Medical device development process securing safety and reliability for medtech startups through Intended Use

(안전과 유효성 확보를 위한 의도된 용도 바탕의 의료기기)

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(Abstract)

Developing safe and effective medical devices boils down to developing devices that are compliance for the manufacturer's "Intended Use". "Compliance for Intended Use" means the realization of a medical device that is safe and effective for a specified medical indication in a particular patient population, achieved through a trusted organization and engineering processes. In other words, it's all about medical device development in a nutshell. This article explains what that means.

Introduction

The development of a medical device starts with an analysis of the user needs. However, while user needs can be a driver for why you want to develop and bring a device to market, it's not the beginning of the actual development of the device. It's a kind of a necessity for a product or service, but qualitative and abstract.

To secure compliance for medical device international standards, it is necessary to explicitly translate the specified user needs into the "Intended Use" intended by a manufacturer. Once such a "Intended Use" is established, full-scale, formal medical device development can be started.

Definition of "Intended Use"

There are two international standards related to quality management systems that define Intended Use. One is ISO 14971 for risk management and the other is IEC 62366-1 for usability.

The definition of "Intended Use" as described in ISO 14971, clause 3.6 is herewith;

"use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer."

Furthermore, this standard is saying 6 items as the typical elements of the "Intended Use" like below;

① intended medical indication,
② patient population,
③ part of the body or type of tissue interacted with
④ user profile,
⑤ use environment, and
⑥ operating principle

On the other hand, this "Intended Use" is described in IEC 62366-1, clause 3.23 as follows;;

"summary of the important characteristics related to the context of use of the MEDICAL DEVICE"

And this standard is also saying 6 items as the typical elements of the "Intended Use" like below;

① intended medical indication,
② patient population,

③ part of the body or type of tissue interacted with
④ user profile,
⑤ use environment, and
⑥ operating principle

In the end, we can see that “Intended Use” is essentially the same concept in both of these standards, but the definitions they describe differ based on their different perspectives on risk management and usability.

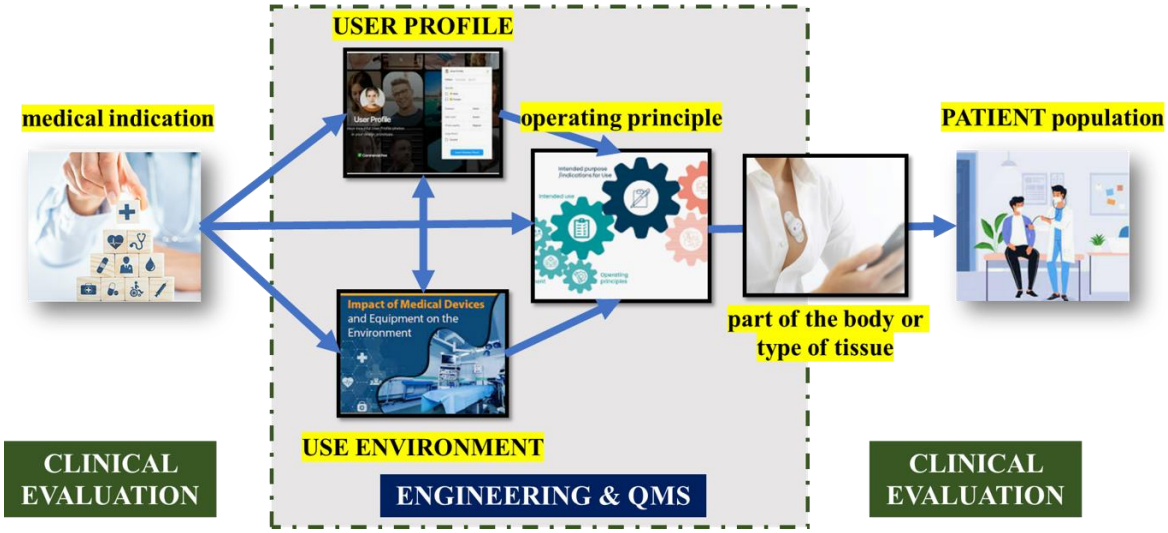
“Intended Use” and Device Development

Medical device design and development can be regarded as the realization of a device that performs as intended for the “Intended Use” by the manufacturer to meet the user needs. In other words, it's about implementing the device to secure compliance for its “Intended Use”.

If we characterize the six elements that make up “Intended Use” mentioned above, we can see that they are interrelated, as shown in Figure 1. Three elements (user profile, use environment, and operating principle) are addressed in engineering and QMS processes. The other two elements (medical indication and patient population) are associated with clinical evaluation, when appropriate, including clinical investigations. The remaining element (part of the body or type of tissue) is covered by both.

To put this in terms of the work of the manufacturer implementing the realization of the device, in order to develop a device with a valid "medical indication" for a specific "patient population", the manufacturer considers the "use environment", "user profile", and "operating principle" of the device as input requirements to the development, and considers the " part of the body or type of tissue" in examining the interaction between the device and the user (including the patient population) to ensure good usability.

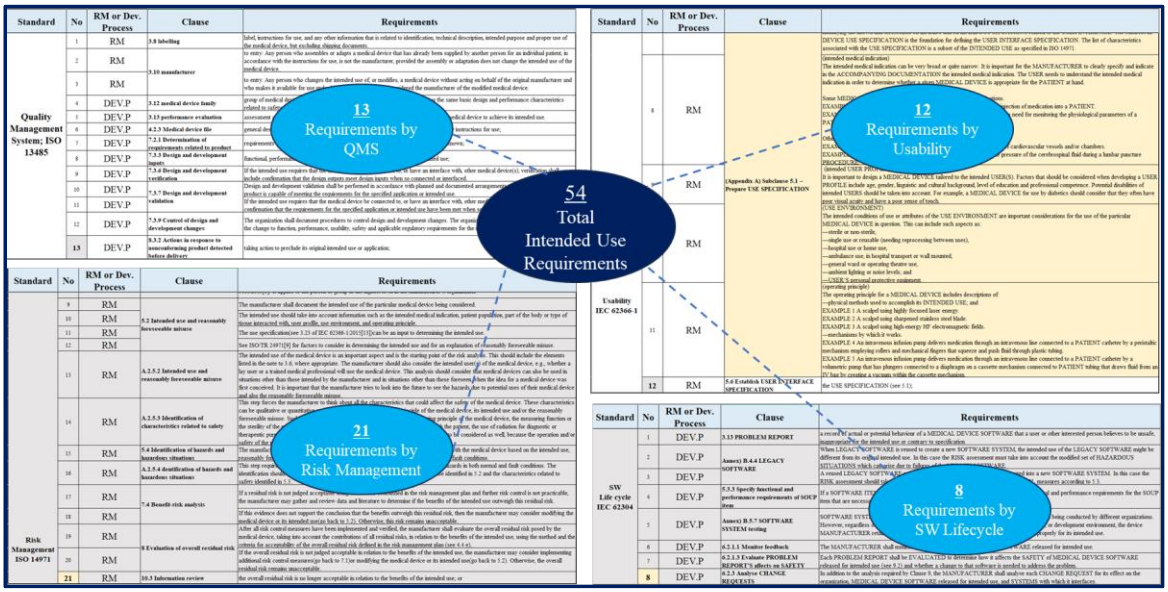
In the end, if we define the design and development characteristics of a medical device by focusing solely on its “Intended Use”, we can say that;



(Fig-1, Conceptual schematic of Intended Use compliance and device development, by Teamnubiz)

Medical device development is the process of making a medical device fit for its “Intended Use”, and more specifically, it is the realization of a medical device that is safe and effective for its specified medical indication in a specific patient population and user profile through a reliable organization which can be achieved through QMS of ISO 13485 and engineering

process defined in ISO 14971 for risk management, IEC 62366-1 for usability and IEC 62304 for software lifecycle.



(Fig-2, 54 Identify requirements related with "Intended Use" in QMS and process standards, by Teamnubiz)

Identify the requirements related with "Intended Use" in QMS(ISO 13485) and process standards.

As shown in Figure 2, a total of 54 requirements related to "Intended Use" mentioned in the QMS standard (ISO 13485) and its associated mandatory process standards (ISO 14971, IEC 62366-1 and IEC 62304) are identified.

Breaking down these identified requirements, we need to ensure conformance for 13 requirements in QMS, 21 in risk management, 12 in usability, and 8 in SW lifecycle. In terms of how we practically address each requirement, we can divide them into development management processes and risk management processes, which are discussed in more detail in the following sections.

How to address the requirements related with "Intended Use" considering compliance in each harmonized standards.

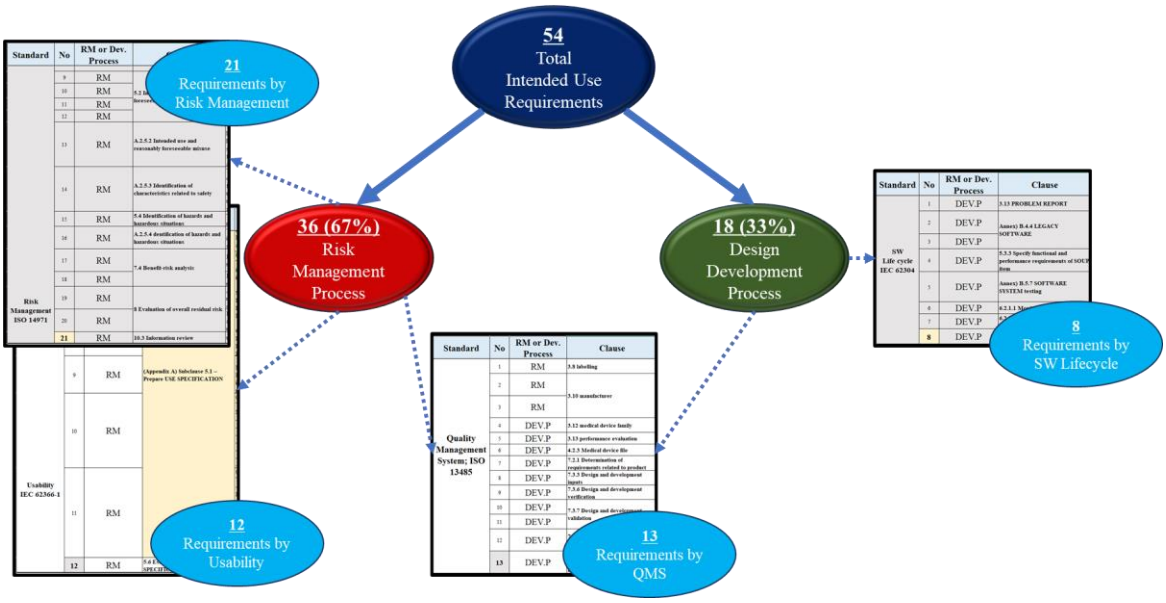
The development of safe and effective medical devices requires an integrated development management process and risk management process, as required by quality management systems (ISO 13485, FDA 820).

The purpose of addressing requirements related to "Intended Use" through the development control process is to achieve effectiveness of device functions and performance that are fit to achieve "Intended Use" through the process of development input, output, review, verification, and validation as described in ISO 13485. 7.3. for device system development and IEC 62304 for software development.

The other purpose of addressing requirements related to "Intended Use" through the risk management process is to secure safety of device functions and performance that are fit to achieve "Intended Use" through the process of risk analysis, evaluation, control, review overall residual risk and monitoring as described in ISO 14971 for device system risk management and IEC 62366-1 for usability.

A diagrammatic representation of the above description is shown in Figure 3.

Of the 54 requirements, 36(67%) can be



(Fig-3, Categorization of addressing requirements related with "Intended Use", by Teamnubiz)

addressed by the risk management process, which in turn handles 21 in ISO 14971, 12 in IEC 62366-1 and 3 in IEC 13485.

Of the 54 requirements, 18(33%) can be addressed by the development process, which in turn handles 10 in IEC 13485 and 8 in IEC 62304.

Conclusion

To put this in terms of the work of the manufacturer implementing the realization of the device, in order to develop a device with a valid "medical indication" for a specific "patient population", the manufacturer considers the "use environment", "user profile", and "operating principle" of the device as input requirements to the development, and considers the " part of the body or type of tissue" in examining the interaction between the device and the user (including the patient population) to ensure good usability.

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Medical device development is the process of making a medical device fit for its "Intended Use", and more specifically, it is the realization of a medical device that is safe and effective for its specified medical indication in a specific patient population and user profile through a reliable organization which can be achieved through QMS of ISO 13485 and engineering process defined in ISO 14971 for risk management, IEC 62366-1 for usability and IEC 62304 for software lifecycle.

References;

[1] ISO 13485: Third Edition 2016(E), Quality Management System

[2] ISO 14971: Third Edition 2019(E), Risk Management

[3] IEC 62366-1: First Edition 2015(E), Application of usability engineering to medical devices

[4] IEC 62304: Edition 1.1 2015, Software life cycle processes

[5] FDA 820, Quality System Regulation

[6] DESIGN CONTROL of FDA 21 CFR 820.30, GUIDANCE FOR MEDICAL DEVICE MANUFACTURERS

[7] ISO 14969, Medical devices - Quality management systems - Guidance on the application of ISO 13485:2003

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