

Risk management in pharmaceutical and life sciences

The purpose of risk management in any industry has traditionally been to protect and preserve a business. It can however, also be used to manage public perception and leverage growth and competitiveness.

This sector comprises sub-sectors such as pharmaceuticals, medical devices, biotechnology and sub-supply products and services. It is by its very nature a highly regulated and onerous environment with multiple regulatory, audit and documentary compliance demands placed upon it. However, a successful risk management programme needs to be all-encompassing and not focused solely on prescriptive regulatory requirements.

In order to prevent such a narrow risk focus, a comprehensive and perpetual risk assessment is a critical starting point in achieving an effective risk management programme and enhancing strategic success.

Notwithstanding fundamental risk assessment priorities many businesses in this industry may also be required to comply with Sarbanes Oxley (SOX) requirements. In that respect we provide a full suite of SOX services to the pharmaceutical and life sciences sector including SOX pre IPO readiness assessments, ongoing SOX testing programs and SOX lean assessments.

Our tailored risk management approach and methodology

At Grant Thornton, we have extensive knowledge and experience in providing tailored risk management solutions to this industry. Some characteristics of our bespoke risk management service methodology and approach are outlined below:

- performing an initial risk assessment of the existing risk universe of a business, what has and has not been considered by the organisation. Considering all risk categories in the context of the business's strategic plans and by adopting a SWOT analysis (Strengths, Weaknesses, Opportunities and Threats);
- interviewing and surveying the sense of risk with management, to determine their appreciation for an

understanding of risk and how it impacts their day-to-day roles and their business as a whole;

- determining and assessing senior managements' risk appetite and how it is communicated throughout the organisation via policies and procedures, tolerances and limits;
- reviewing the existing internal control environment and control activities in the context of the business achieving its strategic and operational objectives, optimum reporting reliability and compliance with applicable laws and regulations; and
- delivering an end-to-end risk management solution to management and facilitating communication and training workshops to ensure 'buy-in' by all parties so as to achieve a maximum return on investment and yield tangible benefits from the process immediately and on an ongoing basis.

Risks in the pharmaceutical and life sciences industry

Below is an indication of what we consider to be some of the inherent risks within this sector. These risks relate to the core processes that exist within pharmaceutical and life science businesses in developing, manufacturing and distributing their products and services to customers:



Regulatory:

- increase in regulatory requirements;
- changes in any oversight body;
- Foreign Corrupt Practices Act (FCPA)/payments to government officials;
- Anti-Money laundering (AML) requirements;
- Irish Medicines Board (IMB) requirements; and
- General Data Protection Regulation (GDPR).



Human resources:

- shortage of specialist skills;
- loss of key personnel; and
- succession planning.



Operational:

- Good Manufacturing Practice (GMP) requirements;
- Research and Development (R&D) pipeline/product lifecycle;
- supply chain risk;
- transfer pricing;
- generic products;
- patent expiry;
- packaging and product specification; and
- global resource management.



Economic:

- foreign currency exposure;
- health insurance costs; and
- generic product trends/innovation.



Political:

- BREXIT;
- corporation tax rate threat;
- grant aid structure;
- transfer pricing;
- R&D tax credit relief; and
- VAT.



IT:

- cyber security;
- business continuity;
- privacy of information (GDPR);
- batch traceability;
- whistle-blowing; and
- insufficient data analytics capability.



Other:

- contamination risk;
- reputation risk;
- environmental;
- Intellectual Property (IP) rights protection; and
- public perception.

Contact

Risk management is critical to the preservation and success of any organisation. Should you require any further information or advice in relation to our risk management or our SOX assurance services please feel free to contact a member of the Business Risk Services team.

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