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Global Regulatory Information Management System Market Size Study & Forecast, By End-use (Pharmaceutical Sector, Medical Device Sector, Other), and Regional Analysis, 2023-2030

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Abstracts

Global Regulatory Information Management System Market is valued at approximately USD 1.83 billion in 2022 and is anticipated to grow with a healthy growth rate of more than 10.4% over the forecast period 2023-2030. A Regulatory Information Management System (RIMS) is specialized software used in the life sciences industry to streamline and manage regulatory processes. To manage and expedite regulatory processes, the life sciences sector uses Regulatory Information Management Systems (RIMS), which are specialist software programs. It centralizes regulatory documentation, makes it easier to prepare and track submissions, oversees change control, keeps audit trails, creates reports, and interfaces with other systems to support effective regulatory operations. In the heavily regulated life sciences industry, RIMS is vital to maintaining regulatory compliance, improving productivity, lowering risks, and facilitating successful product approvals. The rapid development of pharmaceutical industries with a robust IT sector, soaring demand, and increasing adoption of centralized RIMS among medical device companies, coupled with the growing focus on enhanced efficiency in RIMS through technologically advanced systems.

In addition, the market is subject to high regulatory scrutiny, particularly due to the increasingly complex regulations in pharmaceuticals and medical devices, which propel the adoption of RIMS. For instance, the impending implementation of the ICH Q12 guideline (currently in the draft stage) significantly impacts the quality and regulatory systems of pharmaceutical companies. RIMS systems facilitate the management and tracking of these regulatory changes, aiding in the timely planning and submission of regulatory requirements. Moreover, the market witnessed significant merger and

acquisition (M&A) activity among top players. These companies are employing strategic measures like geographical expansion, collaborations, partnerships, and joint ventures to enhance their market influence. For instance, in May 2023, LexisNexis Reed Tech- a data management and analytics solution in the life sciences sector, extended its collaboration with RegDesk, a provider of RIMS platforms. This collaboration aims to assist global medical device companies in navigating the growing complexity of complying with dynamic global regulations more effectively. Furthermore, the increase in integration of advanced technologies such as AI, ML, & predictive analytics, as well as the rise in focus on customization for industry-specific needs presents various lucrative opportunities over the forecasting years. However, the high data security and privacy concerns and the complexities associated with integrating RIMS with existing enterprise systems are hindering the market growth throughout the forecast period of 2023-2030.

The key regions considered for the Global Regulatory Information Management System Market study include Asia Pacific, North America, Europe, Latin America, and Middle East & Africa. North America dominated the market in 2022 owing to the rapid expansion of the medical device industry, as well as the high presence of technologically advanced pharmaceutical companies in the United States and Canada. The region benefits from a multitude of suppliers offering comprehensive regulatory solutions, including RIMS and regulatory submissions. Additionally, the growing adoption of RIMS, especially within the pharmaceutical sector, has spurred enduring partnerships between manufacturers and RIM providers, driving market expansion. For instance, in October 2022, Calyx announced an extension of its contract with a top-ten pharmaceutical company, enabling the utilization of the Calyx Regulatory Information Management (RIM) system for critical clinical trial data submissions to international regulatory bodies until 2026. Whereas Asia Pacific is expected to grow at the highest CAGR over the forecast years. The rising adoption of centralized RIMS among medical device companies and the growing demand for pharmaceuticals due to the increasing prevalence of chronic illnesses are significantly propelling the market demand across the region.

Major market players included in this report are:

K?rber AG

ArisGlobal LLC

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AmpleLogic Inc.

Calyx

Amplexor Life Sciences, LLC

Ennov Group

MasterControl Solutions, Inc.

Rimsys

Ithos Global Inc.

Recent Developments in the Market:

In April 2023, Ennov completed the acquisition of Samarind, a leading provider of Regulatory Information Management (RIM) solutions. This strategic move was intended to bolster Ennov's global presence within the RIM software market.

In May 2023, ArisGlobal finalized the acquisition of SPORIFY, a specialist in Regulatory Data Solutions. This acquisition is part of ArisGlobal's strategy to enhance its LifeSphere Regulatory solutions by integrating advanced data governance capabilities, benefiting its life sciences clientele.

In February 2023, ArisGlobal unveiled a novel Regulatory Information Management (RIM) solution called Investigational Product RIMS. This introduction is designed to meet the rising needs of life sciences and medical device firms.

Global Regulatory Information Management System Market Report Scope:

Historical Data – 2020 - 2021

Base Year for Estimation – 2022

Forecast period - 2023-2030

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Report Coverage - Revenue forecast, Company Ranking, Competitive Landscape, Growth factors, and Trends

Segments Covered - End-use, Region

Regional Scope - North America; Europe; Asia Pacific; Latin America; Middle East & Africa

Customization Scope - Free report customization (equivalent to up to 8 analysts' working hours) with purchase. Addition or alteration to country, regional & segment scope*

The objective of the study is to define the market sizes of different segments & countries in recent years and to forecast the values for the coming years. The report is designed to incorporate both qualitative and quantitative aspects of the industry within countries involved in the study.

The report also caters to detailed information about the crucial aspects such as driving factors & challenges that will define the future growth of the market. Additionally, it also incorporates potential opportunities in micro markets for stakeholders to invest along with a detailed analysis of the competitive landscape and product offerings of key players. The detailed segments and sub-segment of the market are explained below:

By End-use:

Pharmaceutical Sector

Medical Device Sector

Other

By Region:

North America

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Canada

Europe

UK

Germany

France

Spain

Italy

ROE

Asia Pacific

China

India

Japan

Australia

South Korea

RoAPAC

Latin America

Brazil

Mexico

Middle East & Africa

Saudi Arabia

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South Africa

Rest of Middle East & Africa

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