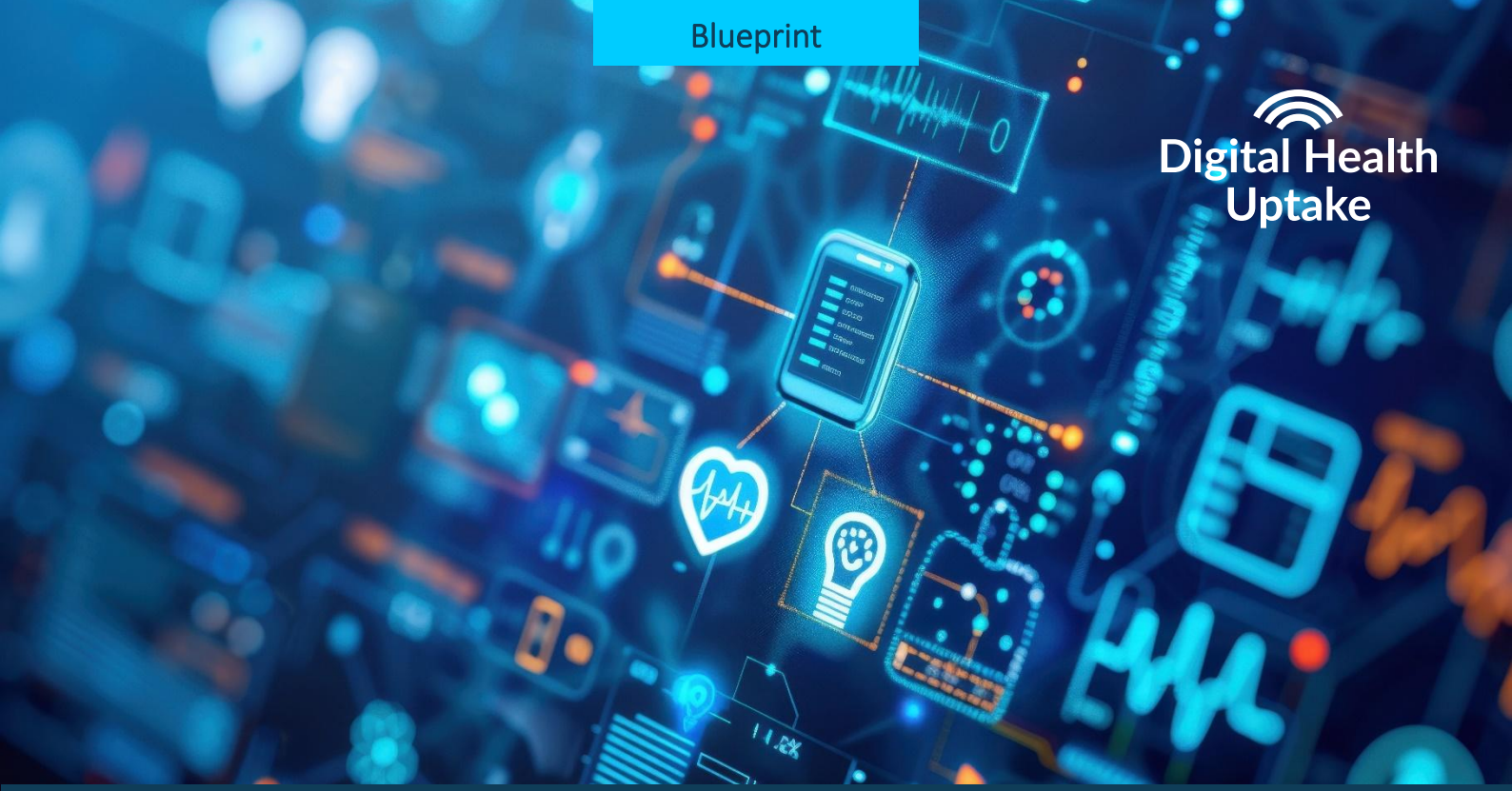
Blueprint



Digital Health Uptake

Are you prepared to manufacture a Software as a Medical Device (SaMD)?

A step-by-step guide

Bringing a Software as a Medical Device (SaMD) to market requires more than just technical know-how. Kinetikos Health created this blueprint following three events co-hosted by DigitalHealthUptake about the implementation of the EN ISO 13485:2016/A11:2021. This document is the result of a careful analysis of the standard. It is designed to be a useful tool for medical device manufacturers.

4 November 2024

BLUEPRINT - Are you ready for the journey?

1 Have you clearly defined the purpose and scope of your SaMD?

Before you dive into development, ask yourself: "What problem are we solving?" Understanding the clinical need and intended use of your SaMD is key to defining its scope and targeting the right market.

In case you have already started your development, verify if it is clear whether the software being developed is a medical device or not, according to the definition in the applicable regulations.[1]

2 Do you know the regulatory landscape?

Another key question to ask is: "W*hich markets will the software be available in?*". Whether you're aiming for FDA approval in the US, CE marking in the EU, or other country-specific requirements, identifying the classification and risk level of your SaMD is crucial.

Once identified, develop a clear roadmap for regulatory submissions and approvals. Include timelines, necessary documentation, and key contacts for the submission process.

3 Is your quality management system (QMS) ready?

Quality is not just a box to tick—it is the backbone of your product's success. Do you have a QMS in place that aligns with ISO 13485, tailored for SaMD?

If not, this is a crucial step for ensuring your processes meet regulatory standards.[2]

[1] Article 1 and 2 of the MDR

[2] Article 10 of the MDR

4
Have you established a clear development plan?

How will you approach development, while keeping compliance in mind? Create a detailed software development lifecycle (SDLC) plan, including phases for design, development, verification, and validation.[3]

5
Are your requirements and specifications clear?

Do you have a precise roadmap for your product's features and functionalities?

Define the necessary requirements the SaMD must meet, including functional, performance, usability, and safety criteria.[4]

6
How are you managing risks?

In a regulated space, risk management is mandatory. Perform a risk management analysis in line with ISO 14971.[5] Identify potential risks in the SaMD lifecycle and create mitigation strategies.

7
Have you implemented design controls?

Are you documenting every step of the design process to ensure it aligns with requirements and testing?

Incorporate design controls into the development process. These should include traceability matrices and regular design reviews to ensure the product meets specifications.[6]

[3] Requirements 7.1 and 7.3.2 EN ISO 13485/A11:2021
[4] Requirements 7.2.1 and 7.3.3 EN ISO 13485/A11:2021
[5] Requirement 7.1 EN ISO 13485:2016/A11:2021
[6] Requirement 7.3.5 EN ISO 13485:2016/A11:2021

8 How will you approach development and testing?[7]	The development phase is where ideas become reality, but testing is where they get validated.
	Assemble a multidisciplinary team to ensure the SaMD is designed and built with all perspectives considered.
	Don't forget the importance of document procedures for all stages of SaMD development with controls for software configuration management to track, verify, and validate changes.
	During the development of the SaMD, consider monitoring continuously to guarantee that the software meets performance and safety standards during development and deployment.
	To have a controlled deployment, verify and validate software to ensure it meets requirements and performs as intended under various conditions

9 **Are your verification activities ready to go?**	Does your SaMD work as intended? Perform tests to ensure the SaMD meets design input requirements, including unit, integration, and system testing.[8]

10 **Have you thought about validation?**	How can you prove that your SaMD meets the user's needs? Validate the SaMD in a real-world environment to ensure it meets the needs of the user and performs as intended. Validation activities must confirm that the final product meets user needs, regulatory requirements, and is ready for market release.[9]

[7] Requirement 7.3 EN ISO 13485:2016/A11:2021
[8] Requirement 7.3.6 EN ISO 13485:2016/A11:2021
[9] Requirement 7.3.7 EN ISO 13485:2016/A11:2021

11 Is usability testing and clinical validation on your radar?[10]	Even the best software can fail if users cannot navigate it effectively! Plan and conduct clinical evaluations and usability testing, if needed, to demonstrate safety and effectiveness.
12 **Do you have a post-market surveillance plan?[11]**	Establish procedures for post-market monitoring, including incident reporting, user feedback, and periodic reviews.
13 **Is your technical documentation ready for submission?**	Are your technical documents in order? Regulators want details. Prepare the necessary regulatory submissions such as a 510(k), PMA, or CE Technical Documentation. Ensure all documentation is complete and ready for review.[12][13]

[10] Article 10 of the MDR and requirement 7.3.3 EN ISO 13485:2016/A11:2021

[11] Article 83 of the MDR

[12] Requirement 4.2.3 EN ISO 13485:2016/A11:2021

[13] Team-NB Position Paper Best Practice Guidance for the Submission of TD under Annex II and III of MDR (EU) 2017/745

14 **How will you navigate regulatory submissions?**	Ready to push the submission button? At this stage, this means submitting all required documentation to the relevant regulatory bodies for approval of the SaMD. The goal is to demonstrate that the SaMD meets all regulatory, safety, and performance standards for its intended use. This process is crucial to obtaining market authorisation, such as FDA clearance, CE marking, or other global regulatory approvals, depending on the target market.
15 **Are you prepared to efficiently address regulatory feedback?**	After review, the regulatory body will provide feedback on whether the submission is approved, rejected, or requires modifications. Be prepared to define and implement a Corrective and Preventive Action (CAPA) Plan to answer to the regulatory body. Upon approval, the SaMD can be legally marketed within the jurisdiction, and the appropriate certificates (e.g., 510(k) clearance or CE mark) are issued.
16 **How will you ensure the design transfer?**	Upon receiving regulatory approval, deploy the SaMD. Design and development outputs should be adequately transferred to manufacturing to ensure production aligns with design specifications. All the information should be accurately and thoroughly communicated to the production team. Ensure all support, maintenance, and user training systems are in place.[14] Navigating the path to bringing a SaMD to market is complex and challenging. However, it is entirely achievable with careful planning and a strategic approach. Each milestone brings us closer to delivering meaningful innovation in healthcare.

[14] Requirement 7.3.8 EN ISO 13485:2016/A11:2021

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