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Winning in Life Sciences
Are you agile enough?

Foreword

Navigating the life sciences and healthcare market place has never been more demanding.

In this post-recession era, many global health systems will be impacted by a series of austerity measures. Pricing and re-imbursement pressures, high hurdles for innovation, and the need to demonstrate economic value can only get more severe. Patent expiry, and the lack of new products coming to market, means that life sciences companies will struggle to deliver top-line growth. Companies have re-structured their commercial models to meet the demands of the mature health markets and to focus on value and market access.

Despite the wave of mergers and acquisitions over the last ten years, the overall market has not consolidated – which is surprising. Scale for scale's sake is of little benefit for big pharmaceutical companies these days. Acquisition strategies have tended to focus on building share in selected disease areas, entering new growth markets such as the emerging economies, diversifying, or driving out short term cost synergies. There has been consolidation among the generics companies where margins are tight and scale is important.

Access to innovation, and the productivity and costs of R&D remain critical issues. New models for research require focus, a step change in collaboration, innovative partnering and financing models. The majority of new products coming to market these days result from a collaboration, licensing deal, or an acquisition. Development is under pressure to establish new, more efficient operating models as the cost of clinical trials escalates. Investment in R&D is under increasing scrutiny and companies are becoming more transparent on the apparent "R&D ROI".

Risk and regulatory pressures remain. Healthcare compliance, adverse events and product withdrawals, fraud and counterfeit, espionage and security are all major challenges in the life sciences industry and failure in these risk areas can have substantial and lasting impact. Strengthening risk management capabilities, and building organisation resilience in the event of failure, are important priorities for successful life sciences companies.

Standardisation, shared services, IT cost effectiveness, procurement transformation, working capital and inventory reduction – this is the language of an industry focused on cost, efficiency and effectiveness. There is no doubt that whatever your role in a life sciences company, the word "austere" applies as much internally these days, as it reflects the reality of the health market place we serve.

Deloitte has a unique depth and breadth of skills to help you navigate this complex industry environment. Our "OneDeloitte" approach combines our skills into integrated services that are tailored to this industry and to your specific requirements. I hope you find this brochure of interest and please feel free to contact us if you have any questions or need assistance.

Simon Hammett
EMEA Life Sciences and Healthcare Lead Partner

Seeking value beyond products
Pushing performance forward

Product differentiation is necessary but no longer sufficient for success in R&D. Innovation must propel the drug development business model allowing configuration of distinctive commercial propositions.

The progressive decline in productivity of the industry's 'small molecule blockbuster model' is now well accepted. Confronted with a steep rise in the cost of product innovation, which has far outpaced commercialisation success rates, companies are now fundamentally rethinking how to approach drug development.

The pursuit of 'scale economies' was formerly a common driver of R&D strategy. We are now witnessing a widespread dismantling of cumbersome innovation structures established in the 1990s. The transformation mantra of this decade will be to focus relentlessly on the seemingly irreconcilable objectives of reducing development cost and time while realising marked improvements in the clinical and commercial differentiation of new compounds. Research and target defined disease sub-populations allow pharmaceutical companies to streamline the development of therapies that offer greater focus, enhanced efficacy and improved safety profiles.

Payers are increasingly demanding value-based pricing and conditional reimbursement; this drive to 'contract for outcomes' requires the industry to assume financial risk. Forward-thinking pharmaceutical companies will derive competitive advantage from taking on a greater accountability for the achievement of improved health outcomes. In this environment, R&D needs to determine a health benchmark for each pipeline proposition, assembling and trialing sets of products and services that demonstrate tangible health improvements.

In order to push performance forward, organisations must:

- Better manage risk and potential returns, by rationalising disease areas within the portfolio, placing renewed emphasis on depth of scientific expertise and disease biology understanding.
- Harness compound opportunities regardless of originator, fostering external innovation networks that drive up pipeline value.
- Dispel fixed costs in favour of a variable cost infrastructure that can flex in line with pipeline throughput, is tax-efficient, and centered on strategic service partnerships.
- Achieve a geographic distribution of drug development centres that supports continued growth in traditional territories, facilitating greater participation in the regulatory and healthcare systems of emerging markets.
- Underpin management commitment to report the planned and actual financial return from the R&D outlay, against a backdrop of greater scrutiny on ROI from pharmaceutical R&D.
- Incorporate a leaner and more streamlined clinical study approach, grounded on clear 'line of sight' between protocol, data collection strategy and desired outcome.
- Support the shift to a service-centric approach where R&D configures, trials and commercialises product/service bundles that generate revenue according to their ability to achieve agreed 'service levels' or health outcomes in a defined patient population.

How can we help?

- Performing disease area reviews, including support with divesting non-core therapeutic areas and acquisition or in-licensing of assets in strategic diseases.
- Highlighting opportunities to simplify and standardise global R&D structures.
- Developing and implementing clinical outsourcing strategies.
- Deploying lean six sigma methods in drug development to achieve excellence in clinical and drug supply operations.
- Assessing opportunities to claim applicable R&D tax incentives, and reduce costs through VAT savings and improved financial and contract controls.

Developing the correct technique
Managing regulatory risk and compliance

Does your company have a comprehensive, systematic and efficient process in place to identify risk and enable compliance with regulatory requirements?

Aside from the regulatory impact of new product development, new market penetration, reorganisation and mergers; 'business as usual' provides significant challenges to compliance capability. The increasing volume of regulatory requirements and guidelines is impacting Life Sciences organisations' research and development, patent, clinical trial, manufacturing, distribution and marketing activities whilst at the same time, fines and penalties associated with non-compliance are on the rise.

The risks of non-compliance due to distributor and agent collaboration are increased by:

- The use and geographical spread of third party sales forces.
- Clinical research organisations with different internal regulations.
- More prevalent contract manufacturing and licensing agreements.

The combination of these factors, together with more global trading patterns and a shift towards emerging markets, are increasing the potential for non-compliance and impacting on brand reputation.

Industry trends also have influence. For example, the changing customer procurement arrangements and greater interaction with payers, the increased investment required in R&D, the further strengthening of the need to 'do the right thing' and amplification of the penalties of getting it wrong.

For these reasons, systematic and efficient processes that ensure compliance with regulatory and legislative requirements are imperative for Life Sciences organisations.

Compliance frameworks need to be efficient and streamlined, encompassing sufficiently robust thoroughness, to stand up to regulatory scrutiny and ensure that there are 'no surprises'. An integrated approach is essential:

- Firstly, to co-ordinate the various elements of the compliance framework including culture/tone at the top, risk assessment, training, IT controls, financial controls, human resources and internal audit.
- Secondly, to ensure there are no gaps or overlaps between the activities of various functions across the business.

With a consistent, integrated framework applied across the organisation, this will help to ensure that your compliance regime is effective, efficient and easily scalable to accommodate regulatory developments and entry into new markets. Perfecting your technique helps to ensure that you rise above in today's industry challenges.

How can we help?

- Facilitating the identification and assessment of compliance risk.
- Developing efficient and co-ordinated compliance frameworks to address the regulations specific to your organisation.
- Rationalising your regulatory control frameworks, reducing duplication of effort and cost.
- Assessing whether controls are designed and operating effectively across your organisation and sites.
- Reviewing IT systems to identify gaps in compliance with relevant legislation.
- Investigating instances of non-compliance and/or quantifying economic and financial impact of disputes.

Increased merger activity was a spring board to the Life Sciences sector Now that we have the momentum, can we carry the form?

Since the economic downturn, market observers have been trying to spot those who execute the perfect landing and those who wipe-out.

Life Sciences companies have been pursuing different M&A strategies, but the underlying reasons for deals are common:

- Lack of innovation in R&D leading to fewer and more expensive new product launches.
- Accessing new science and technology platforms.
- Bringing key assets in-house to realise the commercial value of a partnership/collaboration.
- Diversification into new product areas and geographies.
- Establishing a more focused product portfolio, suited to growth markets.
- Building scale and realising synergies in operations.

Competition for targets with high quality assets is still intense. So, what has changed in the current economic environment and why has the market heated up?

- Like all markets, asset prices have fallen and matchmaking between former competitors has been rife, as the opportunity to acquire a previously 'unaffordable' rival has become a realistic proposition.
- Life sciences corporations have been consistently generating cash at a time of poor credit liquidity and have been looking to take advantage of rivals weakened by cash constraints.
- The more mature health markets are ever more challenging with the focus of longer term growth switching to emerging economies.
- A shortage of Venture Capital funding has inevitably led biotech companies to do deals with large pharmaceutical companies.
- The scale of patent expiries for major drugs, and the lack of innovation in R&D have come to a head, making M&A a matter of survival.

The current positive sentiment within the industry has seen increased speculation with the same question consistently being asked – who next? Will the big mergers trigger a wave of consolidation across the pharma sector? Will biotechnology, medical devices and diagnostic companies follow suit? Are we on the brink of convergence across all the sectors, to form integrated healthcare companies?

In this environment, companies need to be agile, quick to seize on opportunities, and require a robust stance on M&A strategy. Natural ability and a good eye for a transaction, also helps when walking the path to success.

How can we help?

- M&A strategy.
- Target identification.
- Valuation and deal negotiation.
- Financial and commercial due diligence.
- Guidance for public companies regarding the Takeover code.
- Post-merger integration.
- Organisational redesign.

The key to effective IT
Finding the balance to unlock performance in LS & HC industries

How can we help?

- Optimise IT effectiveness: Design and deploy an optimal IT operating model to drive closer business-IT integration and more efficient internal working.
- Reduce cost to serve: Identify and deliver rapid and sustainable cost savings from IT without degrading business service.
- Deliver collaboration platform: Design and deploy a robust collaboration capability, underpinned by strong and secure authentication and security.
- Build new CRM capabilities: Design the new commercial model, select the best technology solution and build your CRM solution, define the KPIs and drive the behaviours to deliver success.

A changing industry and a dynamic healthcare market makes having an effective IT function the key to unlocking and delivering business value.

With transient market conditions, the focus within Life Sciences has shifted and managing down the cost to serve is becoming increasingly important. This may happen in the form of straight G&A reduction, improving productivity in R&D, leveraging technology to support leaner manufacturing or budget reduction in Sales and Marketing. With evolving business practices, such as, innovation networks, personalised healthcare and new commercial models, there now a greater demand for new innovative technology solutions.

This places two very different priorities on IT:

1. Improve efficiency and reduce the cost to serve.

2. Develop new, agile and flexible capabilities to support new business models.

In an industry where IT costs eat up 3% of revenue, a 10-20% cost reduction is a significant saving. The key challenge is to reduce the cost of IT without degrading performance, while simultaneously supporting new business innovation. Only by clearly understanding how IT drives business value, will organisations be able to equip themselves with the tools vital to meet this challenge. Whilst IT spend must be reduced, the impact on business has to be minimised. To perform this 'balancing act' an efficient, optimised IT function, closely aligned to the business units is critical.

In conjunction with cost reduction, new business models rely on robust and flexible technology platforms. Open innovation networks require flexible and secure collaboration capabilities. This allows external partners to access a firm's core infrastructure while retaining tight control over its data and intellectual property. The emergence of Key Account Management within the new commercial model demands new thinking around the use of IT to support the sales force. 'Best in breed' products including Cedegim Dendrite, Veeva and salesforce.com are emerging as competitors to traditional CRM solutions like Siebel. All the while, companies are increasingly looking to the 'cloud' to deliver rapid functionality in a more cost efficient way.

Developing these new capabilities and leveraging emerging technologies, while operating at a lower overall cost to serve, are the key challenges facing IT in the modern Life Sciences firm. The organisations who meet this challenge are the ones who will be successful.

Patent box
Rewarding your efforts

How can the introduction of the patent box to the UK enhance your tax competitiveness?

The patent box is the leading financial measure to come out of the UK Government's Office for Life Sciences. It provides for a 10% corporation tax rate on all income arising from UK patents (compared to the current 28% rate). The regime will apply from April 2013 but only in respect of patents granted after July 2011.

No further information is available at present on how the regime will achieve the effective 10% rate. A number of differing methods are already in use in Western Europe. The intention is to engage in an Industry Consultation process in 2010 in order to introduce the law in the Finance Bill 2011.

There is therefore a need for industry to engage fully with the UK Government to ensure that the wide variety of circumstances of UK and Internationally headed groups, both large and small, can benefit from the patent tax.

Prior to the patent box it has it has not always been imperative to know which company within a group holds a particular patent, or earns the income from it. The patent box will require much greater precision over ownership, in order to ascertain which entity can benefit.

A reasonable assumption is that ownership for these purposes means 'economic ownership', rather than legal ownership. Thus where patents are licensed in to a company and then worked on to increase value, that licensee company will benefit from the patent box. However, it is currently unclear how the regime will apply to more complex scenarios.

Even where the economic owner of the patent IP within the group can be identified, there is a need to determine how much of an income stream can be attributed to patent IP, and how much to other intangibles, such as goodwill, or marketing. For many companies the ability to specify the patent value embedded in products will require careful analysis.

The possibilities for tax-efficient planning using a patent box are wide – after all, it is a tax-efficient measure in its own right. There is clearly tax efficiency in placing expenses outside the patent box and income inside the patent box, with options ranging from simple allocation, to transfer pricing and ultimately to complex sale and leaseback arrangements.

Many large groups have established tax efficient IP holding structures outside the UK and may therefore need to reorganise more patent income into the UK in order to benefit from a UK patent box. Any changes may also need to take into account the ongoing industry tax consultation on 'Controlled Foreign Companies' as this will affect the UK tax treatment of IP held offshore.

The introduction of the patent box regime, combined with the existing R&D tax credit provisions could result in UK Life Science business being subject to very low effective tax rates. Whether this causes an influx of patent income, and associated high value manufacturing and employment into the UK, remains to be seen.

How can we help?

- Assisting with responses to the UK tax authorities consultation process on how the regime should work in detail.
- Valuing of patents and modelling of potential benefits.
- International tax planning regarding determining benefits of holding intellectual property onshore or offshore and assisting with the implementation of changes.

Protecting your winning edge
Managing risk of cyber espionage

With an increasing focus on innovation in the Life Sciences industry, the protection of intellectual property from espionage is a high priority on many organisations' agendas. Attacks on systems and infrastructure threaten to undermine investment in innovative products and give generics and competitors a commercial advantage.

In May 2009, President Obama remarked that losses from cyber-crime, including industrial espionage, **"had cost the US economy a staggering USD 8 billion over a two year period."** Industries holding high-value intellectual property have historically been victim to industrial espionage. Today, industrial or 'corporate espionage' is perpetrated over the Internet against information systems and infrastructure for commercial and political ends.

For Life Sciences, countering the threat from cyber espionage is about protecting innovative ideas and concepts to remain competitive in the market. Cyber security is not just about fixing technical vulnerabilities; it is about protecting R&D and being able to reassure investors that their money is safe.

The threat of cyber espionage to Life Sciences organisations has been further heightened by intense M&A activity. After the mega-mergers of Pfizer-Wyeth, Merck-Schering and Roche-Genentech, industry interest has turned to the 'diversifiers'. Those companies, the diversifiers who are making multiple acquisitions to diversify their business models in this exceptionally competitive environment are more aggressively collecting intelligence on competitors, opportunities and market activity. Organisations need to be on their guard against these activities.

Regulatory and legal risks for companies in opaque and emerging markets are high because the legal norms are inconsistent with, for example, those in Europe. Legal disputes caused by cyber security incidents could be politically or commercially influenced, and organisations should be aware of these risks.

For Life Sciences organisations, cyber espionage has potentially crippling effects, including:

- Time to market may be significantly increased.
- Loss of R&D productivity.
- Loss of stakeholder and investor confidence.
- Regulatory fines and penalties.
- Loss of revenue and profits.

How can we help?

- Data loss prevention.
- Cyber security threat intelligence collection.
- Vulnerability management/penetration testing.
- Security culture and training.
- Incident response, investigation and recovery.

Transforming Finance to perform at its best
Fuelling your organisation through finance

Finance, the fuel of the organisation, can play a key role to ensure you are ready to perform under pressure.

Current market situations are driving Life Sciences organisations to be more effective than ever, and finance is leading the way. Reducing the cost of finance activities is a prerogative to be achieved while operating in an increasingly complex regulatory environment with ever more demanding shareholder expectations. The disintegration of the Chief Operating Officer role has left CFOs with a breathtaking range of new responsibilities. Given these pressures, it's no wonder that CFO turnover is on the rise and the role itself is under greater scrutiny, internally and externally. Is the job itself getting out of hand?

What top issues are keeping CFOs awake at night?

- Professionalising the finance function – meeting business objectives by contributing to the performance and strategic direction of the business in addition to transaction processing and managing cost.
- Controlling internal finance processes – ensuring that controls meet compliance requirements while also being sensible for the business.
- Getting the story behind the numbers – producing accurate and timely reports that help facilitate management discussions around 'what to do' rather than 'where they came from'?
- Acquiring and developing talent – finding individuals with the right skills, capabilities, knowledge and adaptability to accomplish your objectives.

The modern Finance Function is expected to deliver in four key roles outlined below. To succeed in these roles, the CFO must create a Finance function that exceeds stakeholder expectations, achieves desired performance levels and drives value throughout the organisation:

- **Steward,** providing control over the organisation's assets, ensuring it meets its compliance obligations and directing the management of risk.
- **Operator,** delivering efficient Finance processes to support the production of financial information and driving the cost effectiveness agenda across the organisation.
- **Strategist**, analysing organisational performance and interpreting financial information to support the planning and execution of strategic initiatives across the organisation.
- **Catalyst,** stimulating the wider organisation to execute the changes necessary to support the effective performance of the Steward, Operator and Strategist role.

To deliver across these four roles is not easy. There are many variables, many debates to be had and often no single 'right' answer. Just like an athlete, the Finance function needs focus, drive and discipline to achieve it's best in a challenging and competitive environment.

How can we help?

- Internal controls, risk and accountability: Managing the CFOs risk and reducing the burden of maintaining the regulatory environment without compromising its integrity.
- Information quality: Ensuring the data the company relies on is accurate and provides the most meaningful reporting and information.
- Cost reduction: Reducing costs while continuing to add value.
- Operating model: Organising finance to serve the needs of the different stakeholders.
- Talent management: Attract, develop and retain the talent required to fulfil finance's mission.
- Linking business activities to shareholder value: Creating a common language that empowers management to see themselves the way investors do.
- Investment management: Ensuring investments in innovation and growth yield the greatest returns.
- Strategy execution: Partnering with other senior managers to drive strategy execution across the enterprise.

Leaping into an uncertain future
Establishing commercial models that excel in a dynamic environment

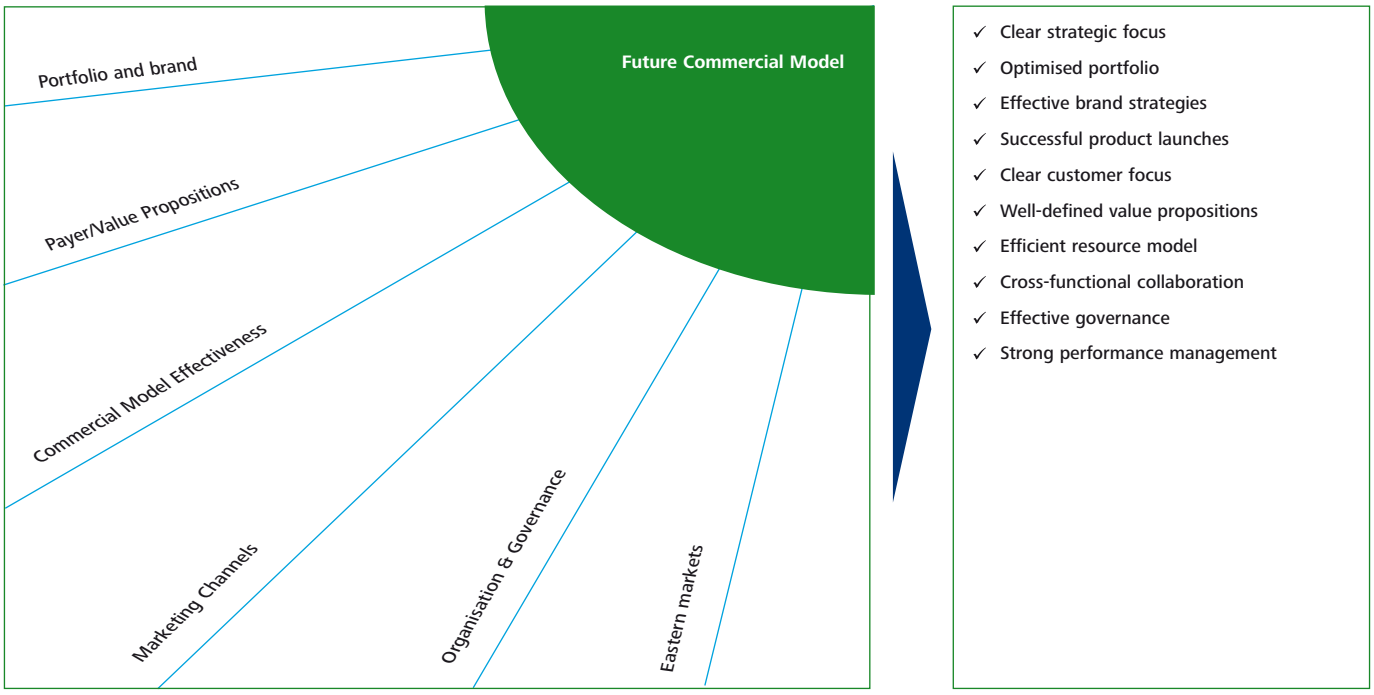
Commercial models in life sciences are shifting. Companies must identify the right model fast and implement it effectively, whilst leaving sufficient flexibility to cope with the unexpected.

How can we help?

- Key Account Management.
- Product launch strategies.
- TA, brand and regional strategies.
- Digital marketing initiatives.
- Product value propositions and HTA support.
- Organisational optimisation, governance and performance management.
- Design and project management of commercial model changes.

Life science companies are severely disrupting their existing commercial models in Europe, in response to a number of external trends and internal challenges. These include market access pressure, increasing importance of payers, patent expiries, a switch towards generics, introduction of more specialist products, downsizing of legacy primary care sales forces, and the growing importance of Eastern European markets.

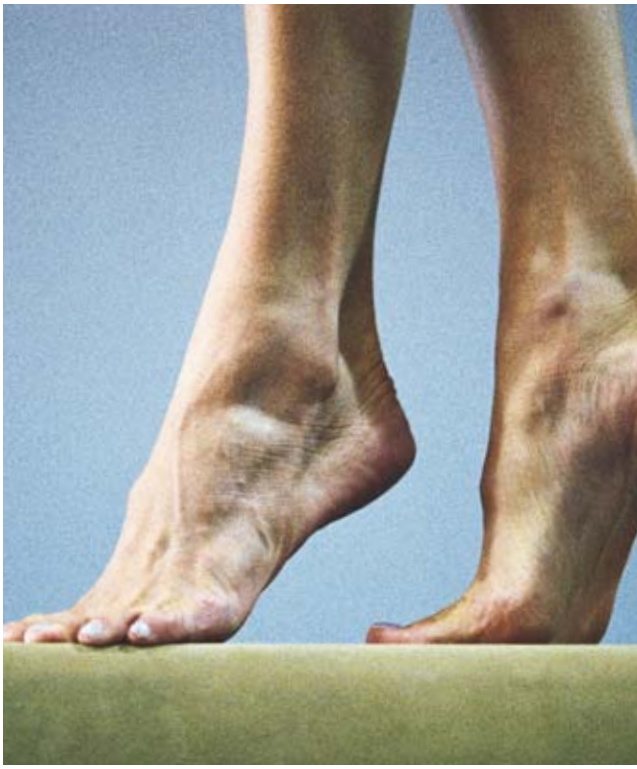
Newly established models must support a higher level of customer and patient focus, defining a position as a partner within the healthcare system. A companies' ability to be agile in their dealings with ongoing change in Europe along with the "know how" to approach national markets in an individual manner, is a must. Rolling out and refining key account management, driving forward the digital market and balancing the channel mix is all included within the new models being deployed. There is also a need to focus on market access and understand the potential of Health Technology Assessment. Effective governance structures and streamlined performance management ensure that increasing complexity does not impede commercial success.



The commercial model sits at the heart of any organisation, and successfully delivering change is not a straightforward task. To succeed, challenges must be identified swiftly, responses planned strategically, with execution delivered in an effective and pragmatic way.

Preparation through visualisation
Creating the resilient organisation

Does your organisation have the resilience capability to protect its reputation, revenue, regulatory alignment and resources in a crisis?



A crisis can take many forms and if poorly managed, can significantly impact a Life Sciences organisation's position in the market place. The ability to respond to a crisis and maintain business continuity is essential to minimise or avoid costly consequences.

An organisation as resiliency involves identifying the activities that are critical to the business, developing continuity strategies, implementing and then maintaining them. A typical programme will include:

- Risk mitigation: to identify risks and mitigate them to reduce the likelihood of an event that can disrupt the business.
- Crisis management: for senior management to manage the event and include elements such as invocation, rapid decision making and managing external communications.
- Business continuity management: to develop business continuity provisions for departments.
- IT Service continuity: implement, maintain and test the technical solutions required to support business continuity.

Successful implementation and maintenance of an effective resilience programme can be the difference between weathering a crisis unscathed or picking up the costly pieces of being battered by the elements.

Life Sciences organisations are complex organisations in structure, process, systems and critical third party relationships. An incident in one area can rapidly escalate into a crisis as other related areas are affected. Life Sciences companies are particularly vulnerable as business continuity for regulated activities is a mandatory requirement and, if shown to be inadequate, may lead to regulatory censure. In addition, supplier business continuity capabilities can directly affect the ability of the company to respond to an incident and IT service continuity activities have to maintain the validation status of GxP related systems. The Life Sciences industry attracts a high level of media focus and an incident is likely to be rapidly picked up and reported on widely.

In Life Sciences, organisations have focused their effort in developing capabilities to manage regulatory visits and product-related crises, such as recalls. Other areas, particularly in the IT resilience and recovery space, have not yet reached a level of maturity where senior management can be confident that they would be effective in a real incident.

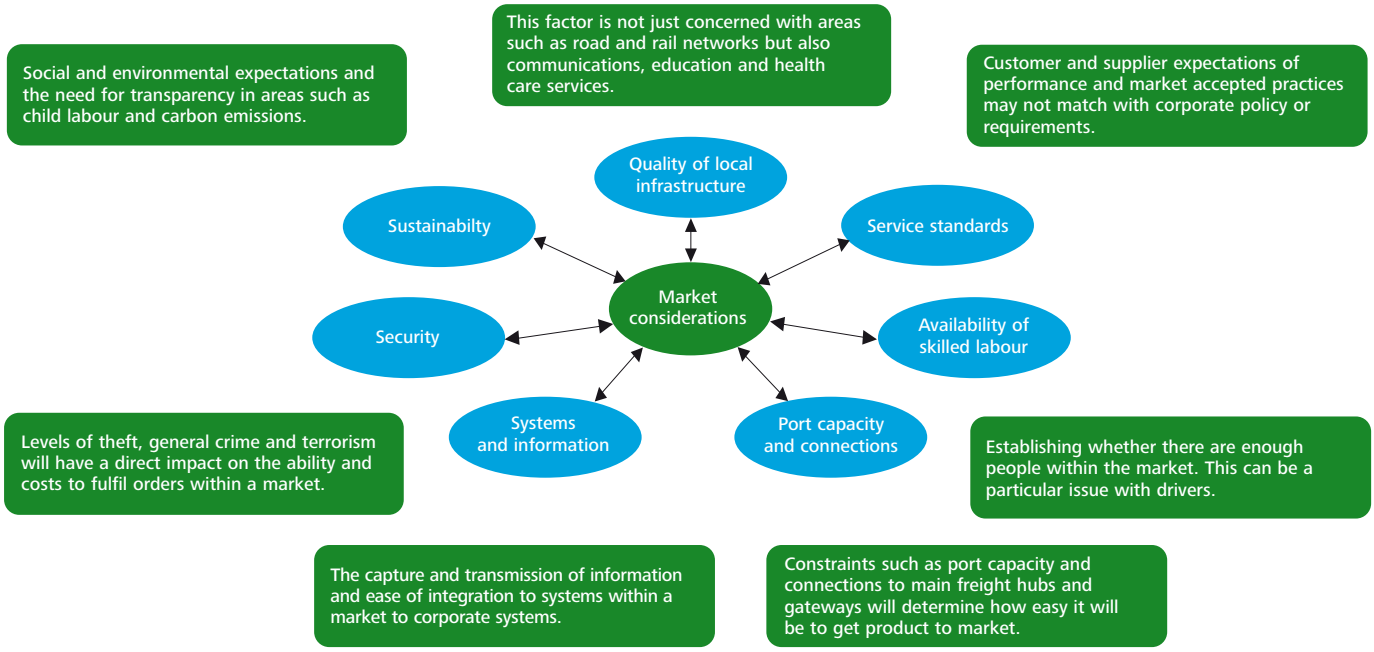
With the help of in-depth experience within the Life Sciences industry it is possible to focus on helping organisations understand their current resilience capabilities and to develop/implement solutions to bridge the gap.

How can we help?

- Assessing the adequacy of your current resilience programme.
- Design and implementation of a resilience programme.
- Designing complex simulations to game out different crises.
- IT service continuity programme solution design, implementation and testing.
- Implementation of resilience tools to streamline implementation and management.

Visualising the path to success
Reducing the COGS in your L&D machine

As Life Sciences reduce COGS, it remains a common theme that the cost of Logistics and Distribution (L&D) has tended to rise by comparison.



How can we help?

- On-time delivery improvement.
- Logistics and distribution strategy.
- RFP development for logistics services.
- Supply chain synchronisation.
- Transportation visibility solutions.
- Transportation planning.
- Electronic customs declarations.

The challenge being faced within Life Sciences is that traditionally the cost of L&D has tracked that of Cost of Goods Sold (COGS). As both have been an upward trend to date, the efforts to reduce COGS by all Pharma businesses should also mean reducing that of L&D – however, the reduction is not materialising.

So why is this?

Many businesses have declared strategies in the emerging markets. Substantial growth plans of many of the original operations networks are being re-engineered to accommodate new suppliers in maturing economies. The need to replicate information flows, clean data and capabilities both of the parent L&D community but also third party logistic providers has been slow. The opportunities to reduce costs has become complex and often no single strategy will fit all geographies.

When assessing the approach to distributing a product within the market, regardless of size or maturity, there are a number of key considerations that should be taken into account:

Understanding how individual markets compare in these areas will allow life science companies to plan an appropriate market entry, delivering a strategy to extract the most value from sales and product development investments.

The solution isn't about being the best across the entire value chain, but being selective about achieving leading practice in areas where your markets or business performance derives best value. The compound impact means that you optimise the cost by ensuring you excel at only those subjects where there is a market or cost advantage.

Therefore it is better to think in terms of simple building blocks of capability. Then applying the maturity levels to this, to evaluate your own needs and likely journey.

Trust in your natural ability but train to succeed
Managing your business partners

Are your business partners operating in line with your expectations, with your interests in mind and in a compliant manner?

The importance of third party business partners in the Life Sciences industry has always been key in ensuring global reach and the development/promotion of products. Organisations work with third parties in a variety of capacities. These may include clinical trials, contract manufacturing and supply, and sales and marketing. Ensuring that these relationships are operating as expected and increasing your visibility of these partners is not only good governance, but also good risk management.

Your partners can have a material impact on your business, through a number of different factors:

Financial risk of being overcharged or underpaid by partners is a common concern as well as the regulatory risk of your partners behaving in a non-compliant manner. Alongside this, there is the reputation to the risk of your partners. By acting in such a way to negatively impact your brand and the operational risk of your partners not providing visibility into their operations.

Addressing these risks need not be a costly and time consuming exercise. We have found that assessing a partner's adherence to their contractual terms and conditions can generate material return on investment. For example, identifying financial anomalies in relation to royalties, supplier charging and distributor rebates will enable you to make financial recoveries. Identifying partner non-compliance with regulations can avoid fines and charges which limit the impact on future supply chains.

In particular it has been seen that Life Science organisations are particularly interested in performance of R&D based organisations and the inherent contractual risks including CROs. Through looking at 'in and out' licensing deals to assess revenue flows are being treated correctly, assessing counterparty risks along the distribution channel and focusing on vendor management and compliance around supplier contracts.

Any Contract Risk and Compliance team (CRC) must have in-depth experience in the Life Sciences industry and be focussed on helping organisations understand and manage their third party risk. In particular, the Deloitte CRC has designed specific tools and methodologies around assessing your third party risks. For example, the Contract Risk Assessment Methodology allows our clients to get an in-depth view of the risks inherent within existing contracts, whereas D-SCAN methodology allows for a systematic validation of financial data against contractual terms and conditions. Both of these approaches have proven to deliver added value for our clients and have provided them with the tools to make important changes both contractually and within their organisations.

How can we help?

- Helping you understand your third party relationships and the current contract and vendor management processes in place.
- Helping you understand the risks inherent in existing and future contractual relationships.
- Assessing the contract compliance of your third parties to identify financial recoveries and areas for improvement.
- Performing risk assessments to identify your key points of risk and consider remediation actions.

Grants and incentives
Making the most of the apparatus available

Grant aid can provide the momentum and support to get projects moving.

The Life Sciences sector is recognised by many Government bodies as a key player within the economy. Although there are many routes to achieve funding, finding the right pathway through the options available and establishing a good fit can be difficult. What type of project may trigger grant support?

If your medium-term investment plans include the following, there could be an opportunity to access grant:

- Locations: Expanding at existing location(s), relocating or rationalising.
- Capital equipment: Investment in replacement or additional equipment (plant and machinery, fixtures and fittings, land and buildings etc).
- Research and Development: Creating new products or developing existing ones.
- Personnel: The creation of new jobs and/or the development of the existing/new workforce.
- Environmental: Energy efficient expenditure e.g. new biomass heat and power facility or reducing the carbon footprint.

Despite some cut backs in public spending, most grant fund pots are still open and accepting applications. Grant money has no servicing costs and may only require repayment in exceptional circumstances. The availability of grant funding can bring a very positive impetus to a project.

Around the UK there are literally hundreds of grant schemes available to life science companies.

The areas of focus which we believe can bring the most value are as follows:

- Research and Development. A significant area of funding which can range from local direct grant support, through to collaborative projects, with partners in the UK or around Europe. This is one of the largest sources of grant funding. The level of assistance on offer can be up to 50% for large companies and 75% for small/ medium-sized companies.
- Capital investment/job creation. Assistance can be available to support medium-term investment plans of a business. The grant may be based on capital expenditure or in the case of new jobs, cover part of the salary cost of newly created roles.
- Training. This is an important area of Government funding. Some programmes are currently being updated although there is a key focus on developing skills. Potentially higher levels of support may be available for smaller and medium-sized companies.
- Energy efficiency. The Government has a wide range of programmes available to encourage companies to reduce their carbon footprints. This may include carbon surveys, R&D grants (up to £500,000) and interest free loans to encourage investment in energy efficient capital expenditure.

Looking to a brighter economic future, the number of companies seeking funding to support their investments is expected to rise, leading to more competition. A well crafted application may pay dividends as the reward of committed Government funding is not to be missed.

How can we help?

- Identify appropriate fund schemes.
- Structure the case for grant.
- Assist with negotiations.
- Assistance to prepare accompanying submission document.
- Advise on grant tactics.
- Advise on grant offer conditions.
- Assist with the audit of grant claims.

Transforming how you compete
Facilitating individual excellence to win as a collective

For any organisation embarking on business transformation, the journey from vision to benefit needs to be effectively managed, with the impact on the organisation, leaders and people understood.

Deloitte's Transformation framework

How can we help?

- Vision development, alignment and communication.
- Leadership development and coaching.
- Engagement and communication management.
- Organisational design and implementation, workforce transition management.
- Employee cost reduction.
- Ensuring effective decision making at all levels of the business.
- Talent management.
- Strategy translation and execution through people, development of culture and ways of working.
- Development of skills, competencies and comprehensive performance management strategy and execution.
- HR transformation and optimisation.
- People related/HR M&A support.

As life science companies emerge from the recent economic storm, it is essential to take stock and ensure that business vision and goals are aligned across all levels of an organisation. By investing time upfront to discuss where your journey is taking you; what is the end goal and what would be the positive and negative outcomes on the way; this allows the organisation to focus on achieving it's results. Clear benefits should be outlined and an honest approach to the challenges ahead should be taken whilst explaining to different stakeholder groups what the change specifically means for them.

To allow a smooth transition, it is beneficial to engage with leadership early in the organisation design to achieve visible sponsorship of the transformation journey. Leaders should be visible in directing change and allowed to assimilate the proposed impact of the transformation. Messages cascaded through the leadership channel are more likely to be impactful, unless business leaders buy into the change – businesses and teams won't.

A strong programme management team can drive results more effectively than people with a day job. Clear accountabilities in the decision making process defined before embarking on the change journey is imperative. Through collective involvement, utilising a cross section of employees in designing the future organisation allows for greater buy-in. However, it must be ensured that the business has advance notice to organise their resources and time effectively. Utilising an empathetic approach ultimately provides encouragement to those most involved.

All change must be driven forwards by developing a compelling case and driving demand through the articulation of what the business will get that it doesn't have today. If the business does not want or think it needs the changes, the transformation will fail. With any transient period, expectations should be managed. Recognition should be given that not all messages will be good ones. Focusing on the 'hygiene' factors first and providing clear timelines will mean that employees concerns about jobs security will be most effectively dealt with.

Organisations, as complex as those in Life Sciences need to understand the extent to which different stakeholder groups are affected by these changes. Putting in place a targeted change plan, addressing each group's specific needs gives the best opportunity to consider how best to incentivise employees to change their behaviours and ways of working.

Changing global economies and market pressures are putting unprecedented challenges in the paths of Life Sciences companies. Cost reduction, restructuring, business relocations, and strategic/operational partnership development are all key strategies in the drive to remain competitive in a changing business landscape. Ensuring your people are aligned and working with you to achieve these aims is a critical factor in delivering successful change. Our Organisational Transformation framework provides a comprehensive approach to addressing this need.

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