Cortellis Regulatory Intelligence

Keeping up to speed with the ever-changing global regulatory environment is vital to professionals involved in the development of drugs, biologics, medical devices and IVDs across the product life-cycle.

The challenge
With many different sources of information, finding and analyzing what you need for submissions and beyond is a time-consuming task. To make the right decisions for your organization, fast access to accurate information can make all the difference.

The solution
Cortellis Regulatory Intelligence is your single, comprehensive source for global regulatory information to help you make faster, more informed decisions.

Access and benefit from trusted content to ensure efficiency and regulatory compliance:
- Understand the local regulatory environment in all countries where you do business.
- Save time tracking regulatory changes.
- Share information easily across your organization.
- Anticipate regulatory obstacles with accessible analytics.

Cortellis Regulatory Intelligence is an intuitive and comprehensive intelligence tool. See the full picture of the regulatory landscape, and reach critical decisions more efficiently. Reduce the time you spend searching and analyzing information by starting from one central point.

- Global regulatory comparisons – Granular comparisons of regulatory requirements in countries and markets of your interest, covering the critical areas of regulatory for drugs, biologics, medical devices and IVDs.
- Regulatory intelligence reports – Exclusive intelligence reports to support you with the analysis of regulatory information. Plan your multi-country filing, stay ahead of legislations and guidelines, use Product Information tables to compare existing and emerging products, identify new indications for your product and prepare for committee meetings and inspections.
- Regulatory summaries – Continuously updated by our experts, these summaries support your country filings, guide you through individual country registration processes, and help you decide the most efficient submission routes for your products.
- Reference documents – Updated daily, this repository of documents give you a complete history of the regulatory landscape, giving you additional insights and more context for your research. This also includes documents obtained through FOI requests, exclusive English translations, and historical regulatory documents that have been removed from agencies’ websites. We also include Product Approval Information from various countries to help you compare and refine your tactical plans.
Analytics – question, examine, interpret and compare
Transform information into insight with Spotfire powered regulatory analytics in Cortellis. Easily exported to PowerPoint, you can share and update your findings quickly. Available as an add-on module to your subscription, these dynamic visualizations help you interpret data in a new way, providing actionable answers faster.

FDA advisory committee meetings
Strategically prepare for advisory committee meetings. These easily exported analytics help you:

• Gain intelligence on how a committee might approach your product before it is under review.
• Gain insight into similar products.
• Predict outcomes better through a deeper understanding of previous trends.

FDA warnings and untitled letters
Analyze and learn from past events quickly and easily. Use these analytics to help:

• Progress towards a better compliance – View the most commonly observed mistakes and identify corrective measures needed to strengthen compliance.
• Observe tendencies over time periods – Understand what hits companies most currently.

Regulatory Professional Services
Our Regulatory Services team has a deep experience in Regulatory Affairs and Regulatory Intelligence, supported by an extended network of in-countries regulatory professionals worldwide. The team leverages this regulatory expertise in combination with Clarivate Analytics proprietary databases and advanced technologies to help you make the best strategic decisions.

Our services include
• regulatory spotlights,
• customized comparative tables,
• regulatory landscaping and trend reports, and
• customized dashboards.

For more information visit: clarivate.com/cortellis-regulatory-intelligence/

Cortellis Regulatory Intelligence
Regulatory intelligence solution for professionals worldwide coverage of documents on Drugs, Biologics, Medical Devices and IVDs

Available modules for Drugs, Biologics, Medical Devices and IVD

Region modules
• ASEAN
• European Union
• Gulf Cooperation Council (GCC)*
• International
• Mercosur
• SICA*

Country modules
• Algeria
• Argentina
• Australia
• Austria
• Belgium
• Brazil
• Bulgaria
• Canada
• Chile
• China
• Colombia
• Costa Rica
• Croatia
• Cyprus*
• Czech Republic
• Denmark
• Egypt
• Estonia
• Finland
• France
• Germany
• Greece
• Guatemala
• Hong Kong
• Hungary
• Iceland*
• India
• Indonesia
• Iraq
• Ireland
• Israel
• Italy
• Japan
• Jordan
• Kenya
• Latvia
• Lebanon
• Lithuania
• Luxembourg*
• Malaysia
• Malta*
• Mexico
• Morocco
• Netherlands
• New Zealand
• Nigeria
• Norway
• Panama
• Peru
• Philippines
• Poland
• Portugal
• Romania
• Russian Federation
• Saudi Arabia
• Serbia
• Singapore
• Slovakia
• Slovenia
• South Africa
• South Korea
• Spain
• Sweden
• Switzerland
• Taiwan
• Thailand
• Tunisia
• Turkey
• Ukraine
• United Arab Emirates
• United Kingdom
• USA
• Venezuela
• Vietnam

Country modules marked with * will only be available for Drugs and Biologics.

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