Software as Medical Device
Definition and Classification in EU, US, China, and Japan

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Compliance & Risks

Q&A Session

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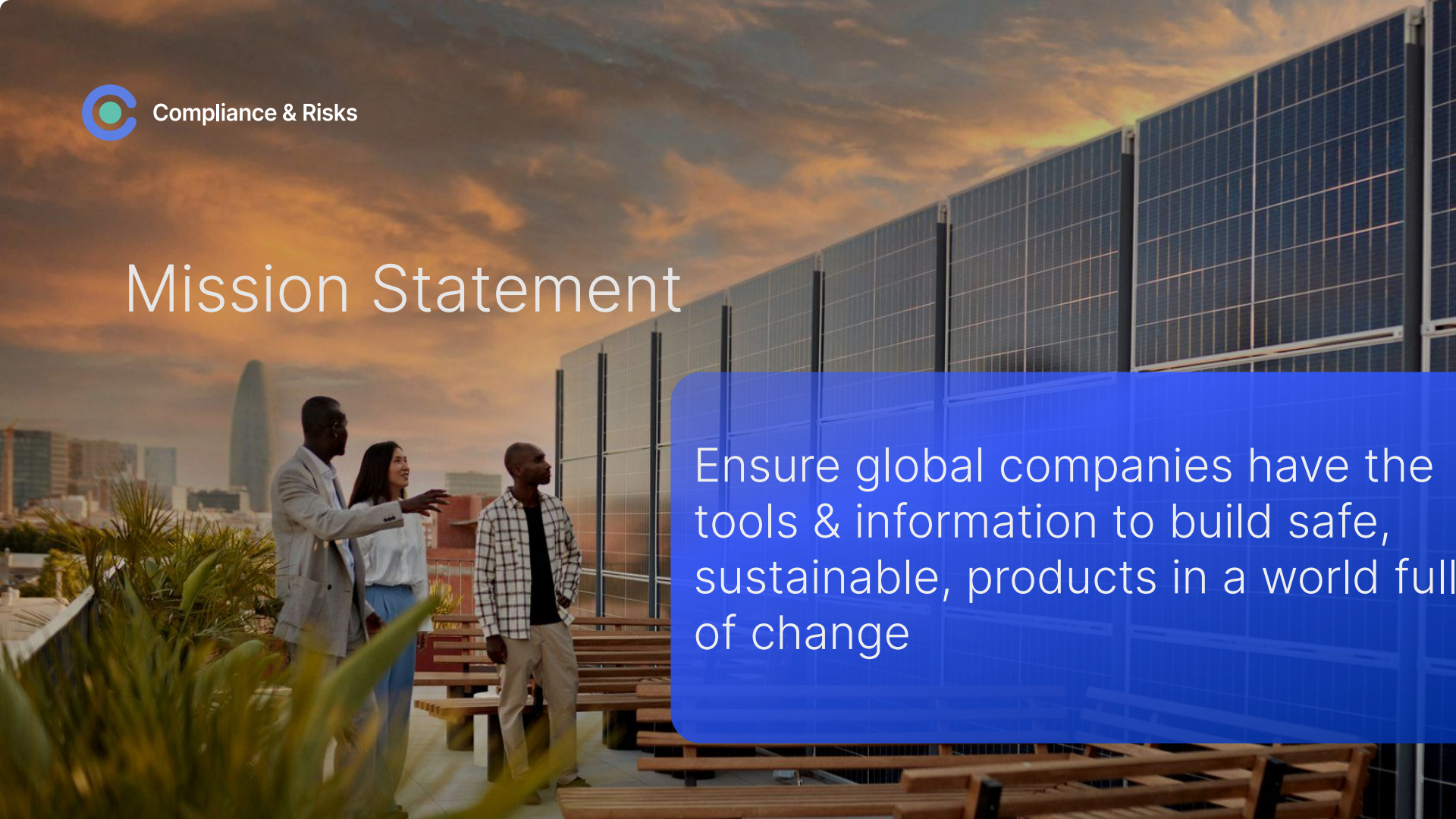

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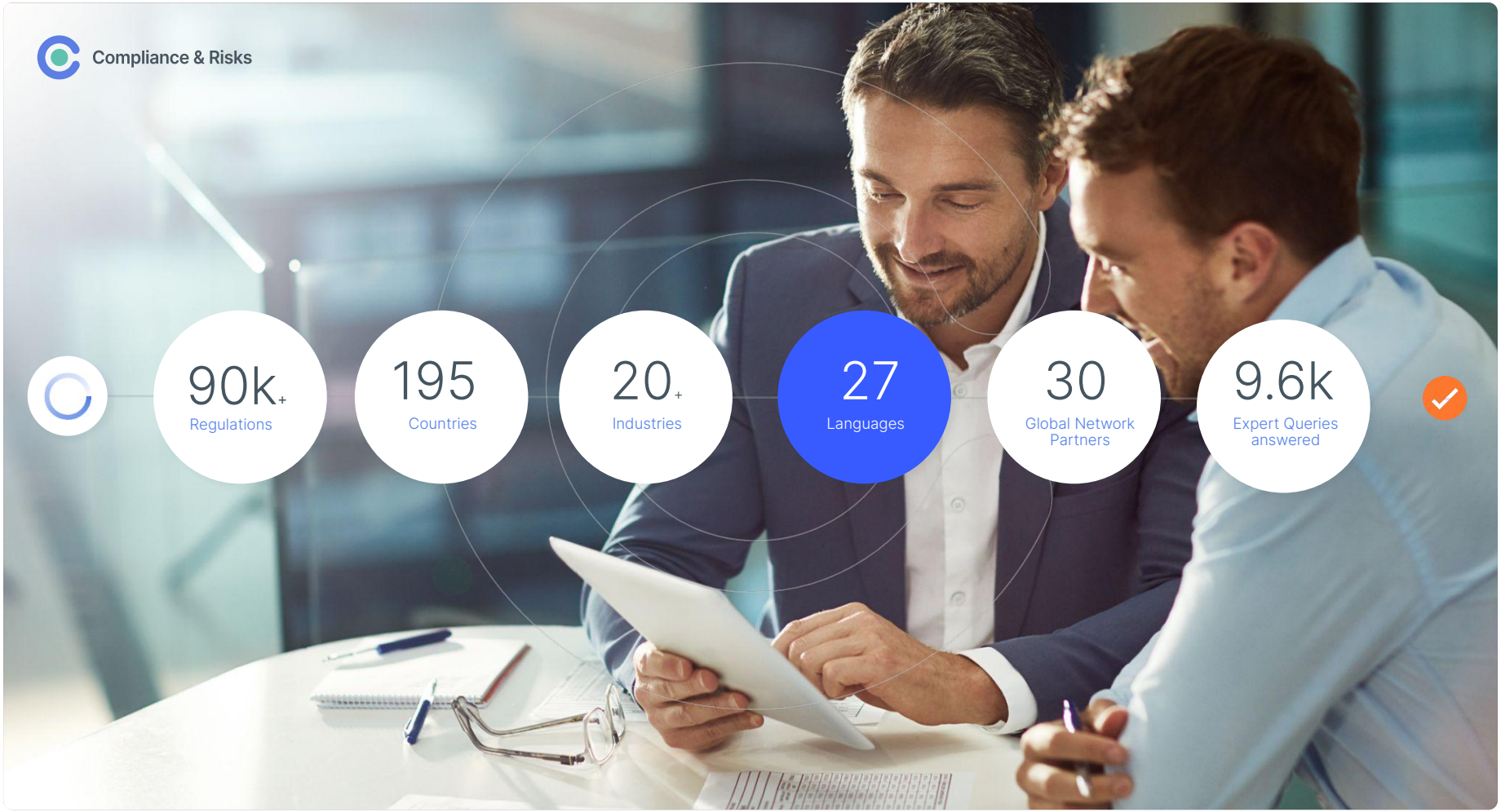

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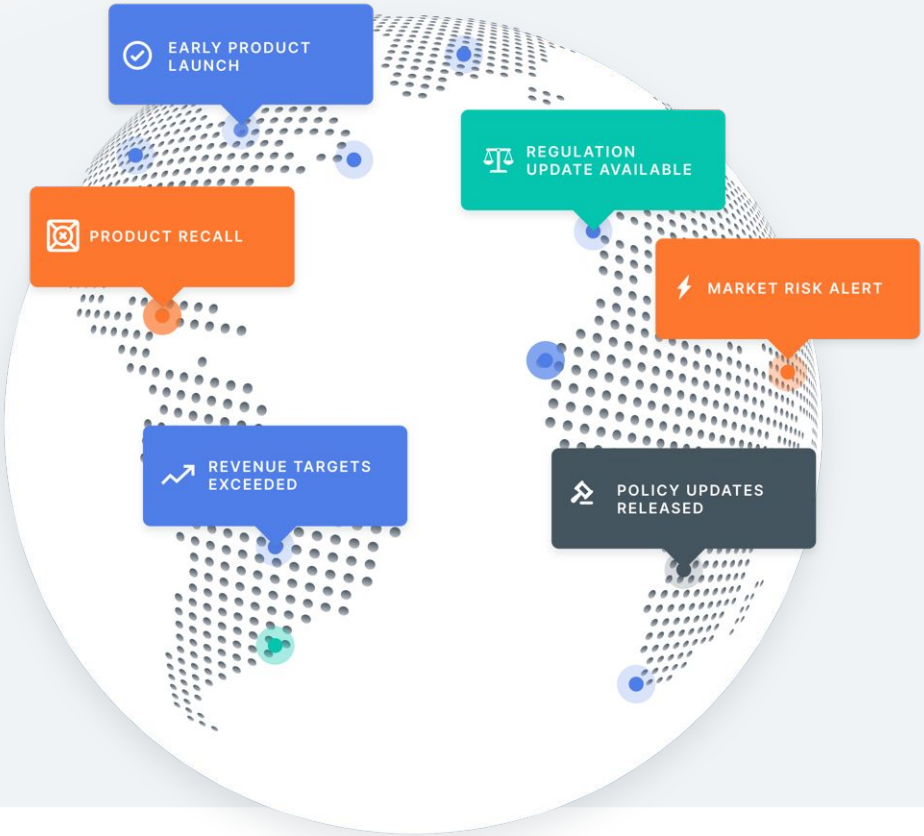


01

Definitions of SaMD

SaMD - What is it?

"Software intended for one or more medical purposes that perform those purposes without being part of a hardware medical device."

The International Medical Device Regulators Forum (IMDRF)

"Medical Device Software (MDSW)" is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the medical devices regulation or in vitro diagnostic medical devices regulation

EU MDR Article 2

"Software that meets the definition of a device in 181 section 201(h) of the FD&C Act and is intended to be used for one or more medical purposes without being part of a hardware device."

FDA

"Software intended for one or more medical purposes that runs on general-purpose computing platforms and perform those purposes without being part of a hardware medical device."

China Administrative Regulations on Manufacturing
Software as a Medical Device

Software as a Medical Device refers to software that falls under the definition of "medical devices" under the Act, including:
- Disease diagnosis software or discs containing its data
- Disease treatment softwiare or discs containing its data
- Disease prevention software or discs containing their data

Japan Ministry of Health, Labour and Welfare (MHLW)

EU

- MDCG 2019-11 Guidance on Qualification and Classification of Software in MDR and IVDR

- “*Software*” is defined as a set of instructions that processes input data and creates output data.

- “Medical Device Software (MDSW)” is software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a “medical device” in the medical devices regulation or in vitro diagnostic medical devices regulation.

USA

Food Drugs and Cosmetics Act, 21 U.S.C. 301, 1938

The term “device” means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is—

(1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,

(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or

(3) intended to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

The term “device” does not include software functions excluded pursuant to section 360j(o) of this title.

China

Administrative Regulations on Manufacturing Software as Medical Device, Notice No. 43, 2019

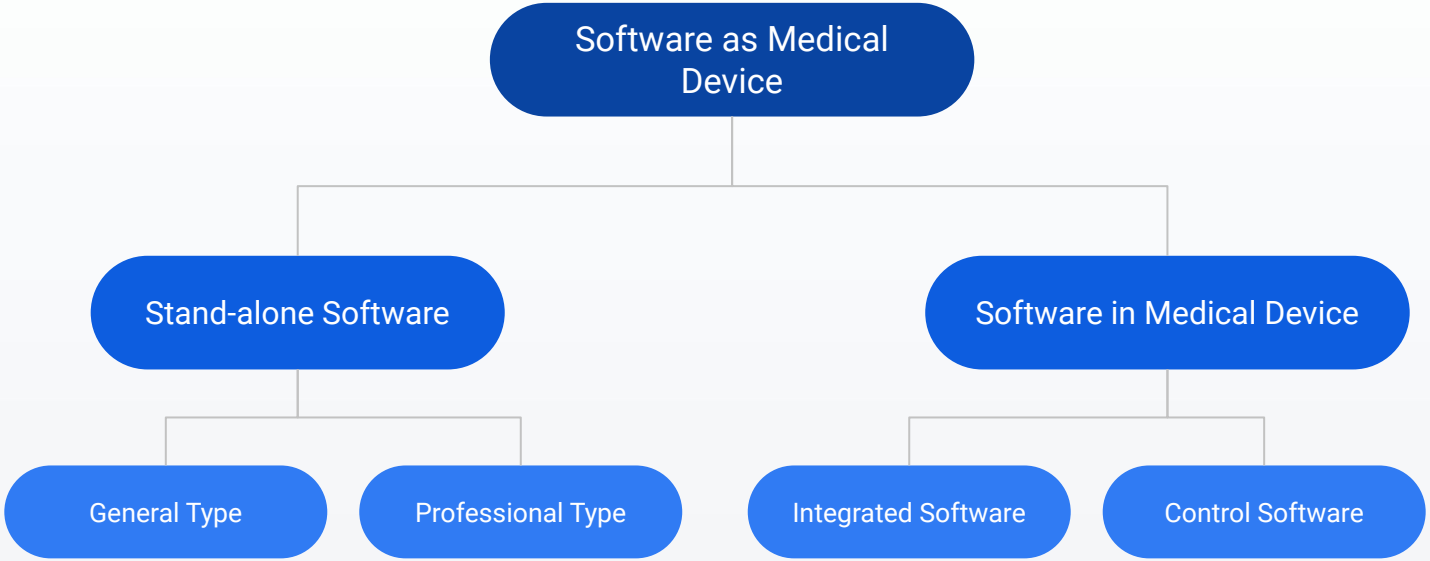
Registration and Review of Medical Device Software, Guidelines, March 2022

Software as Medical Device consists of the following two

- "*Stand alone Software*" means software intended for one or more medical purposes that runs on general-purpose computing platforms and perform those purposes without being part of a hardware medical device

- "*Software in Medical Device*" means software intended for one or more medical purposes that controls or drives medical device hardware or runs on a medical computing platform. The medical computing platform must comply with safety requirements for medical electrical equipment (GB 9706 series), laboratory electrical equipment (GB 4793 series), or active implantable medical devices (GB 16174 series); the medical computing platform and general computing platforms may be used jointly to form a system, the entire system is regarded as a medical computing platform.

China


Software as Medical Device
Stand-alone Software
Software in Medical Device
General Type
Professional Type
Integrated Software
Control Software

Japan

- Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
- Enforcement Order of the Act – Appended Table 1
- Guidelines Regarding the Eligibility of the Program As a Medical Device, March 2023

Software as a Medical Device refers to software that falls under the definition of “medical devices” under the Act, including:

1.- Disease diagnosis software or discs containing its data
2.- Disease treatment software or discs containing its data
3.- Disease prevention software or discs containing their data

02

Other Types of Software

EU

- ”*Software driving or influencing the use of a device*” is defined as software which is intended to drive or influence the use of a (hardware) medical device and does not have or perform a medical purpose on its own, nor does it create information on its own for one or more of the medical purposes described in the definition of a medical device or an in vitro diagnostic medical device. This software can, but is not limited to:

(a) operate, modify the state of, or control the device either through an interface (e.g., software, hardware) or via the operator of this device

(b) or supply output related to the (hardware) functioning of that device

- Hospital Information Systems
- Decision Support Software
- Information System
- Communication System
- Web systems for monitoring of data

USA

- *Software Excluded*
- *Mobile Medical Application*

“ a mobile application” or “mobile app” is defined as a software application that can be executed (run) on a mobile platform (i.e., a handheld commercial off-the shelf computing platform, with or without wireless connectivity), or a web-based software application that is tailored to a mobile platform but is executed on a server, and either are intended:

· to be used as an accessory to a regulated medical device; or

· to transform a mobile platform into a regulated medical device.

- *Off the Shelf Software Use in Medical Devices*

OTS Software refers to a generally available software component used by a device manufacturer for which the manufacturer cannot claim complete software life cycle control (e.g., operating system, printer/display libraries).

USA

Clinical Decision Support Software (CDS), in order to be excluded from the device definition:

- Not intended to acquire, process, or analyze a medical image or a signal
- Intended for the purpose of displaying, analyzing, or printing medical information about a patient or other medical information
- Intended for the purpose of supporting or providing recommendations to an HCP about prevention, diagnosis, or treatment of a disease or condition
- Intended for the purpose of enabling an HCP to independently review the basis for the recommendations that such software presents so that it is not the intent that the HCP rely primarily on any of such recommendations to make a clinical diagnosis or treatment decision regarding an individual patient

Medical Device Data System (MDDS)

- Non-Device-MDDS: Software functions that are solely intended to transfer, store, convert formats, or display medical device data and results.
- Device-MDDS: Hardware functions that are solely intended to transfer, store, convert formats, or display medical device data and results.

China

System Software – software designed to ensure the normal operation of a computer system, such as operating system software and virtual machine software

Application Software – software designed to fulfil specific needs of computer users, such as browser software, database, and security software.

Intermediate Software – software between system software and application software, It relies on the support of system software and at the same time provides support for application software, such as distributed computing platform software.

Support software – software designed to develop and test other software, such as software development tools and software testing tools

China

Essential Software – other medical device software and intermediate software for medical purpose

External Environment Software – other system software, general application software, general intermediate software and supporting software

Japan

Guidelines Regarding the Eligibility of the Program As a Medical Device, March 2023

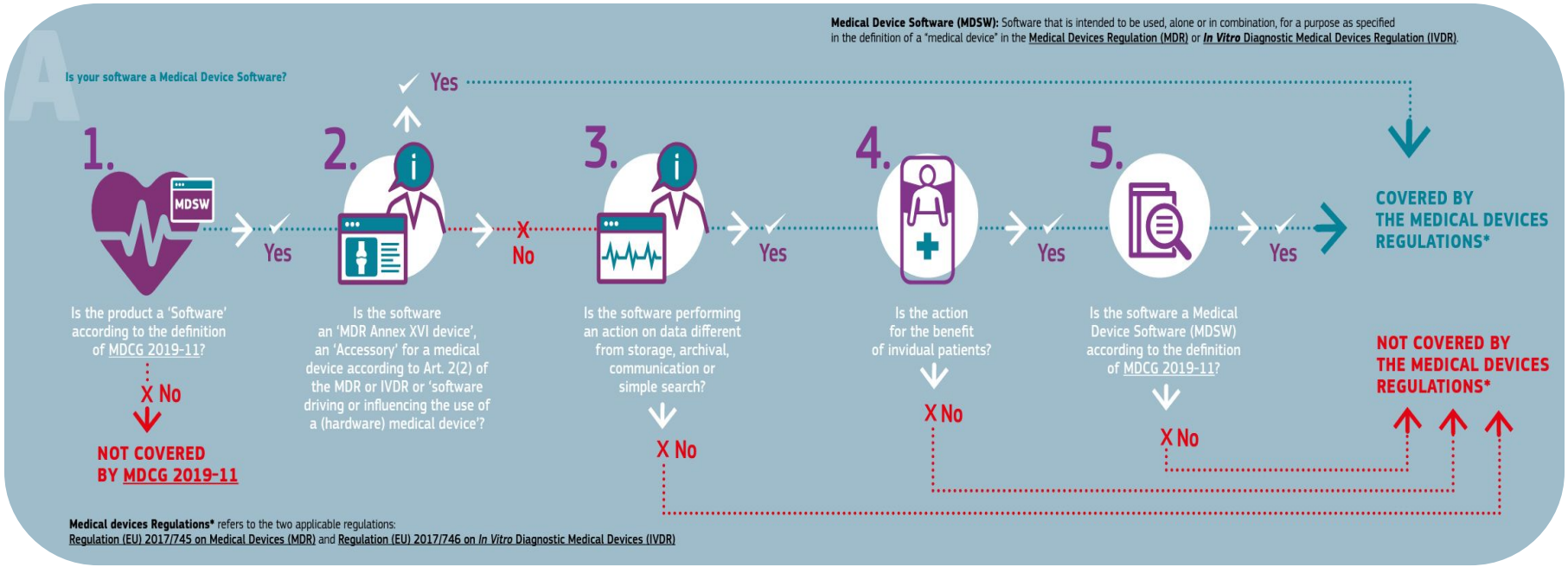
- Software provide information vs. Disease Risk Indicating Software
- Public known information vs. Individual cases
- Risk of affecting human life or health

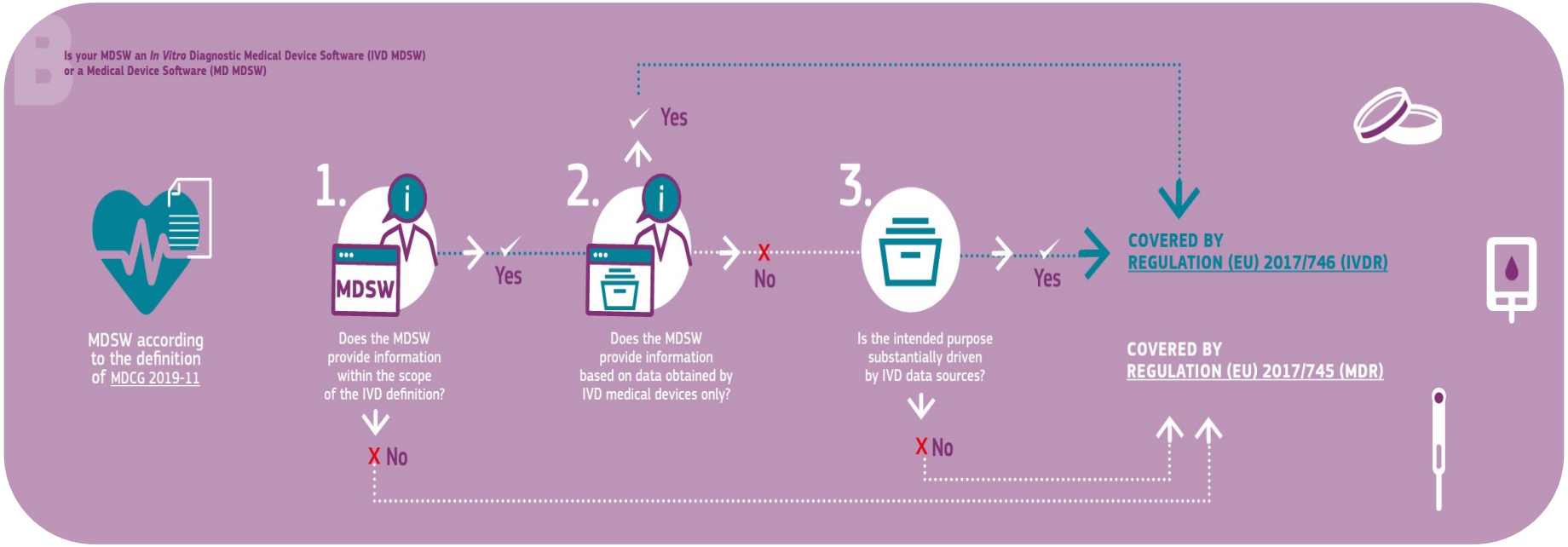
03

Guidance and Examples on Qualification of SaMD

EU – Qualification Criteria

- Intended medical purpose
- Fulfil the definition of software and the definition of medical device or IVDR
- Accessories of medical device
- Manual on borderline and classification for medical devices under Regulation (EU) 2017/745 on medical devices and Regulation (EU) 2017/746 on in vitro diagnostic medical devices


Medical Device Software (MDSW): Software that is intended to be used, alone or in combination, for a purpose as specified in the definition of a "medical device" in the Medical Devices Regulation (MDR) or In Vitro Diagnostic Medical Devices Regulation (IVDR).
Is your software a Medical Device Software?
Yes
1.
MDSW
Yes
Is the product a 'Software' according to the definition of MDCG 2019-11?
X No
NOT COVERED BY MDCG 2019-11
2.
X
No
Is the software an 'MDR Annex XVI device', an 'Accessory' for a medical device according to Art. 2(2) of the MDR or IVDR or 'software driving or influencing the use of a (hardware) medical device'?
3.
Yes
Is the software performing an action on data different from storage, archival, communication or simple search?
X No
4.
Yes
Is the action for the benefit of invidual patients?
X No
5.
Yes
Is the software a Medical Device Software (MDSW) according to the definition of MDCG 2019-11?
X No
COVERED BY THE MEDICAL DEVICES REGULATIONS*
NOT COVERED BY THE MEDICAL DEVICES REGULATIONS*
Medical devices Regulations* refers to the two applicable regulations:
Regulation (EU) 2017/745 on Medical Devices (MDR) and Regulation (EU) 2017/746 on In Vitro Diagnostic Medical Devices (IVDR)


Is your MDSW an *In Vitro* Diagnostic Medical Device Software (IVD MDSW) or a Medical Device Software (MD MDSW)
MDSW according to the definition of MDCG 2019-11
1.
MDSW
Does the MDSW provide information within the scope of the IVD definition?
Yes
X No
2.
Yes
Does the MDSW provide information based on data obtained by IVD medical devices only?
X No
3.
Is the intended purpose substantially driven by IVD data sources?
Yes
X No
COVERED BY REGULATION (EU) 2017/746 (IVDR)
COVERED BY REGULATION (EU) 2017/745 (MDR)

USA

How to Determine Your Product is a Medical Device

If you are still unsure whether your product would be considered a device software function, please contact digitalhealth@fda.hhs.gov

Digital Health Policy Navigator – A tool to help in determining whether your product's software functions are potentially the focus of the FDA's oversight

- Step 1: Is the software function intended for a medical purpose?
- Step 2: Is the software function intended for administrative support of a health care facility?
- Step 3: Is the software function intended for maintaining or encouraging a healthy lifestyle?
- Step 4: Is the software function intended to serve as electronic patient records?
- Step 5: Is the software function intended for transferring, storing, converting formats, or displaying data and results?
- Step 6: Is the software function intended to provide clinical decision support?
- Step 7: Does the Device Software Functions and Mobile Medical Applications Guidance apply?

China

Medical Device Classification Catalogue, Announcement No. 104, 2017

- only stand alone software

- 6 categories, 51 examples

与 2002 版分类目录对应关系

一级产品类别	2002 版产品类别	备注
21-01 治疗计划软件	6870-1 功能程序化软件	/
21-02 影像处理软件	6870-2 诊断图象处理软件	/
	6870-4 影象档案传输、处理系统软件	
21-03 数据处理软件	6870-3 诊断数据处理软件	/
21-04 决策支持软件	/	新增。此类软件提供辅助诊断或者用药建议等决策。
21-05 体外诊断类软件	/	单独设置。体外诊断软件有一定的特殊性，软件可能既包括图像处理，也包括数据处理，所以不能按照图像处理软件和数据处理软件进行分类。
21-06 其他	/	新增。康复训练软件有特殊性，不能按照图像处理软件和数据处理软件进行分类。

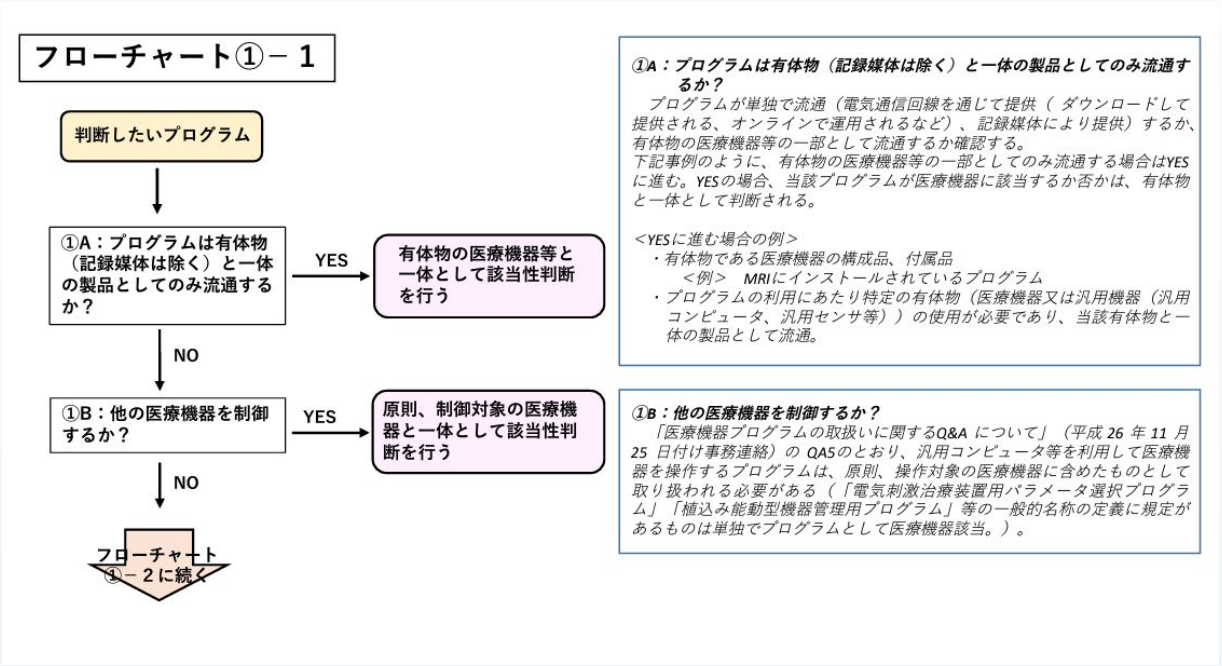
China

Medical Device Classification System

http://app.nifdc.org.cn/biaogzx/login.do?formAction=login&systemType=2

Japan

- Guidelines Regarding the Eligibility of the Program As a Medical Device, March 2023



Japan

Examples of Determining the Eligibility of the Program as a Medical Device

- Items that fall under medical device
- Items that do not fall under medical devices

- programs intended for personal use

- programs intended for use by medical professionals

- a program that performs the same processing as general medical devices (Class I MD)

Medical Device Program Case Database

https://www.mhlw.go.jp/content/11120000/001100725.xlsx

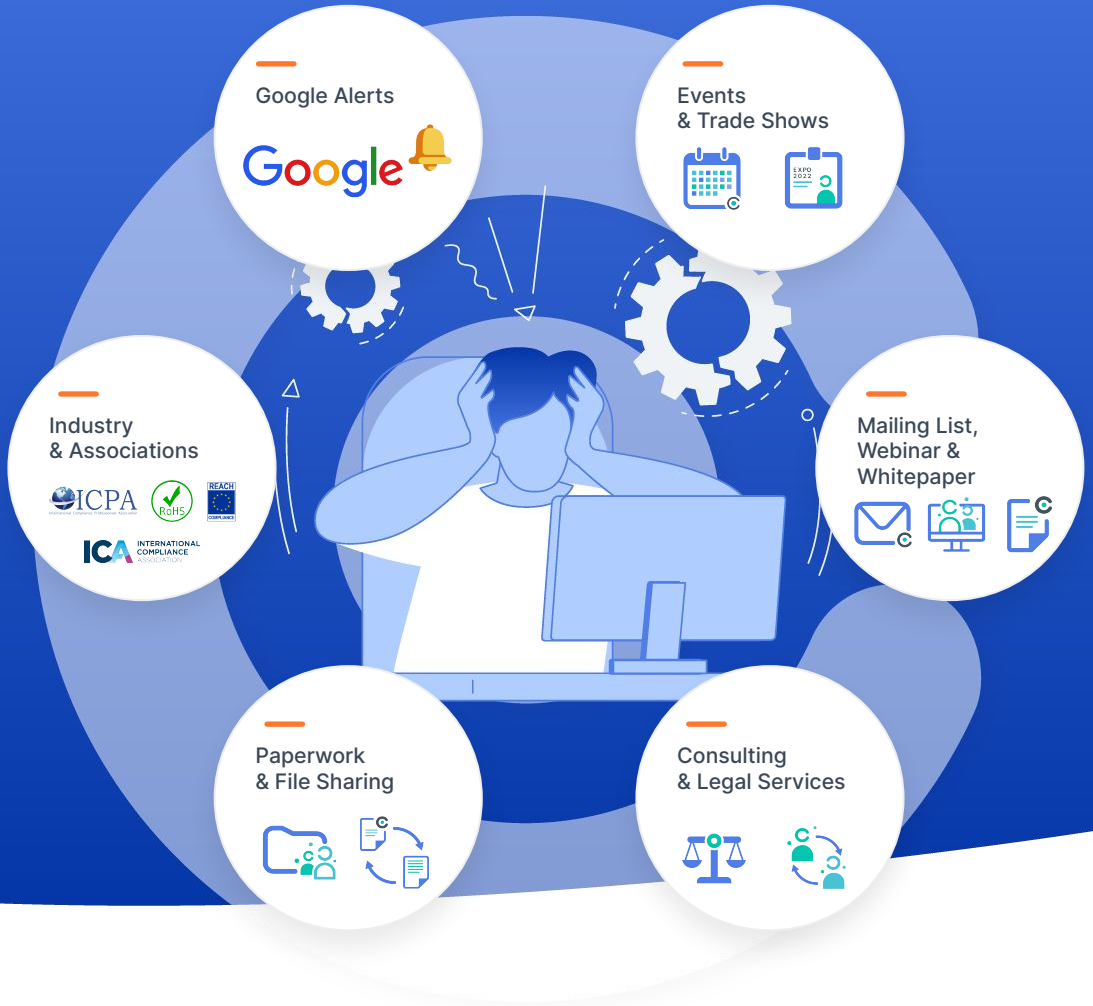
Q&A on Guidelines Regarding the Eligibility of the Program As a Medical Device, March 2023

04

Classification Rules

- IMDRF Guidance on Possible Framework for Risk Categorization and Corresponding Considerations provides several clarifying points to the SaMD definition which would help with identification and classification of SaMD
- EU MDR Chapter II Software, which drives a device or influences the use of a device, shall fall within the same class as the device; If the software is independent of any other device, it shall be classified in its own right.
- Classification Rule 11 sets out classification of software
- FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices is intended to provide information to industry regarding the documentation to include in premarket submissions for software devices, including standalone software applications and hardware-based devices that incorporate software.
- China Rules on Classification of Medical Devices and Catalogue
- Japanese Medical Device Nomenclature (JMDN)

Trying to keep on top of it all...



04

A Smarter Way to Manage Product Compliance

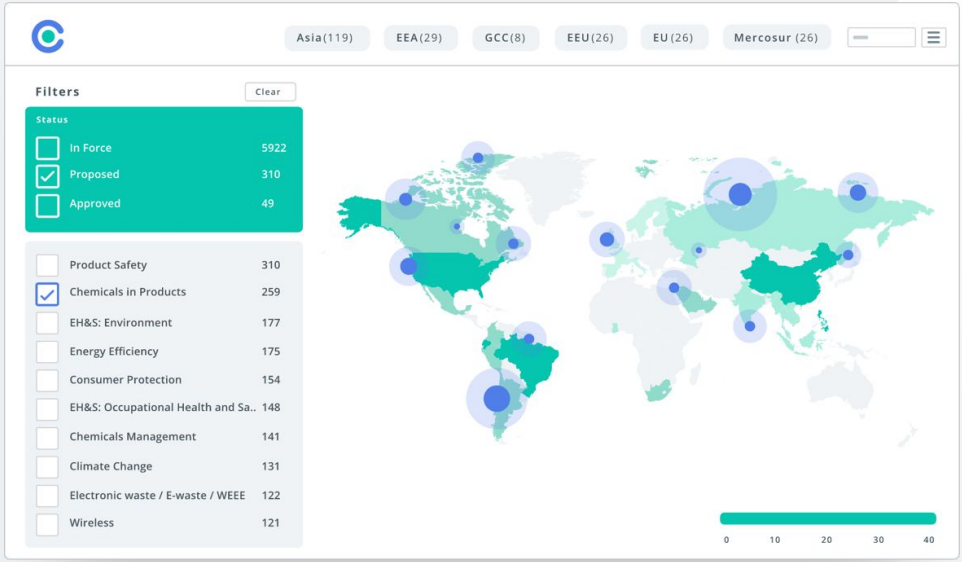
Holistic Market Access Solutions

TECHNOLOGY - C2P

C2P

The Key to Unlocking Market Access

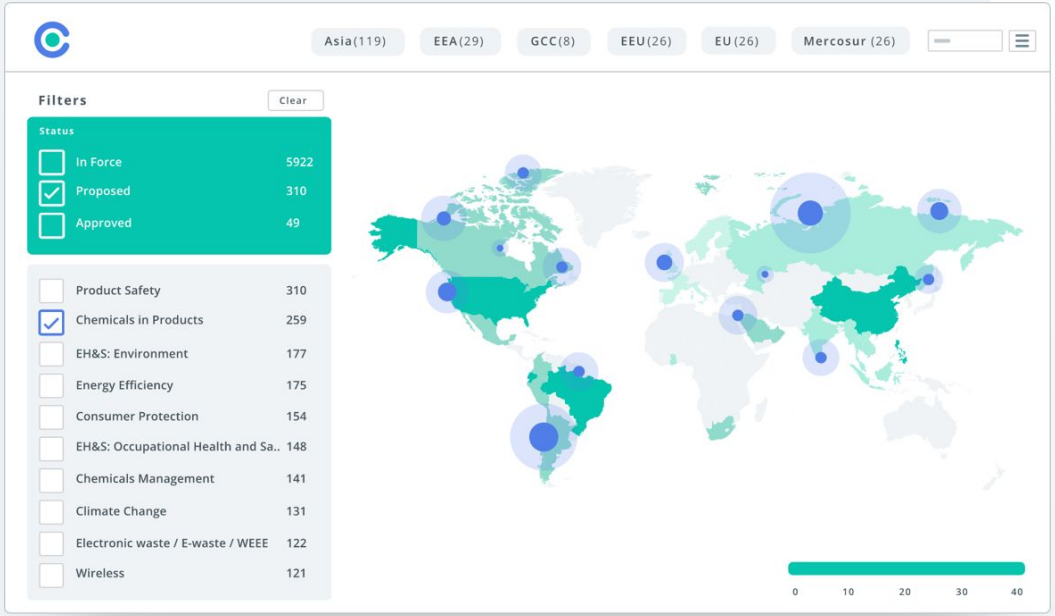
- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



TECHNOLOGY - C2P

Manage everything in One Place...

- Design, build, and collaborate on new products with confidence
- Keep all compliance evidence up to date & live linked back to their Regulations, Standards & Requirements
- Continually monitor regulatory changes & keep ahead of proposed changes before they happen
- Integrate with other systems to enable streamlined business processes

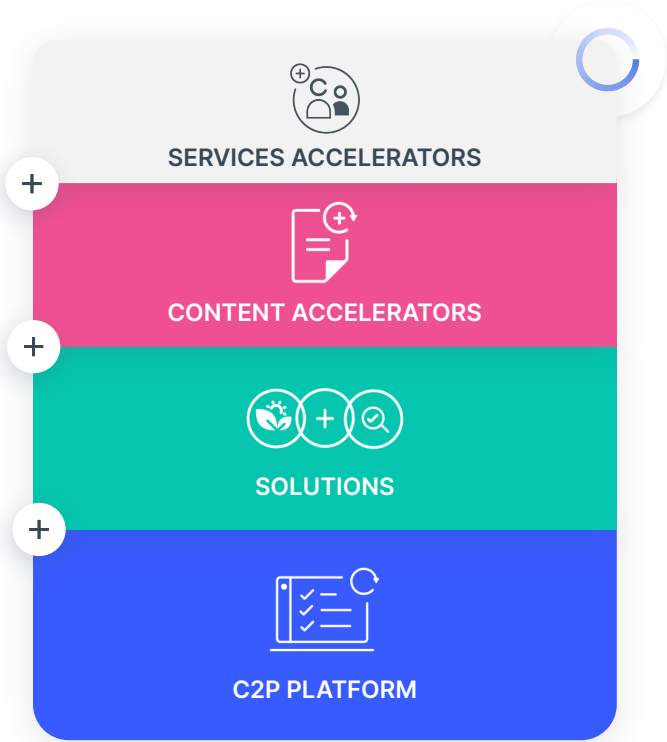


TECHNOLOGY - C2P

Tailored to meet your needs...

- Comprehensive capabilities that enable enterprise-wide management of regulations, standards, requirements and evidence

- Add-on packages to accelerate market access through:
  - Use-case specific solutions
  - Global regulatory content
  - Professional services



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Unrivalled Global Medical Device Coverage

- Compliance news & alerts, requirements types, topics, materials & substances, products covered, key dates, deadlines, exceptions & exemptions
- Commentary from regional experts in the Americas, EMEA & Asia

41+
Topics covered

195
Countries monitored

13,485+
Regulatory Sources

REGULATORY CONTENT

Medical Devices Focus Areas

Our content coverage helps you manage critical product compliance issues easily

- Definition and Classification of Medical Devices
- Safety & Efficacy / Performance Requirements
- Conformity Assessment Procedures
- Cybersecurity
- Technical Documentation
- Labeling and Packaging
- Testing (clinical trial and evaluation)
- Mandatory Unique Device Identification (UDI) mechanisms
- Requirements for Qualified Persons
- Registration
- Post-Market Surveillance and Consumer Protection

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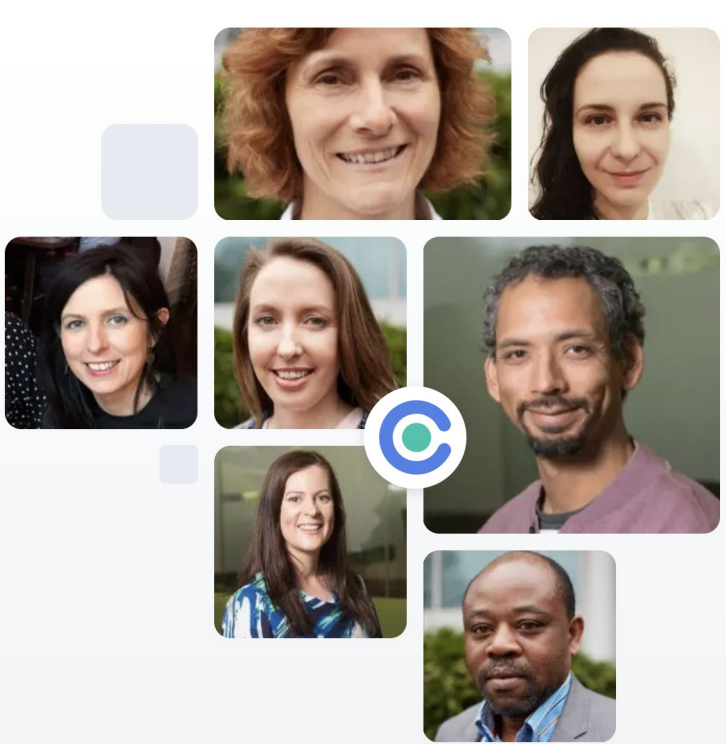
- Extensive Knowledge Partner network
- Expertise across products, geographies & policy areas
- Addressing questions on laws & regulations including purpose, applicability, requirements highlights & more.



Q&A

Thank you!

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