

Five Emerging Risks for Life Sciences



Life science leaders are under pressure to perform in the face of increasingly complex and potentially catastrophic risks to financial performance and reporting, capital allocation and working capital, product quality, human safety, market and product competition, pricing and margin, and intellectual property.

Pharmaceutical and medical device manufacturers are particularly attractive targets for fraud, counterfeiting, and cybercriminal activity due to the nature of therapeutic care products and devices, the sensitivity to patient safety and protected data, and the pressures these organizations face to protect intellectual property, adhere to regulatory requirements, and urgency to restore critical systems and data.

To sufficiently protect the organization, life science leaders need to fully understand the potential impact of risks to performance, the vulnerabilities in their environment, and understand how a variety of risks could potentially unfold — as well as grasp how well-prepared the organization is to identify, manage, and respond to risk.

In speaking with our BDO life science clients, five emerging risk themes were identified due to their potential direct and indirect impacts on organizational performance.

1 / Labor Challenges



RISK: The ability to attract, retain, and motivate talent continues to be a challenge for most industries, and is not just limited to purely compensation constraints. The life sciences industry is grappling with a significant staffing challenge, fueled by the soaring demand for skilled professionals adept at merging technology with life sciences, alongside a notable vacancy rate and distinct recruitment hurdles.

MANAGEMENT STRATEGIES: BDO supports clients in creating and implementing intentional talent management and employee engagement programs and designing unique employee incentive structures for employee and team performance that align with organizational goals and constraints. This includes better training programs, developing clear career paths and opportunities for high-performing individuals and teams, and intentionally building an engaging, team-oriented work environment.

2 / Brand and Reputation



RISK: How an organization is perceived by patients and healthcare providers, investors and the marketplace, regulators, and competitors affects and amplifies a host of other issues including the ability to attract talent, maintain market and investor confidence, and collaborate and work productively with regulators, suppliers, partners, and other stakeholders.

MANAGEMENT STRATEGIES: BDO works with clients to prepare for and respond to risk events, sometimes in real time alongside the client. We assist life science clients on crisis and incident response as part of an overall resilience strategy for the organization. This includes identifying and assessing potential risks, developing reaction and response plans, engaging internal and external stakeholders in proactive and effective communication strategies, and engaging partners, vendors, and other key stakeholders in thoughtfully preparing for communication expectations for roles, responsibilities, and service level agreements should a risk event occur.

3 / IT Disaster Recovery and Cybersecurity



RISK: Cybersecurity is a major concern across all industries. Life sciences has exposure to multiple vulnerabilities including distributed and decentralized production; research and development; supply chain dependencies with multiple partners and vendors; aged systems; sensitive data on clinical patients, personnel, formulations; and intellectual property that are highly valuable targets for corporate espionage and ransomware attacks.

MANAGEMENT STRATEGY: BDO guides clients through the process of enhancing IT disaster recovery and cyber resilience capabilities with a robust, multi-layered cybersecurity strategy that includes software assessment and update cycles, perimeter security and detection, employee engagement and training, and risk assessment and alert capabilities. We can help clients optimize business continuity and disaster recovery capabilities by managing redundant systems and off-site data backup capabilities and develop clear processes and protocols for communicating an event and preparing for an extended downtime while also working to restore critical operations and capabilities.

4 / Regulatory and Performance Reporting



RISK: Life science organizations at all stages of maturity need to optimize their control framework, technology environment, and processes for aggregating and reporting on relevant performance and risk data. There are numerous stakeholders and audiences that have a variety of expectations including markets seeking financial information, regulatory filings, quality, and safety.

MANAGEMENT STRATEGY: Optimizing control frameworks and adhering to accounting principles and standards are crucial for accurate reporting and compliance.

5 / Leveraging Data and Enabling Technology




RISK: The ability to achieve many performance goals depends on understanding and defining risks and leveraging data to make risk-informed decisions.

MANAGEMENT STRATEGY: BDO supports the implementation of strong data analytics tools and capabilities to leverage data to achieve performance goals. Accessing, synthesizing, and assessing data for market analytics, labor analytics, compliance requirements, or financial reporting is no longer a competitive advantage. BDO enables organizations to access timely and useful data while also providing clients with the education to use these systems and data. This analysis could include transaction and activity monitoring, supplier and vendor integrity and consistency, prescription and usage trends, sales and channel monitoring, contracting, and risk exposure.

How BDO Can Help

Developing strong risk and resilience capabilities supports the potential success of life sciences companies at every stage of their growth trajectory. BDO's integrated approach to risk management helps companies focus on their success while enabling effective strategies to navigate the challenges they face and protect human health, private data and information, and the organization itself.



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