Regulatory Update

Stay Compliant: Medical Device Industry 2022

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Compliance & Risks

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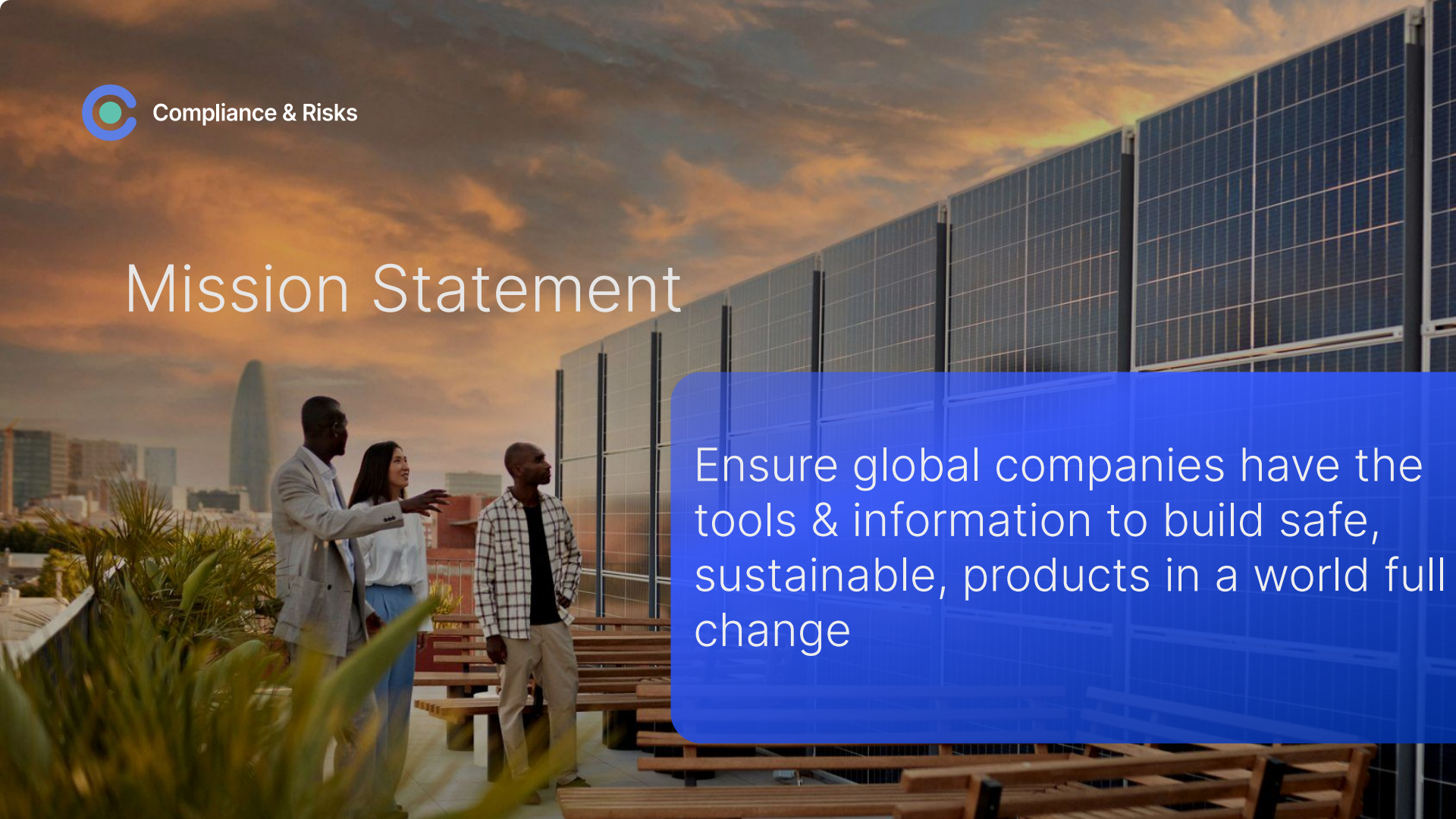
Mission Statement



Ensure global companies have the tools & information to build safe, sustainable, products in a world full change

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Sources
195
Countries
20+
Industries
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Languages
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Expert Questions answered in 2021

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Unlocking Market Access

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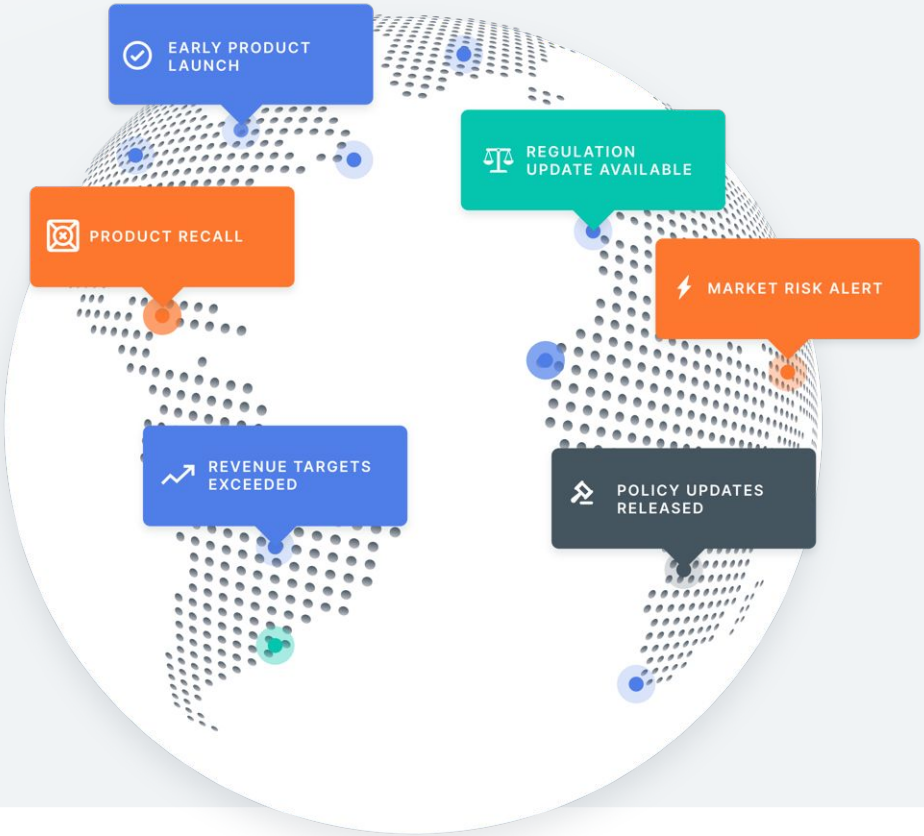


Stay Compliant: Medical Device Industry 2022

Compliance & Risks

EU

- General Principles of Clinical Evidence for In Vitro Diagnostic Medical Devices (IVDs), Guidance Document, MDCG 2022-2, Jan 2022
  - outlines the general principles of clinical evidence and provides guidance on the continuous process of performance evaluation for IVDs, as set out in Regulation (EU) 2017/746

- Guidance on significant changes regarding the transitional provision under Article 110(3) of the IVDR, Medical Devices, MDCG 2022-6, May 2022
  - intended to provide clarification on the concept of ‘significant changes in the design and intended purpose’ under IVDR Article 110(3).

- Application of IVDR Requirements to ‘Legacy Devices’ and to Devices Placed on the Market Prior to 26 May 2022, Guidance Document, MDCG 2022-8, May 2022
  - Regulation (EU) 2022/1121 extended the transitional provisions of Regulation (EU) 2017/746 on in vitro diagnostic medical devices (IVDR), in particular its Article 110(3), in terms of scope and timing.

EU

- Questions and Answers on the Unique Device Identification System, Guidance Document, MDCG 2022-7, and Summary of Safety and Performance Template, Guidance Document, MDCG 2022-9, May 2022

- Harmonised Administrative Practices and Alternative Technical Solutions until Eudamed is Fully Functional (for IVDR), Guide Doc, MDCG 2022-12, July 2022
  - Provides guidance on the application of certain IVDR provisions during the absence of Eudamed
  - Describes harmonised administrative practices and alternative technical solutions for the exchange of information until Eudamed becomes fully functional.

- Transition to the MDR and IVDR - Notified Body Capacity and Availability of Medical Devices and IVDs, Guidance Document, MDCG 2022-14, Aug 2022
  - Sufficient capacity of notified bodies
  - Actions to enhance notified body capacity, to avoid shortage of medical devices.

EU

- Common Specifications for Certain Class D In Vitro Diagnostic Medical Devices in Accordance with Regulation (EU) 2017/746, Regulation (EU) 2022/1107, July 2022
    - To ensure a continuous high level of safety and performance of devices, as a transitional measure, it is presumed that devices in conformity with Decision 2002/364/EC are in conformity with the requirements for certain performance characteristics set out in Annex I of Regulation (EU) 2017/746 until 25 July 2024.
- Implementing Regulation on the tasks of and criteria for European Union reference laboratories in the field of in vitro diagnostic medical devices , Regulation (EU) 2022/944, June 2022
    - Develops the scope of the tasks of the EU reference laboratories as depicted in article 100 of Regulation (EU) 2017/746
- Proposed -Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Regulation (EC) 1907/2006 - Proposed Amendment - (on adding synthetic polymer microparticles to Annex XVII) Draft Regulation, September 2022
    - Proposal to restrict the placing on the market of microplastics

EU

- Team-NB Application of Hybrid Audits to Quality Management System Assessments Under MDR/IVDR, Guidance Document, Sept 2022
  - Notified bodies' collective position on the aspects to be considered when employing ICT-based auditing in QMS audits specifically to MDR/IVDR and especially in the context of hybrid audits.

- Reclassification of groups of certain active products without an intended medical purpose, Draft Reg, 2022, Aug 2022
  - Ensure products without a medical purpose that fall under the Medical Device Regulation are appropriately classified by risk, and subject to the same pre- and post-market requirements as comparable medical devices.

- Status of the EU-switzerland Mutual Recognition Agreement (MRA) for In Vitro Diagnostic Medical Devices, Notice, May 2022
  - As of 26 May 2022, for new IVDs, Swiss manufacturers will be treated as any other third country manufacturer intending to place its devices on the EU market.
  - For IVDs placed on the market after 26 May 2022, Swiss manufacturers and third country manufacturers whose authorised representative was previously established in Switzerland must designate an authorised representative established in the EU.

Ireland

- In Vitro Diagnostic Medical Devices, Regulations, S.I. No. 256/2022, May, 2022.
  - The regulations confer functions on the Health Products Regulatory Authority in relation to IVDs.
  - Provide for various matters in relation to performance studies of IVDs

- In Vitro Diagnostic Medical Devices (Registration), Regulations S.I. No. 365, 2022, July 2022
  - provide for registration requirements in relation to in vitro diagnostic medical devices placed on the market in the State.

- European Union (National Research Ethics Committees for Performance Studies of In Vitro Diagnostic Medical Devices) Regulations, S.I. No. 257/2022, Jul 2022
  - Support the main features of the IVDR.

India

- [Proposed] India: Drugs, Medical Devices and Cosmetics Bill, July 2022
  - The Bill will replace the existing Drugs and Cosmetics Act, 1940
  - The Bill comprises regulations on online pharmacies, clinical testing, medical devices, Homeopathy amongst others
  - The Drugs, Medical Devices and Cosmetics Act, 2022 will extend to the whole of India.

- Indian Ministry of Health and Family Welfare published several amendments to Medical Devices Rules, G.S.R. 78(E), 2017
  - Proposed Amendments on registration of Class A medical devices, Draft Rule, Sept 2022
  - Registration through online system for medical devices

India

- Stability Studies of In-vitro Diagnostic Medical Device, Draft Guide Doc, July 2022
  - Guide to aid manufacturers in the preparation of scientific information to be provided in support of claimed shelf life, in use stability and shipping studies for Class C and Class D IVD MD license applications and Post approval change application filed in pursuant to the Medical Devices Rules, 2017.

- Overview on Performance Evaluation of In vitro Diagnostic Medical Device, Draft Guidance Doc, July 2022
  - Guidance is to facilitate the manufacturers/ importers / testing laboratories of IVDs in India.

- Post-Market Surveillance of In-vitro Diagnostic Medical Devices, Draft Guidance Document, July 2022
  - Provides guidance on the requirements of reporting of Adverse Events for certain IVDs

Australia

- Considerations for Implementing the Proposed Australian Medical Device UDI Regulatory Framework published in August 2022
  - Third consultation paper published by the TGA relating to the Australian implementation of a Unique Device Identification (UDI) System for medical devices.

- Active Medical Devices, Guidance Document published in July 2022
  - Guidance document covering requirements, definitions regarding active devices.

- Medical device patient information leaflets and implant cards Guidance published in March 2022
  - From 1 December 2021 all implantable and Active Implantable Medical Devices (AIMD) are required to have patient information materials available in the form of both Patient Information Leaflets (PILs) and Patient Implant Cards (PICs), unless specifically excluded from these requirements.

Australia

- In 2022, the Therapeutic Goods Administration (TGA) within the Australian Government Department of Health published several amendments to Therapeutic Goods (Medical Devices - Information that Must Accompany Application for Inclusion) Determination, 2018
    - Amendment to on extension to the timeframe for acceptance of ISO 13485 certificates supporting applications for Class 2 and 3 IVDs

- Amendment to the Therapeutic Goods (Medical Devices) Regulations, SR No. 236, 2002
    - on extension of transitional period for IVD companion diagnostics from 1 July 2022 to 26 May 2026.
    - This aligns with similar arrangements in the European Union (EU)

UK

- Government response to consultation on the future regulation of medical devices in the United Kingdom, June 2022
  - Post-Brexit regulatory framework for medical devices was scheduled to take effect in 2023.
  - Standstill for one further year to 2024.

- UK: Medical Device Software Applications, Guidance, September 2022
  - Medical devices: software applications (apps) was updated by the Medicines and Healthcare products Regulatory Agency.
  - Provides Information on when software applications are considered to be a medical device and how they are regulated.
  - Gives examples of software and apps which meet the definition of a medical device and it outlines requirements for UKCA marking of medical devices.

USA

- Ensuring Cybersecurity of Medical Devices, Senate Bill 3983, House Bill 7084, Mar 2022
  - Several minimum cybersecurity requirements that manufacturers must attain
  - Strengthening Cybersecurity for Medical Devices

- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions, Draft Guidance Document, April 2022
  - Recommendations to industry regarding cybersecurity device design, labeling, and the documentation that FDA recommends be included in premarket submissions for devices with cybersecurity risk.

- Conducting Remote Regulatory Assessments, Draft Guidance, 87 FR 44129, Aug 2022
  - Describes the Agency's current thinking regarding its use of remote regulatory assessments (RRAs)
  - Provides answers to frequently asked questions regarding what RRAs are, when and why FDA may use them, and how FDA may conduct them, among others.

USA

- Computer Software Assurance for Production and Quality System Software, Draft Guidance, Sept 2022
  - Recommendations on computer software assurance for computers and automated data processing systems that are used as part of medical device production or the related quality system.
  - Help manufacturers to keep current with the dynamic and rapidly changing technology landscape
  - Comments on the draft guidance are to be submitted by November 14, 2022

- Policy for Device Software Functions and Mobile Medical Applications, Document Guidance, Sept 2022
  - FDA is issuing this guidance to communicate how the Agency intends to apply its regulatory oversight to certain software, including device software functions and mobile medical applications (MMAs) intended for use on mobile platforms or on general-purpose computing platforms.

Brazil

- Regulating Software as a Medical Device (SaMD), Resolution RDC No. 657, July 2022
  - Regulates software as a medical device (SaMD) and considers as a medical device
  - Effective from July 2022, establishes the requirements for the regularization of software as a medical device (Software as a Medical Device – SaMD).

- Good Manufacturing Practices for Medical Products and In Vitro Diagnostic Products, Resolution RDC No. 665, Mar 2022
  - This Resolution deals with Good Manufacturing Practices (GMP) for Medical Products and Products for Diagnostic Use In Vitro and establishes the requirements for methods and controls used in the manufacturing, design, procurement, labelling, packaging, storage, distribution, installation and technical assistance applicable to the manufacture of the products, aiming to ensure that the products are safe and effective.

Brazil

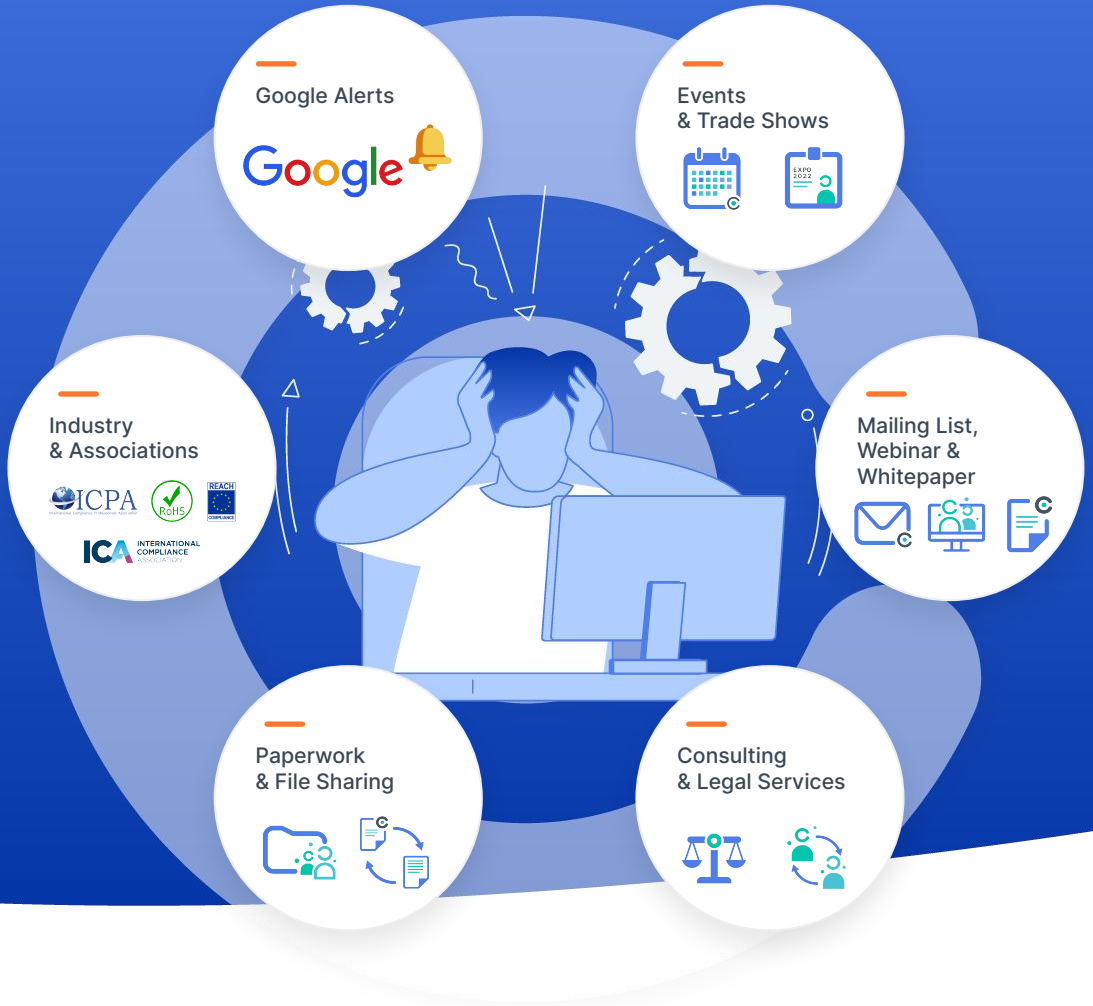
- [Proposed] Essential Safety and Performance Requirements Applicable to Medical Devices and In Vitro Diagnostic (IVD) Medical Devices, Draft Resolution RDC No. 1112, September 2022
  - Provides the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices.
  - Provides the essential safety and performance requirements applicable to medical devices and in vitro diagnostic (IVD) medical devices.

- Approving the Conformity Assessment Requirements for Breast Implants, Portaria No. 5, Feb 2022
  - The Brazilian Institute of Metrology, Standardization and Industrial Quality (INMETRO/CONMETRO) published Portaria No. 5 on Conformity Assessment Requirements for Breast Implants.
  - Establishes the criteria and procedures for assessing the conformity of these implants.
  - Provides details on the steps of conformity assessment, certification models, criteria for classification into families, etc. It also sets out the labelling requirements in Annex B.

China

- Matters Concerning the Filing of Class I Medical Devices, Announcement No. 62, Aug 2022
  - Simplified filing requirements, Additional requirements for details including product name and description, intended use and model/specification
- China: Implementing Quality Management for Clinical Trials of Medical Devices, Circular No. 21, Mar 2022
  - Circular to implement quality management measures for the clinical trials of medical devices per Quality Management Practice for Clinical Trials of Medical Devices
  - From 1 May 2022, clinical trials of medical devices that have not yet passed the ethics review shall be conducted in accordance with Announcement No. 28 of 2022, and projects that have already passed the first ethics review may be conducted in accordance with the original documentation.
- China: Guiding Principles for the Registration Review of 27 Medical Device Products, Notice No.35, Sept 2022
  - China National Medical Products Administration has organized and formulated 27 guidelines for the registration and review of medical device products

Trying to keep on top of it all...



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A Smarter Way to Manage Product Compliance

Holistic Market Access Solutions

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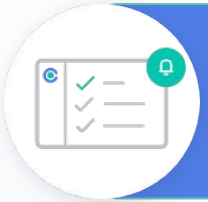
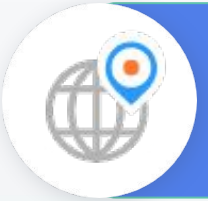
Unlock Market Access, by ...



Demonstrating Compliance

For what is required



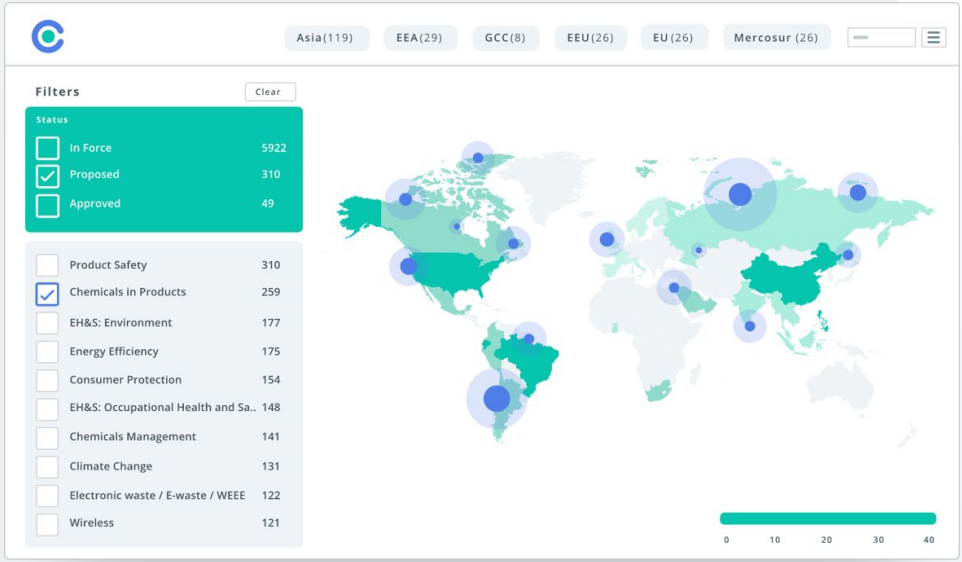
Driven by Global Regulations & Standards

TECHNOLOGY - C2P

C2P

The Key to Unlocking Market Access

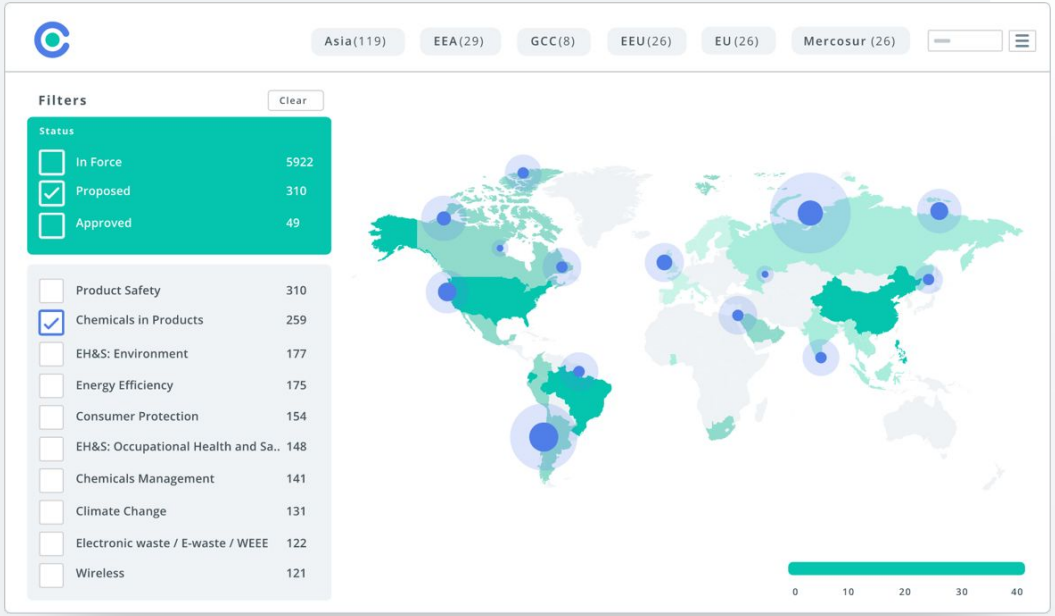
- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



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

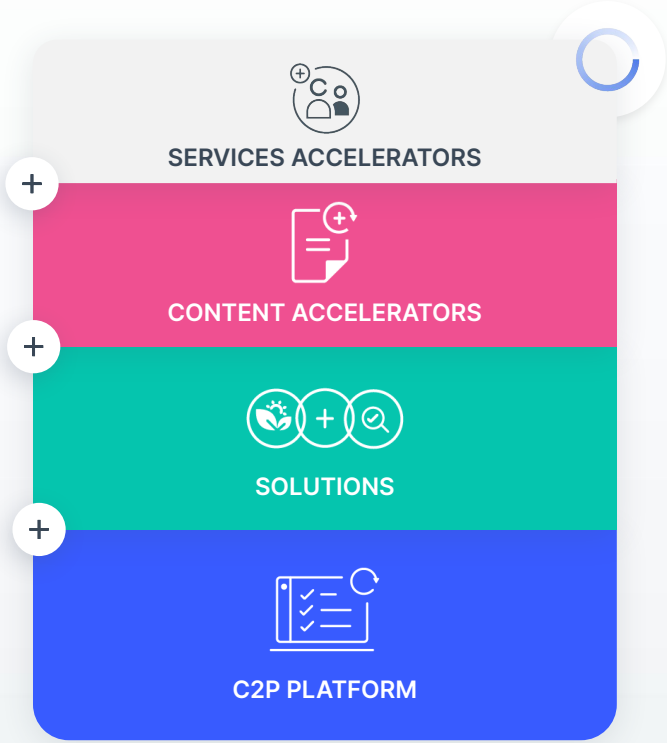


TECHNOLOGY - C2P

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



Q&A

Thank you!