Medical Devices Post-market Surveillance Regulations in China, Japan, and South Korea

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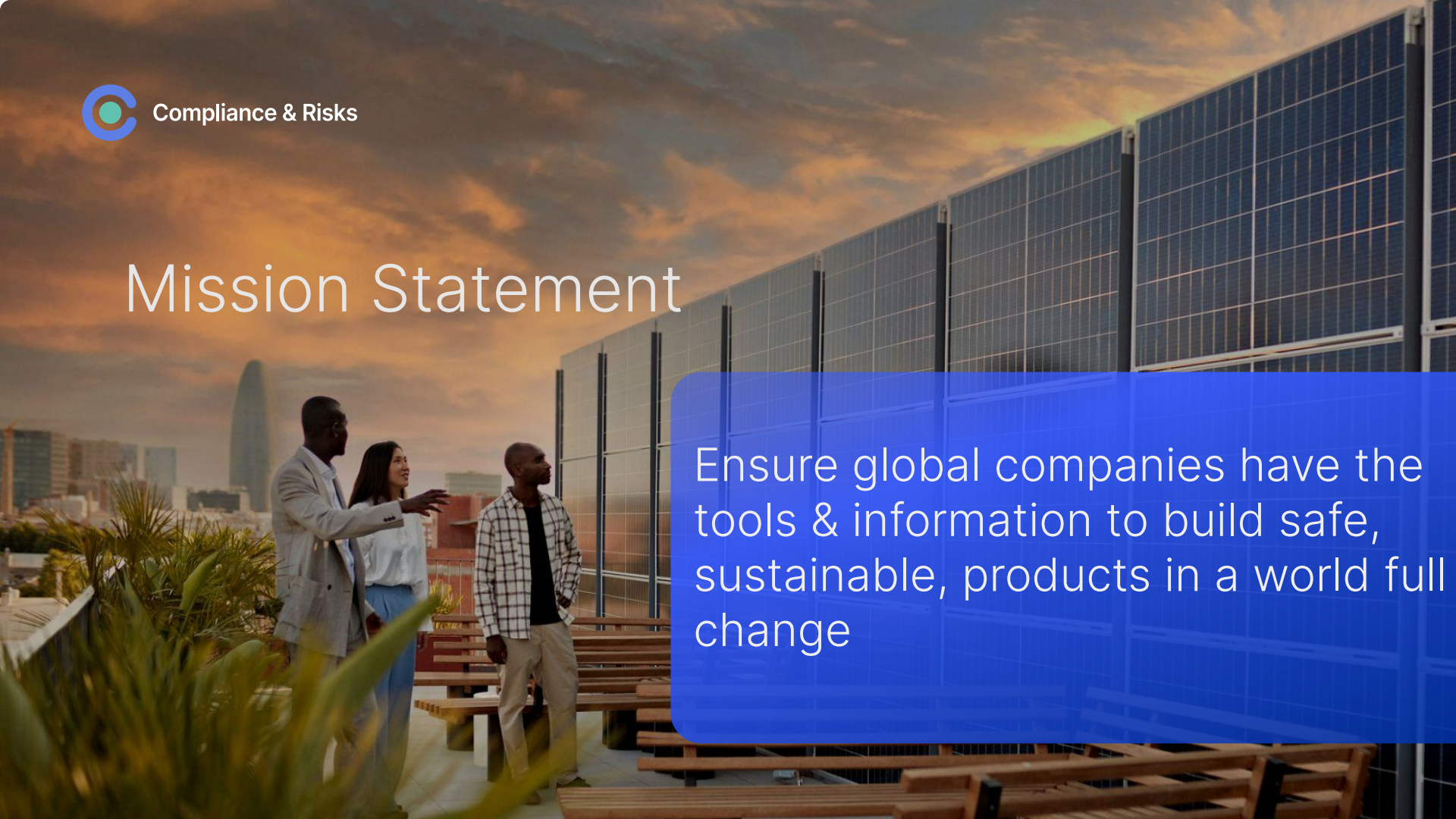
Compliance & Risks

Overview

1. Overview of regulations on Post-market Surveillance in China
2. Overview of regulations on Post-market Surveillance in Japan and South Korea
3. Comparison of regulations across jurisdictions
4. Introducing C2P - Holistic Market Access Solutions

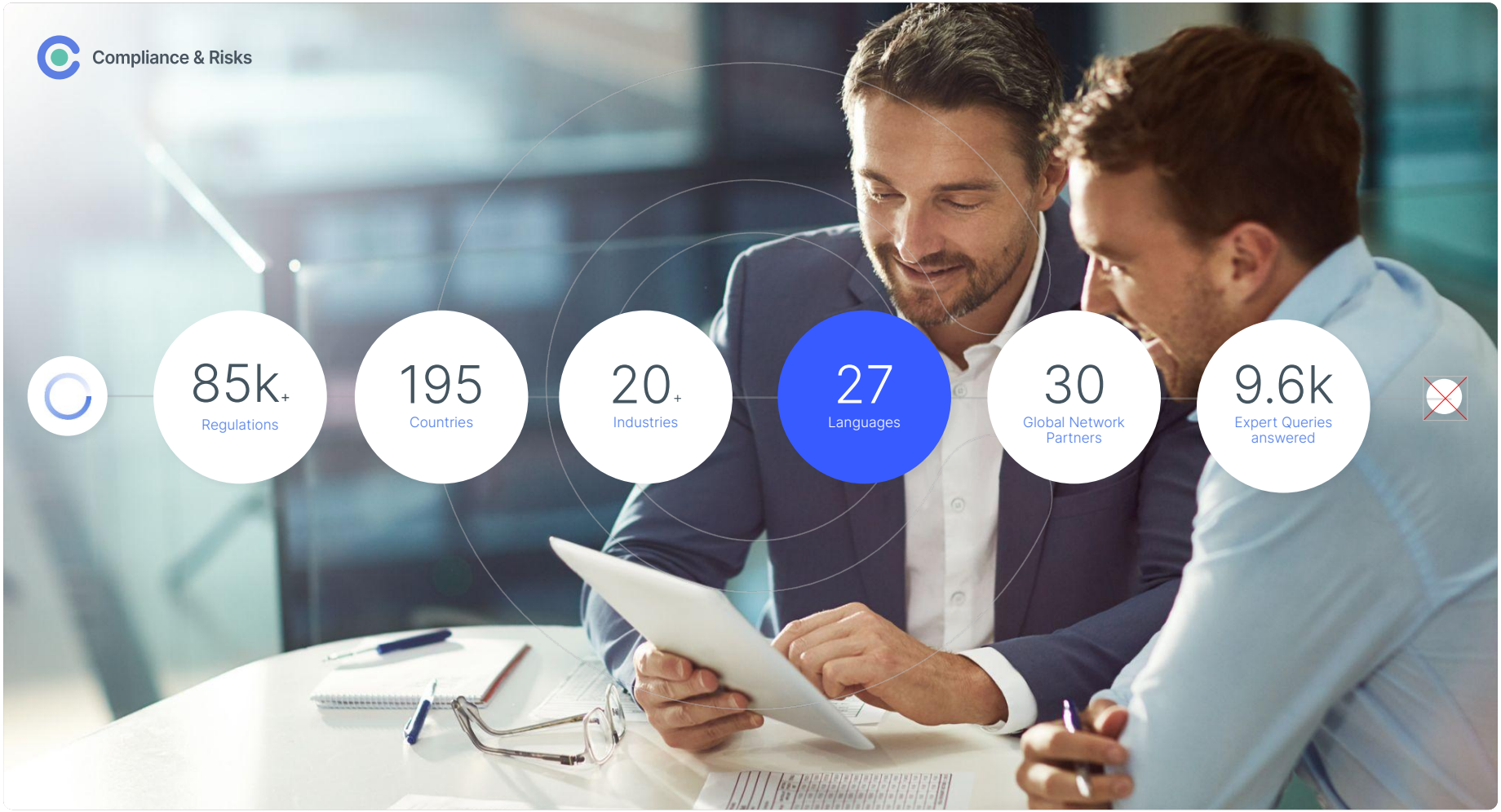
Compliance & Risks

Mission Statement



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

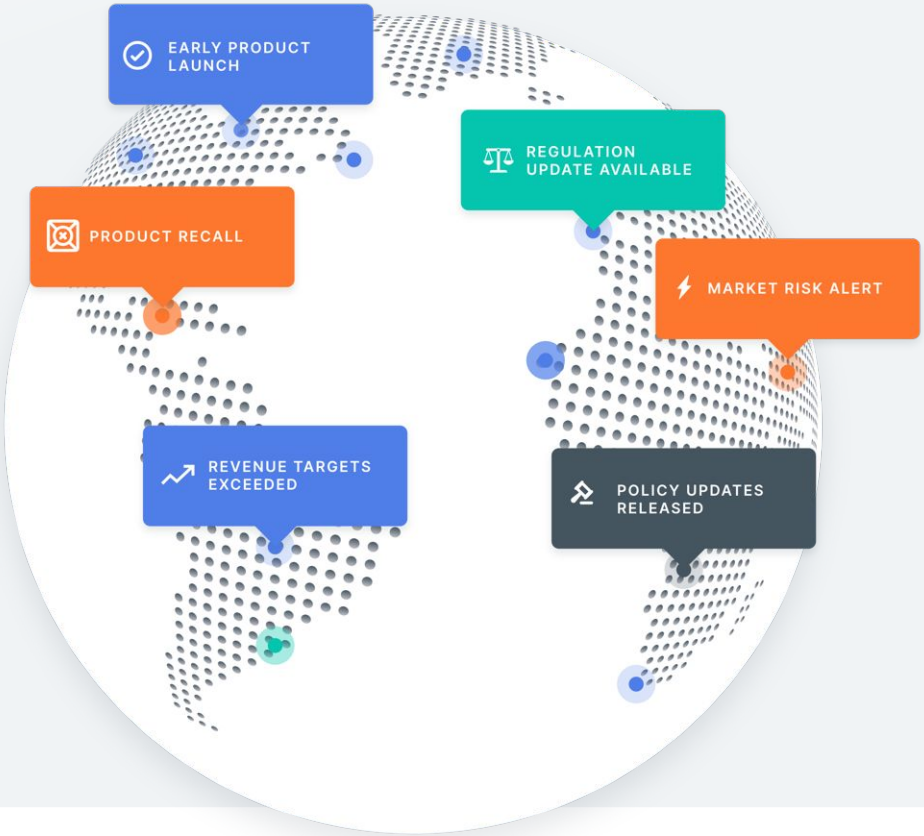
Trusted by the World's Leading Brands


Compliance & Risks
85k+
Regulations
195
Countries
20+
Industries
27
Languages
30
Global Network Partners
9.6k
Expert Queries answered

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.



01

China

Overview of regulations on Post-market Surveillance

Post-market Surveillance in China

General Products

- Product Safety Law and Consumer Protection Law
- Standardization Law
- Regulations on post-market inspection.

Medical Device

- Order No. 739, 2021
- Administrative Measures on Medical Device Adverse Event and Re-evaluation
- Administrative Measures for the Recall of Medical Devices, Order No. 29, 2017

General Product Post-market Surveillance

Medical Device Post-market Surveillance System

Order No. 739

Chapter 5 of Order No. 739 sets down the framework of post-market surveillance system in China

Medical device registration holders and filers must set up adverse event monitoring system and report to the authorities

National Medical Products Administration shall set up and maintain adverse event monitoring data network

Medical Products Administration’s responsibilities

Re-evaluation and recall of defective medical devices

Supervision and Administration of Medical Devices, Order No. 739, 2021

Stricter measures on post-market surveillance

- Registration holder responsibility
- Professional Inspectors
- Extended Inspection System
- UDI Tracking and Recall System
- Penalty System

Medical Device Post-market Surveillance System

Administrative Measures on Medical Device Adverse Event and Reevaluation, Order No. 1, 2018
(Draft amendments proposed on 23 November 2021)

Responsibilities of national and local authorities, national and local monitoring agencies, medical device registration holders, and medical device distributors and users.

Principles for adverse event report and evolution

Requirements on medical devices subject to key supervision: Catalogue of Medical Devices Subject to Key Supervision (2009)

Risk Management

Re-evaluation of medical devices

Medical Device Post-market Surveillance System

Administrative Measures for the Recall of Medical Devices, Order No. 29, 2017

Responsible Person: registration holders and fillers, and an agent designated by an overseas manufacturer of imported medical devices

3 Levels

Level 1: the use of the medical device may cause serious health hazards;
Level 2: the use of the medical device may cause temporary or reversible health hazards;
Level 3: the medical device is less likely to cause harm but still needs to be recalled.

Article 10

- Establish medical device quality management systems
- Collect and record complaints and medical device adverse event information
- Analyze the collected information, and identify possible defects
- Conduct investigations and evaluations.

Report the collected information to the Medical Products Administration.

Article 14 - Release product recall information to the public.

Other Relevant Regulations

- Inspection Rules for Medical Devices, Notification No. 9, 2020
- Regulations on Medical Device Clinical Trial, Announcement No. 28, 2022
- Strengthening the Graded Supervision of the Production and Operation of Medical Device, Notice No. 78, September 2022
- Announcement No. 124, 2022 on medical device companies implementing responsibility on safety and quality assurance
- Administrative Measures on Operation of Medical Device, Order No. 54, 2022
- Administrative Measures on Oversea Inspection of Drugs and Medical Devices, Announcement No. 101, 2018

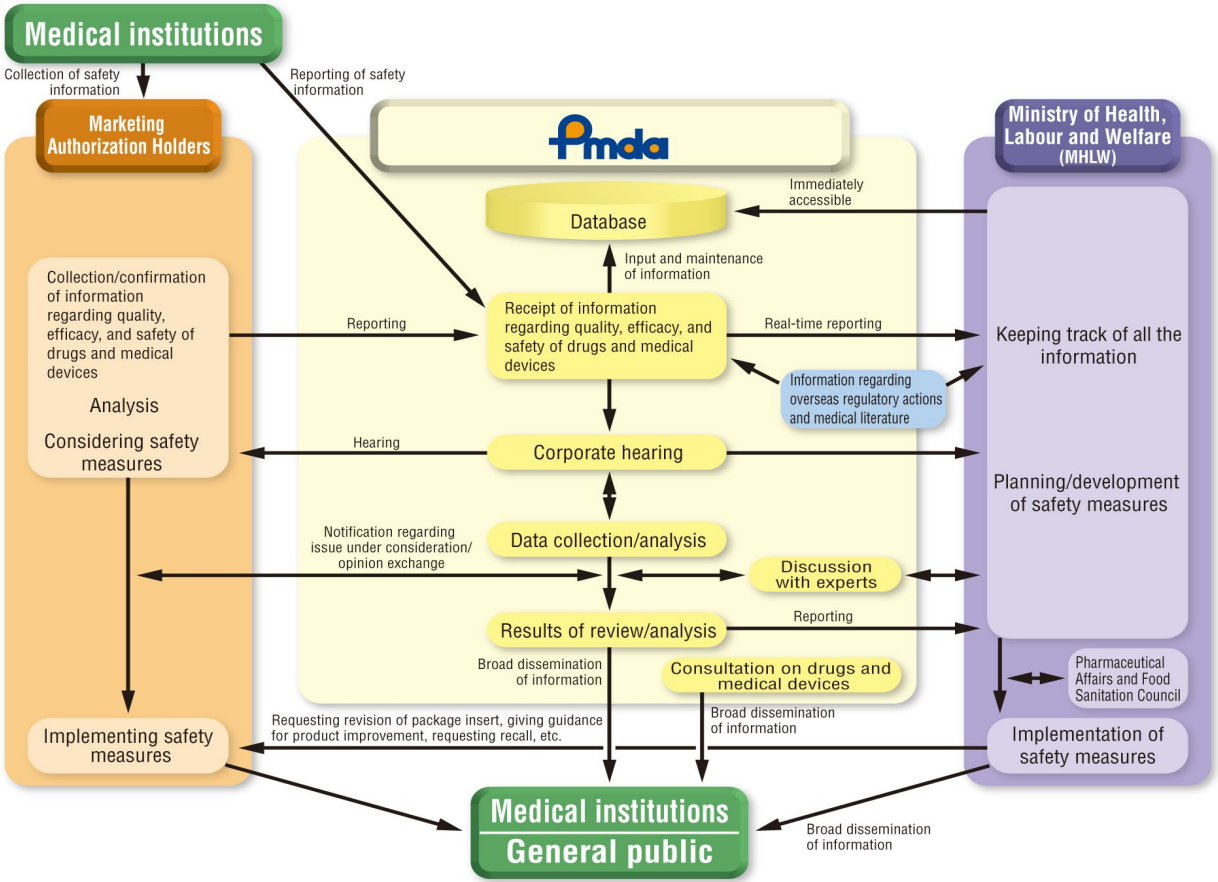
02

Japan and South Korea

Overview of regulations on Post-market Surveillance

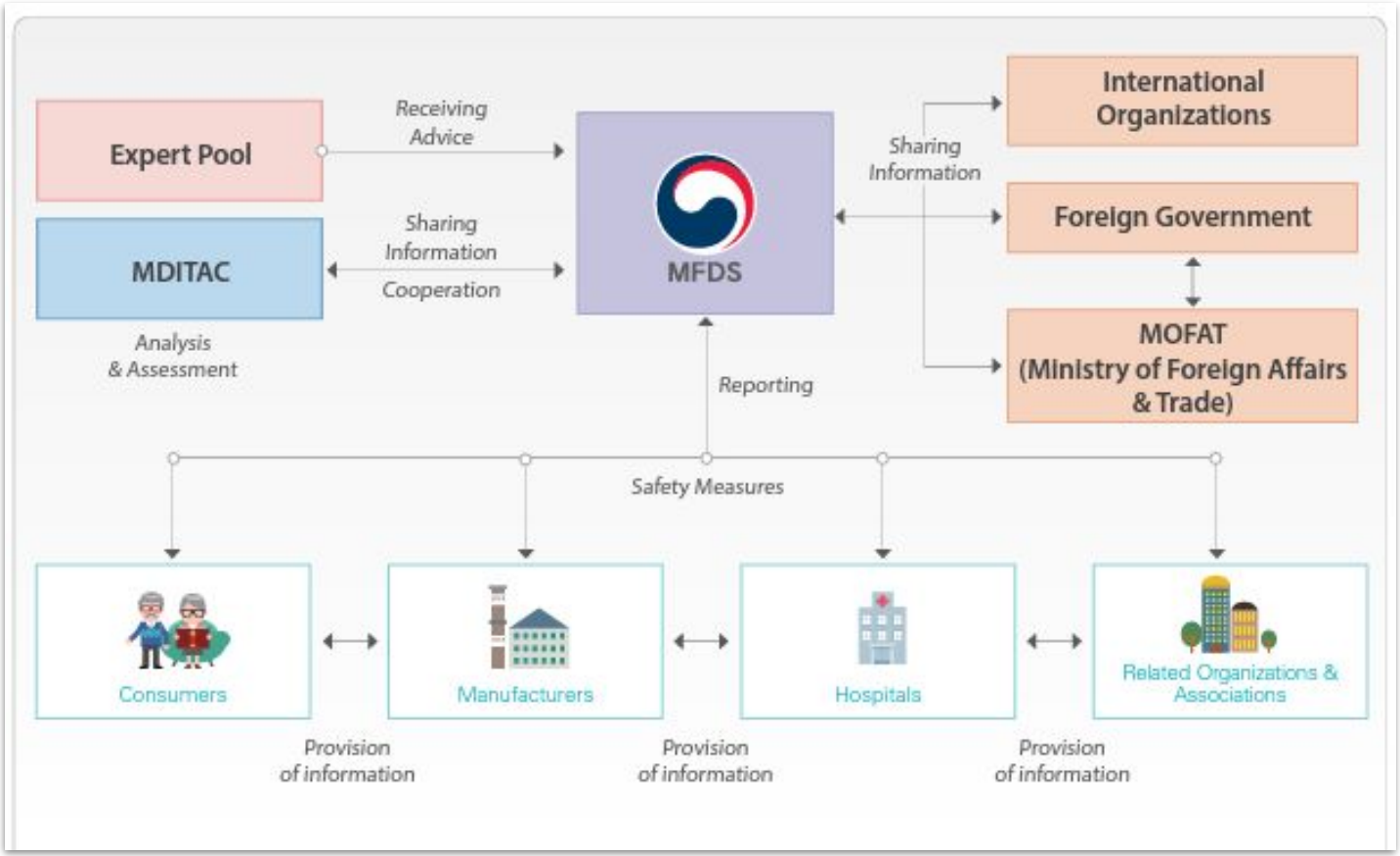
Japan Key Regulations

- Law Ensuring Quality, Effectiveness and Safety of Pharmaceutical Products and Medical Devices, Law No. 63, 2019
- Order for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
- Regulation for Enforcement of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices
- Post-sales Safety Management for Pharmaceuticals, Quasi-drugs, Cosmetics, Medical Devices, and Regenerative Medicines, Ministerial Ordinance No. 135, 2004
- Medical Device Post Market Surveillance and Testing Rules, Ministerial Ordinance No. 38, 2005


Medical institutions
Collection of safety information
Reporting of safety information
Marketing Authorization Holders
Pmda
Ministry of Health, Labour and Welfare (MHLW)
Immediately accessible
Database
Input and maintenance of information
Collection/confirmation of information regarding quality, efficacy, and safety of drugs and medical devices
Analysis
Considering safety measures
Reporting
Receipt of information regarding quality, efficacy, and safety of drugs and medical devices
Real-time reporting
Keeping track of all the information
Information regarding overseas regulatory actions and medical literature
Hearing
Corporate hearing
Planning/development of safety measures
Notification regarding issue under consideration/ opinion exchange
Data collection/analysis
Discussion with experts
Reporting
Results of review/analysis
Broad dissemination of information
Consultation on drugs and medical devices
Pharmaceutical Affairs and Food Sanitation Council
Requesting revision of package insert, giving guidance for product improvement, requesting recall, etc.
Broad dissemination of information
Implementing safety measures
Implementation of safety measures
Medical institutions
General public
Broad dissemination of information

South Korea Key Regulations

- Medical Device Act , Enforcement Decree and Enforcement Regulations
- Regulations on Designation of Medical Devices Subject to Tracking Management, Notice No. 2020-29
- Regulations on Submission of Data on Medical Devices Subject to Tracking Management, Notice No. 2020-29
- Regulations on Integrated Information Management for Medical Devices, Notice No. 2019-46
- Regulations on Management of Safety Information for Medical Devices, Notice No. 2022-34
- Regulations on Post-marketing Investigation of Medical Devices, Notice No. 2022-14


Expert Pool
Receiving Advice
MDITAC
Sharing Information
Cooperation
Analysis & Assessment
MFDS
Reporting
International Organizations
Sharing Information
Foreign Government
MOFAT (Ministry of Foreign Affairs & Trade)
Safety Measures
Consumers
Manufacturers
Hospitals
Related Organizations & Associations
Provision of information
Provision of information
Provision of information

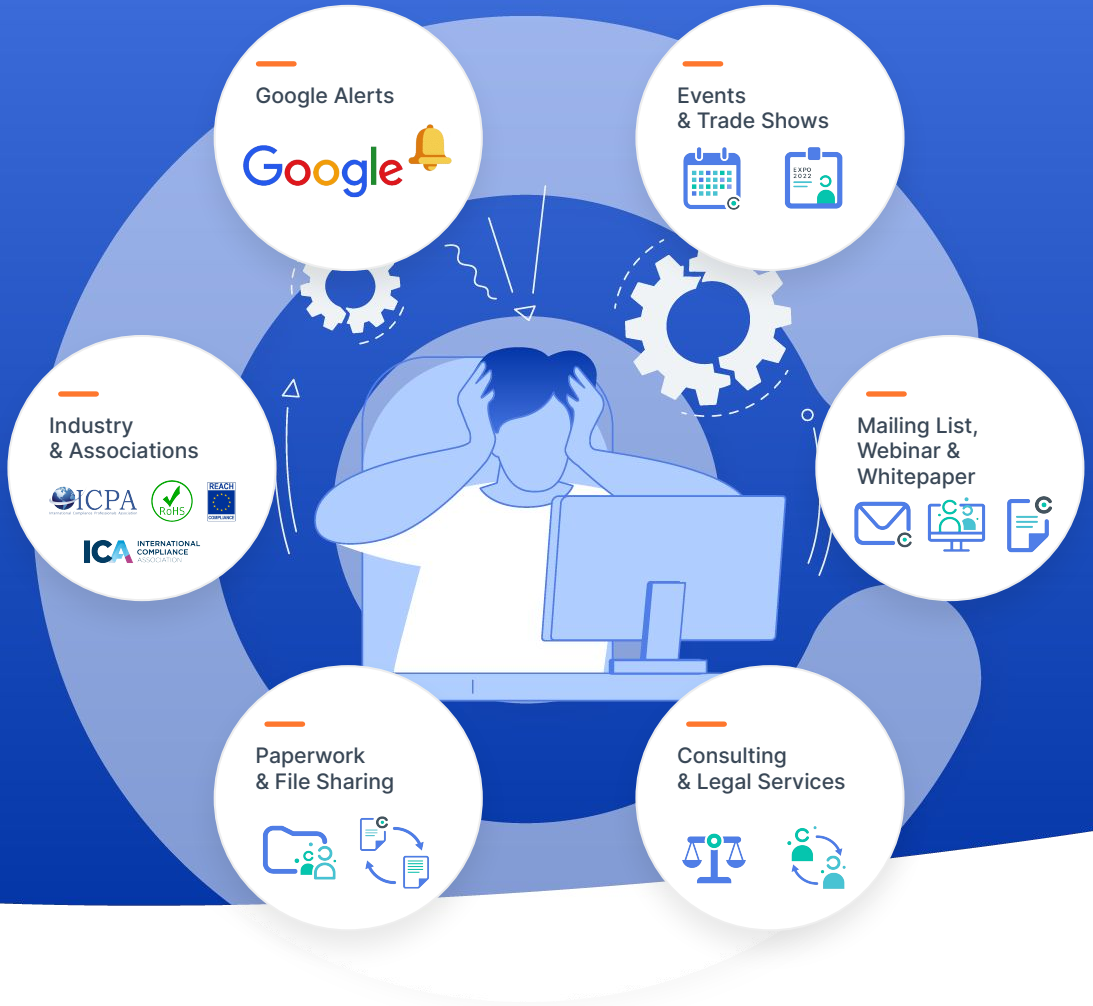
03

Comparison

Regulations across jurisdictions

Jurisdiction	China	Japan	South Korea
Responsible Person	Registration Holder/Filler	Japanese Marketing Authorization Holders (MAH) who distributing the product in Japan	Medical device manufacturers, importers, distributors and their Korean License Holders
Products Scope	Catalogue of Products subject to Key Supervision	All Products	Products subject to Tracking Management
Responsible Authorities	National Medical Products Administration and local authorities	Pharmaceuticals and Medical Devices Agency (PMDA) and the Ministry of Health, Labor and Welfare (MHLW)	Ministry of Food and Drug Safety
Adverse Event Report	Medical Device Adverse Event Monitoring Database System; Individual events (7 days); Group events (12 hours)	PMDA online reporting system; Report immediately to Japan office; Office to report to PMDA within 15 calendar days	Integrated Medical Device Information System (IMDIS); Life-threatening adverse events (within 7 days); additional report to be submitted within 8 days; Others – 30 days

Trying to keep on top of it all...



04

A Smarter Way to Manage Product Compliance

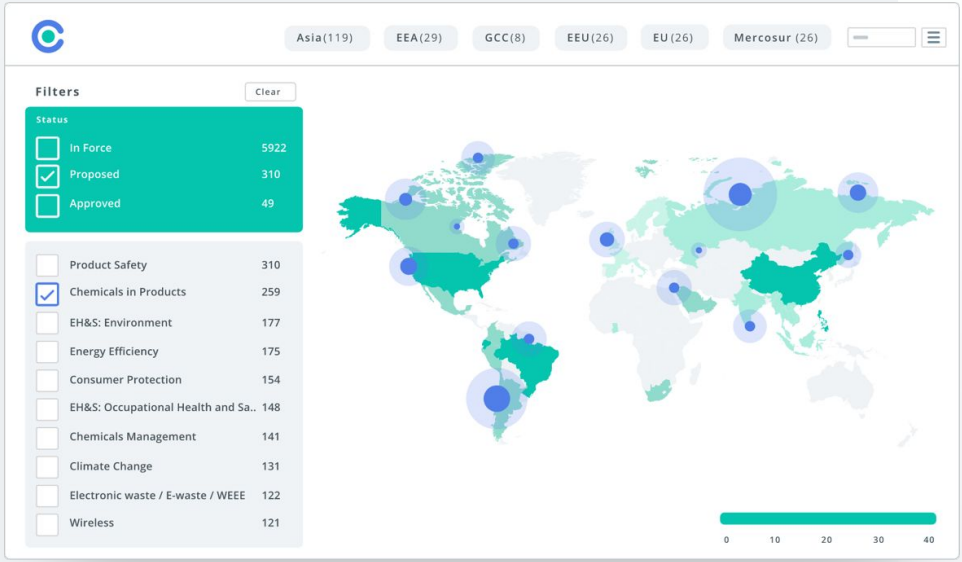
Holistic Market Access Solutions

TECHNOLOGY - C2P

C2P

The Key to Unlocking Market Access

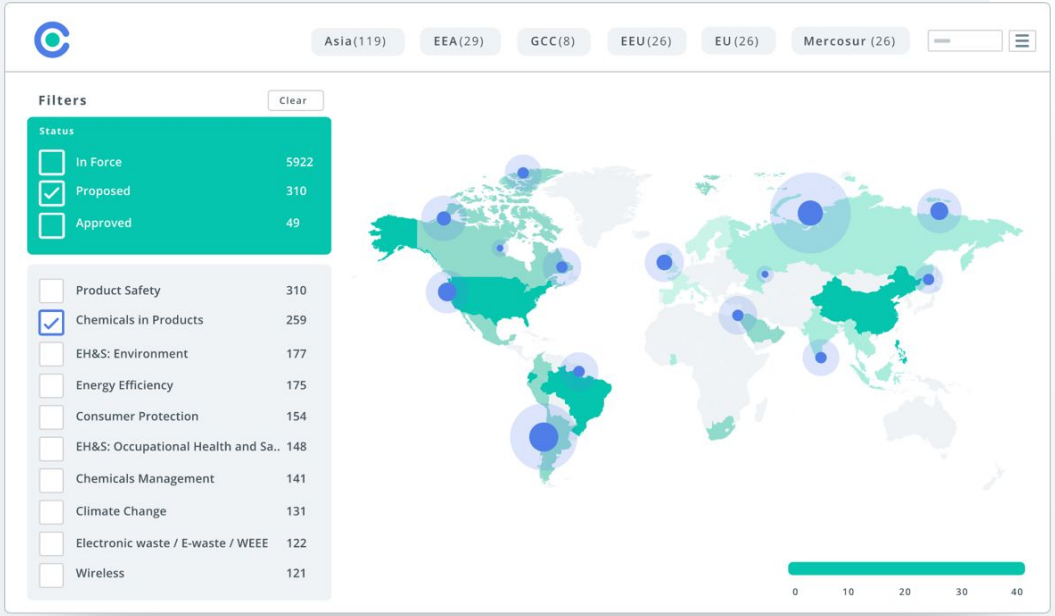
- Enterprise grade technology
- Cloud based platform
- Access to regulatory coverage in 195 countries
- Heatmaps with what's hot & where
- Intelligent search
- AI powered probability analysis
- Productivity tools to improve team collaboration



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

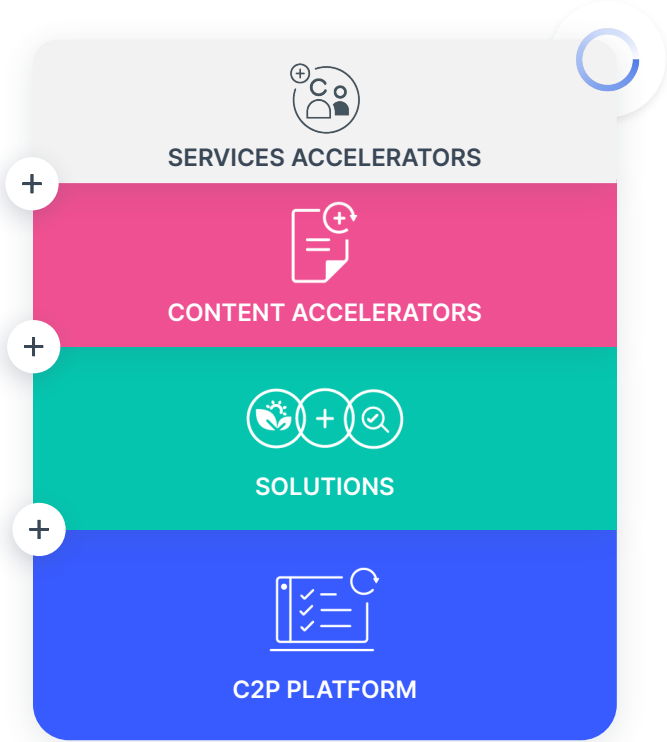


TECHNOLOGY - C2P

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



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

13,485+
Regulatory Sources

REGULATORY CONTENT

Medical Devices Focus Areas

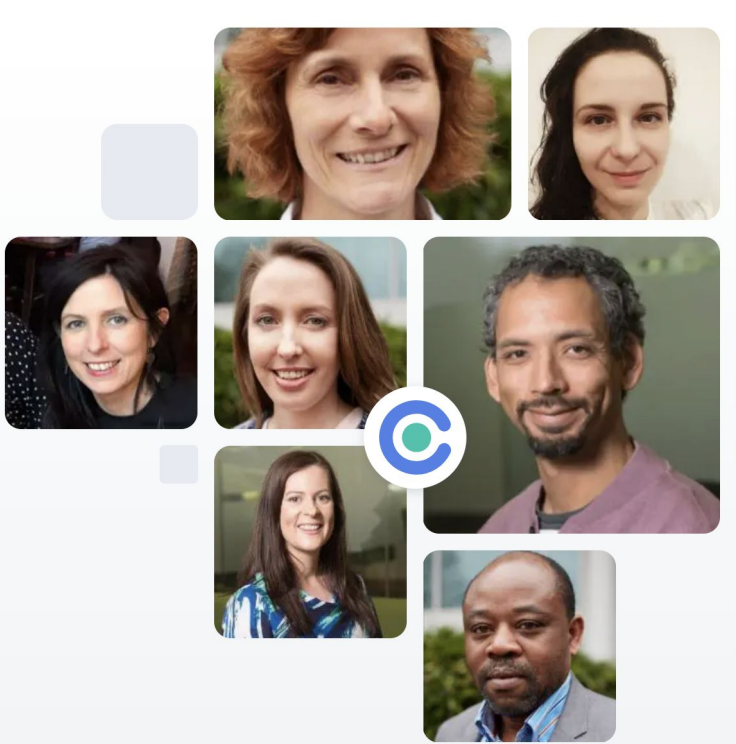
Our content coverage helps you manage critical product compliance issues easily

- 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

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.



Q&A

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