

This report on the regulatory affairs outsourcing market studies the current as well as future prospects of the market globally. Regulatory affairs outsourcing is rapidly gaining popularity in the global outsourcing market. Pharmaceutical, life science and medical device manufacturing companies are in constant collaboration with various outsourcing companies to get their drugs/devices approved and/or launched in the global market. These regulatory affairs service providers also provide other important services such as pharmacovigilance, medical writing and clinical trial services to pharma, biotech and medical device companies. Presently, these regulatory service providers help these companies to get quick and timely approval/launch of their products with several other advantages such as reduced cost, more time for organization's staff toward core activities and easy penetration in other countries. This report comprises an elaborate executive summary, which includes a market snapshot that provides information about various segments and sub-segments of the market. It also provides information and data analysis of the global regulatory affairs outsourcing market with respect to market segments based on the type of regulatory service provided and their geographic regions.

The regulatory affairs outsourcing market has been segmented into five major service segments: regulatory affairs; clinical trial applications and product registrations; regulatory writing and publishing; regulatory consulting and legal representation; and others. The market segments have been extensively analyzed on the basis of their usefulness, efficacy, generated revenue and geographic coverage. The market size and forecast in terms of USD million for each service type has been provided for the period from 2012 to 2020, considering 2013 as the base year. The report also provides the compounded annual growth rate (CAGR %) for each market segment for the forecast period from 2014 to 2020.

Geographically, the regulatory affairs outsourcing services market has been categorized into four regions: North America, Europe, Asia Pacific, and Rest of the World (ROW). The market size and forecast for each of these regions has been provided for the period from 2012 to 2020, along with their respective CAGRs for the forecast period from 2014 to 2020, considering 2013 as the base year. The research study also incorporates the competitive scenario in these regions. A detailed qualitative analysis of the factors responsible for driving and restraining the growth of the market and future opportunities has been provided in the market overview section. This section of the report also provides market attractiveness analysis, Porter's five forces analysis and the key players' market share analysis in 2013 in order to present a thorough analysis of the overall competitive scenario in the global regulatory affairs outsourcing market.

A list of recommendations has been provided for new entrants as well as existing market players to assist them in taking strategic initiatives to establish a strong presence in the market and increase market share. The report also profiles major players of the regulatory affairs outsourcing market on the basis of various attributes such as company overview, financial overview, business strategies, product portfolio and recent developments. Major players profiled in this report include Quintiles Transnational Holdings, Inc., Covance, Inc., Pharmaceutical Product Development, LLC, PAREXEL International Corporation, ICON plc, Charles River Laboratories International, Inc., WuXi AppTec, Criterium, Inc., Medpace, Inc., Promedica International, Accell Clinical Research, LLC, Clinilabs, Inc. and PRA International, Inc.

The global regulatory affairs outsourcing market has been segmented as follows:

Regulatory Affairs Outsourcing Market, by Services
- Regulatory Affairs
- Clinical Trial Applications and Product Registrations
- Regulatory Writing and Publishing
- Regulatory Consulting and Legal Representation
- Others

Regulatory Affairs Outsourcing Market, by Geography

- North America
- Europe
- Asia Pacific
- Rest of the World (RoW)

Contents:

Chapter 1 Introduction
1.1 Report Description
1.2 Market Segmentation
1.3 Research Methodology

Chapter 2 Executive Summary
2.1 Market Snapshot: Global Regulatory Affairs Outsourcing Market
2.2 Comparative Analysis: Global Regulatory Affairs Outsourcing Market Revenue, by Geography, 2013 & 2020 (Value %)

Chapter 3 Global Regulatory Affairs Outsourcing Market Overview
3.1 Introduction
3.2 Market Drivers
3.2.1 Healthcare Companies Increasingly Prefer to Outsource Their Regulatory Services to CROs
3.2.2 Rising Cost of R&D Activities, Supported by Large Number of Patent Expirations would Boost Demand for Regulatory Affairs Outsourcing Services
3.2.3 Vast Documentation Required During Drug/Device Approval Processes would Increase the Importance of Regulatory Affairs Outsourcing Services
3.3 Market Restraints
3.3.1 Hidden Costs and Rapid Pricing Fluctuations for Regulatory Services Offered by Different CROs Globally
3.3.2 High Risk Associated with Data Security
3.4 Market Opportunities
3.4.1 Huge Scope for Rapid Growth of Regulatory Services in Emerging Economies
3.4.2 Shifting Focus of Pharmaceutical and Life Science Companies Toward Outsourcing of their Key Activities
3.5 Porter’s Five Forces Analysis: Global Regulatory Affairs Outsourcing Market
3.5.1 Bargaining Power of Suppliers
3.5.2 Bargaining Power of Buyers
3.5.3 Threat of Substitutes
3.5.4 Threat of New Entrants
3.5.5 Competitive Rivalry
3.6 Value Chain Analysis: Global Regulatory Affairs Outsourcing Market
3.7 Market Attractiveness Analysis: Global Regulatory Affairs Outsourcing Market, by Geography
3.8 Competitive Landscape
3.8.1 Market Share Analysis, by Key Players: Global Regulatory Affairs Outsourcing Market, 2013 (Value %)

Chapter 4 Global Regulatory Affairs Outsourcing Market, by Services
4.1 Overview
4.1.1 Global Regulatory Affairs Outsourcing Market Revenue, by Services, 2012 – 2020 (USD Million)
4.1.2 Comparative Analysis: Global Regulatory Affairs Outsourcing Market Revenue, by Services, 2013 & 2020 (Value %)
4.2 Regulatory Affairs
4.2.1 Outsourcing of Regulatory Affairs: Global Market Revenue, 2012 – 2020 (USD Million)
4.3 Clinical Trial Applications and Product Registrations
4.3.1 Outsourcing of Clinical Trial Applications and Product Registrations: Global Market Revenue, 2012 – 2020 (USD Million)
4.4 Regulatory Writing and Publishing
4.4.1 Outsourcing of Regulatory Writing and Publishing: Global Market Revenue, 2012 – 2020 (USD Million)
4.5 Regulatory Consulting and Legal Representation
4.5.1 Outsourcing of Regulatory Consulting and Legal Representation: Global Market Revenue, 2012 – 2020 (USD Million)
4.6 Other Regulatory Affairs
4.6.1 Outsourcing of Other Regulatory Affairs: Global Market Revenue, 2012 – 2020 (USD Million)
Chapter 5 Global Regulatory Affairs Outsourcing Market, by Geography
5.1 Overview
5.1.1 Global Regulatory Affairs Outsourcing Market Revenue, by Geography, 2012 – 2020 (USD Million)
5.2 North America
5.2.1 North America Regulatory Affairs Outsourcing Market Revenue, 2012 - 2020 (USD Million)
5.3 Europe
5.3.1 Europe Regulatory Affairs Outsourcing Market Revenue, 2012 - 2020 (USD Million)
5.4 Asia Pacific
5.4.1 Asia Pacific Regulatory Affairs Outsourcing Market Revenue, 2012 - 2020 (USD Million)
5.5 Rest of the World (RoW)
5.5.1 RoW Regulatory Affairs Outsourcing Market Revenue, 2012 - 2020 (USD Million)

Chapter 6 Recommendations
6.1 Target the Emerging Markets of Developing Economies
6.2 Develop Strategic Alliances with Life Science, Pharmaceutical and Medical Device Companies
6.3 Ensure High Level Security of Vital and Confidential Data

Chapter 7 Company Profiles
7.1 Accell Clinical Research, LLC
7.1.1 Company Overview
7.1.2 Financial Overview
7.1.3 Product Portfolio
7.1.4 Business Strategies
7.1.5 Recent Developments
7.2 Charles River Laboratories International, Inc.
7.2.1 Company Profile
7.2.2 Financial Overview
7.2.3 Product Portfolio
7.2.4 Business Strategies
7.2.5 Recent Developments
7.3 Clinilabs, Inc.
7.3.1 Company Overview
7.3.2 Financial Overview
7.3.3 Product Portfolio
7.3.4 Business Strategies
7.3.5 Recent Developments
7.4 Covance, Inc.
7.4.1 Company Overview
7.4.2 Financial Overview
7.4.3 Product Portfolio
7.4.4 Business Strategies
7.4.5 Recent Developments
7.5 Criterium, Inc.
7.5.1 Company Overview
7.5.2 Financial Overview
7.5.3 Product Portfolio
7.5.4 Business Strategies
7.5.5 Recent Developments
7.6 ICON plc
7.6.1 Company Overview
7.6.2 Financial Overview
7.6.3 Product Portfolio
7.6.4 Business Strategies
7.6.5 Recent Developments
7.7 Medpace, Inc.
7.7.1 Company Overview
7.7.2 Financial Overview
7.7.3 Product Portfolio
7.7.4 Business Strategies
7.7.5 Recent Developments
7.8 PAREXEL International Corporation
7.8.1 Company Overview
7.8.2 Financial Overview
7.8.3 Product Portfolio
7.8.4 Business Strategies
7.8.5 Recent Developments
7.9 Pharmaceutical Product Development, LLC
7.9.1 Company Overview
7.9.2 Financial Overview
7.9.3 Product Portfolio
7.9.4 Business Strategies
7.9.5 Recent Developments
7.10 PRA International, Inc.
7.10.1 Company Overview
7.10.2 Financial Overview
7.10.3 Product Portfolio
7.10.4 Business Strategies
7.10.5 Recent Developments
7.11 Promedica International
7.11.1 Company Overview
7.11.2 Financial Overview
7.11.3 Product Portfolio
7.11.4 Business Strategies
7.11.5 Recent Developments
7.12 Quintiles Transnational Corporation
7.12.1 Company Overview
7.12.2 Financial Overview
7.12.3 Product Portfolio
7.12.4 Business Strategies
7.12.5 Recent Developments
7.13 WuXi AppTec
7.13.1 Company Overview
7.13.2 Financial Overview
7.13.3 Product Portfolio
7.13.4 Business Strategies
7.13.5 Recent Developments

List of Figures:

FIG. 1 Regulatory Affairs Outsourcing: Market Segmentation
FIG. 2 Global Regulatory Affairs Outsourcing Market, by Services, 2013 (USD Million)
FIG. 3 Comparative Analysis: Global Regulatory Affairs Outsourcing Market Revenue, by Geography, 2013 & 2020 (Value %)
FIG. 4 Porter's Five Forces Analysis: Global Regulatory Affairs Outsourcing Market
FIG. 5 Value Chain Analysis: Global Regulatory Affairs Outsourcing Market
FIG. 6 Market Attractiveness Analysis: Global Regulatory Affairs Outsourcing Market, by Geography (2013)
FIG. 7 Market Share Analysis, by Key Players: Global Regulatory Affairs Outsourcing Market, 2013 (Value %)
FIG. 8 Comparative Analysis: Global Regulatory Affairs Outsourcing Market Revenue, by Services, 2013 & 2020 (Value %)
FIG. 9 Outsourcing of Regulatory Affairs: Global Market Revenue, 2012 – 2020 (USD Million)
FIG. 10 Outsourcing of Clinical Trial Applications and Product Registrations: Global Market Revenue, 2012 – 2020 (USD Million)
FIG. 11 Outsourcing of Regulatory Writing and Publishing Global Market Revenue, 2012 – 2020 (USD Million)
FIG. 12 Outsourcing of Regulatory Consulting and Legal Representation: Global Market Revenue, 2012 – 2020 (USD Million)
FIG. 13 Outsourcing of Other Regulatory Affairs: Global Market Revenue, 2012 – 2020 (USD Million)
FIG. 14 North America Regulatory Affairs Outsourcing Market Revenue, 2012 – 2020 (USD Million)
FIG. 15 Europe Regulatory Affairs Outsourcing Market Revenue, 2012 – 2020 (USD Million)
FIG. 16 Asia Pacific Regulatory Affairs Outsourcing Market Revenue, 2012 – 2020 (USD Million)
FIG. 17 RoW Regulatory Affairs Outsourcing Market Revenue, 2012 – 2020 (USD Million)
FIG. 18 Charles River Laboratories International, Inc.: Annual Revenue, 2011 – 2013 (USD Million)
FIG. 19 Covance, Inc.: Annual Revenue, 2011 – 2013 (USD Million)
FIG. 20 ICON plc: Annual Revenue, 2011 – 2013 (USD Million)
FIG. 21 PAREXEL International Corporation: Annual Revenue, 2011 – 2013 (USD Million)
FIG. 22 Quintiles Transnational Corporation: Annual Revenue, 2011 – 2013 (USD Million)
FIG. 23 WuXi AppTec, Inc.: Annual Revenue, 2011 – 2013 (USD Million)
List of Tables:

TABLE 1 Market Snapshot: Global Regulatory Affairs Outsourcing Market
TABLE 2 Global Regulatory Affairs Outsourcing Market Revenue, by Services, 2012 – 2020 (USD Million)
TABLE 3 Global Regulatory Affairs Outsourcing Market Revenue, by Geography, 2012 – 2020 (USD Million)

Ordering:
Order Online - http://www.researchandmarkets.com/reports/3030053/
Order by Fax - using the form below
Order by Post - print the order form below and send to

Research and Markets,
Guinness Centre,
Taylors Lane,
Dublin 8,
Ireland.
Fax Order Form
To place an order via fax simply print this form, fill in the information below and fax the completed form to 646-607-1907 (from USA) or +353-1-481-1716 (from Rest of World). If you have any questions please visit http://www.researchandmarkets.com/contact/

Order Information
Please verify that the product information is correct and select the format(s) you require.

Web Address: http://www.researchandmarkets.com/reports/3030053/
Office Code: SCD2SI2S

Product Formats
Please select the product formats and quantity you require:

<table>
<thead>
<tr>
<th>Quantity</th>
<th>Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electronic (PDF)</td>
<td>USD 4795</td>
</tr>
<tr>
<td>Single User</td>
<td></td>
</tr>
<tr>
<td>USD 7795</td>
<td></td>
</tr>
<tr>
<td>1 - 5 Users</td>
<td></td>
</tr>
<tr>
<td>Enterprisewide</td>
<td>USD 10795</td>
</tr>
</tbody>
</table>

Contact Information
Please enter all the information below in BLOCK CAPITALS

Title: Mr [ ] Mrs [ ] Dr [ ] Miss [ ] Ms [ ] Prof [ ]
First Name: __________________________________________ Last Name: ______________________________________
Email Address: * ______________________________________
Job Title: __________________________________________
Organisation: _______________________________________
Address: __________________________________________
City: _______________________________________________
Postal / Zip Code: __________________________________
Country: ___________________________________________
Phone Number: ______________________________________
Fax Number: ________________________________________

* Please refrain from using free email accounts when ordering (e.g. Yahoo, Hotmail, AOL)
Payment Information

Please indicate the payment method you would like to use by selecting the appropriate box.

☐ Pay by credit card: You will receive an email with a link to a secure webpage to enter your credit card details.

☐ Pay by check: Please post the check, accompanied by this form, to:
Research and Markets,
Guinness Center,
Taylors Lane,
Dublin 8,
Ireland.

☐ Pay by wire transfer: Please transfer funds to:

<table>
<thead>
<tr>
<th>Description</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Account number</td>
<td>833 130 83</td>
</tr>
<tr>
<td>Sort code</td>
<td>98-53-30</td>
</tr>
<tr>
<td>Swift code</td>
<td>ULSBIE2D</td>
</tr>
<tr>
<td>IBAN number</td>
<td>IE78ULSB98533083313083</td>
</tr>
<tr>
<td>Bank Address</td>
<td>Ulster Bank, 27-35 Main Street, Blackrock, Co. Dublin, Ireland.</td>
</tr>
</tbody>
</table>

If you have a Marketing Code please enter it below:

Marketing Code: ________________

Please note that by ordering from Research and Markets you are agreeing to our Terms and Conditions at http://www.researchandmarkets.com/info/terms.asp