



LIFE SCIENCES INDUSTRY SPOTLIGHT

Enterprise Risk Management

An Engine for Achieving Performance

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Five Questions

Life Sciences Leaders Should Ask About Enterprise Risks

Today's life sciences providers — encompassing drug manufacturers, medical device organizations, and bioscience labs — operate in a volatile and varied risk environment. AI adoption, cyberattacks, and geopolitical economic uncertainty are just a few of the risks that, if left unchecked, can derail operations before leaders have time to react to the initial problem. As a result, enterprise risk management (ERM) has become less about compliance and more about operational survival.

Some organizations may manage these risks in isolation — a compliance report here, a heat map there — treating risk management as a periodic exercise rather than an operating discipline. That approach is no longer sufficient. A strong ERM strategy connects risk directly to performance, giving leaders the coordinated visibility and accountability needed to protect production and make faster decisions under pressure.

The following questions and answers shed new light on ERM and how an ERM assessment can help a life sciences organization reduce risk and operational disruption.

What Are The Most Significant Enterprise Risks Facing Life Sciences Organizations Today?

- ▶ **Supply chains** remain as top concern for pharmaceutical, biotech, and medical device companies due to global manufacturing, distribution, and sourcing networks.
- ▶ **Tariff instability** affects most life sciences companies, again, due to the global nature of the industry. While pre-commercial organizations may not rank it among their top ten risks, the subject is still critical due to investor awareness.
- ▶ **Drug pricing and reimbursement** fluctuations create financial instability.
- ▶ **Third-party risk** is widespread as life sciences organizations rely on contract manufacturers, service providers, and suppliers across multiple jurisdictions.
- ▶ **Data protection and cybersecurity** risks are prime concerns that vary across the industry from personally identifiable information to intellectual property.
- ▶ **Product quality** failures create significant risks to operations, financing, and reputation. In fact, pharmaceutical organizations generally put processes in place to prevent medication recalls because they are a “never” event.
- ▶ **Adapting to innovation** means organizations must assess their needs, obtain the right software and hardware, and provide proper guidance.
- ▶ **FDA regulations** remain one of the top concerns for all life sciences organizations, considering how the FDA regulates drugs and manufacturing facilities.
- ▶ **Other regulatory compliance risks** include a myriad of evolving national and global regulations, as well as the Inflation Reduction Act of 2022, and the Executive Order dated May 12, 2025, about most-favored national drug pricing.



How Have Top Risks Changed in Recent Years, and What New Risks Are Emerging?

- ▶ **Supply chains** are increasingly vulnerable to disruption due to tariff uncertainty, political instability, and diplomatic breakdowns.
- ▶ **Regulatory volatility** continues to affect manufacturing and distribution, as well as research and development. Some life science organizations must comply with the Inflation Reduction Act of 2022, and the Executive Order dated May 12, 2025, about most-favored national drug pricing, while all organizations watch for evolving national and global regulations.
- ▶ **AI adoption** continues to rise in part due to external pressure from investors and customers looking to reduce costs and speed up productivity. To remain competitive, many life sciences organizations face the need to accelerate their adoption while managing costs and developing strict governance protocols.
- ▶ **Financial pressures** mount for life science leaders with limited access to funding while also reducing costs, managing reimbursement variabilities, and moving ahead with projects.
- ▶ **Data protection and cybersecurity** risks continue to rise as cyber criminals become more sophisticated. With innovations rapidly evolving, it has become more difficult to protect patient privacy, manage large volumes of patient data, and safeguard valuable intellectual property.

Where Do Life Sciences Organizations Most Commonly Struggle With ERM?



Starting the conversation about ERM can seem overwhelming, especially to smaller companies. Leaders and decision makers may not think of ERM as a business discipline that supports performance and decision making.



Financing concerns overshadow the need for a formal risk management program, especially for smaller, non-public companies and startups.



Fragmenting risk across functions within the organization makes it difficult to develop a comprehensive view of the organization's interconnected risks.



Without a formal, structured ERM framework, life science leaders may find it difficult to monitor third-party dependencies and complex supply chains.



Some organizations find it easy to identify risks but challenging to implement a robust ERM plan that establishes accountability across various functions and outlines risk mitigation obligations.

How Can Life Sciences Leaders Better Connect Risk Management to Operational Performance and Strategy?



Conduct a thorough ERM assessment to identify and prioritize risks across the organization



Develop strong ERM then embed it into strategic business plans, while evaluating all initiatives through a risk lens.



Assign clear accountability to pertinent stakeholders rather than centralizing risk ownership inside a single compliance function. Doing so connects ERM directly to the people who control the organization's operational and strategic outcomes.



Focus on decision making instead of reporting. Rather than defaulting to static risk inventories, use ERM to clarify strategies and decision makers.



Give key stakeholders access to both quantitative and qualitative data to help them understand how risks could affect business performance.



Align risk management with strategic planning for performance and production to help ERM function as a defensive activity that can drive cost savings, efficiency, and better resource allocation.



How Can an ERM Assessment Build Resilience and Agility?



An ERM assessment creates visibility into interconnected risks, helping enable more coordination between functions in the organization. For life sciences leaders, mapping out this step might include reviewing both supply chain vulnerabilities and third-party risks.

By gaining a thorough understanding of potential changes or events, organizations can align ERM processes with shifting business conditions and strategic objectives. Life sciences organizations might built redundancies into their approved third-party suppliers to cover disruptions due to the geopolitical environment

The results from an ERM assessment can help a tech organization establish controls, create clear escalation triggers, and clarify both ownership and accountability. While life science leaders should consider ERM a business discipline, they are also bound to comply with a myriad of standards, laws, and regulations.

Embedding risk considerations into broader business processes instead of treating ERM as a standalone function can position the organization to withstand shocks to business performance and adapt to technological innovation.

Turning Risk into a Performance Opportunity

For life science organizations, the challenge is not identifying enterprise risks but translating risk documentation into integrated business planning. An enterprise risk assessment can shift ERM from a reactive, compliance-focused exercise to a strategic tool that supports long-term planning and performance. Organizations that make this transition are better positioned to sustain operations during disruptions and remain focused on strategic priorities rather than continuously responding to the latest crisis.

BDO's eBook, **Enterprise Risk Management: An Engine for Achieving Performance**, explores how life science organizations are replacing static heat maps and siloed risk efforts with an integrated ERM strategy that strengthens resilience, improves accountability, and supports better decision-making across the enterprise. BDO's [ERM services](#) offer tailored risk management strategies designed to help life science leaders protect their organizations and achieve their performance goals, with a cross-functional approach spanning protection, innovation, and operations.

Explore the **Enterprise Risk Management: An Engine for Achieving Performance** ebook ►





Contact BDO today to learn more about our **Enterprise Risk Management services** and how we can help your organization build resilience for the future.

Have questions or want to learn more? Contact us!

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