



Deloitte.

R&D and Regulatory Advisory
Services to the Pharmaceutical
Industry

Achieving operations excellence

Helping you deliver
improved returns
on your investment
in R&D

Introduction

Welcome to Achieving operations excellence in pharmaceutical research and development.

The global economic environment continues to prove challenging with relentless downward pressure on healthcare budgets and constraints on market access and the pricing of new medicines.

Across the healthcare industry, there is a recognition of the need to deliver greater value by demonstrating improved patient outcomes at a lower cost for providers.

This brochure describes how we are helping life sciences companies respond to these challenges by working with them to transform their core operational platforms for new product development and management – to achieve more, with less, and faster.

How we support operations excellence activities

As we work alongside our clients in their continued drive to achieve operations excellence in the business of science, we help them to:

- **access the best science** – through novel business models that promote networked R&D;
- **reduce the cost of success** – by reducing fixed costs in favour of more efficient variable costs, and enhancing governance and decision making;

- **enhance operating income** – delivering large scale change across Finance, Procurement and IT to sustain and improve operating income;
- **develop compelling payer propositions** – by collaborating with healthcare providers to identify opportunities to improve diagnostic and care pathways through real world evidence;
- **safeguard licence to operate** – helping organisations stay at the forefront of changing regulatory, safety and compliance requirements.

Together, these focus areas lead towards **improving the return on investment from drug research & development** and the industry's significant outlay in medicines innovation.

Who we serve

Our senior practitioners bring decades of industry and consulting experience with pharmaceutical majors, biotechnology organisations and contract research organisations.

Our services

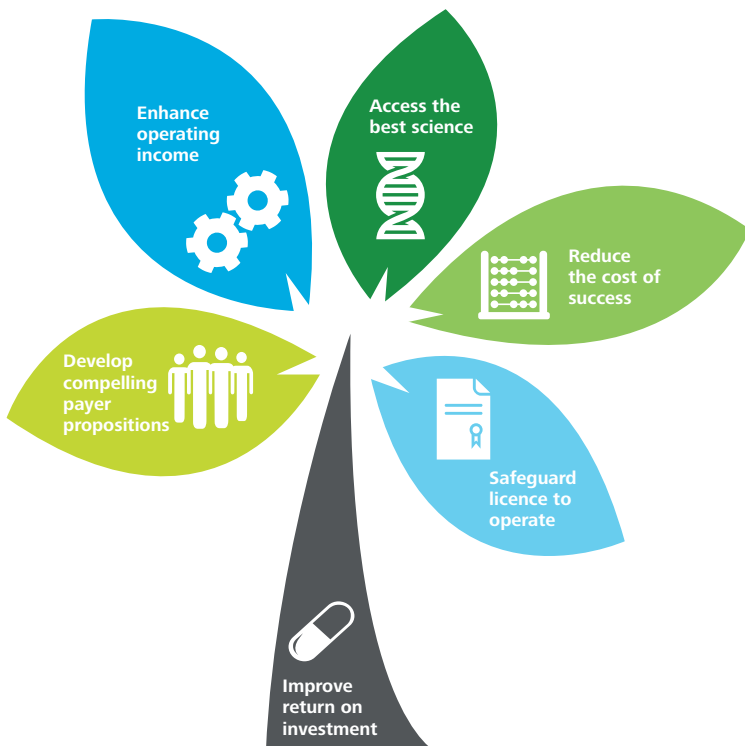
This brochure summarises the services we provide, with case examples of how we help life sciences organisations achieve operations excellence when bringing innovative new products safely to market for the benefit of patients. These services include:

- designing and implementing strategic change;
- delivering productivity improvement in R&D;
- safeguarding your licence to operate.

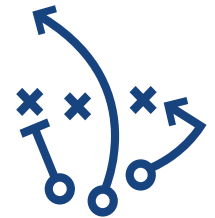
My team and I would welcome the opportunity to discuss in more detail how Deloitte could work with you to inspire, plan and deliver your ambitions for operations excellence across your R&D and Regulatory functions.



Julian Remnant
R&D Advisory Partner
Life Sciences Operations Excellence
Deloitte MCS Limited



Designing and implementing strategic change



Executable strategy to realise your vision

R&D leadership continues to be challenged by increasing costs and low returns, but we see new strategies and operating models emerging to counter this trend.

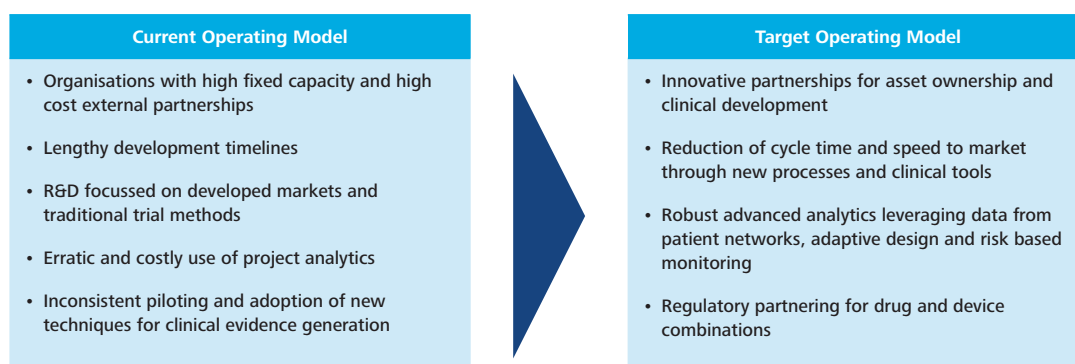
Pharmaceutical R&D is based on science and product development, taking up to 15 years from discovery to launch. During this time organisations need to adapt to changing internal and external priorities. These changes range from new internal R&D strategies and business models to externally facing events including mergers, collaborations and alliances. Our 2014 analysis of R&D returns examines the investments and rewards for a cohort of large pharmaceutical innovators. In addition, it identifies strategies to improve returns against key value levers, which we have observed in both pharmaceutical companies and those focussed on other industries. These include:

- increasing product value through innovation investments, therapy area focus and project team choices;
- lowering cycle time by using improved governance, investment and new decision tools;
- reducing costs by challenging the overall R&D spend, reducing the cost of failure and enhancing investment choices both in infrastructure (facilities and labour) and project based activities.

What we do

Our team has a wealth of experience in improving global performance in R&D. We can help your organisation analyse and address the fundamental challenges of improving productivity, which include:

- challenging the current R&D strategy or business model based on a review of innovation, cost and cycle times. This process identifies opportunities to improve outputs and meet your strategic goals;
- reviewing the global R&D operating model to help your organisation achieve higher throughput whilst maintaining or reducing costs and protecting quality;
- developing plans for change to a new business or operating model including layers for customers, organisation design, partners, information, systems and process improvement.



Case examples

- We worked with the R&D Head & CFO of a large pharmaceutical company on their post-merger global design. Our team used industry benchmarks for structure, size, information management and risk analysis to improve the implementation model and reduce key risks.
- We created a revised R&D strategy for a medical technology company to align their development portfolio to the needs of the business and market following a refresh of global product priorities.

Key contact:
Colin Terry

Delivering R&D productivity improvement



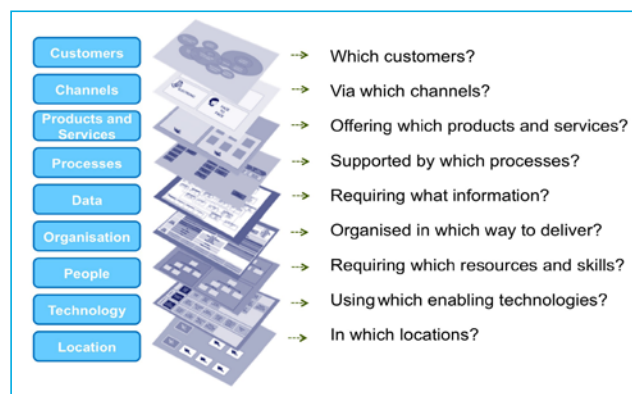
Proactive change to deliver tomorrow's innovation

The average cost of developing a pharmaceutical product has risen to approximately \$1.4 billion, yet the commercial value has not increased.

Our 2014 analysis of R&D returns points to a modest increase in pipeline valuations, reversing the trend of declining returns.

Despite these pointers to an upturn in productivity, we anticipate that R&D leaders will remain under pressure to demonstrate prudent use of shareholder funds. For example, Heads of R&D will be expected to liberate budget through productivity improvements in order to fund and develop an expanding pipeline of promising compounds. Developing more science, with less capital, and faster, will remain business as usual for the medium term.

Example operating model design questions



What we do

Our Target Operating Model (TOM) and methodology provides you with a clear representation of how the various components of your organisation can be configured and operate together to execute your strategy. Developing and testing operating model options enables a clear and common understanding of the current state, possible future states, a roadmap for how to achieve the target state and the value of change to your organisation.

Case examples

Using lean six sigma and Deloitte proprietary methods and tools such as TOM, we have helped the following R&D organisations adapt to achieve demanding improvements in productivity:

- A clinical development function to work through a complex restructuring programme to realise \$200M in annual cost savings from consolidation, standardisation and streamlined operations.
- A research services function to gain better visibility and understanding of the cost, capacity, and capability profile of the organisation with a view to improving operational decision making, strategic scenario planning, and to maintain alignment of research capabilities with therapy area needs. We identified 10-12% savings and efficiencies to be re-deployed to meet future demand or reduced cost.
- A late stage development organisation to improve governance of a \$100M portfolio of non-drug projects by developing a five year roadmap aligned to the business strategy, so that solutions work better together, implementation is accelerated and project investment appraisals are evaluated and prioritised more effectively.
- A clinical operations group where we enabled a smooth transition into a new organisational structure, simplifying reporting lines, reducing management overheads, and delivering globally harmonised best practices, resulting in the rationalisation of 50% of processes by removing overlaps and duplication.

Key contact:
Julian Remnant

Safeguarding your licence to operate







Acclimating to the changing regulatory and risk environment

Pharmaceutical companies and their staff are under more legislated responsibility than ever before.

We work in partnership with our clients to optimise end-to-end regulatory activities and apply innovative solutions to improve quality and compliance.

The life sciences sector has a robust, complex and evolving regulatory landscape driven by patient health, safety, and protection at its core, while also adapting to different guidelines and mandates throughout the world. Adding to this complexity are the factors of rapid change, increased scrutiny, more sophisticated risk-monitoring techniques, and coordination across agencies and regions.

We believe in a proactive approach to regulatory change through a quality by design approach. This supports a reduction in the costs of remediation and potential fines whilst enabling our clients to stay ahead of the legislation and maintain the necessary licence to operate.

The top regulatory and risk environment issues facing industry in 2015			
 Transparency	Increased transparency in clinical operations is shining an ever brightening light on clinical trial quality, and will require diligence when companies prepare their public disclosures	 Drug & Device Safety	The need for global oversight in an increasingly networked landscape requires new controls and risk management capabilities
 Security & Privacy	Digitisation and the proliferation of EMRs (Electronic Medical Record), networked-devices, mHealth, cloud and data sharing among stakeholders increase SGP complexity	 Intellectual Property Protection	Companies continue to struggle in their efforts to globally enforce intellectual property (IP) rights, particularly in emerging markets

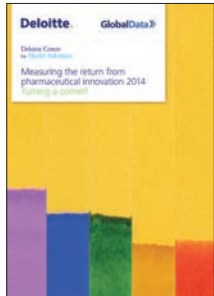
What we do

We help the world's largest pharmaceutical companies to transform, optimise and effectively run compliant businesses. In the last three years we have helped more than 20 companies to prepare for regulatory inspections, remediate inspection findings, and prepare for future regulations.

Case examples

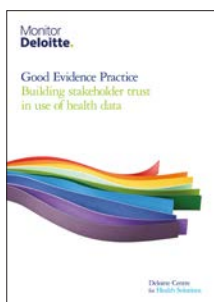
- We developed and implemented processes to improve Pharmacovigilance System Master File (PSMF) maintenance and compliance. Our services included bringing the required subject matter knowledge and project management experience to effectively design, plan and manage the change necessary to co-ordinate regular collection and collation of globally sourced information.
- We led the assessment and implementation of regulatory changes and implemented transitional/continuous improvement strategies for long term operational effectiveness. Our services spanned key global functions including: regulatory, drug safety, clinical development, biometrics, epidemiology, global medical affairs and data informatics.
- We prepared and coordinated more than 50 CAPA activities. Our services included transformation of activities to deliver on PV Commitments, labelling, XEVMPD reporting, DHPC RMP/RMinA, PASS/PAES, PSUR/PBRER optimisation, Bertrand Act/Market Cessation, eSubmissions and regulatory system decommissioning.
- We designed future end-to-end processes for transparent clinical trial data sharing and IDMP.
- We provided dedicated computer systems validation (CSV) services to support technical realignment during optimisation and harmonisation of regulatory and safety processes.

Key contact:
David Nestor



Measuring the return from pharmaceutical innovation 2014

The pressure on research and development leaders to identify and successfully develop promising, innovative medicines is relentless. Generating a return from significant annual investment in new product innovation is challenged by market austerity, regulatory scrutiny and scientific uncertainty. The 2014 report examines the underlying factors that could influence projected returns including: portfolio mix or focus, company size and R&D spend, and the proportion of science originating from outside the company. We provide our insights to help R&D leaders to understand the tangible, actionable drivers to successfully bring innovative new products profitably to market. To learn more about our 2014 study, please visit www.deloitte.co.uk/measuringrndreturns2014



Good evidence practice: Building stakeholder trust in the use of health data

Healthcare data present a unique opportunity to develop real world evidence insights into existing diagnostic and treatment pathways, to identify unmet need and to demonstrate the actual clinical and economic impact of interventions within the healthcare system. This evidence enables R&D organisations to prioritise their pipeline investments more effectively, better understand underlying causes of disease and identify opportunities for indication expansion and business development. Given the acceptance of GCP, we believe that an analogous approach should be developed to guide real world evidence studies. We have termed this approach Good Evidence Practice.



Healthcare and life sciences predictions 2020: A bold future?

In this report we set out ten provocative statements predicting the world of 2020. Each prediction is articulated and brought to life through a series of portraits which imagine how patients, healthcare professionals and life sciences organisations might behave in this new world. Our predictions lean more towards an optimistic view of the future, although we recognise that many in our industry are sceptical about the constraints and therefore pace of change. We describe the big trends rolled forward to 2020 and some of the constraints that will need to be overcome. We also provide examples and evidence, based on the here and now, that show that the predictions are perfectly plausible, perhaps inspiring and surprising.



2015 Global life sciences outlook: Adapting in an era of transformation

Aging populations, chronic/lifestyle diseases, emerging-market expansion, and treatment and technology advances are expected to spur life sciences sector growth in 2015. However, efforts by governments, health care providers, and health plans to reduce costs, improve outcomes, and demonstrate value is dramatically altering the health care demand and delivery landscape. It is becoming increasingly evident that the global life sciences sector is operating in an era of significant transformation. The report outlines some of the top issues facing the global life sciences sector, provides a snapshot of activity in a number of geographic markets, and suggests considerations for companies as they seek to grow revenue and market share in 2015 and beyond.

"Deloitte provides a wide range of strategic, financial, operational and regulatory compliance risk services."

"Deloitte provides one of the widest ranges of capability in the industry and the relationship models to support large program initiatives. The breadth of these capabilities and the organisational ability to integrate these skills together allow Deloitte to focus on a variety of strategic issues such as pricing and profitability, strategic commercial models, and partnering models for R&D."

"Deloitte conducts a wide range of work in support of pricing, profitability, go-to-market strategies, and local sales and marketing alignment."

What our clients say about us



"Deloitte implemented extremely well on the ground working effectively with our team."

Life Sciences CFO

"Deloitte brought a strong teaming approach which was very different from our previous experience of external support."

VP & Transformation Leader

"Deloitte provided real challenge to our thinking. We are now building a stronger organisation and operating model with your insights and findings."

VP & Transformation Leader

"Your expertise in the field, experience on similar projects in other big pharma companies and pragmatic approach helped our team deliver a sound information management strategy and implementation plan."

VP Regulatory

"A pleasure to work with you, I would like to thank you for your support. Let's keep in touch for future work to come."

EU-QPPV

"The Deloitte team were fast to pick up the topics and issues and to generate solutions. The team were also very flexible in responding to changing priorities and needs."

R&D Change Programme Lead

"You successfully supported the team to translate the business need into technical language."

Associate Director, PV

Key contacts



We welcome the opportunity to discuss in more detail how we could work with you to inspire, plan and deliver your ambitions for operations excellence. If you have any questions, please get in touch with the contacts below:



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To learn more about Deloitte's Healthcare and Life Sciences practice, please visit: www.deloitte.com/uk/en/industries/life-sciences-and-healthcare

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