Compliance & Risks

Webinar

Stay Compliant: Medical Device Industry 2024 Regulatory Update

12th of June, 2024

→ | complianceandrisks.com

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Product Compliance Insights Roadshow

Expert Speakers | Industry Networking

LONDON	JUNE 20
MINNEAPOLIS	JUNE 25
PARIS	JUNE 27
CHICAGO	JUNE 27
LOS ANGELES	JULY 17+18

Webinar Platform Tips

Q&A Session

Slides & Webinar Recording

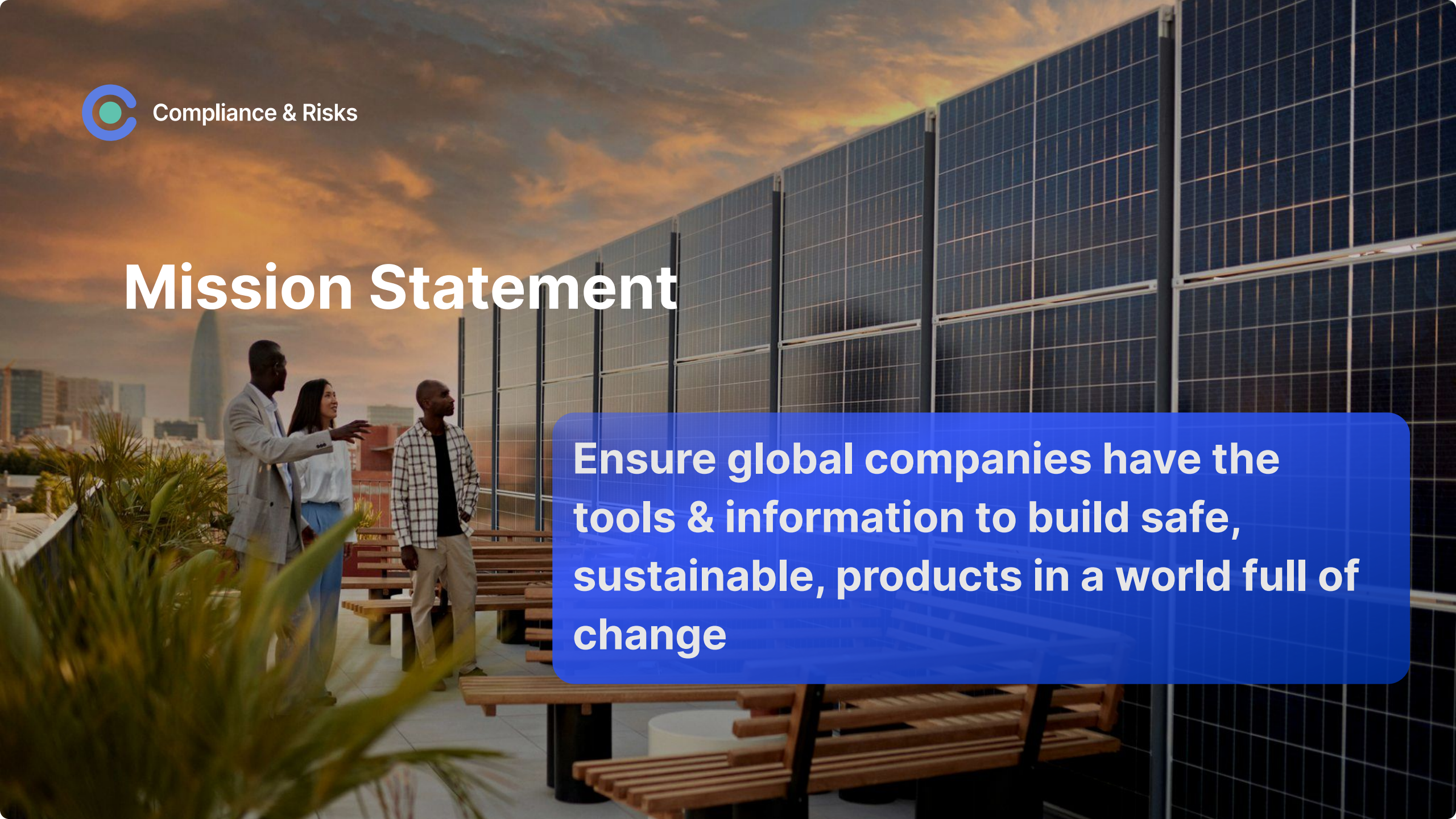
Request a Demo

Compliance & Risks

Meet the Team

Denise McDermott
Senior Regulatory Specialist and Team Lead

Vish Karasani
Product Marketing Manager


Compliance & Risks
Mission Statement
Ensure global companies have the tools & information to build safe, sustainable, products in a world full of change

Trusted by the World's Leading Brands

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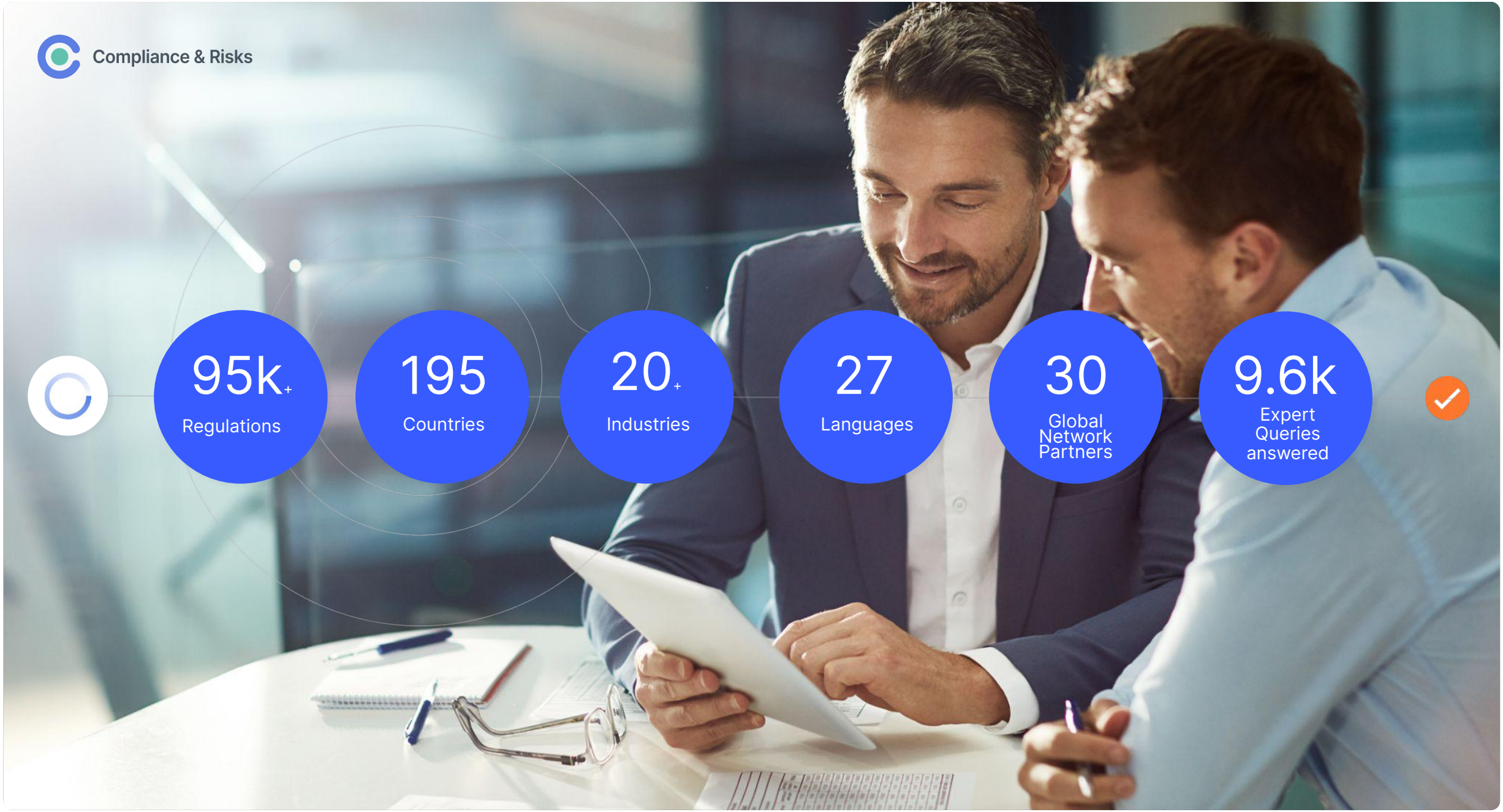
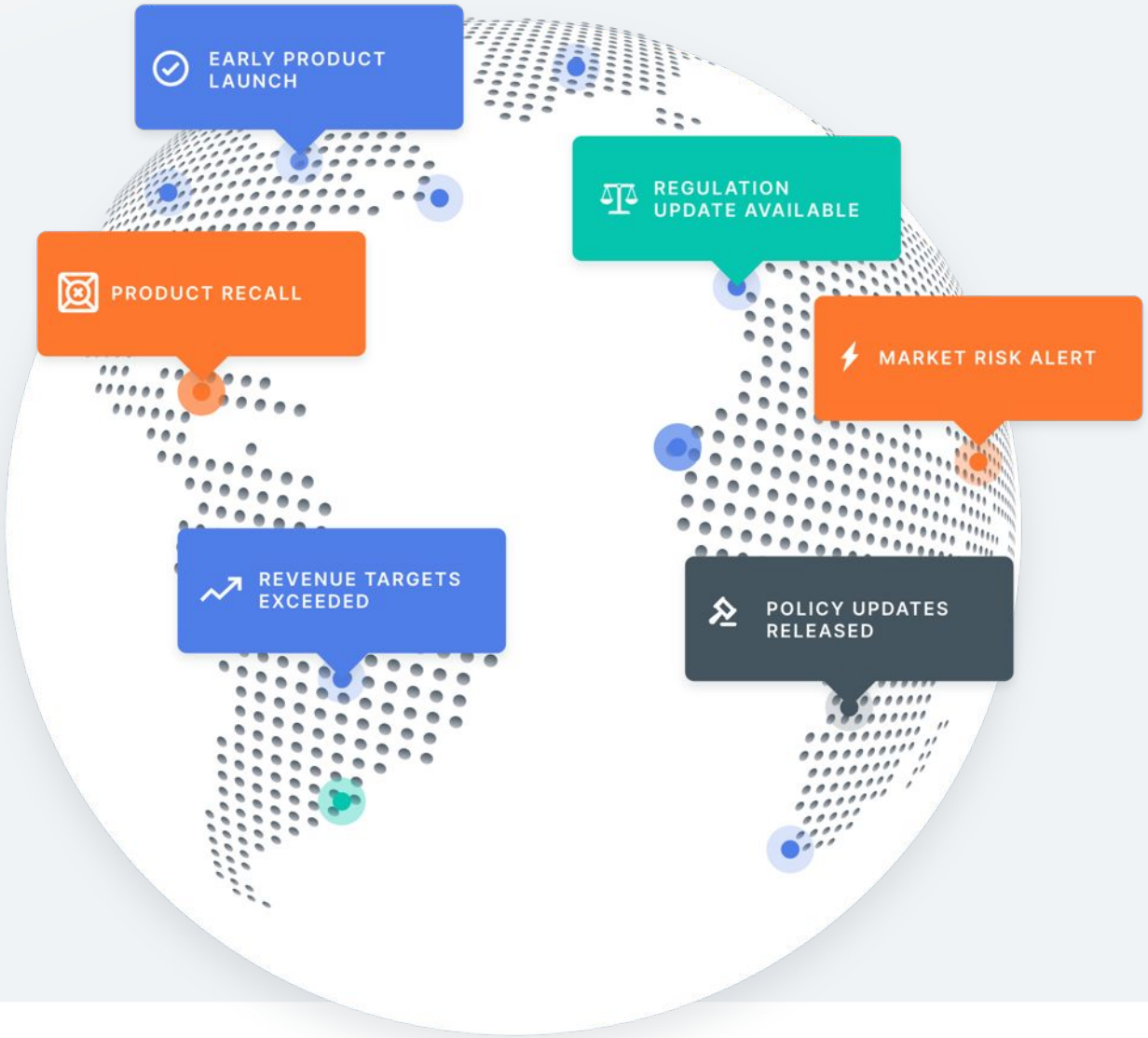


WHAT WE DO

Unlocking Market Access

Keep on top of regulatory changes and their impact worldwide. Early warning alerts, impact probability, productivity workflow tools and so much more.



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Medical Device Industry 2024 Regulatory Update

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EU

IVDR

Proposal for an extension of the transitional periods for certain legacy in vitro diagnostic medical devices (IVDs), under certain conditions, gradual roll-out of EUDAMED modules, obligation on manufacturers to provide prior notice in case of disruption of supply of certain medical devices and in vitro diagnostics.

Proposed transition timelines apply to devices that are transitioning to the IVDR, and that meet certain conditions

- **31 December 2027** for Class D devices
- **31 December 2028** for Class C devices
- **31 December 2029** for Class B and A sterile devices

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EU

MDR

Regulation (EU) 2023/607 - Extension of MDR transition timelines.

Transition timelines apply only to devices that are transitioning to MDR and meet specific conditions set out in the Regulation including; submitting an MDR application by the **26 May 202**4 and having a signed formal written agreement with a Notified Body by the **26 Sep 2024.**

- **26 May 2026 -** Class III custom-made implantable devices
- **31 Dec 2027 -** Class III and class IIb implantable devices,
- **31 Dec 2028 -** Other class IIb, class IIa and Class I sterile devices and Class I devices with a measuring function

Removal of ‘sell off provision’ for both the MDR and IVDR.

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EU

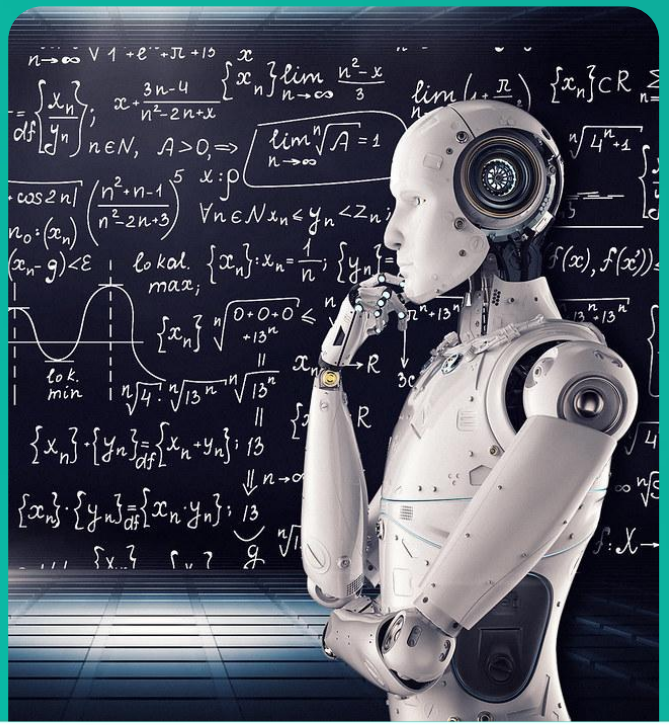
AI Act

- Artificial Intelligence Act (AIA)- regulatory framework for products and technologies utilizing AI components - Approved by the European Council on 21st May.
- The AIA distinguishes between AI applications that present

  I. an intolerable risk,
  II. a high risk, and
  III. a low or negligible risk.

Art. 6 lists two conditions for the assessment of high-risk devices;

- used as a safety component of a product, or the AI system is itself a product, and
- are required to undergo a third-party conformity assessment



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EU

- Harmonised standards
  - Commission Implementing Decision (EU) 2024/815, under the MDR, broadens references across various medical device categories.
  - Commission Implementing Decision (EU) 2024/817, under the IVDR, adds references for the sterilisation of healthcare products and packaging for terminally sterilised medical devices.
- The European Commission updated the Language Requirements Overview documents.

- Several new MDCG documents published in 2024:

MDCG 2024-1: Device Specific Vigilance Guidance (DSVG) Template, Jan 2024

MDCG 2024-2: Procedures for the updates of the EMDN Feb 2024

MDCG 2024-3: Guidance on content of the Clinical Investigation Plan for clinical investigations of medical devices, Mar 2024

MDCG 2024-4: Safety reporting in performance studies of in vitro diagnostic medical devices under Regulation (EU) 2017/746, Apr 2024

MDCG 2024-5: Guidance on the Investigator's Brochure content, Mar 2024

MDCG 2024-6 - 8: Preliminary re-assessment review (PRAR) and assessment review (PAR) form templates for MDR and IVDR, May 2024

MDCG 2022-9 rev.1; Summary of safety and performance template, Apr 2024

MDCG 2022-9 rev.1, rev 2; Appropriate surveillance

Ireland

Guide for Health Institutions that Manufacture and Use In-house IVDs

- Published in May 2024, this guide provides an overview of legislation and key concepts relevant to in-house IVDs. It is targeted towards health institutions in Ireland that manufacture and use in-house IVDs.
- The requirements of the IVDR are described, taking into account national legislation for IVDs (S.I. No. 256 of 2022 and S.I. No 365 of 2022).
- Provides practical considerations for health institutions and outlines information that must be notified or submitted to the HPRA. This guide does not cover in-house medical devices under Regulation (EU) 2017/745.

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UK

Implementation of Future Regulations

CE marked medical devices may be placed on the Great Britain market to the following timelines:

- medical devices compliant with EU MDD or EU AIMDD - up until the sooner of expiry of certificate or **30 June 2028**
- IVDs compliant with EU IVDD - up until the sooner of expiry of certificate or **30 June 2030**, and
- medical devices/IVDs, including custom-made devices, compliant with EU MDR/IVDR - up until the **30 June 2030.**

Statement of policy intent: international recognition of medical devices - 21 May 2024

- Intention to introduce alternative routes to market utilising approvals from other countries and Medical Device Single Audit Program (MDSAP) certificates, in addition to the current UKCA (UK Conformity Assessed) marking process.
- Comparable regulator countries (CRCs) for the proposed framework will be: Australia, Canada, EU and USA.

UK

Artificial Intelligence

The Medicines and Healthcare products Regulatory Agency (MHRA) set out its strategic approach to artificial intelligence (AI).

Policy Paper: Impact of AI on the regulation of medical products

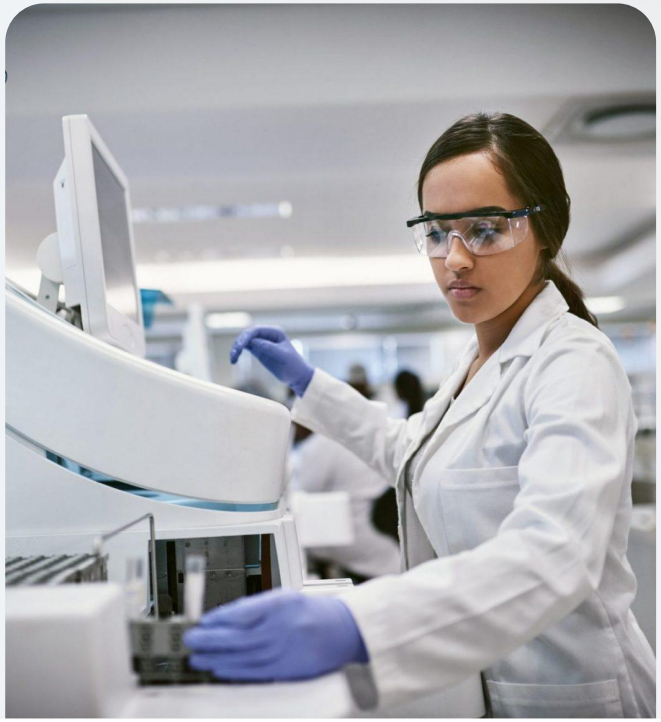
- “Where AI is used for a medical purpose, it is very likely to come within the definition of a general medical device, meaning it must meet the requirements of the UK Medical Devices Regulations 2002 (as amended) in order to be on the market in the UK”.
- MHRA programme of regulatory reform for medical devices- includes ensuring there is proportionate regulation of AIaMD

UK

Public Consultation on Common specifications for high-risk IVDs

The MHRA launched a public consultation to seek views on the inclusion of common specification requirements before certain IVDs can be placed on the market.

- Also seeking views on the removal of the Coronavirus Test Device Approval process, to avoid duplication of regulatory requirements for COVID-19 tests against the common specification requirements.
- Aim to improve the safety profile of high risk IVD devices
- Consistency with European Union (EU) regulations.
- The consultation will close on Friday 14 June 2024.



Switzerland

Medical devices that were not transferred under from MDD to MDR may no longer be placed on the market in Switzerland **after 26 May 2024**.

- Swiss MedTech published a Guidance on placing of “legacy” devices on the Swiss market after 26 May 2024

Swissmedic information sheet on **Medical Device Software** with several updates;

- Class I medical device software (MDSW)
- Regulatory requirements in terms of General Safety & Performance Requirements (GSPRs), technical documentation, clinical/performance evaluation, and labelling & UDI, in alignment with the EU MDR/IVDR.
- Updated references to the legal framework in Switzerland, references to EU legislation, MDCG guidelines

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Australia

Medical Device Reforms and New Guidance

- Program of reforms to strengthen the regulation of medical devices in Australia.
  - **Strategy 1:** Improve how new devices get on the market
  - **Strategy 2:** Strengthen monitoring and follow-up of devices already in use
  - **Strategy 3:** Provide more information to patients about the devices they use
- New Consultations
  - **Consultation:** Companion diagnostics guidance update
  - **Consultation:** Availability of Instructions For Use (IFU) in more flexible formats

New Zealand

Therapeutic Products Act

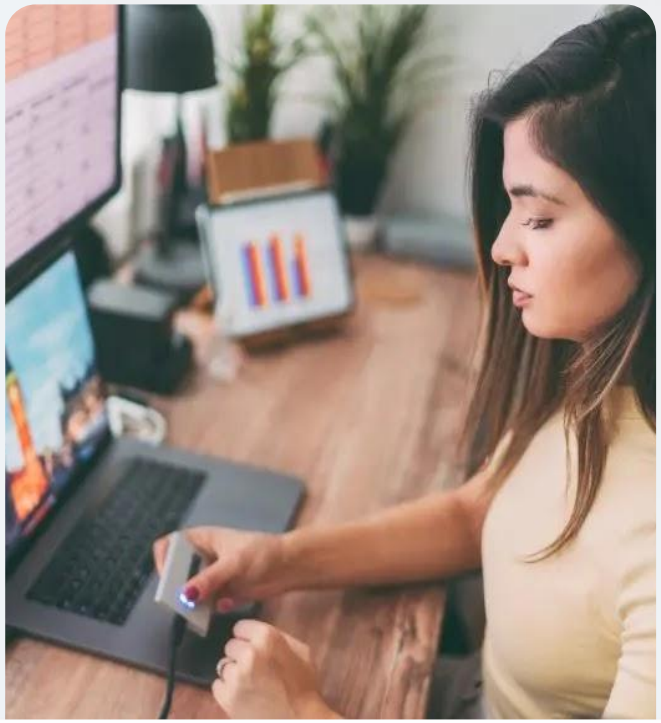
- New Zealand: Therapeutic Products Act No. 37, approved in July 2023, covers medicines, certain medical devices and natural health products.
- On 8 May 2024, the New Zealand Government announced that the Therapeutic Products Act will be repealed by the end of 2024.
- According to the press release, the Government will develop a new regulatory regime to replace the Medicines Act, which is acknowledged to be out of date. Key stakeholders will be consulted in the process of drafting new legislation.

India

Guidance on Stability Studies of In-vitro Diagnostic Medical Device (IVDMD)

- In April 2024, the Central Drug Standard Control organisation (CDSCO) published a Guidance Document on Stability Studies of In-vitro Diagnostic Medical Device (IVDMD)

- Guidance for manufacturers in preparation of a premarket review document for IVDMD Import or Manufacturing License Applications.

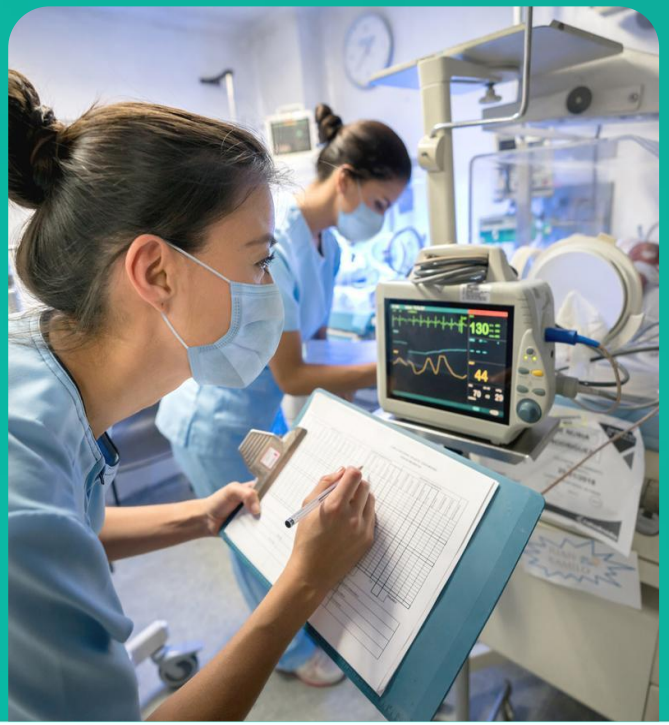


Malaysia

Faster Approval for Establishment License Application

- In March 2024, the Malaysia Medical Device Authority published an announcement on faster approval times for establishment license applications
- 14 to 21 Working days from date of application

→ | Check the Announcement | Medical Device Authority (MDA)



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South Korea

Draft Notice

- Draft Notice No. 2024-266 - Proposed amendment to the Standards on Manufacturing and Quality Control of In Vitro Diagnostic (IVD) Medical Devices
- Enable the utilisation of MDSAP audit results during initial domestic GMP audits, additional audits, and change audits, if the certification has been obtained through the Medical Device Single Audit Program (MDSAP).

USA

Final Rule on Laboratory Developed Tests

- In April 2024 the FDA published its final rule which amends the definition of “in vitro diagnostic product” to include “when the manufacturer of these products is a laboratory,”
- As a result, the FDA will regulate Lab Developed Tests (LDTs) more strictly and treat them like in vitro diagnostic products.
- FDA is phasing out its enforcement discretion policy for LDTs over the course of four years in five stages.

USA

Remanufacturing of medical devices

- Remanufacturing of Medical Devices Guidance Document
  - The FDA clarifies distinction between device remanufacturing and servicing in final guidance.
  - The FDA clarifies existing regulatory requirements for remanufacturers.
  - Includes recommendations for information that should be included in labeling of devices that are intended to be serviced over their useful life.

USA

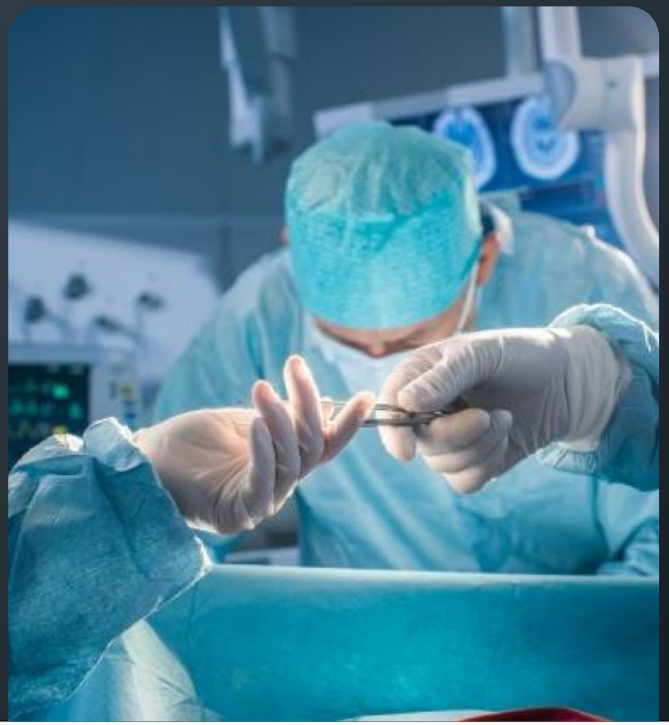
Quality Management System Regulation

- The FDA published its Quality Management System Regulation (QMSR) final rule
  - Amends the Code of Federal Regulations; 21 CFR Part 820, by incorporating by reference the quality management system requirements of the 2016 edition of ISO 13485.
  - Additional requirements, which include requirements for control of records, those relating to labelling and packaging, and those surrounding risk management,
  - The FDA has stated that they will develop a new inspection process to align with the requirements of the new QMSR.
  - The new rule will become effective on 2nd February 2026

Canada

Significant change guidance

- Draft guidance on how to interpret ‘significant change’ of a medical device revised Feb 2024
- This guidance document has been updated to expand on the definition of “significant change” in the Medical Devices Regulations.
- Outlines the crucial elements of what constitutes a significant change and when you must obtain an amendment to your authorization before making the modified device available in Canada



Brazil

Normative Instruction 290/2024

- The Brazilian Agency for Sanitary Surveillance (ANVISA) published Normative Instruction No. 290/2024 in April 2024
- It streamlines the evaluation process for medical devices and IVDs that have already been approved by foreign authorities.
- Equivalent Foreign Regulatory Authority (EFRA), include;
    - Australia Therapeutic Goods Administration (TGA) - Australian Register of Therapeutic Goods (ARTG);
    - Health Canada (HC) - Medical Device Licence;
    - US Food and Drug Administration (US FDA) - 510(k) Clearance, Premarket Approval (PMA) or 513(f)(2); and
    - Japan Ministry of Health, Labour and Welfare (MHLW) - Premarket approval.

Mexico

Labelling of medical devices

- Mexico: Labelling of Medical Devices, Draft Standard PROY-NOM-137-SSA1-2024
  - Clarification on country of origin
  - Abbreviations are now allowed within the address details.
  - Medical devices imported as samples must be labeled following the manufacturer’s Quality Management System (QMS) and must include the statement "Prohibited for sale"

Colombia

Medical Device Policy 2024-2026

- The Colombian Ministry of Health and Social Protection issued Resolution No. 184, which approved the Medical Device Policy for 2024-2026
- Enhance equitable access to medical devices for the Colombian population by improving factors that influence their availability, quality, and continuity, as well as ensuring their safe and appropriate use.
- Objectives of the Policy include;
  - Design a medical device information system that integrates existing tools and identifies those required to respond to the decision-making needs in the sector;
  - Establish guidelines that contribute to the strengthening of research, development and clinical practice regarding medical devices;
  - Implement strategies to increase the availability and affordability of prioritized medical devices, in accordance to the epidemiological profile of the Colombian population;
  - Strengthen post-market guidelines, regulation and technical regulations with emphasis on promoting the quality and safety of medical devices.

How do you Manage Changes to Products, Markets, Regulations & Customer Preferences?

Trying to keep on top of it all...

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KEY CHALLENGES

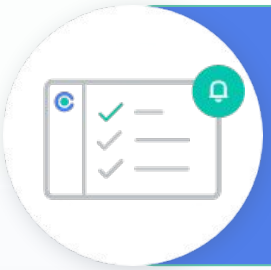
Hidden Cost of Compliance

- Large, unmanageable spreadsheets to keep track of changes
- Disjointed processes & data silos with ‘dumb’ documents
- Redesigning and retesting products
- Stop-ship in the field and rework on the production line

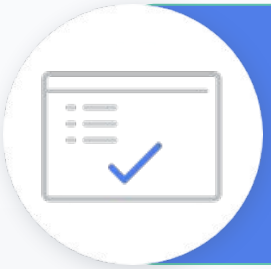
02

A Smarter Way to Manage Product & ESG Compliance

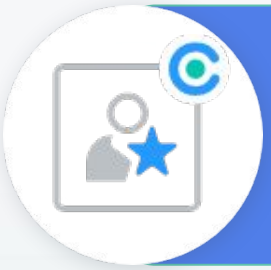
Holistic Market Access Solutions



Powerful Enterprise Technology



Extensive Global Regulatory Content



Team of Subject Matter Experts

Holistic Market Access Solutions...

“Can I sell product X in market Y?”

→ Achieve market access

“Can I continue to sell product X in market Y when there is a change?”

→ Maintain market access

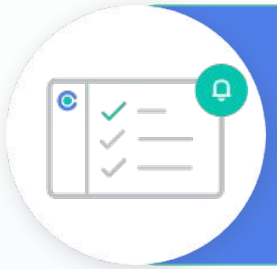
“What do I need to do to sell product X into a new market?”

→ Expand market access

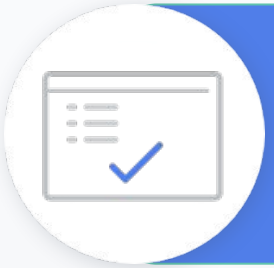
Accelerate the ability to

Achieve, Maintain & Expand Market Access for all products in all markets

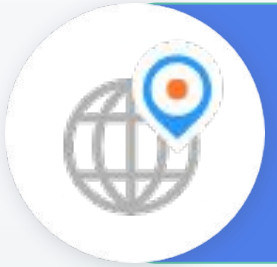
Achieve your business objectives, by ...



Demonstrating Compliance



For what is required

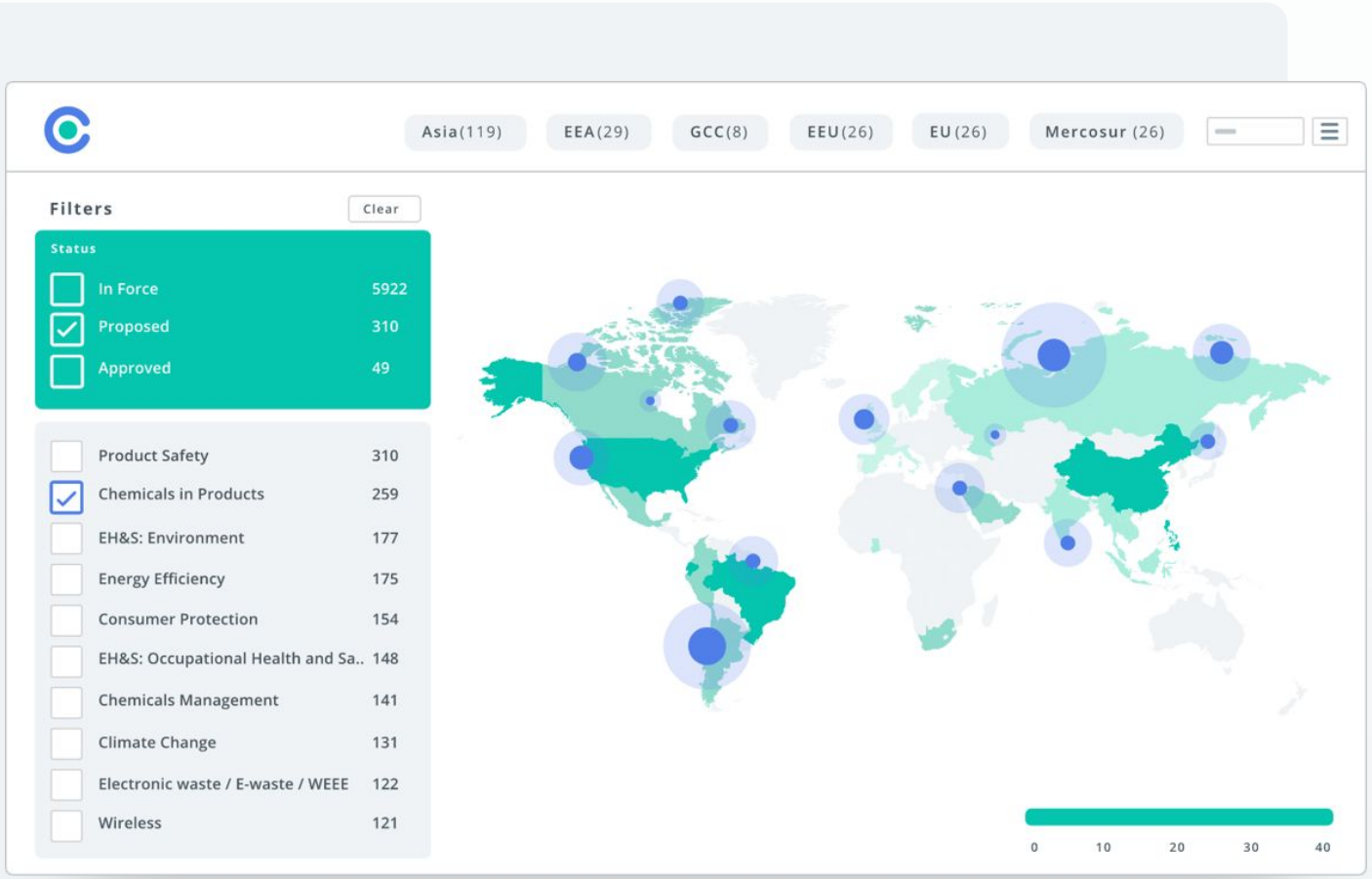


Driven by Global Regulations & Standards

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

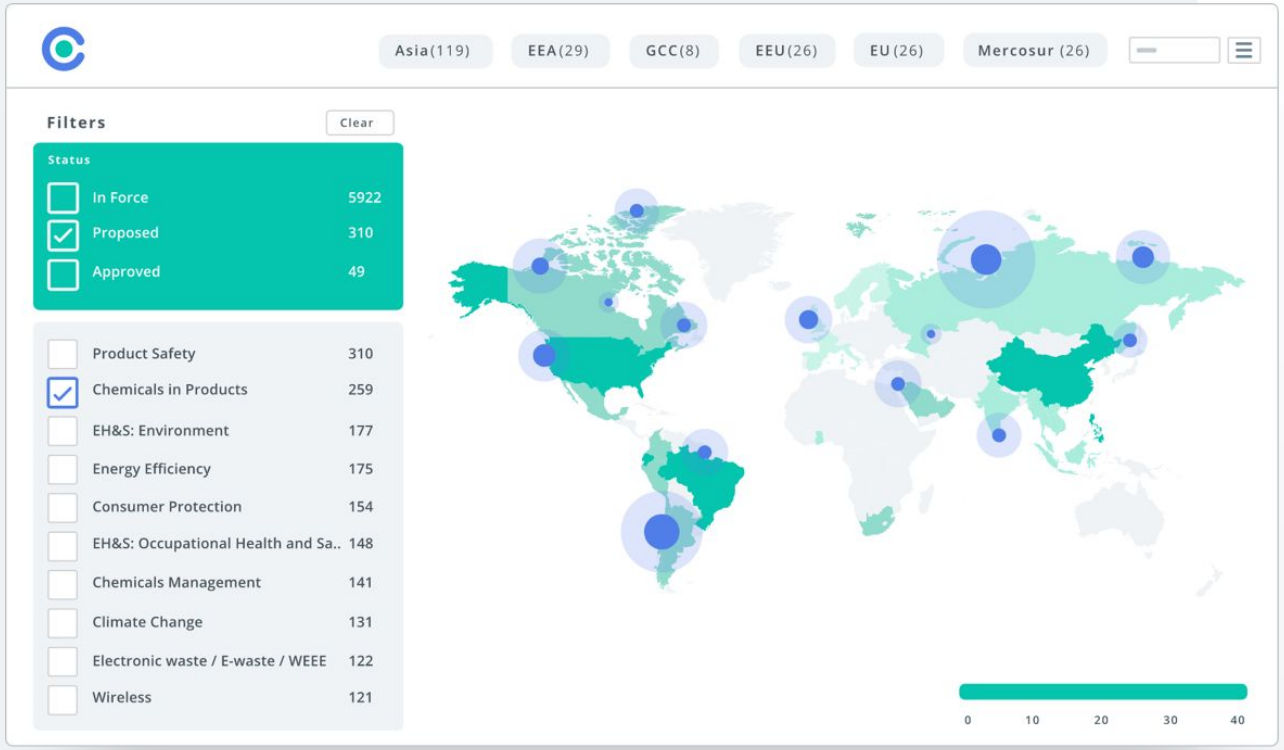


TECHNOLOGY - C2P

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

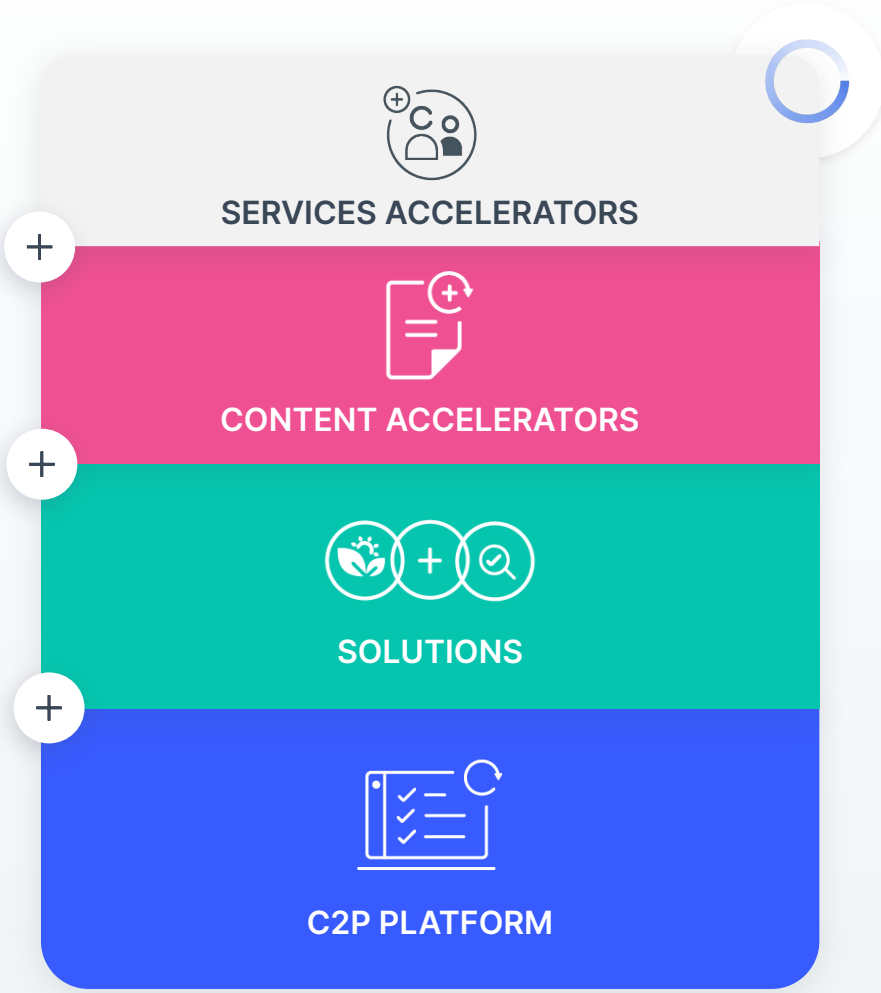


TECHNOLOGY - C2P

Tailored to meet your needs...

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

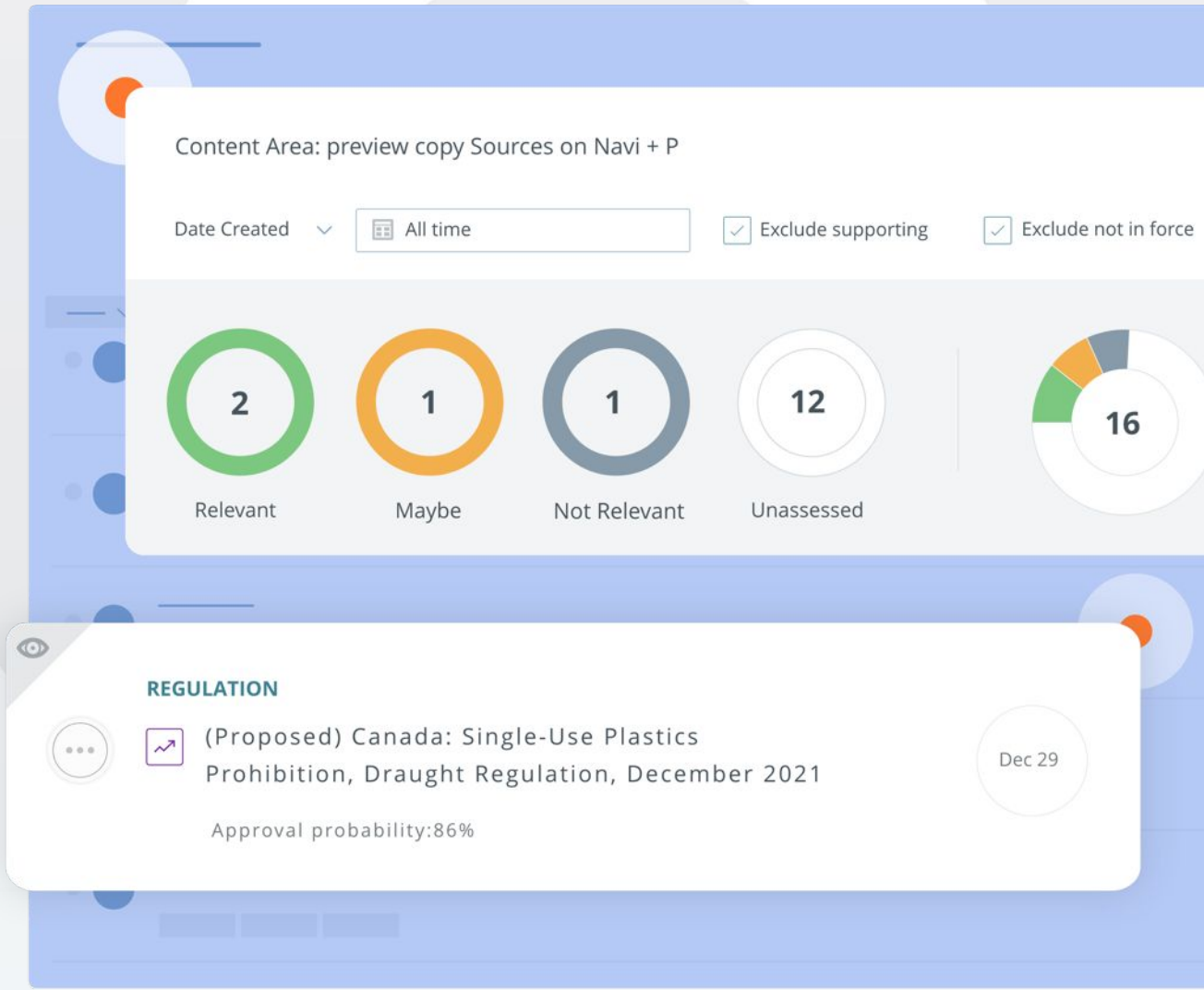
- Add-on packages to accelerate market access through:
  - Use-case specific solutions
  - Global regulatory content
  - Professional services



TECHNOLOGY - C2P

Timely Information Is Critical for Medical Device Manufacturers

Reducing Time & Cost-to-Market is seen as one of the most important drivers of staying competitive for the Medical Device industry in the next 5 years



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REGULATORY CONTENT

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

23,120+
Regulatory Sources

REGULATORY CONTENT

Medical Devices Focus Areas

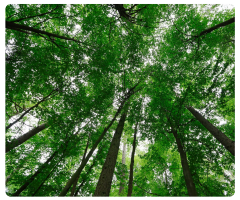
Our content coverage helps you manage critical product compliance issues easily

- 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

REGULATORY CONTENT

Unrivalled Global ESG Coverage

ESG



ESG Reporting

Environment

Climate Disclosures

ESG

Supply Chain Due Diligence

Governance

Anti Bribery & Corruption

Social

Human Rights - Affected Communities

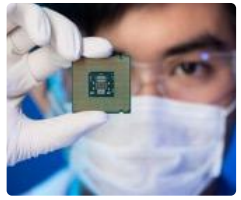
Social

Labor & Employment

Social

Human Trafficking & Slavery

Environment

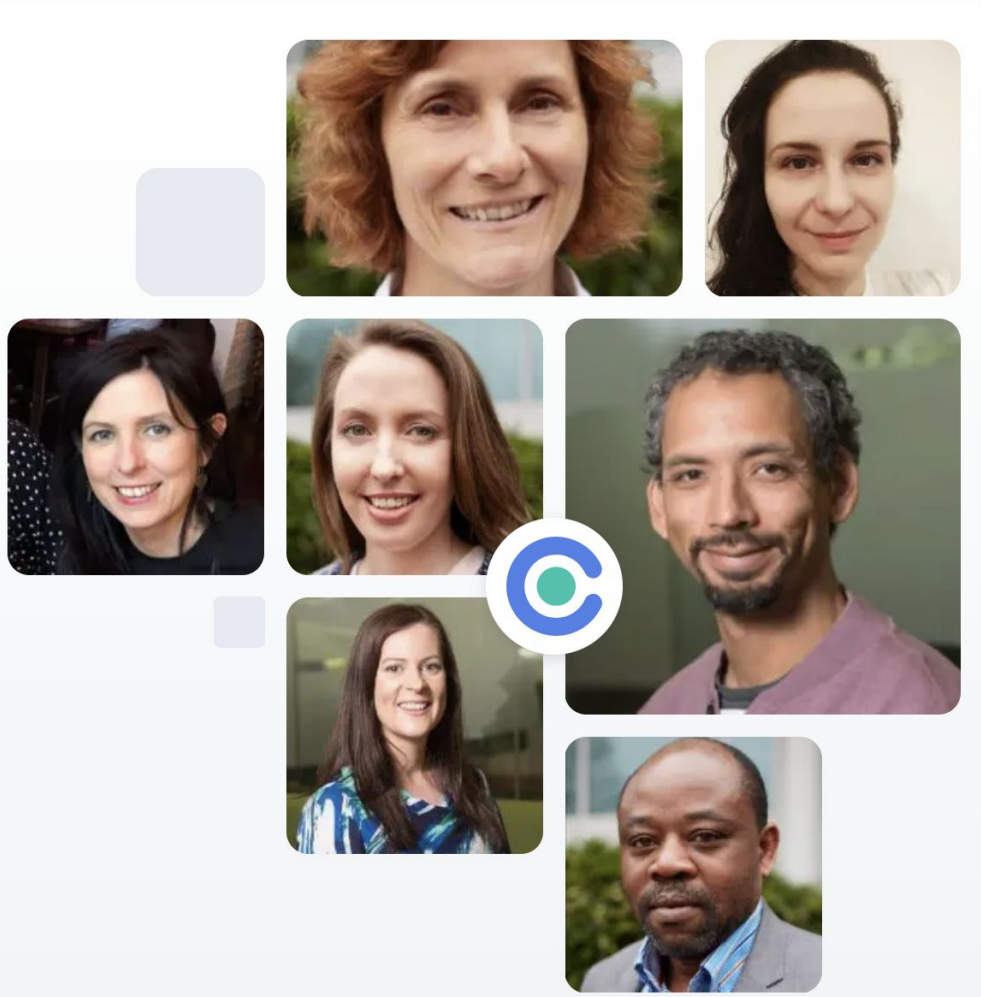


Sustainable Resource Use

SUBJECT MATTER EXPERTISE

Ask our Experts at the click of a button...

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



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Q&A

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Thank You!

Denise McDermott
Senior Regulatory Specialist and Team Lead

Vish Karasani
Product Marketing Manager

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Product Compliance Insights Roadshow

Expert Speakers | Industry Networking

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