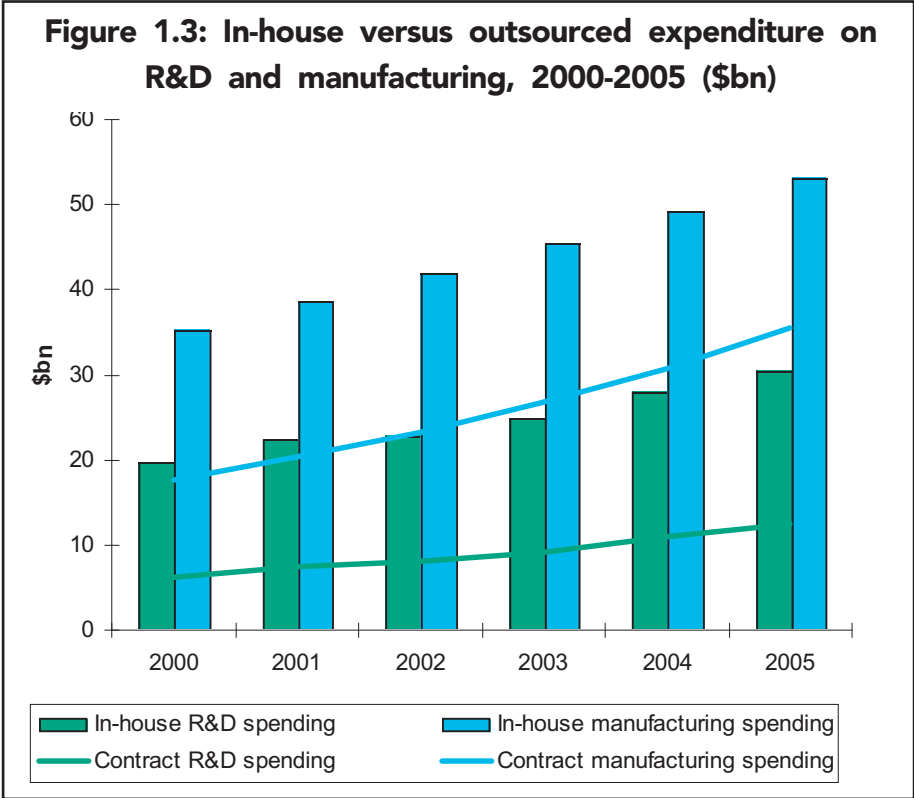


Pharmaceutical Outsourcing Strategies

Market expansion, offshoring and strategic management in the CRO and CMO marketplace

A new healthcare management report

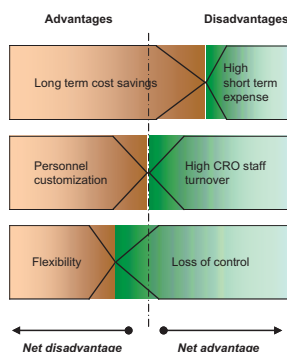


Discover the future of pharmaceutical outsourcing and develop effective long term strategies with the help of this new management report...

Pharmaceutical Outsourcing Strategies

Market expansion, offshoring and strategic management in the CRO and CMO marketplace

Figure 2.11: Potential advantages and disadvantages of using a CRO



Source: Pharmaceutical Outsourcing Strategies

"In general, CROs allow drug developers to save on the long term expenses of establishing a comprehensive in-house infrastructure for pre-clinical and/or clinical testing. This is a strong advantage, as these expenses can often encompass dozens of highly paid B.S., M.S. and Ph.D. level staff members, extensive testing facilities and equipment in addition to variable costs related to patient recruitment..."

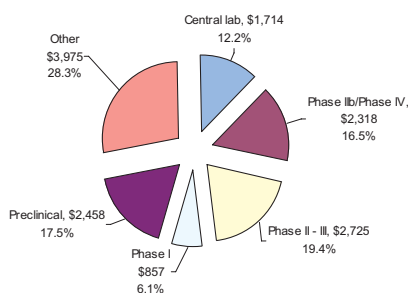
Over the last decade outsourcing has become an important strategic issue for pharmaceutical companies. Rising pressure to reduce costs and time-to-market has led to outsourcing not only of traditional non-core functions such as manufacturing and clinical trials, but also increasingly of technically demanding areas such as drug discovery and biotech R&D.

Pharmaceutical Outsourcing Strategies is a new report which provides a comprehensive and up to date review of contract research and manufacturing, in addition to key strategies for pharmaceutical companies to optimize their relationships with contractors. Emerging trends are evaluated and offshore outsourcing opportunities are analyzed in the rapidly growing markets of **Eastern Europe, China and India**.

Use this report's best practice case studies and unique examination of future outsourcing trends - including cutting edge technologies and novel contract alliances to ensure that you implement the optimal strategies for your company's needs.

Key findings of the report...

Figure 1.4: Contract research revenues by segment, 2005 (\$m)



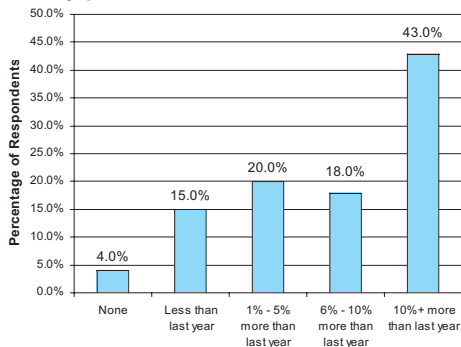
Source: Pharmaceutical Outsourcing Strategies

"Phase II - III studies are the most popular service performed by CROs, accounting for 19.1% of total fees. Pre-clinical studies follow with 17.5% of fees and Phase Ib/Phase IV studies took third place with 16.5%. ..."

- **Although Eastern Europe possessed the most established infrastructure for outsourcing in 2005**, the local pharmaceutical industries in India and China are growing quickly and over the next five years, are expected to account for a significantly greater portion of both contract research and contract manufacturing work.
- **In recent years, the portfolio of services offered by CROs has widened dramatically to include R&D enabling technologies** (e.g. drug discovery, genomics, high throughput screening, combinatorial chemistry) using proprietary techniques for which they often own the intellectual property rights. Portfolios may also include post-commercialization services such as contract sales and marketing.
- **CROs are now seeking new revenue opportunities by entering into partnering relationships with sponsors** in which they share the risk and rewards of developing a particular product. (PPDI case study)
- **In quickly-changing and highly technology-dependent areas like drug discovery and biotechnology**, costs are considerably higher for drug developers to establish state-of-the-art facilities in-house, therefore, outsourcing is often less expensive.

Key questions answered in this report

Figure 1.1: Degree of outsourcing to be conducted by pharmaceutical outsourcers in 2006



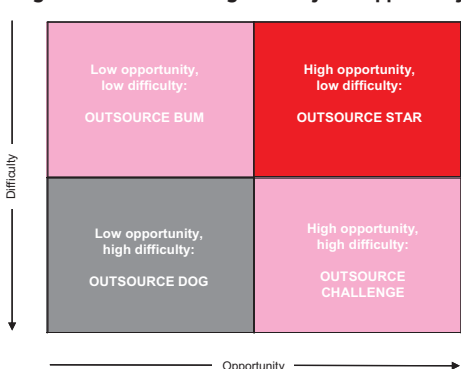
Source: Pharmaceutical Outsourcing Strategies

"Because of the broad range of skills required to bring a novel compound to market, drug developers have always relied, to a greater or lesser extent, on contract service organizations, since even the largest, most financially stable pharmaceutical companies often do not have sufficient resources to possess these skills in-house..."

- What are the associated advantages and disadvantages of using CRO's and CMO's?
- What new portfolio of services are CRO's now providing?
- What are the emerging fields in the pharmaceutical outsourcing market?
- How are sponsors minimizing relationship risks with contractors?
- Why outsource manufacturing and risk costly technology transfer delays?
- How are smaller CROs now competing with larger, full service groups?
- How is eTechnology being applied by CRO's and CMO's to reduce time and cost?

Top five reasons to order your copy today

Figure 5.14: Outsourcing difficulty vs. opportunity



Source: Pharmaceutical Outsourcing Strategies

"The opportunities and difficulties associated with outsourcing a particular project often vary considerably with the sponsor, contractor, and the unique aspects of the drug itself...The decision to outsource R&D and/or production of these Outsource Stars is relatively straightforward. Similarly, Outsource Dogs or projects with low opportunity and high difficulty are also easy to address..."

- **Critically assess offshore outsourcing in Eastern Europe, India and China**, focusing on key current issues such as patent protection and related legislative changes.
- **Analyze best practice outsourcing strategies undertaken by the industry's key players including Wyeth, Novartis and GlaxoSmithKline** and ensure that you implement these into your future processes.
- **Integrate into your outsourcing processes** strategies to mitigate a range of IP, confidentiality, financial, performance risks associated with using research and manufacturing contractors.
- **Understand how eTechnologies such as internet based patient recruitment and electronic data capture will** enable you to reduce the time and cost associated with drug discovery and increase the data integrity of clinical trials.
- **Understand how Pharmaceutical Contract Research Alliances (PCRA's) are enabling niche contractors** to compete more effectively with large full service CRO's.

This new report will provide you with...

Table 2.2: Recent drug recalls, 2000-2006

Drug	Company	Use	Recall date	Reason	# affected patients
Exanta	AstraZeneca	Venous thrombo-embolism	Feb 2006	Liver toxicity	< 1 million
Bextra	Pfizer	Pain	Apr 2005	Cardiovascular effects	11 million
Vioxx	Merck & Co.	Pain	Sep 2004	Cardiovascular effects	84 million
Baycol	Bayer	Cholesterol	Aug 2001	Fatal rhabdomyolysis	6 million
Raplon	Organon	Pain	Mar 2001	Deaths from bronchospasm	1 million
Lotronex	GSK	Irritable bowel syndrome	Nov 2000	Ischemic colitis	< 1 million
Propulsid	J&J	Heartburn	Mar 2000	Fatal heart rhythm disturbances	30 million
Rezulin	Pfizer	Diabetes	Mar 2000	Fatal liver toxicity	10 million

GSK = GlaxoSmithKline; J&J = Johnson & Johnson

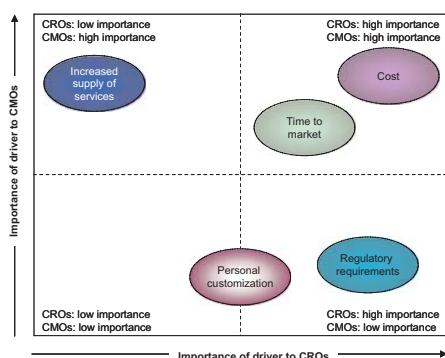
Source: Pharmaceutical Outsourcing Strategies

"Many recent drug withdrawals have been very high profile, affecting a large number of users and resulting in a high number of associated fatalities or other significant events. The most significant withdrawal to date has been Merck & Co's Vioxx, which was recalled in September 2004 after more than 80m prescriptions had been written for the drug worldwide since its introduction in 1999..."

- **Analysis of the drivers of pharmaceutical outsourcing and how these have evolved over time**, highlighting the growing pressures to bring drugs to market more quickly and the increased complexity of clinical trials and regulatory submissions.
- **Sizing of contract research and manufacturing markets** with analysis of the positions of key players such as Avecia, Quintiles and Covance.
- **Examination of offshore outsourcing in Eastern Europe, India and China** that focuses on key current issues such as patent protection and related legislative changes.
- **Analysis of emerging areas of outsourcing** including drug discovery, biotechnology and distribution.
- **Case studies describing successful implementation of different outsourcing strategies** - including Wyeth, Novartis and GlaxoSmithKline.

Hot issues covered in the report...

Figure 2.7: Drivers of CRO and CMO usage, 2005



Source: Pharmaceutical Outsourcing Strategies

"In 2005 cost was the most important driver for both contract research and contract manufacturing services. Time to market is also extremely important for both. Other drivers, however, vary in importance between CROs and CMOs..."

- **Increasing imperatives to bring new drugs to market quickly.** Intensifying competition among developers of branded pharmaceuticals has made reducing time to market increasingly important; the ability of CROs to cut clinical trial times is now critical to the drug development process.
- **Virtual drug developers, representing the next evolutionary step in outsourced drug development.** These are companies that outsource a large majority of their functions to a network of contractors, while only retaining very core functions such as business development, fundraising and finance.
- **Biotech contractors.** With a rising number of now biological compounds subject to different regulations and research processes, there has been an emergence of a large number of biotech contractors.
- **Offshore patent challenges.** Although the Indian and Chinese laws protecting pharmaceutical patents have historically been weak, recent changes have resulted in greater levels of protection and lower risk of using offshore outsourcers.

Sample information from the report

Chapter 2: Drivers of pharmaceutical outsourcing

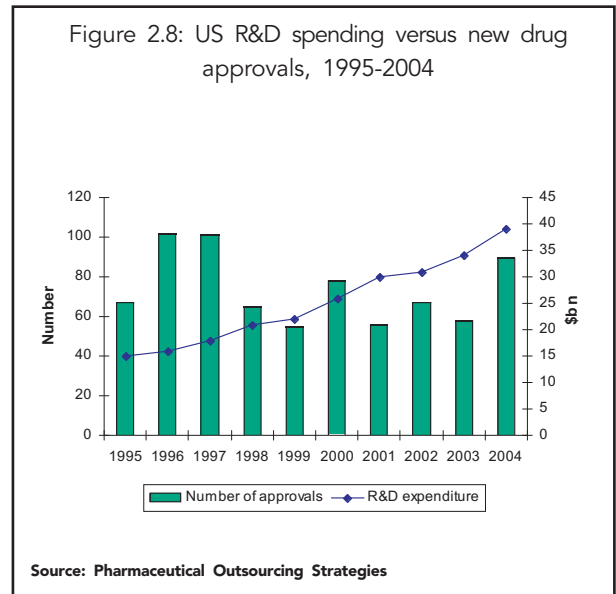
Minimizing time to market

As more blockbuster drugs lose patent protection and R&D productivity continues to decline, minimizing time to market for new drugs is becoming increasingly important. By 2008, an unprecedented number of blockbuster drugs will lose patent protection and become subject to competition from low priced generics, slowing the double digit growth the pharmaceutical industry had experienced previously. From 2000 to 2005, for example, the compound annual growth rate (CAGR) for global blockbuster revenues was an estimated 19.5% and comprised nearly a third of a typical blockbuster marketing company's total revenues, on average. For some companies, including Merck & Co, Pfizer and Amgen, blockbusters comprise more than half of total sales. The pharmaceutical industry is thus under pressure to introduce innovative products from R&D pipelines onto the market at or above historical rates to replace this revenue loss resulting from generic competition.

To generate these products, R&D expenditure has risen dramatically in recent years. In the US alone, R&D spending has risen from \$4bn in 1985 to \$26bn in 2000 to \$39bn in 2004, according to the Pharmaceutical Research and Manufacturers' Association of America (PhRMA). Such rising expenditure on R&D would not be a concern if the number of new drugs were rising, however, this is not the case. As shown in Figure 2.8, although R&D spending has consistently increased over the past decade, the number of new drug approvals continues to fluctuate with no apparent relationship to spending.

Bringing drugs to market more quickly is one means of countering a lower number of product approvals, since this allows companies to realize revenues from drug sales earlier. For blockbusters with annual sales of more than \$1bn, revenues from an early launch can be substantial and amount to more than \$2.7m per day.

CROs have been shown to be able to reduce the time required to bring a drug to market. Conducting studies on a multinational and multi-centre basis, where the management of data and knowledge of separate national regulatory systems suits itself to CRO use, CROs are able to shorten clinical testing times by as much as 30%, on average. Sponsors typically take an average of 88 weeks to complete clinical Phase I trials, compared with 66 weeks for a CRO. For Phase II trials, sponsors require 139 weeks, versus an average of 81 weeks for a CRO. Time savings for Phase III trials are similar, with sponsors taking about 140 weeks, compared with 97 weeks for a CRO.



Order this report today to find out more...

Pharmaceutical Outsourcing Strategies

Market expansion, offshoring and strategic management in the CRO and CMO marketplace

TABLE OF CONTENTS

CHAPTER 1: THE PHARMACEUTICAL OUTSOURCING MARKET

- The concept of outsourcing
- Approaches to outsourcing
- Outsourcing research and development
 - Services offered by CROs
 - The role of CROs in clinical trials
 - Expiring patents on blockbusters
 - The role of CROs in pre-clinical trials
- Outsourcing manufacturing
- Strategic pricing
 - Services offered by CMOs
- Sizing the CRO and CMO markets
 - Overview of the CRO market
 - Sizing the CRO market
 - Overview of the CMO market
 - Sizing the CMO market
- Conclusion

CHAPTER 2: DRIVERS OF PHARMACEUTICAL OUTSOURCING

- Outsourcing research and development
 - Drivers of outsourcing research and development
 - Increased complexity of clinical trials and regulatory submissions
 - Rising data requirements
 - Cost savings
 - Minimizing time to market
 - Advantages and disadvantages of using CROs
 - LT cost savings vs. high ST expenses
 - Personnel customization vs. CRO high staff turnover
 - Flexibility vs. loss of control
- Outsourcing manufacturing
 - Drivers of outsourcing manufacturing
 - Cost savings
 - Increased supply of contract manufacturing services
 - Advantages and disadvantages of using CMOs
 - Long term cost savings vs. high short term expenses
 - Lead time savings vs. relationship management time losses
 - Access to expertise vs. quality control
- Conclusion

CHAPTER 3: EMERGING AREAS OF OUTSOURCING

- Drug discovery
 - Specialized discovery service providers
 - Case study: WuXi PharmaTech
 - Contract research organizations
 - Contract manufacturing organizations
- Biotech
 - Biotech contractors
 - Contract research organizations
 - Contract manufacturing organizations
 - Case study: Ortho Biotech Products
- Distribution
 - The mechanics of pharmaceutical distribution
 - Wholesaler distribution
 - Direct distribution
 - Agency distribution
 - Mail order
 - Self-distribution
 - Parallel importing
 - Pharmacy benefit management
 - Outsourcing distribution
- Conclusion

CHAPTER 4: OFFSHORE OUTSOURCING

- Introduction
- Offshore outsourcing of contract research
- Offshore outsourcing of contract manufacturing
- Eastern Europe
 - Contract research in Eastern Europe
 - CRO developments in Eastern Europe
 - Contract manufacturing in Eastern Europe
 - CMO developments in Eastern Europe
- India
 - Contract research in India
 - Patent issues in India
 - CRO developments in India
 - Contract manufacturing in India
 - CMO developments in India
 - Early stage collaborations
- China
 - Contract research in China
 - Patent Issues in China
 - CRO developments in China
 - Contract manufacturing in China
 - CMO developments in China
- Offshore outsourcing market
- Case study: Wyeth
- Conclusion

Pharmaceutical Outsourcing Strategies

Market expansion, offshoring and strategic management in the CRO and CMO marketplace

CHAPTER 5: OPTIMIZING THE OUTSOURCING PROCESS

- Introduction
- Outsourcing agreements
 - Contract research agreements
 - Case study: Pharmaceutical Product Development (PPDI)
 - Contract manufacturing agreements
- Assessing sourcing needs, opportunity and difficulty
- Assessing quality vs. cost savings
- Strategic management of outsourcing
 - Selecting outsourcing partners
 - Managing partnerships
 - Timelines and preventing overruns
 - Risks and mitigation
 - Confidentiality and intellectual property risks
 - Personnel risks
 - Company volatility risks
 - Production risks
 - Case study: Novartis
- Conclusion

CHAPTER 6: THE FUTURE OF PHARMACEUTICAL OUTSOURCING

- Introduction
- Pharmaceutical contract research alliances
- eTechnology
 - Internet-based recruitment of clinical trial patients
 - Electronic data capture, storage and retrieval
 - Clinical trial data
 - Central laboratory data
 - In silico technologies
 - Case study: Entelos
- Virtual drug development companies
 - Non-profit virtual drug development groups
 - Big pharma virtual drug development groups1
 - Case study: GlaxoSmithKline
- Conclusion

CHAPTER 7: APPENDIX

LIST OF FIGURES

- Figure 1.1: Degree of outsourcing to be conducted by pharmaceutical outsourcers in 2006
- Figure 1.2: Importance of contract organization characteristics to pharmaceutical outsourcers
- Figure 1.3: Revenues of leading CROs, 2005 (\$m)
- Figure 1.4: Contract research revenues by segment, 2005 (\$m)
- Figure 1.5: Revenues of leading CROs, 2005 (\$m)
- Figure 1.6: Contract manufacturing revenues by segment, 2005 (\$m)
- Figure 2.7: Drivers of CRO and CMO usage, 2005
- Figure 2.8: US R&D spending versus new drug approvals, 1995-2004
- Figure 2.9: Potential advantages and disadvantages of using a CRO
- Figure 3.10: Importance of different characteristics in biotech CMO selection, 2005
- Figure 4.11: Relative pharmaceutical research and manufacturing capabilities in India, China and Eastern Europe, 2005
- Figure 4.12: Contract research revenues by region, 2005 (\$m)
- Figure 4.13: Contract manufacturing revenues by region, 2005 (\$m)
- Figure 5.14: Outsourcing difficulty vs. opportunity
- Figure 5.15: Impact of low prices on outsourcing outcomes
- Figure 6.16: Characteristics of different contractor relationships

LIST OF TABLES (ABRIDGED)

- Table 1.1: Summary of drug testing objectives by phase
- Table 2.2: Recent drug recalls, 2000-2006
- Table 3.3: Capabilities of leading CROs and CMOs in emerging areas
- Table 3.4: Selected specialty drug discovery contractors
- Table 4.5: Advantages and disadvantages of international outsourcing
- Table 4.6: Eastern European operations of leading CROs
- Table 4.7: US FDA new drug application data generated from India
- Table 5.8: Typical opportunities and difficulties of outsourcing

FAX BACK TO: +44 (0) 207 900 6688

 or scan and e-mail to
marketing@globalbusinessinsights.com
I would like to order the following report...
1

 (Please use **BLOCK CAPITALS**)

 Hard Copy (extra £50/€75/\$95)
 Please allow 28 days for delivery

 Interactivity (extra £50/€75/\$95)
 Search, customize & translate content

Please select a license type:
2

	GB£	EUR€	US\$
<input type="checkbox"/> Single User (eCopy)	1495	2160	2875
Access permitted for one individual only			
<input type="checkbox"/> Site License	2995	4330	5750
Access permitted for every individual based at one location			
<input type="checkbox"/> Company License	5600	8100	10795
Global access for every individual member of staff at the company			

 To ask a question about license types, email: marketing@globalbusinessinsights.com
Communications Feedback

Please let us know if any of the following factors influenced your purchase...

- | | |
|---|---|
| <input type="checkbox"/> Email/Fax/Postal promotion | <input type="checkbox"/> Trade Press |
| <input type="checkbox"/> Brochure | <input type="checkbox"/> My Account Manager |
| <input type="checkbox"/> Table of Contents | <input type="checkbox"/> Conference materials |
| <input type="checkbox"/> Colleague Recommendation | <input type="checkbox"/> Website/web search |

Recipient details (if different from Payor)

Title: Mr/Mrs/Ms **(Please use BLOCK CAPITALS)**

First Name: _____ Last Name: _____

Email _____

Job Title _____

Department _____

Address _____

City _____ State/Province _____

Country _____ Post Code/ZIP _____

Tel _____ Fax _____

Company details
3

Company name: _____



EU companies (except UK) must supply VAT / BTW / MOMS / MWST / IVA / FPA number:

Purchase Order Number (if required) _____

Payment method
4

 Please indicate your preferred currency: GB£ EUR€ US\$

Total order value is _____

- I will forward a check payable to Business Insights Limited.
- Please invoice my company (please complete invoice address below)
- I would like to pay by bank transfer (email address required)
- Debit my credit/charge card:  Amex  Visa  Mastercard

Card No _____

Expiry Date ____ / ____ Signature _____

Payor details
5

 Title: Mr/Mrs/Ms **(Please use BLOCK CAPITALS)**

First Name: _____ Last Name: _____

Email _____

Job Title _____

Department _____

Address _____

City _____ State/Province _____

Country _____ Post Code/ZIP _____

Tel _____

Fax _____

Sign here to confirm your order:
ORDERS WITHOUT A SIGNATURE CANNOT BE PROCESSED



By completing this form you agree that the data in the form will be used for the purpose of processing your order. We may also use your data to keep you informed of our products and services. As an international organization, Business Insights may need to process your data in countries which do not have data protection laws, or which have standards lower than the EU. Business Insights seeks to protect your personal data. You have a right to see and correct your data by writing to us. In case of queries, contact info@globalbusinessinsights.com. Please tick the relevant box(es) if you would not like Business Insights to contact you by:

 Email Post Fax Phone

Occasionally, our client list is made available to other companies for carefully selected correspondence. Please check here if you do not wish to receive such correspondence by:

 Email Post
This order is subject to our standard terms and conditions, a copy of which is available on request.

Marketing Department
marketing@globalbusinessinsights.com
Code Ref: Website

www.globalbusinessinsights.com

+44 (0) 20 7551 9700

Registered Office: Business Insights Ltd, Mortimer House,
37-41 Mortimer Street, London W1T 3JH.
UK Registered Number: 05006037