Navigate local and global regulations for informed strategic decision-making

Empower MedTech innovation with regulatory data, insights and expertise

Ensure compliance, increase approval rates and access new markets

Staying current with the ever-changing regulatory landscape is challenging, often introducing uncertainty around maintaining compliance. Cortellis Regulatory Intelligence™ is a timely and comprehensive database that spans all regulatory functions across the device development life cycle, helping MedTech professionals engaged in regulatory affairs.

- Stay on top of regulatory changes and shape future trends with ease.
- Maintain compliance throughout the full device life cycle.
- Choose the best regulatory pathway and increase the efficiency of approval submissions.
- Understand regional differences and select the best pathway for a globally compliant regulatory strategy.

Stay on top of regulatory changes and shape future trends with ease.

Clarivate™

Maximize insights with high quality, comprehensive data underpinned by extensive domain knowledge and expertise.

75 Countries and regions

900+ Exclusive human English translations

270+ Regulatory summaries

74K+ Reference documents

18 Global regulatory comparisons

700+ Regulatory intelligence reports

Expertise spanning the device development lifecycle.

Cortellis Regulatory Intelligence™ streamlines post-market surveillance

- Identify common and divergent regulatory requirements in multiple countries to compare pre-post approval reporting requirements
- Find and assess all relevant regulations related to your asset in marketed settings
- Track competitors' risk management programs to benchmark your own portfolio.

Cortellis Regulatory Intelligence™ enhances quality management systems for Medical devices and IVDs

- Track current and future GXP requirements in global markets
- Proactively prepare for upcoming FDA inspections and develop remediation plans
- Assess FDA inspection documents (e.g., FDA483s) to understand inspector behavior
- Deepen your understanding of regulatory shifts by reading source documents and translations.

Track current and future GXP requirements in global markets

Territory and regional coverage for Cortellis Regulatory Intelligence — Medical devices and IVDs:

North America

- Canada,
  United States

International

- World Health Organization (WHO), International Conference on Harmonization (ICH)

Middle East, Africa

Algeria, Egypt, Iraq, Israel, Jordan, Kenya, Lebanon, Morocco, Nigeria, Saudi Arabia, South Africa, Tunisia, United Arab Emirates

Europe

- European Union[1], Eurasian Economic Union (EAEU)[1]
- Austria, Belgium, Bulgaria, Croatia, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Netherlands, Norway, Poland, Portugal, Romania, Russian Federation, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine, United Kingdom

Asia Pacific

- ASEAN[1]
- Australia, Hong Kong, India, Indonesia, Japan, China, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand, Vietnam

Latin America

- MERCOSUR[1]
- Argentina, Brazil, Chile, Colombia, Costa Rica, Guatemala, Mexico, Panama, Peru, Venezuela

[1] Coverage of regional body only.

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