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AI In Regulatory Affairs Market Size, Share & Trends Analysis Report By Component (Software/Platforms, Services), By Deployment Mode (Cloud-based, On-premises), By Application (Regulatory Intelligence, Dossier Management, Document Management), By End-use, By Region, And Segment Forecasts, 2025 - 2033

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Abstracts

The global AI in regulatory affairs market size was estimated at USD 1.31 billion in 2024 and is projected to reach USD 6.65 billion by 2033, growing at a CAGR of 18.60% from 2025 to 2033. The growing complexity of regulatory submissions and rising cost pressures in drug development and regulatory operations are significant factors contributing to market growth.

In addition, the rising cost pressures in drug development and regulatory operations, and technological advancements are some other factors fueling market growth further. The increasing complexity and volume of global regulatory requirements across the pharmaceutical, biotechnology, and medical device sectors drive the AI in regulatory affairs industry. AI platforms reduce time and labor costs by automating routine tasks such as data extraction, document validation, and submission formatting. Predictive analytics allow regulatory teams to forecast submission timelines and optimize resource allocation. Artificial intelligence (AI) also supports regulatory strategy planning, enabling faster approvals and market entry. For instance, in March 2025, ArisGlobal launched LifeSphere Unify, an R&D compliance platform harmonizing safety, medical affairs, regulatory, and quality data for efficiency and compliance.

Another key driver is the rising demand for real-time regulatory intelligence and decision

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support as the industry faces rapid innovation in drug development, including advanced therapies, biologics, and personalized medicine. AI-powered platforms gather actionable insights from large and diverse datasets, helping regulatory professionals anticipate trends and respond more efficiently. In addition, outsourcing regulatory affairs functions to AI-enabled service providers is growing, offering cost-effective and scalable compliance solutions. For instance, in September 2025, Parexel partnered with Weave Bio to accelerate regulatory submission processes and speed time to market for new therapies. Parexel is Weave's CRO design partner, leveraging regulatory expertise to enhance Weave's AI platform.

Global AI In Regulatory Affairs Market Report Segmentation

This report forecasts revenue growth at the global, regional, and country levels and provides an analysis of the latest industry trends in each of the sub-segments from 2021 to 2033. For this study, Grand View Research has segmented the global AI in regulatory affairs market report based on component, deployment mode, application, end-use, and region:

Component Outlook (Revenue, USD Million, 2021 - 2033)

Software/Platforms

Services

Deployment Mode Outlook (Revenue, USD Million, 2021 - 2033)

Cloud-based

On-Premises

Application Outlook (Revenue, USD Million, 2021 - 2033)

Regulatory Intelligence

Data Migration & Integration

Dossier Management

Document Management

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- Spain
- Denmark
- Sweden
- Norway

Asia Pacific

- China
- Japan
- India
- South Korea
- Australia
- Thailand

Latin America

- Brazil
- Argentina

MEA

- South Africa
- Saudi Arabia
- UAE
- Kuwait

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CHAPTER 9. COMPETITIVE LANDSCAPE

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