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Welcome

Regulatory Developments in Medical Devices: Your Questions Answered

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At Compliance & Risks

We help our clients monitor and manage regulations, standards, requirements and evidence to better mitigate risk.

- Peace of mind
- Brand protection
- Increased market access
- Future proofing of the business by aligning with global trends

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End-to-End Regulatory Solutions

Market Access

- Customized research
- Consider new products & countries
- Compare obligations in multiple jurisdictions
- Understand regulations at a high level or deep analysis

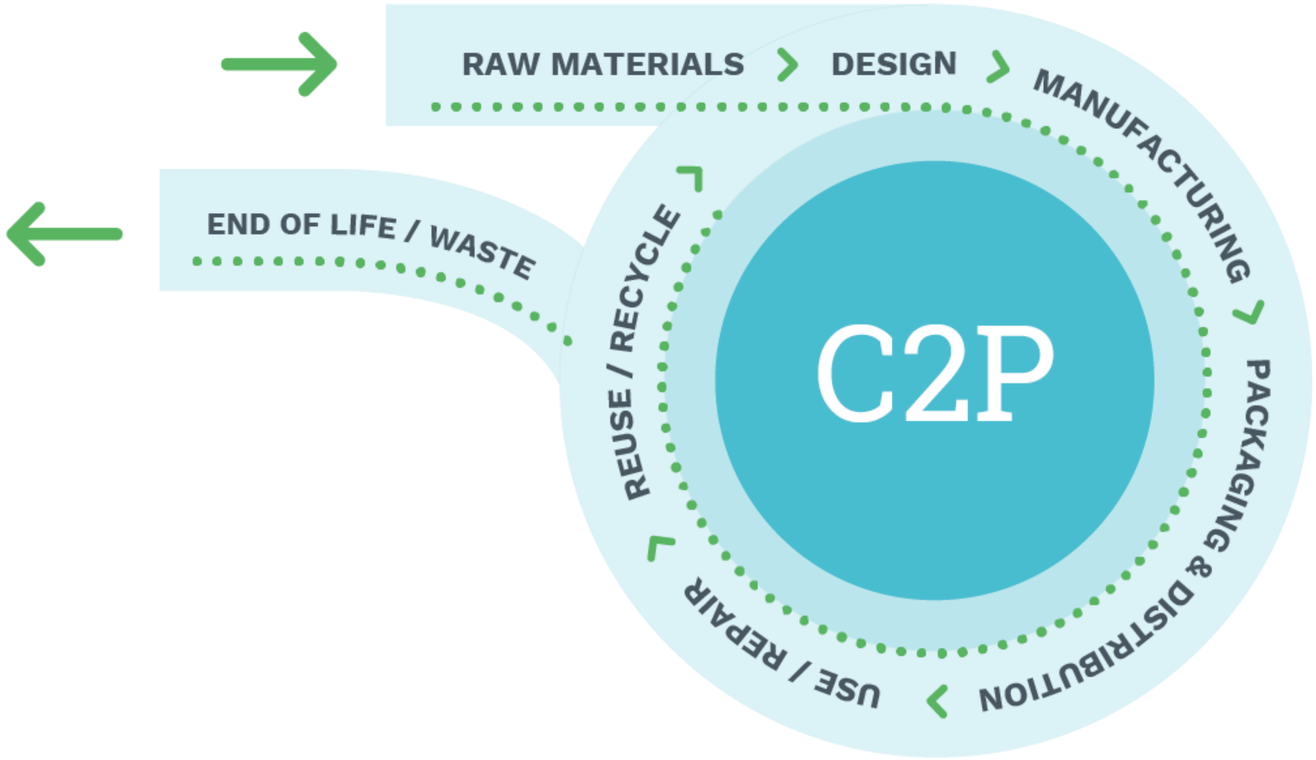
C2P Platform

- Regulations, standards & requirements
- Proposed & enacted regulations
- Global daily monitoring and alerts
- Efficient workflow tools
- Knowledge Management
- SME support

Managed Services

- Fulfil specific compliance functions
- Full suite of compliance skills
- 23 languages
- On-site and/or off-site delivery

Content



- Batteries
- Brexit News
- California Proposition 65
- Carbon Footprinting
- Chemicals in Products
- Chemicals Management
- Chemicals & EH&S: Environment
- Chemicals & EH&S: OH&S
- Circular Economy
- Climate Change
- Conflict Minerals
- Consumer Protection
- Corporate Social Responsibility
- COVID-19
- Cybersecurity
- Data Protection
- Ecodesign
- Ecolabeling
- EH&S (Environment)
- EH&S (Occupational Health & Safety)
- Electromagnetic Compatibility
- Electronic Waste/WEEE
- Energy Efficiency
- EU Drinking Water Directive
- EU REACH
- Food Contact Materials
- Globally Harmonized System
- Human Trafficking and Slavery
- Illegal Logging
- Medical Device
- Nanotechnology
- Non-Financial Reporting Directive
- Packaging
- Product Safety
- Single-use Plastics
- Textiles
- Transboundary Movements of Hazardous Waste
- Transport of Dangerous Goods
- Water Efficiency
- Wireless

Global Coverage – over 200 countries

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Cooley

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products.cooley.com

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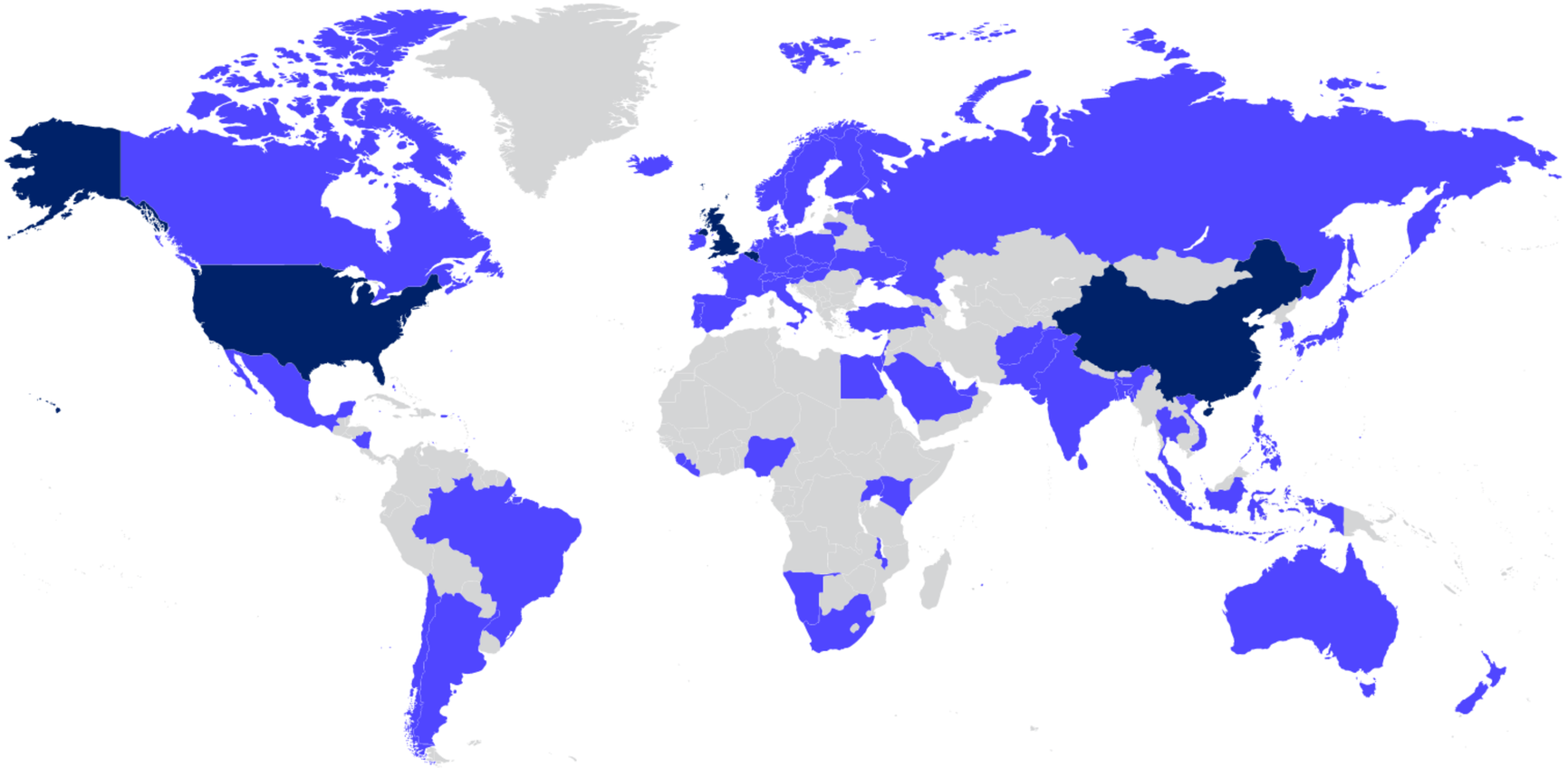
Worldwide Coverage



1300+ lawyers

in 17 offices across
US, Europe and Asia

Serving clients in

90+ countries

across six continents

How we help our clients

Design, manufacture and launch	• Design-stage review • Help clients plan and implement product market launches • Identify and support global compliance for product testing and labeling • Work with companies to identify and implement applicable product standards
Ongoing risk and compliance management	• Help clients identify regulatory risks, business threats and opportunities • Assist with international product surveillance and recall strategies • Advise on risk assessments, recalls and other corrective actions • Develop systems to comply with global regulations • Identify waste and recycling obligations
Product Liability and Consumer engagement	• Coordinating and defending consumer claims in multiple countries • Defending large scale product liability claims • Advise on marketing, advertising, consumer warranty and other consumer-facing issues • Identify and understand applicable consumer legislation and obligations • Manage complex consumer engagement and PR and reputational risks following safety issues
Regulator engagement and policy advisory work	• Support and guide clients on positive international regulator engagement and relationship building • Help clients understand the impact of emerging/future regulation • Work with clients to influence regulatory policy • Advise on global regulatory positions • Advise on and support managing mandatory global product recall reporting obligations

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Regulatory Developments: EU

- Application of Medical Device, Regulation (EU) 2017/745 (MDR) on 26 May 2021
- List of Guidance Documents published to facilitate the smooth implementation of the MDR
- Factsheet for Class I Medical Devices, February 2021
- Guidance Document on Qualification of Medical Devices, March 2021
- Implementation Rolling Plan for Regulation (EU) 2017/745 (MDR) and Regulation (EU) 2017/746 (IVDR), April 2021
- Stronger Rules on Medical Devices, Press Release, May 2021
- Position Paper on Implementation of UDI Requirements for Contact Lenses, Spectacle Frames, Spectacle Lenses & Ready Readers, May 2021

Regulatory Developments: EU (continued)

- Q&A Section on Application of Regulation on Medical Devices Questions and Answers, May 2021
- Guidance on Harmonised Administrative Practices and Technical Solutions under EUDAMED, MDCG 2021-01
- Guidance Document on Certification of Class D In Vitro Diagnostic Medical Devices Requirements, MDCG 2021-04
- Guidance for Standardisation of Medical Devices, MDCG 2021-05
- Clinical Investigations of Medical Devices, MDCG 2021-06
- Guidance Document on Clinical Investigation of Medical Devices Notification Report, MDCG 2021-08
- Guidance Document on Status of Appendixes E-I of IMDRF N48 Under the EU Regulatory Framework for Medical Devices, MDCG 2021-10
- Guidance on Implant Card – 'Device types', MDCG 2021-11
- European Medical Device Nomenclature, FAQ, MDCG 2021-12
- More to come

Regulatory Developments: UK

- Publication of Medicines and Medical Devices Act, 2021
- Guidance Document on Medical Device Software Applications, January 2021
- Draft Medical Devices (Northern Ireland Protocol) Regulations Proposed in June 2021

Regulatory Developments: China

- Publication and Enforcement of Order No. 739 on Supervision and Administration of Medical Devices, June 2021
- Draft Order on Administrative Measures on Registration of In-vitro Diagnostic Reagent Proposed in March 2021
- Draft Order on Administrative Regulations on Medical Device Clinical Trial Quality Control Proposed in May 2021
- Draft Medical Device Clinical Trial Plan and Other 6 Documents Published for Public Comment in May 2021
- Draft Principles on Classification of Artificial Intelligence (AI) Medical Device Software
- Draft Principles on Registration of Artificial Intelligence (AI) Medical Device

Your Questions Answered

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Your Questions Answered:

- What will complying with EU MDR require of you?

- How can you prepare for the EU IVD Regulation coming into force in May 2022?

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Entry into application of MDR and IVDR

- Both MDR and IVDR are Regulations
- This means that, unlike Directives, the Regulations are directly and immediately applicable in the EU Member States without national implementing measures
- Practical impact of IVDR

- Currently within IVDD+/- **20%** IVDs require intervention of a notified body in conformity assessment
- From **26 May 2022** within IVDR +/- **80%** IVDs will require intervention of a notified body in conformity assessment

Only 5 Notified Bodies designation to IVDR so far

Entry into application of MDR and IVDR

- Application
  - MDR – 26 May 2021
  - IVDR – 26 May 2022

- CE Certificates of Conformity issued by notified bodies in accordance with the MDD and IVDD will remain valid until the end of the period indicated on the certificates:
  - For maximum 3 years after application of the MDR – 27 May 2024
  - 2 years after the application of the IVDR – 27 Mary 2024

- Conditions:
  - The medical devices must continue to comply with the relevant current Directives
  - There must be no significant changes in the design and intended purpose of the medical devices
  - The requirements of the Regulations relating to post-market surveillance, market surveillance, vigilance, registration of economic operators and of devices shall apply in place of the corresponding requirements in those Directives

Your Questions Answered:

- Will new medical device regulation increase the product liability risks for businesses?

- To what extent will the UK position diverge from the EU one in light of Brexit?

- What are the key changes in China’s revised Regulations on Medical Device

- Market Authorization Holder Scheme
- New measures to encourage innovation and speed up approval process

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Thank You

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