COMBINATION PRODUCTS SUMMIT
COLUMBUS, OH • NOVEMBER 7–9, 2022

QMS STRATEGIES FOR DIGITAL HEALTH TECHNOLOGIES – DEVICE AND NON-DEVICE

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Facilitator: Chin-Wei Soo, Genentech

Agenda

- Device and non-device types
- Applicable regulations and standards
- Considerations for QMS strategy
- Consistent approach to lifecycle for device and non-device software
- Example QMS strategy
- Q&A

Device and non-device types

Medical Device with embedded software (SiMD)

- Well established and well understood regulations, standards, and guidance documents
- May or may not be possible to update the software once the device leaves the production line

Connected Drug Delivery Device with embedded software (SiMD)

- Must enable and be designed for implementation of end-to-end, state-of-the-art security and data privacy protection measures
- May or may not be possible to update the software once the device leaves the production line

Software as a Medical Device (SaMD)

- Must be designed to cater for patient safety, end-to-end and state-of-the art security, data privacy, and data integrity aspects
- Frequent modifications in response to real-world performance and user feedback

Non-device software

- Software product not regulated as Medical Device and not subject to other explicit health authority regulation or expectations
- Other than that, same characteristics as SaMD

Physical devices

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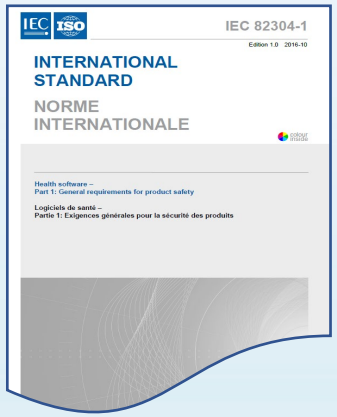
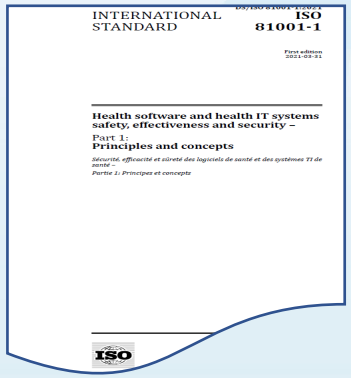
Applicable regulations and standards

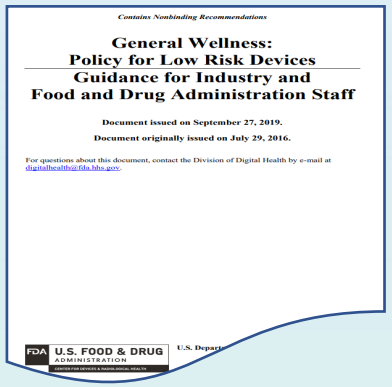
- in the context of standalone software products. Non-exclusive.

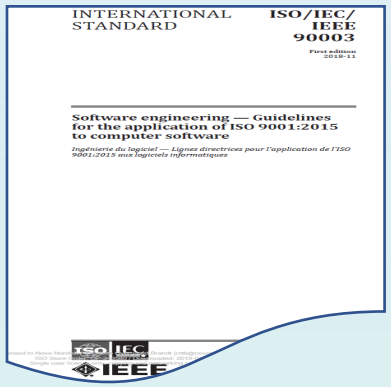
Non-device and device


IEC 82304-1
Edition 1.0 2016-10
INTERNATIONAL STANDARD
NORME INTERNATIONALE
Health software –
Part 1: General requirements for product safety
Logiciels de santé –
Partie 1: Exigences générales pour la sécurité des produits


TECHNICAL SPECIFICATION
ISO/TS 82304-2
First edition
Health software —
Part 2:
Health and wellness apps—Quality and reliability
PROOF/ÉPR

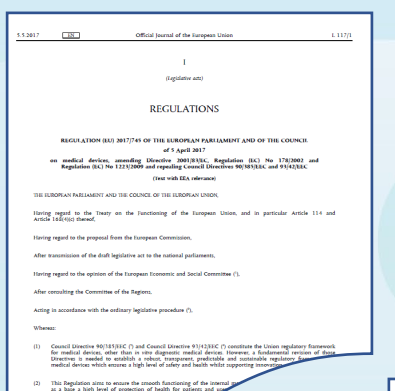

INTERNATIONAL STANDARD
ISO 81001-1
First edition
2021-08-01
Health software and health IT systems safety, effectiveness and security –
Part 1:
Principles and concepts
Sécurité, efficacité et sûreté des logiciels de santé et des systèmes TI de santé –
Partie 1: Principes et concepts

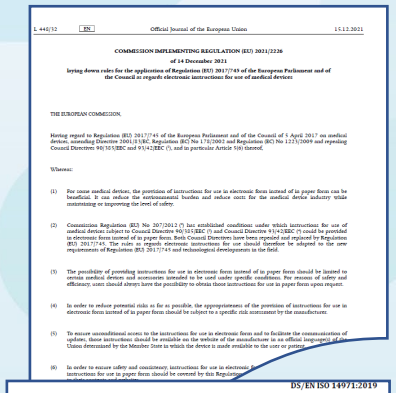

Contains Nonbinding Recommendations
General Wellness:
Policy for Low Risk Devices
Guidance for Industry and
Food and Drug Administration Staff
Document issued on September 27, 2019.
Document originally issued on July 29, 2016.
For questions about this document, contact the Division of Digital Health by e-mail at digitalhealth@fda.hhs.gov.
FDA U.S. FOOD & DRUG ADMINISTRATION

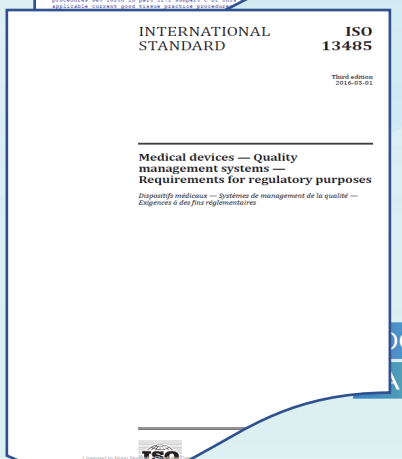

INTERNATIONAL STANDARD
ISO/IEC/IEEE 90003
First edition
2018-11
Software engineering — Guidelines for the application of ISO 9001:2015 to computer software
Ingénierie du logiciel — Lignes directrices pour l'application de l'ISO 9001:2015 aux logiciels informatiques

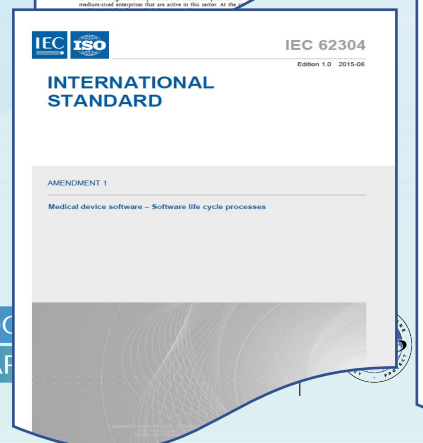
Device

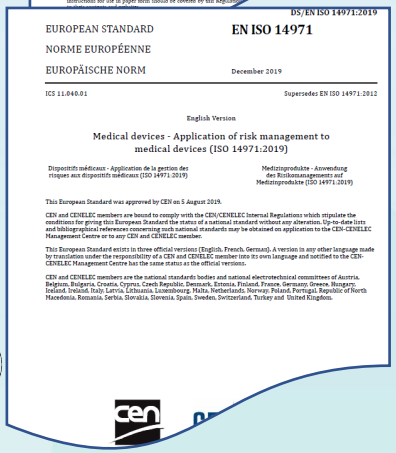

FDA
FDA Home | Medical Devices | Database
CFR - Code of Federal Regulations Title 21
The information on this page is current as of April 1 2017.
For the most up-to-date version of CFR Title 21, go to the Electronic Code of Federal Regulations (eCFR).
TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES
PART 820QUALITY SYSTEM REGULATION
Subpart A--General Provisions
Sec. 820.1 Scope.


5.7.2017 EN Official Journal of the European Union L 117/1
REGULATIONS
REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 5 April 2017
on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC
(Text with EEA relevance)
THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,


L 44/32 EN Official Journal of the European Union 15.12.2021
COMMISSION IMPLEMENTING REGULATION (EU) 2021/2226
of 14 December 2021
laying down rules for the application of Regulation (EU) 2017/745 of the European Parliament and of the Council as regards electronic instructions for use of medical devices
THE EUROPEAN COMMISSION,
Having regard to Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (1), and in particular Article 10(8) thereof,
Whereas:


INTERNATIONAL STANDARD
ISO 13485
Third edition
2016-03-01
Medical devices — Quality management systems — Requirements for regulatory purposes
Dispositifs médicaux — Systèmes de management de la qualité — Exigences à des fins réglementaires


IEC 62304
Edition 1.0 2015-06
INTERNATIONAL STANDARD
AMENDMENT 1
Medical device software – Software life cycle processes


DS/EN ISO 14971:2019
EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM
EN ISO 14971
December 2019
ICS 11.040.01
Supersedes EN ISO 14971:2012
English Version
Medical devices - Application of risk management to medical devices (ISO 14971:2019)
Dispositifs médicaux - Application de la gestion des risques aux dispositifs médicaux (ISO 14971:2019)
Medizinprodukte - Anwendung des Risikomanagements auf Medizinprodukte (ISO 14971:2019)
This European Standard was approved by CEN on 5 August 2019.
CEN and CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN and CENELEC member.
This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN and CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.
CEN and CENELEC members are the national standards bodies and national electrotechnical committees of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

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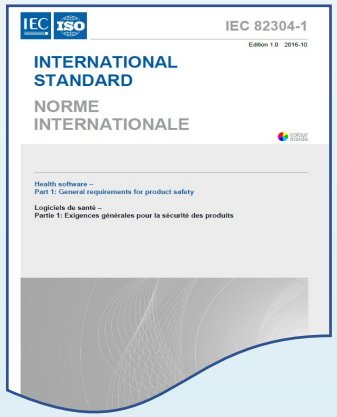
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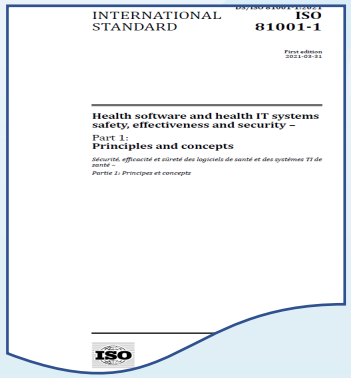
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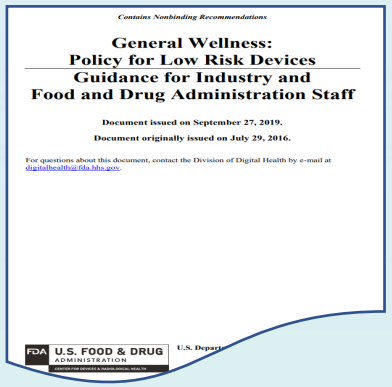
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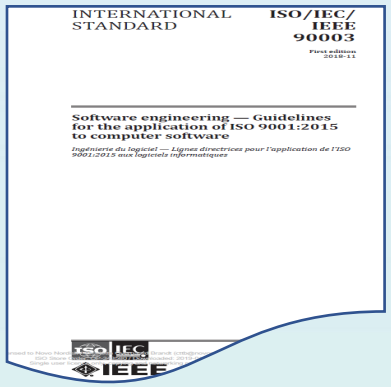
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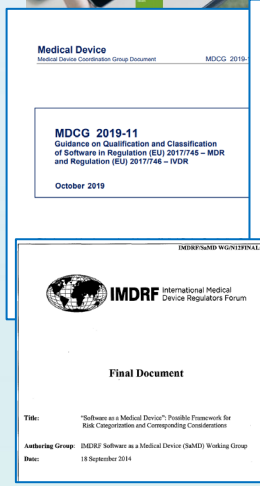
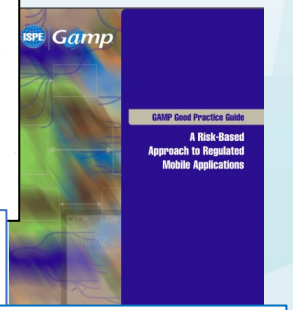
First edition 2018-11
Software engineering — Guidelines for the application of ISO 9001:2015 to computer software
Ingénierie du logiciel — Lignes directrices pour l'application de l'ISO 9001:2015 aux logiciels informatiques

Device

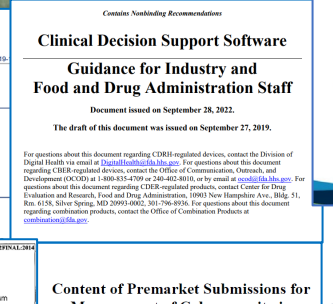

Is your software a
Medical Device?


Contains Nonbinding Recommendations
Policy for Device Software Functions and Mobile Medical Applications
Guidance for Industry and Food and Drug Administration Staff
Document issued on September 27, 2019.
Document originally issued on September 25, 2013.
This document supersedes "Mobile Medical Applications" issued February 9, 2015.
For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health by e-mail at digitalhealth@fda.hhs.gov.
For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8

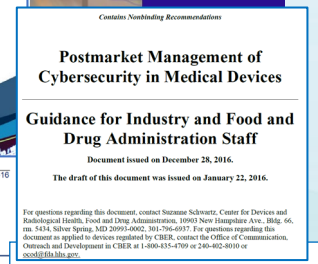

IMDRF/SaMD WG/N23 FINAL: 201
IMDRF International Medical Device Regulators Forum
FINAL DOCUMENT
International Medical Device Regulators Forum
Title: Software as a Medical Device (SaMD): Application of Quality Management System
Authoring Group: IMDRF SaMD Working Group
Date: 2 October 2015


ISPE Gamp
GAMP Good Practice Guide
A Risk-Based Approach to Regulated Mobile Applications

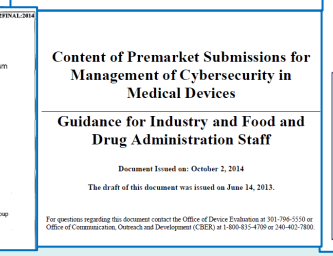
Medical Device
Medical Device Coordination Group Document MDCG 2019-
MDCG 2019-11
Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR
October 2019

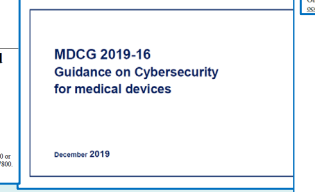

Contains Nonbinding Recommendations
Clinical Decision Support Software
Guidance for Industry and Food and Drug Administration Staff
Document issued on September 28, 2022.
The draft of this document was issued on September 27, 2019.
For questions about this document regarding CDRH-regulated devices, contact the Division of Digital Health via email at DigitalHealth@fda.hhs.gov. For questions about this document regarding CBER-regulated devices, contact the Office of Communication, Outreach, and Development (OCOD) at 1-800-835-4709 or 240-402-8010, or by email at ocod@fda.hhs.gov. For questions about this document regarding CDER-regulated products, contact Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6158, Silver Spring, MD 20993-0002, 301-796-8936. For questions about this document regarding combination products, contact the Office of Combination Products at combination@fda.gov.

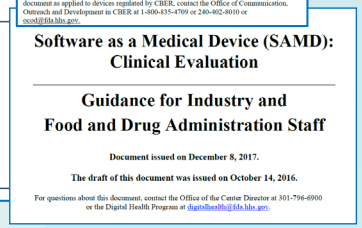

Australian Government
Department of Health
Therapeutic Goods Administration
Classification of active medical devices (including software-based medical devices)
Industry guidance
Version 1.0, October 2021
TGA Health Safety Regulation
Medical Device
Medical Device Coordination Group Document MDCG 2019-16


Contains Nonbinding Recommendations
Postmarket Management of Cybersecurity in Medical Devices
Guidance for Industry and Food and Drug Administration Staff
Document issued on December 28, 2016.
The draft of this document was issued on January 22, 2016.
For questions regarding this document, contact Suzanne Schwartz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, rm. 5434, Silver Spring, MD 20993-0002, 301-796-6937. For questions regarding this document as applied to devices regulated by CBER, contact the Office of Communication, Outreach and Development in CBER at 1-800-835-4709 or 240-402-8010 or ocod@fda.hhs.gov.

IMDRF/SaMD WG/N12FINAL:2014
IMDRF International Medical Device Regulators Forum
Final Document
Title: "Software as a Medical Device": Possible Framework for Risk Categorization and Corresponding Considerations
Authoring Group: IMDRF Software as a Medical Device (SaMD) Working Group
Date: 18 September 2014


Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
Guidance for Industry and Food and Drug Administration Staff
Document Issued on: October 2, 2014
The draft of this document was issued on June 14, 2013.
For questions regarding this document contact the Office of Device Evaluation at 301-796-5550 or Office of Communication, Outreach and Development (CBER) at 1-800-835-4709 or 240-402-7800.


MDCG 2019-16
Guidance on Cybersecurity for medical devices
December 2019


Software as a Medical Device (SAMD): Clinical Evaluation
Guidance for Industry and Food and Drug Administration Staff
Document issued on December 8, 2017.
The draft of this document was issued on October 14, 2016.
For questions about this document, contact the Office of the Center Director at 301-796-6900 or the Digital Health Program at digitalhealth@fda.hhs.gov.

Considerations for QMS strategy

- Software may start as non-device but can later have device functions added
- Software may stay non-device
- Software may be device but under enforcement discretion
- Lighter pathway for non-device...device requirements are complex and market authorisation by Health Authorities not relevant
- We want to avoid rework

Considerations for QMS strategy

1

Common process for physical devices and software (SaMD and non-device):

- **the different pathways/ interpretations/deliverables for each must be built in**

2

Separate process for physical devices, common process for SaMD and non-device software with built-in flexibility:

- **pre-defined basic level**
- **Specified add-ons for SaMD**

4

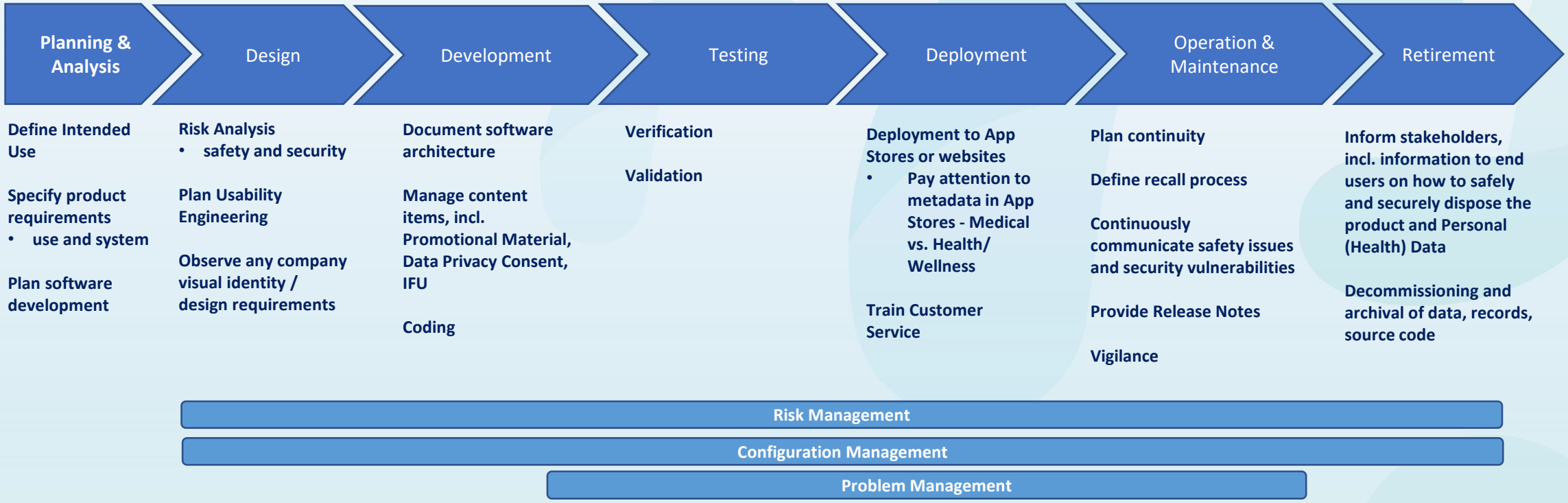
- **Option 1 or 2 for physical devices and SaMD**
- **Include non-device software in the existing process for GxP-regulated software/IT**

3

Different process, SOPs, templates for each product type

- **leverage processes applying across e.g., Management Review, Change Control, CAPA, Complaint Handling, Recall, Customer Service**

Consistent approach to lifecycle for device and non-device software



Example QMS strategy

Management Review

Change Control

CAPA

Postmarket surveillance — *In case of e.g. free text fields*

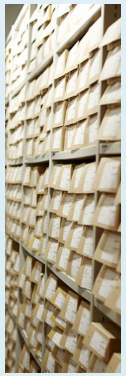
Customer Service

Medical Device with embedded software (SiMD)

- Own process, set of SOPs, and templates
- Separate ISO 13485, EU MDR, and MDSAP certificates for the product type

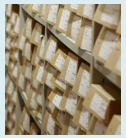
Software as a Medical Device (SaMD)

- Own process, set of SOPs, and templates
- Separate ISO 13485 and EU MDR certificates for the product type



Non-device software

- Own process, SOP, and templates
- Mandatory QA approval of risk management deliverables



For software products intended to later include device functions:

Establish and manage according to the process for SaMD – with certain exceptions

Example QMS strategy

For software products intended to later include device functions:

Establish and manage according to the process for SaMD – with certain exceptions

Not required for non-device software:

- **Analysis and Conclusion of Market Feedback**
- **Clinical Evaluation Planning and Reporting**
- **Human Factors Engineering Planning and Reporting**
- **UDI assignment and registration of UDI in databases**
- **Post-Market Surveillance Plan; post-market activities are however expected**
- **Labelling – replaced however by Accompanying Documents, including Instructions for Use (IFU)**
- **Market authorisation by Health Authorities**

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Q&A

AFDO RAPS HEALTHCARE PRODUCTS COLLABORATIVE