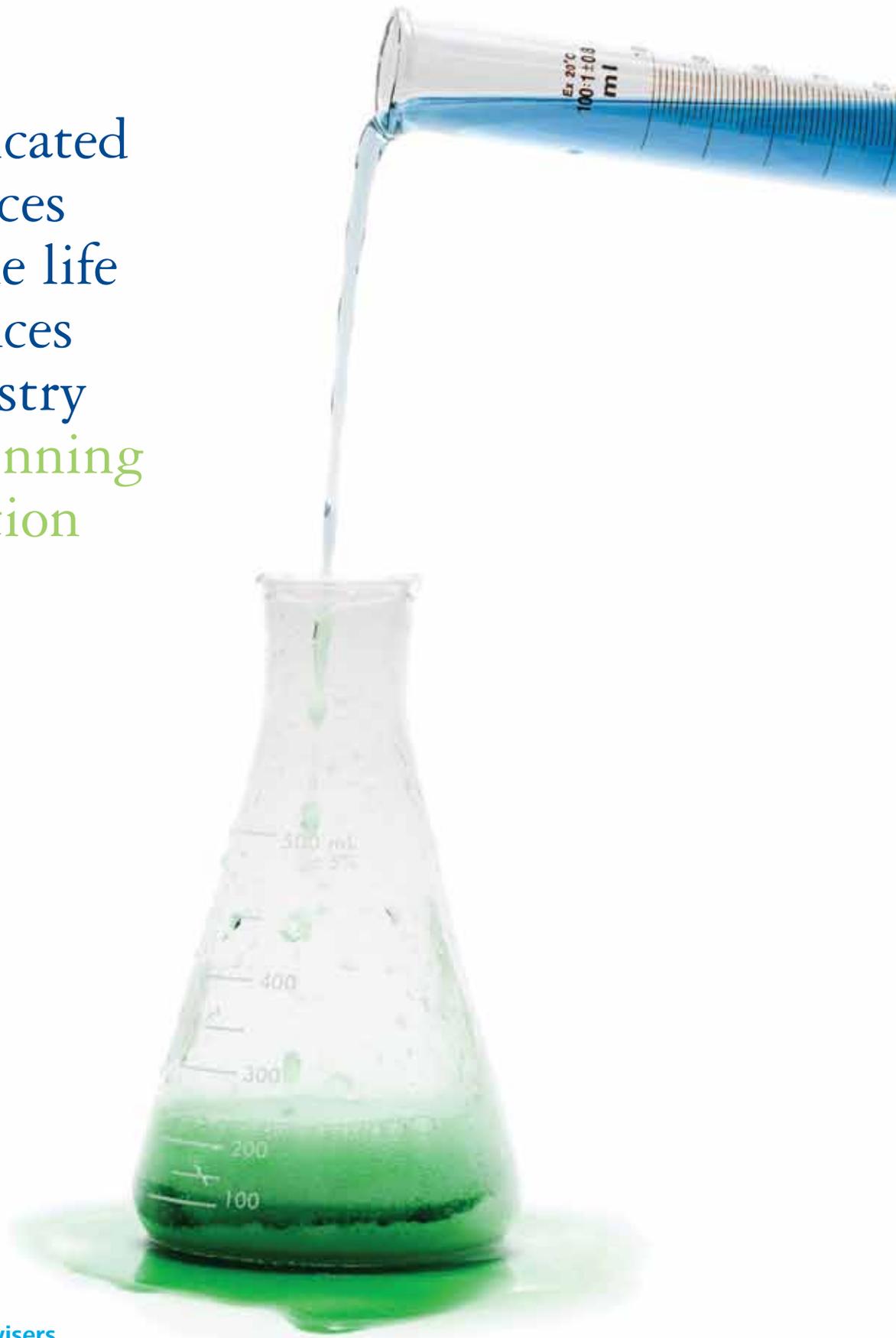


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Leading business advisers

Industry trends and challenges

The life sciences environment has experienced, and continues to experience, significant change.

Globally, the life sciences industry, comprised of pharmaceutical, biotechnology and medical device manufacturers as well as their service providers and distributors, is recognised as a significant driver of economic growth. Ireland has positioned itself as a strategic player in the global life sciences industry. Ireland is considered an attractive location for foreign direct investment by large global multinationals, given its highly skilled workforce and low tax economy, and has also developed a strong, high-growth indigenous life sciences industry. The significant timelines in obtaining regulatory approval in the US has resulted in emerging and mid-sized life sciences companies considering Ireland as a base of operations for further expansion and seek EU regulatory approvals instead.

We understand that today's life sciences companies face many challenges including; a substantial demographic shift in the age profile of populations, pricing and reimbursement pressures, high hurdles for innovation, changes in the approach to disease management towards early diagnosis and prevention, the entry of new technologies, the ever increasing and burgeoning cost of healthcare provision and the ongoing global economic crisis.

In the current climate of increased competition and complexity, there is a requirement for new commercial models, collaboration and partnering, a critical focus on research and development (R&D) productivity, and a requirement to undergo transformational change to ensure lean operations.

Ireland is considered an attractive location for foreign direct investment by large global multinationals, given its highly skilled workforce and low tax economy, and has also developed a strong, high-growth indigenous life sciences industry.

Managing business costs is a considerable challenge and most life sciences organisations are undergoing cost reduction and transformation projects. As Ireland adapts to new economic realities, life science companies are increasingly looking to research, development and innovation to improve profit margin and remain competitive. Access to innovation, and the productivity and costs of R&D, remain critical issues. New models for R&D require focus, a step change in collaboration, innovative partnering and financing models in order to be successful.



The life sciences industry represents a significant source of income to the Irish economy and the future of the industry remains optimistic. The industry is currently facing a number of challenges including:

- Poor R&D productivity with fewer products coming to market
- Major patent expiries opening the door to generics
- A shift to emerging markets
- A challenging fundraising environment
- M&A opportunities - leading to consolidation of sector
- Profit and margin pressure
- A focus on intangible asset/IP transfer valuations
- Stringent and more complex risk and regulatory frameworks
- Late stage failures

The diagram below details these trends and challenges further:

Life Sciences Industry			
Pharmaceuticals	Biotechnology	Medical devices	
<p>Key sector trends:</p> <ul style="list-style-type: none"> • Long R&D lead times with high R&D costs • Must adhere to stringent regulations - importance of clinical trials • High failure rate for new applications • Increased consolidation/partnerships in the sector • Expiry of patents and use of generics 	<p>Key sector trends:</p> <ul style="list-style-type: none"> • Significant investment in R&D • Long product development life cycle and costly clinical trials • High margins achieved by innovative niche products and platform technologies • Large number of campus company projects emerging 	<p>Key sector trends:</p> <ul style="list-style-type: none"> • Relatively short lead-in time to market • Successful market penetration is challenging • Innovation and “first to market” are critical • Increased sector consolidation in recent years • Strong spin-out opportunities emerging 	
<ul style="list-style-type: none"> • More complex supply chain business models • Focus on investment rigour in R&D capital allocation and portfolio decisions • Collaboration / partnering to realise better development success rates • Increased collaboration across the life sciences and technology sectors • Increase competition and industry complexity 			
Key Issues			
Campus/Start up Phase	Growth Phase	Scaling Phase	Multinational/Global
<ul style="list-style-type: none"> • Obtaining initial seed funding • Research, development and innovation grants • Incorporation of a company and satisfying CRO, tax and audit requirements • Ensuring tax issues are properly managed • Managing and protecting intellectual property • Satisfying industry regulations and compliance requirements 	<ul style="list-style-type: none"> • Fundraising (development capital) • Profit margin pressure and managing cashflow • Managing licensing and partnership agreements • Strategic direction, expansion and new market penetration • Satisfying industry regulations and compliance requirements • Retention of key employees and a skilled workforce • Shortage of investment in specialised infrastructure 	<ul style="list-style-type: none"> • Outsourcing and shared services opportunities • Managing cashflow and working capital • Profit and margin pressure • Satisfying industry regulations and compliance requirements • Internal controls • Exit strategy (IPO, MBO, trade sale) • Consolidation and acquisition strategy 	<ul style="list-style-type: none"> • Divestment of non performing business • Leveraging research and development • Accessing and managing partnership agreements • Working capital management and cost/ margin pressure • Managing international taxation issues • Audit and accountancy in a multinational environment • Outsourcing and shared services opportunities

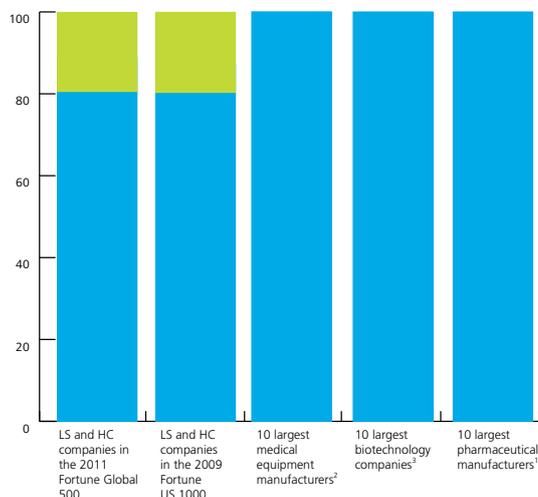
The Deloitte Life Sciences Group

In 2011, Deloitte was ranked as the #1 Life Sciences Consulting practice, based on aggregate revenue in Kennedy's Healthcare Consulting Marketplace 2010-2013: Key Trends, Profiles and Forecasts.

We understand that companies operating in the biotechnology, pharmaceuticals and medical devices sectors face a period of unprecedented challenge and opportunity in a constantly changing environment.

Our breadth of services span the entire development cycle of life sciences companies and are specifically designed to assist you in the face of this environment. We advise a broad range of organisations in the industry (payors, providers and life sciences organisations), and cater to clients through all stages of their life cycle - from university spin outs to large scale organisations.

Deloitte global life sciences and healthcare clients



1. IMS Health (Dec 2010)
2. Medical Product Outsourcing (July/August 2011)
3. Factiva (August 2011)

■ Not serviced by Deloitte
■ Serviced by Deloitte

Source: Deloitte research

Our clients include some of the world's leading multinational corporations, as well as indigenous Irish companies.

Deloitte has a dedicated team of life sciences professionals, with the expertise, resources and relationships to assist life sciences companies, both public and private. We work in an integrated way to deliver a best in class, solution oriented service to our clients through collaboration with our extensive Deloitte international life science network of practitioners.

With our global network of life sciences professionals, in-depth sector experience and cross functional team, we are in a unique position to provide you with a dedicated, industry specific service to meet your requirements.

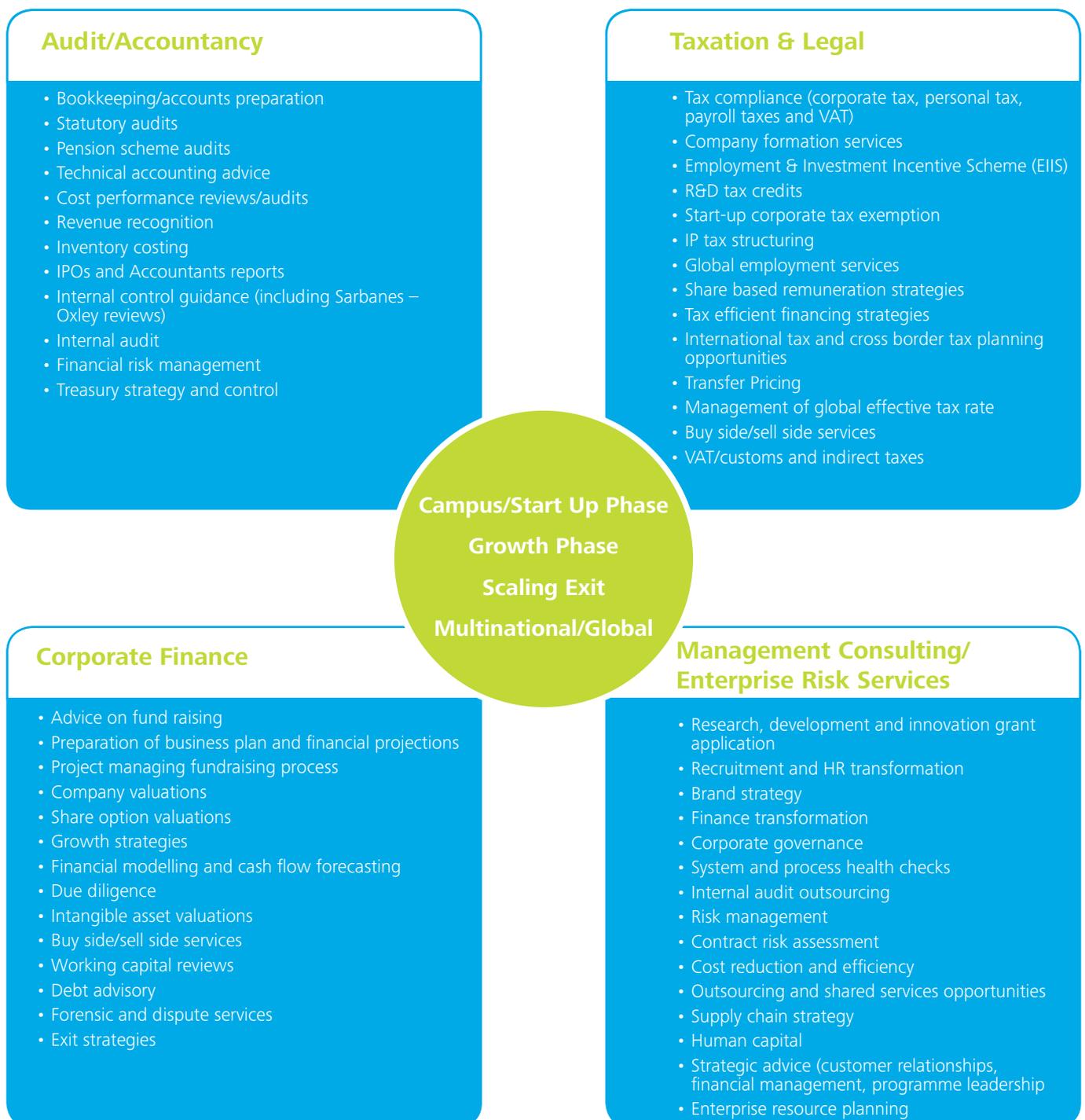
The Deloitte Difference

As one of the most experienced professional services providers in the world, Deloitte offers life sciences organisations the following competitive advantages:

- Experience serving life sciences and healthcare organisations of all sizes, both public and private, including governmental providers
- Leadership in providing cross functional services (tax, audit, consulting and corporate finance services) to the life sciences and healthcare industry
- Thought leadership on life sciences issues and trends
- Depth of specialists with requisite industry and functional experience
- Dedicated local and national resources to address your specific issues and needs
- Credibility with regulatory entities, grounded in professional relationships built over many years
- A reputation for quality that has earned credibility with analysts and the capital markets
- Extensive, long-term investment in our practice, including technology, training, development of specialist thought leadership
- Recognition as an employer of choice, which enables us to recruit and retain people of high quality

Our services

Our breadth of services span the entire development cycle of life sciences companies, and are specifically designed to deliver a seamless service and assist you in delivering value creating opportunities.



Our experience

Complex transactions need a balanced and experienced team.

Case Study 1

M&A advisory – diversification strategy in the medical devices sector

A major Irish construction company engaged Deloitte to advise on the development of a diversification strategy. We identified the medical equipment and supplies distribution sector as offering strong growth opportunities, as well as providing a more stable flow of revenue and profitability over the medium term, complimentary to the cyclical nature of construction. Our team conducted an acquisition search programme, identified targets which met agreed criteria and, with our client, successfully negotiated the completion of four acquisitions over a period of eighteen months, thus creating a substantial new player in the medical equipment and supplies sector in Ireland. Our mix of deal origination and project management skills as well as in-depth knowledge of the life sciences industry ensured our client executed on its diversification strategy.

Case Study 2

A Study of the financing environment for life sciences companies

Deloitte was engaged to prepare a detailed report examining the finance environment for life sciences companies in Ireland. This included primary research in the form of a survey of indigenous life sciences companies at different stages of their funding life cycle, and an analysis of funding options. In addition, we benchmarked the funding environment in Ireland with leading international life sciences clusters. Our work on this engagement has provided us with an in-depth understanding of the funding environment and key challenges for life sciences companies across all stages of their life cycle, placing Deloitte in a unique position to assist growth companies with funding requirements.

Case Study 3

Implementation of a warehouse management system for the Irish manufacturing operations of a global life sciences company

The scope of this strategic project included upgrading the client's entire ERP system and encompassed the implementation of an advanced warehousing solution for our client's new 10,000m² material handling facility, all adhering to strict validation requirements. This project also allowed our client to achieve systems compliance with the FDA's 21 CFR Part 11 regulatory requirements and came in on-time and on-budget. A subsequent successful project facilitated the integration of a third party manufacturing execution system through the implementation of a tier-one middleware solution. The company engaged Deloitte to lead the overall programme as well as to provide specific technical support and assistance in developing the validation master plan.

Case Study 4

Significant audit and accounting experience in the life sciences sector

We act as auditors and accounting advisors to a significant number of large global and domestic companies in this industry and are frequently engaged to provide technical accounting advice on highly complex issues including the treatment of R&D costs, acquisition accounting, transition to International Financial Reporting Standards and inventory standard costing amongst others. We also have significant experience in providing support to non-audit clients in internal control and Sarbanes-Oxley reviews. For example, Deloitte was engaged by a major Irish company in the life sciences industry to advise and assist management with their review of internal control. The scope of this project included documenting existing business processes, identifying key controls, control deficiencies and weaknesses, advising management on the design and implementation of new controls to satisfy their requirements, and the subsequent testing of the operational effectiveness of these controls to ensure compliance. We have also assisted our clients to secure grant-aid from government agencies e.g. Enterprise Ireland. Our ongoing involvement with both audit and accounting advisory life science clients ensures that we have a deep understanding



of the current issues facing companies in this sector and are well placed to respond quickly to audit and accounting requests as they arise.

Case Study 5 **Tax advisor to a range of life sciences companies in Ireland**

Deloitte Ireland has particular expertise in advising life sciences companies on how to structure their business operations from a tax viewpoint, maximising the benefits of Ireland's low 12.5% corporate tax environment as well as the new Irish Intellectual Property tax regime. For example, Deloitte has worked with a leading multinational life sciences company to restructure their European and Middle Eastern business operations, making Ireland the Principal in a Central Entrepreneur Model, thereby maximising the taxable revenues which flowed into Ireland, benefiting from Ireland's low tax environment. We also advised the client on how to best manage any Irish and foreign tax issues arising in relation to their cross-border employees. We are also currently working with an Irish group to structure their IP ownership arrangements in a tax efficient manner, as well as maximising R&D tax credits.

Case Study 6 **Integration of transaction finance activities in the pharmaceutical sector.**

Deloitte were engaged to support the integration of transactional finance activities for one of the largest acquisitions in the industry. The primary objective of the project was the successful planning and execution of Day 1 and Post Day 1 activities surrounding global accounting transactions and related field ledgers in anticipation of the integration.

This effort encompassed the activities of a large scale project including discovery, planning, design, build, test phases, training, knowledge transfer to stabilisation view organisation, deployment, and project close-out phases, as well as support for change management and communications.

The scope of the effort included business process and accounting process design for integration along with resulting implementation in preparation for Day 1 and Post Day 1 stabilisation period. Given the broad geographic and functional nature of the project, a comprehensive and integrated approach was necessary to effectively coordinate and complete these activities. Our team was regionally structured with representation in Europe, United States and Asia.

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