Grant Thornton

Life sciences

Risk insights: Life sciences

A successful risk management programme needs to be all-encompassing and not focused solely on prescriptive regulatory requirements.

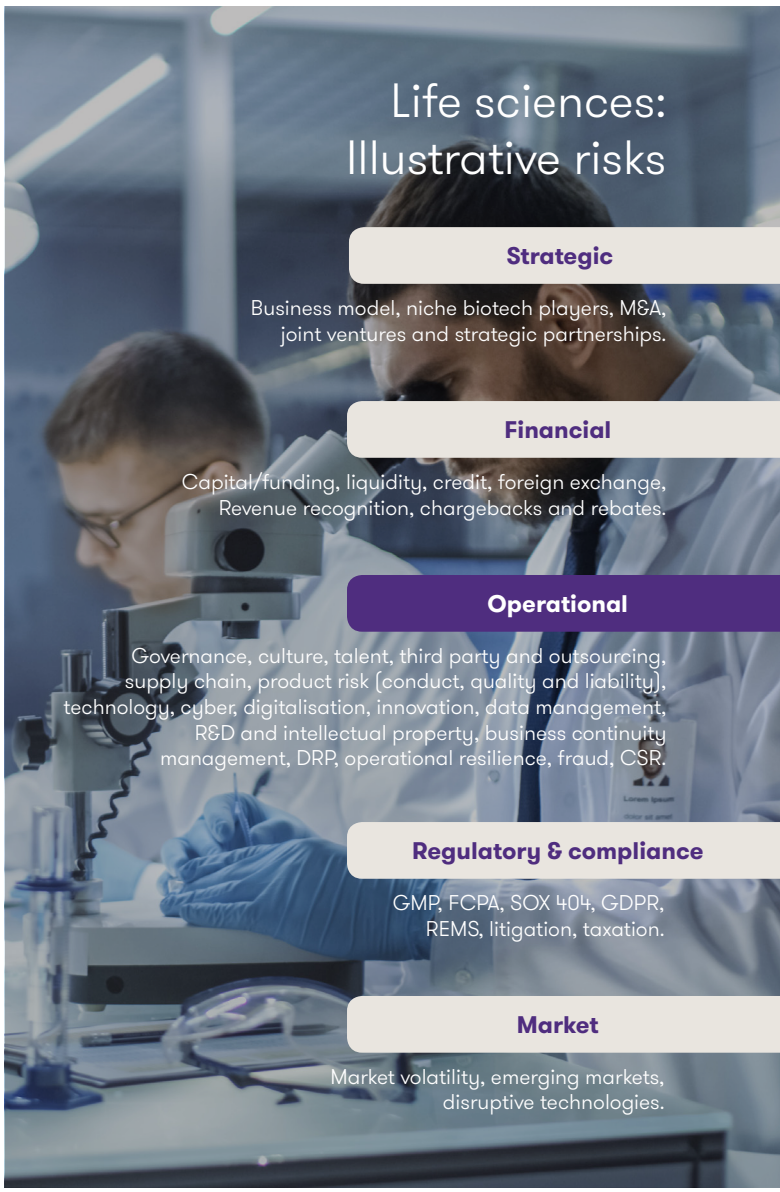
The life sciences industry continues to become ever more dynamic and complex. Comprising bio-technology, pharmaceutical and medical devices as well as other industry sub sectors, this industry remains highly regulated, highly capital intensive and highly reliant on data quality.

Consolidation in the industry continues with strategic acquisitions and alliances happening most notably to strengthen and improve product pipeline, R&D capabilities and in certain cases secure innovative technologies.

These characteristics support the risk management challenge facing life science organisations - that being; the oversight, active management, monitoring and reporting of operational risk. Operational risk in these organisations has become sizeable and multi layered, with many grappling with an enterprise wide view of risk across their organisations. There is a genuine need to move away from an outdated and siloed approach to risk management, largely driven by a heavy regulatory and compliance agenda, if these organisations are to best protect themselves from the growing levels of operational risk that are being experienced.

To optimally manage enterprise risk and most especially operational risk, such organisations need to have robust governance, risk and internal control mechanisms in place. The transparency and integrity of these arrangements can't be overstated most especially given lengthy product lifecycles that have to be financed and resourced and the expectations of the wide reaching stakeholder groups that exist within this industry.

In the context of operational risk specifically, the increased usage of Contract Management Organisations (CMOs) in the research, validation, production, distribution, marketing and selling of products has shone a light on the acute need for truly integrated Third Party Risk Management (TPRM) programmes that are fit for purpose and not only deliver greater competitiveness but also provide enhanced data transparency and support end to end risk management practices.



The use of third parties and TPRM is crucial to the Life Sciences industry and its future growth and competiveness but such programs require a clear and distinct strategy, defined ownership, a transparent and communicated operating model, optimised processes and investment in technology and innovation tools, if they are to contribute value strategically and commercially.

The pandemic has further highlighted the need for an integrated approach to risk management within the Life Sciences sector. Operational risk has been exacerbated by matters such as crisis management, BCM and supply chain contingency planning in many instances and the level of inter-dependencies that exist in such complex organisations. Adequate scenario planning and testing is essential so as to have holistic 'go to' plans in place to address people process, property and technology contingency during times of crisis and in turn work to minimise the crystallisation of operational risk.

How can we help?

Many of our team are senior risk professionals from the life sciences and other regulated sectors. They have held key risk, compliance and internal audit roles in such organisations and bring a wealth of real life experience to the table.

Our Life Sciences specialist sector group and business risk consulting team work together to offer the unique mix of industry subject matter expertise and best fit governance, risk and control solutions to meet your needs. We have helped our life science clients navigate:

- risk assessments and frameworks;
- Third Party Risk Management (TPRM);
- Business Continuity Management (BCM);
- IT/cyber security reviews;
- contract/rebate assurance;
- supply chain third party audits;
- SOX, FCPA, ethics, quality and compliance audits.

Regulatory and product quality focus. No holistic risk management practices in place.

Situation
An international pharmaceutical business needed a holistic assessment of its risk universe and its risk management practices in its domestic business in order to determine how resources would be best used and spent in the management of risk going forward.

Solution
We conducted an enterprise wide risk assessment across the business to identify, quantify and assess risks on a function by function basis and the mechanisms in place to manage same. This assessment was coupled with management risk training and methodology workshops.

Outcome
A comprehensive risk register that provided a single view of risk across the business for the board and management to use as a starting point to implement a risk management improvement project.

A defined risk appetite and clear and standardised approach to risk assessment common to all parts of the business.

A prioritised list of risks requiring immediate attention, most notably highlighting the need for a centralised third party risk management function and framework.

Contact

If you would like more information on our risk consulting services please contact a member of our dedicated team.

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