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.
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.

Areas of expertise

- 01. Medical device classification
- 02. Quality systems requirements
- 03. Clinical investigation
- 04. Marketing approval
- 05. Establishment registration
- 06. Regulatory authorities
- 07. Fees
- 08. Medical device classification
- 09. Inspections of manufacturing sites
- 10. Packaging and labelling
- 11. Reporting
- 12. Pricing and reimbursement
- 13. Advertising
- 14. Device tracking
- 15. Import and export
- 16. Recalls
- 17. Reporting
- 18. Packaging and labelling
- 19. Inspection of manufacturing sites
- 20. Medical device classification
- 21. Quality systems requirements
- 22. Clinical investigation
- 23. Marketing approval
- 24. Establishment registration
- 25. Regulatory authorities
- 26. Fees
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.

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)

**Europe**

- European Union¹, 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**

- ASEAN¹
- Australia, Hong Kong, India, Indonesia, Japan, China, Malaysia, New Zealand, Philippines, Singapore, South Korea, Taiwan, Thailand, Vietnam

**Middle East, Africa**

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

**Latin America**

- MERCOSUR¹
- Argentina, Brazil, Chile, Colombia, Costa Rica, Guatemala, Mexico, Panama, Peru, Venezuela

¹ Coverage of regional body only.
About Clarivate

Clarivate is a leading global information services provider. We connect people and organizations to intelligence they can trust to transform their perspective, their work and our world. Our subscription and technology-based solutions are coupled with deep domain expertise and cover the areas of Academia & Government, Life Sciences & Healthcare and Intellectual Property. For more information, please visit clarivate.com.

For more information contact our experts today:

+1 215 386 0100 (U.S.)
+44 (0) 20 7433 4000 (Europe)
clarivate.com

© 2023 Clarivate. Clarivate and its logo, as well as all other trademarks used herein are trademarks of their respective owners and used under license.