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Regulatory Affairs Outsourcing Market - Global Industry Size, Share, Trends, Opportunity, and Forecast, 2018-2028 Segmented By Service (Regulatory Consulting, Legal Representation, Regulatory Writing & Publishing, Product registration & clinical trial applications, Regulatory Submissions, Regulatory Operations, Other Services), By Category (Pharmaceutical, Medical Device), By Company Size (Small Companies, Medium Companies, Large Companies), By Indication (Oncology, Neurology, Cardiology, Immunology, Other Indications), By Product Stage (Preclinical, Clinical, Premarket Approval), By End Use (Medical Device Companies, Pharmaceutical Companies, Biotechnology Companies), By Region and Competition

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Abstracts

Regulatory Affairs Outsourcing Market is anticipated to witness impressive growth during the forecast period. This can be ascribed to growing research and development activities along with augmenting the volume of clinical trial applications and product registrations. Similarly, growing regulations taken by various governments to contain the cost of drugs are expected to contribute to the economic and competitive pressure, which, in turn, is expected to drive the demand for regulatory affairs outsourcing among life science companies. In 2020, Eli Lilly entered into an agreement to acquire

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Dermira’s immunology portfolio. In addition, the COVID-19 pandemic created an urgent need for vaccines. Thus, the development of vaccines for COVID-19 is likely to have a positive impact on segment growth. Increasing globalization

Increasing globalization had a significant impact on the growth of the Global Regulatory Affairs Outsourcing market. As companies expand their operations globally, they are faced with the challenge of complying with different regulatory frameworks in various regions. This challenge has driven the demand for regulatory affairs outsourcing services as companies look for specialized service providers who can help them navigate the complexities of different regulatory frameworks.

One of the key benefits of outsourcing regulatory affairs services is the expertise that service providers can bring to the table. Service providers who specialize in regulatory affairs have extensive knowledge of the regulatory landscape in different regions, including the applicable laws, regulations, and guidelines. This expertise is critical in ensuring that companies comply with the applicable regulations and avoid costly mistakes. Outsourcing regulatory affairs services allows companies to focus on their core competencies, such as product development and marketing, while leaving compliance-related activities to be specialized service providers. This can help companies improve their operational efficiency, reduce costs, and improve their bottom line. Furthermore, advancements in technology, such as cloud-based regulatory information management systems, have made it easier for companies to outsource regulatory affairs services across different regions. These systems allow service providers to access and manage regulatory information securely, regardless of location. This has made it easier for companies to work with service providers who are located in different parts of the world.

Rising regulatory complexities

Regulatory complexities play a significant role in the growth of the Global Regulatory Affairs Outsourcing Market. Regulatory authorities around the world are increasing their scrutiny of various industries, including healthcare, pharmaceuticals, and medical devices. Compliance with these regulations can be time-consuming and complex, requiring significant resources and expertise. Outsourcing regulatory affairs services can help companies stay on top of regulatory changes and ensure compliance with applicable regulations. Regulatory affairs service providers have extensive knowledge of the regulatory landscape in different regions, including the applicable laws, regulations, and guidelines. They can provide expert advice on compliance-related activities, such as product registration, clinical trial applications, quality assurance, and

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others. Furthermore, regulatory affairs service providers can help companies navigate the complex regulatory requirements of different regions. This includes providing guidance on product labeling and packaging requirements, as well as ensuring compliance with Good Manufacturing Practices (GMPs) and Good Clinical Practices (GCPs). Outsourcing regulatory affairs services can help companies reduce the risk of costly mistakes that can arise from non-compliance with regulatory requirements. These mistakes can lead to delays in product approvals, product recalls, and other negative consequences that can significantly impact a company's bottom line.

Growing demand for specialized expertise

Specialized expertise has been a key factor in the growth of the Global Regulatory Affairs Outsourcing Market. Regulatory affairs are a complex and specialized field that requires in-depth knowledge of various regulatory frameworks, including laws, regulations, and guidelines. As regulatory requirements become increasingly complex and stringent, companies are facing a growing need for specialized expertise to ensure compliance and avoid costly mistakes. Outsourcing regulatory affairs services allows companies to tap into the specialized expertise of regulatory affairs service providers. These providers have extensive knowledge of the regulatory landscape in different regions, as well as the applicable laws, regulations, and guidelines. They can provide expert advice on compliance-related activities, such as product registration, clinical trial applications, and quality assurance, among others.

Furthermore, regulatory affairs service providers can provide specialized expertise in specific areas, such as medical devices, biologics, and pharmaceuticals. This expertise can be particularly valuable for companies that lack in-house regulatory affairs expertise in these areas. By outsourcing regulatory affairs services to specialized service providers, companies can ensure that they have access to the expertise they need to comply with the applicable regulatory requirements. Specialized expertise can help companies stay up to date with the latest regulatory developments and changes. Regulatory affairs service providers are constantly monitoring regulatory changes in different regions and can provide expert guidance on how these changes may impact a company's products or operations.

Cost savings

Cost savings is a significant factor in the growth of the Global Regulatory Affairs Outsourcing Market. Compliance with regulatory requirements can be time-consuming and costly, requiring significant resources and expertise. Companies that lack in-house

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regulatory affairs expertise may need to hire and train staff or use costly external consultants to ensure compliance. Outsourcing regulatory affairs services can provide significant cost savings for companies. Regulatory affairs service providers can offer specialized expertise and resources, often at a lower cost than hiring and training in-house staff or using external consultants. Outsourcing can provide a more flexible and scalable approach to regulatory affairs, allowing companies to scale their regulatory affairs resources up or down as needed, depending on business needs.

Outsourcing regulatory affairs services can help companies avoid costly mistakes that can arise from non-compliance with regulatory requirements. These mistakes can lead to delays in product approvals, product recalls, and other negative consequences that can significantly impact a company's bottom line. Outsourcing regulatory affairs services can help companies improve their operational efficiency. By outsourcing regulatory affairs services, companies can free up internal resources to focus on their core business activities, such as product development and marketing. This can help improve productivity and profitability while still ensuring compliance with regulatory requirements.

Advancements in technology

Advancements in technology have played a significant role in the growth of the Global Regulatory Affairs Outsourcing Market. The increasing adoption of digital technologies has transformed many aspects of the regulatory affairs landscape, creating new opportunities for outsourcing service providers. One major factor that influences the growth of the market is the automation of regulatory affairs processes. The use of advanced software systems and artificial intelligence (AI) tools can help streamline regulatory affairs workflows, reducing the time and effort required to perform compliance-related activities. For example, AI can be used to review large volumes of regulatory documents, helping to identify potential issues and improve the accuracy of regulatory submissions.

Technology has enabled greater collaboration and communication between regulatory affairs service providers and their clients. Cloud-based platforms and other collaboration tools make it easier for regulatory affairs professionals to work together, regardless of their location. This can help improve efficiency and reduce the time and cost associated with regulatory affairs processes. Another area where technology has an impact on the use of real-time data monitoring and analytics. Advanced data analytics tools can help regulatory affairs professionals identify emerging regulatory trends and potential compliance issues, allowing them to proactively address these issues before they become problems. Finally, technology has enabled greater transparency and

accountability in the regulatory affairs process. Digital systems and tools make it easier to track compliance-related activities and provide audit trails, improving compliance and reducing the risk of non-compliance.

Recent Development

In 2021, WIRB-Copernicus Group (WCG) launched a new service called WCG Oncology, which provides comprehensive regulatory and ethical review services for oncology clinical trials.

In 2020, Kinapse (a subsidiary of Syneos Health) launched a new service called Kinapse Quality Labs, which uses advanced data analytics and AI to help clients optimize their regulatory compliance processes.

In 2020, IQVIA launched a new suite of regulatory information management solutions designed to help clients manage the regulatory submission process more efficiently.

In 2019, Qserve Group launched a new platform called QserveConnect, which provides clients with on-demand access to a range of regulatory affairs services, including regulatory strategy, clinical evaluation, and quality management.

In 2019, Accenture launched its Regulatory and Compliance Analytics Solution, a suite of digital tools and services designed to help companies manage regulatory compliance more effectively.

In 2018, Parexel launched its new Regulatory Outsourcing service, designed to help clients navigate complex regulatory environments and improve their time to market.

Market Segmentation

Global Regulatory Affairs Outsourcing Market can be segmented by service, category, company size, indication, production stage, end-use, and by region. Based on service, the market can be segmented into regulatory consulting, legal representation, regulatory writing & publishing, product registration & clinical trial applications, regulatory submissions, regulatory operations, and other services. Based on category, the market can be divided into pharmaceutical and medical devices. Based on company size, the

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market can be segmented into small companies, medium companies, and large companies. Based on indication, the market can be differentiated into oncology, neurology, cardiology, immunology, and other indications. Based on the product stage, the market can be segmented into preclinical, clinical, and premarket approval. Based on end use, the market can be differentiated into medical device companies, pharmaceutical companies, and biotechnology companies.

Market Players

Accell Clinical Research, LLC., Genpact Ltd., CRITERIUM, INC., Promedica International. , WuXi AppTec Co Ltd., Medpace Inc., Charles River Laboratories Inc., ICON plc., Covance, Inc.., Parexel International Corporation., Freyr AS, PHARMALEX GMBH, NDA Group AB, Pharmexon Consulting, Qvigilance, and BlueReg Group are some of the leading players operating in the Global Regulatory Affairs Outsourcing Market.

Report Scope:

In this report, Global Regulatory Affairs Outsourcing market has been segmented into the following categories, in addition to the industry trends, which have also been detailed below:

Regulatory Affairs Outsourcing Market, By Service:

Regulatory Consulting

Legal Representation

Regulatory Writing & Publishing

Product registration & clinical trial applications

Regulatory Submissions

Regulatory Operations

Other services

Regulatory Affairs Outsourcing Market, By Category:

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Pharmaceutical

Medical Device

Regulatory Affairs Outsourcing Market, By Company Size:

Small Companies

Medium Companies

Large Companies

Regulatory Affairs Outsourcing Market, By Indication:

Oncology

Neurology

Cardiology

Immunology

Other Indications

Regulatory Affairs Outsourcing Market, By Product Stage:

Preclinical, Clinical

Premarket Approval

Regulatory Affairs Outsourcing Market, By End Use:

Medical Device Companies

Pharmaceutical Companies

Biotechnology Companies

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Regulatory Affairs Outsourcing Market, By Region:

- North America
  - United States
  - Canada
  - Mexico
- Europe
  - France
  - Germany
  - United Kingdom
  - Italy
  - Spain
- Asia Pacific
  - China
  - India
  - Japan
  - South Korea
  - Australia
- South America
  - Brazil
  - Argentina

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Colombia

Middle East & Africa

South Africa

Saudi Arabia

UAE

Competitive Landscape

Company Profiles: Detailed analysis of the major companies present in the Global Regulatory Affairs Outsourcing Market.

Available Customizations:

With the given market data, TechSci Research offers customizations according to a company's specific needs. The following customization options are available for the report:

Company Information

Detailed analysis and profiling of additional market players (up to five).

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