cognizant®

Digital solutions for regulatory compliance

Our digital solutions help clients streamline their regulatory processes, accelerate submissions and improve compliance globally.

Navigating the global regulatory landscape can be challenging due to varied requirements across regulatory bodies and the frequent rate of changes.

Cognizant provides a holistic set of services to help life sciences clients keep abreast of worldwide regulatory requirements, design and plan their submission strategies, and streamline their regulatory operations.

Our industry-aligned services include:

- End-to-end submission strategy optimization for drugs and medical devices
- Gen AI and machine learning solutions to support document authoring and management
- Health authority monitoring to provide global regulatory intelligence updates
- Comprehensive regulatory operations services, including managing submissions across multiple regions and helping ensure compliance with local and corporate regulatory requirements
- System implementations, upgrades, integration services, as well as service requests and incident management

Drive regulatory compliance excellence through intelligent strategy, comprehensive services and innovative technologies.

Regulatory operations management

Our regulatory submission services take a health authority-aligned, geocentric approach to help clients optimize their drug and medical device submission strategies. Cognizant experts bring a deep understanding of the global regulatory landscape to help life sciences companies navigate complex submission processes efficiently and effectively.

Our experts are trained across the leading regulatory platforms and provide accelerators and tools that help streamline and accelerate the submission process.

We leverage gen AI and machine learning technologies to provide content authoring services and perform compliance checks that help accelerate the authoring process and improve accuracy. This includes managing all documents related to regulatory submissions, such as audits, training materials, letters of communication and product information updates.

We provide regulatory operations support, including submission publishing and tracking, and dossier compilation, including chemistry, manufacturing, and controls (CMC), label management and technical review. We also handle submission validation and archival, as well as health authority query management. Additionally, we offer support for supplementary information such as amendments, variation applications and annual reports.

Cognizant helps ensure that the data submitted to health authorities is compliant with their submission requirements, such as the eXtended EudraVigilance Medicinal Product Dictionary (XEVMPD) requirements from the European Medicines Agency (EMA).

Regulatory intelligence

Our solutions help you stay abreast of global regulatory changes by monitoring global health authority websites and delivering comprehensive impact analysis reports on how the changes affect your submission strategy. Leverage AI to develop a strategic mitigation plan and update internal documentation and standard operating procedures (SOP) accordingly.

Application implementation and managed services

We offer system implementation, enhancement, optimization and upgrade services, supporting integrations across regulatory affairs and functional systems such as regulatory information management systems (RIMS), electronic trial master file (eTMF), product lifecycle management (PLM) and quality systems.

Our managed services include proactive monitoring, regular system health checks, performance tuning, patch management, backup and recovery, and security management to ensure your systems run smoothly and efficiently. Additionally, we provide comprehensive support and maintenance services, including service request and incident management, troubleshooting, issue resolution, user assistance and preventive maintenance to identify and address potential issues before they become critical, ensuring minimal downtime and maximum productivity.

Cognizant's Life Sciences business leaders are committed to advancing science to improve patient outcomes by partnering with clients to drive continuous improvement in the way they do business. Cognizant helps its clients set the pace in clinical development, strengthen their regulatory infrastructure, modernize manufacturing and increase market competitiveness. The Cognizant Life Sciences team provides domain-aligned consulting, technology and business process solutions globally, serving the world's leading pharmaceutical, biotech and medical device companies.

To learn more about Cognizant's Life Sciences practice, please visit: cognizant.com/lifesciences

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Cognizant (Nasdaq-100: CTSH) engineers modern businesses. We help our clients modernize technology, reimagine processes and transform experiences so they can stay ahead in our fast-changing world. Together, we're improving everyday life. See how at at www.cognizant.com or follow us @Cognizant.

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