

## Enterprise Risk Management for Life Sciences Research & Development



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Enterprise Risk Management (ERM) is a systematic approach to managing risks in a consistent and coordinated fashion across the entire organization. In a recent survey when investors were asked about the key benefits of a company having a focused and reliable approach to risk management, the majority of responses were *fewer negative surprises* and *greater certainty of profitability and financial stability*. Within the complex world of life sciences research and development, add to that the demands of regulators, and a cohesive approach to risk management becomes even more essential.

An ERM system should have three goals. First, to protect the organization from risks preventing the achievement of its objectives. Second, to increase the efficiency and effectiveness of operations, and third, to limit risks to the organization's defined risk appetite. The short term and long term benefits of an effective ERM system can be invaluable to pharmaceutical or medical device companies. Most ERM models were developed for publicly traded, revenue-generating companies that typically reside in the Fortune 500 if not the Fortune 100. The analytical process for determining the efficacy of most ERM models has become so complex that the value of the exercise is lost to the volumes of data produced. This process has often ended in 'analysis paralysis.'

Seen as a '*big company*' paradigm, often the leadership of research and development stage companies puts off the implementation of an ERM program, assuming that the process is unnecessarily complex for the early stages of their operations. In its totality, a '*by the book*' ERM process is likely to be more of a hindrance than a help, but, this should never discourage leaders from thinking about risk holistically within their development stage organization. Rather, these criticisms suggest the need to return to the basic components of the ERM model to determine if there might be a few jewels that can be salvaged out of the process and applied to life sciences research and development companies to help their leadership understand and manage their risk.

This paper looks to identify the parts of the ERM model most relevant to development stage life sciences companies. This is not to say that the points addressed do not also resonate for companies who are now marketing products and generating significant revenue, as these companies will likely have a significant portion of their growth predicated on their R&D activities. We hope to provide companies with real tools whose value can be measured in ways that will positively (and quantitatively) impact the organization's performance.

William Gallagher Associates is a leading provider of insurance brokerage, risk management and employee benefits services to firms with complex risks, within industries that include high technology, life sciences, financial risks, healthcare services, energy, and environmental services. WGA has offices in Boston, MA; New York, NY; Hartford, CT; Princeton, NJ; Columbia, MD; Atlanta, GA; and Paris, France.

**Short Term Benefits of Research and Development Risk Management**

- Greater assurance that clinical and organizational opportunities are realized
- Better estimate and realization of appropriate insurance premiums and risk control costs
- Reduction in losses
- Increased regulatory compliance

**Long Term Benefits of Research and Development Risk Management**

- Reduction in capital requirements (operational, risk, signaling)
- Reduction in the cost of capital (insurance can be substituted for equity at lower cost)
- Optimization of capital allocation (investment decisions, control of costs)
- Earnings stabilization
- Improved corporate governance

Because many R&D stage companies will be looking to this process for the first time, focus is likely to be in the *assessment of risk* prior to *its management*. Assessment asks both what is the risk, and how important is it at this stage of the company's development?

The Life Sciences Risk Assessment Process© can be broken into four discrete phases, the first phase being the identification and understanding of liability risk within the research and development organization. Phase 2 takes the information developed in Phase 1 to compile actionable recommendations. The key word here being *actionable*. One could propose risk reduction by attempting to move a clinical program to an unregulated venue such as Mars; but is such a recommendation actionable? Phase 3 then looks to implement and execute the recommendations, and Phase 4 (the most amorphous of the process) is the management, control and evolution of the process. The Risk Assessment process needs to be accepted within the organization to be as fluid and dynamic as the company itself.

In order for the operationalization of Phase 1, *identifying and understanding liability risks to have any functional value*, there has to be input from both internal and external sources. The goals in this phase are to identify the risks involved with clinical research on therapeutic compounds or devices, to prioritize these risks or concerns, and also to perform some form of comparative analysis based on data from like companies. The criteria should be as specific as possible as it relates to 'like companies,' meaning not just size of the company or phase of the clinical studies, but also, whenever possible, the classification of the products under investigation (like to like – i.e. cancer therapeutics to cancer therapeutics). A company focused on autoimmune disorders compared to one developing a lipid-lowering agent will have different clinical challenges in executing their studies and will be looking to very different patient populations and sources for study participants. These considerations (and more) will alter the liability risk assessment of an organization.

Once the assessment has been conducted and the data analyzed on both internal criteria and external criteria as compared to other companies, the priority of concerns can be addressed and action steps identified. The results of this process can then be benchmarked against other firms in a similar industry to measure the efficacy of the company’s actions.

So what is the best way to identify risk within a company focused on research and development in the life sciences? The task could appear daunting. It is a diverse industry since the science and technology is complex, and the regulatory issues can be overwhelming. The most effective solution is to simply put into place a forum whereby key internal constituents talk to each other. It is often the case that the business and the science sides of the house do not communicate consistently, nor do they speak a language familiar to the other. In order for the assessment process to work, there has to be buy in, likely from a number of people within the organization who will see this as, at best, having little value for what they do, and at worst, another painful request from whichever side of the firm they don’t report to. So, the gesture of just asking someone what they think, in the simplest terms possible, will yield the best result.

Table 2. The Life Sciences Risk Assessment Survey Instrument has its basis in the COSO ERM model. The author has modified the survey to simplify the analytical framework to the least number of necessary variables, without abandoning the process to complete subjectivity. Basically, the survey simply requires that the respondent identify the possible risk events they believe fall within their area of responsibility and then assign the event a value for probability and impact. It also asks the respondent to identify their plans for risk response or mitigation.

**Life Sciences Risk Assessment Survey**

Operation Objective/Goal:					
Unit of Measure:					
Risk Tolerance:					
	INHERENT RISK ASSESSMENT			RESIDUAL RISK ASSESSMENT	
Risk Event(s)	Likelihood (1-5) 1 Yr/3/Yr	Impact (1-5) (\$Time or Other Goals)	Planned Risk Response/Mitigation	Likelihood (1-5) 1Yr/3Yr	Impact (1-5) (\$Time or Other Goals)

Multiplying the likelihood of an event by the event’s impact to determine the total risk value assesses the data. The values are then plotted in relation to the total number of risks to produce a picture of where the organization stands in terms of the relative likelihood of risk events of varying severity.

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Prioritizing the concerns identified in the survey is partly driven by the scoring system described here, but will also require input from outside the company. In the absence of anything to compare it to, data can be just numbers on a page. A good risk management consultant that specializes in the Life Sciences R&D sector should be able to assist in identifying, industry-wide, what some of the key risk management issues are for like companies. This information should be supplied via a validated data set. With this, a comparative analysis of key industry concerns to an individual company's concerns should assist management in identifying the priorities for their organization and the appropriate action steps.

Another necessary contribution from outside sources is the identification of the appropriate benchmarking data elements. This is needed to develop a comparative model for the results achieved at the company in relation to other like companies. For many areas, there can be more than one effective solution to the same problem. However, understanding where the company sits in relation to others like it can be a valuable tool in the decision tree to continue or change direction.

Evaluating risk holistically within an R&D stage organization can be one of the most important aspects of developing a sustainable company. The veracity of this statement can be measured against the value of having management know what actually goes on within their organization. The risk assessment process enables management to effectively "stay in touch" and not become myopic from understanding only their area of responsibility. The process also calls for the benchmarking of internal measures to that of similar measures in like organizations, giving management a basis for comparison and action. By developing a fairly accurate picture of the company at each stage, strategic decisions can be made with greater confidence and the need to backtrack and address unknown or unmet threats to financial performance in the future is mitigated.

