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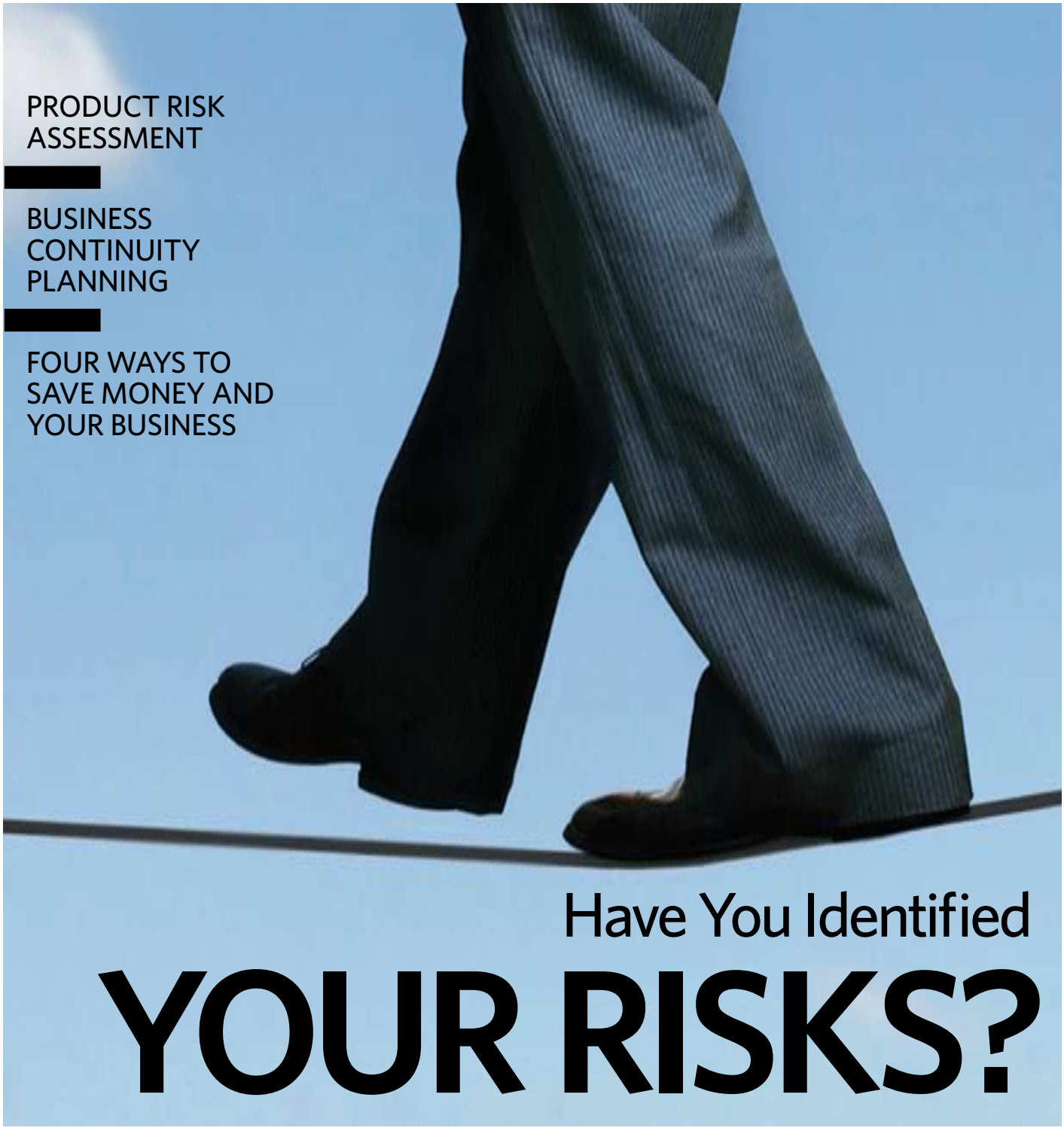
TheScientist

VOL. 20 NO. 11 | NOVEMBER 2006 | WWW.THE-SCIENTIST.COM

MAGAZINE OF THE LIFE SCIENCES



PRODUCT RISK ASSESSMENT

BUSINESS CONTINUITY PLANNING

FOUR WAYS TO SAVE MONEY AND YOUR BUSINESS

Have You Identified YOUR RISKS?

Confronting RISK

Challenges to your business —both daily and long-term competitiveness— lurk in surprising places. Here's how to protect your company.

By Bruce Belzak

To paraphrase Donald Rumsfeld, there is 'what you know,' 'what you know you don't know,' and 'what you don't know you don't know.' While these unknowns have always been present in business, today more boards of directors are asking management the simple question: Have you identified our risks? This is driven in part by the push for corporate transparency, big patent and product liability litigation cases, and the rise of consumer activism. Risk is also extended from the increasing complexity of developing biologics and more complex supply chains as well as an increase in development time for getting a drug to market. For large companies, being blindsided by a risk can damage brand and reputation as well as hurt the bottom line. For small biotechs, an unidentified risk could put the company out of business.

"There is growing risk. The world changes so quickly now," says Dave Young, director of risk management at BD (Becton, Dickinson and Co.), a medical technology company in Franklin Lakes, NJ. "In the past, a company had more time to react or

CASE STUDY:

PRODUCT RISK ASSESSMENT

By Donald Esker and Robert Gaus

CLIENT: A developer and manufacturer of component parts used in medical devices

CHALLENGE: The client had an opportunity to supply component parts for an implantable device. Senior executives rejected the opportunity, nervous that the situation was too similar to a previous problem: A part they had manufactured was used in another type of implant that ended up causing infections. The implant manufacturer was sued, and our client was also named in the lawsuits. The implant manufacturer eventually settled, but the client's defense costs were significant, and the decision was made to avoid all future implant applications. The client's risk manager asked us to evaluate the risk attached to this new opportunity.

EVALUATION: We began by systematically collecting and analyzing the litigation history for the implant product under consideration. Since it was a new type of device, we also looked at the loss history for analogous products. We then looked at the litigation history of products manufactured from similar materials – including nonmedical applications. Finally, we interviewed colleagues and business partners who had experience with similar products.

We use a relative risk model comparing prospective risks to the risks associated with existing products. The process uses a two-axis map with coordinates for frequency (how often a product incident might occur) and severity (the cost of an event in terms of harm or damages). Existing products and prospective products are mapped together, providing a visual indication of the risk. (for an example, see graph 1, "Life Sciences Inherent Risk Map," p. 42) We prefer to use the risk map rather than the raw risk score (risk = frequency multiplied by severity) because the map provides an indication of the ways to improve the risk. We also plot varying positions in the value chain to demonstrate the relative degree of risk versus reward of maintaining or moving downstream (toward the consumer). The implications of a change in position are among the most common concerns, because clients seek to understand the potential increase in risk versus the revenue opportunity – which is typically quite large.

OUTCOME: We learned that the risk profile for the new application had a lower potential severity (in injuries and dollars) and was less likely to occur. Product liability risks for our client (the material supplier) were much lower because of the client's position on the value chain. The risk profile for the new application was on a par with the client's existing book of business.

The client agreed to supply the material subject to contract terms and conditions that assigned liability fairly and required each party to defend, indemnify, and hold them harmless in the event of a claim or lawsuit. The decision to supply this material has opened the doors to other, similar opportunities. Most importantly, it has allowed them to meet and/or exceed growth goals while considering (and pricing) the relative degree of product liability risk within the product's pricing structure.

Clients seek to understand the potential increase in risk versus the revenue opportunity.

Donald Esker is vice president and Robert Gaus is senior vice president at Marsh Risk Consulting.

prepare. Negative news hits a lot quicker" now, he says. Protecting against those risks via enterprise risk management (ERM) programs can lead to competitive advantages that include making better-informed decisions, having greater management consensus and accountability, and increased profitability, according to a 2005 survey by The Conference Board and Marsh, Inc., which compared companies with advanced ERM and those without it. Boards recognize this, with 65% rating ERM as a very high or significant responsibility for a company, according to the survey. Yet only 11% of survey respondents had fully implemented an ERM process.

This relatively low implementation, especially in the face of recognition of benefits, may be owing to the fact that many companies think they are managing risk when they do risk management in specific functional areas such as marketing, sales, and manufacturing. Often, however, extensive coordination does not exist between functions or throughout the entire company via a formal process. Also, companies should have one person to coordinate this process, "somebody accountable in the company and with a scope broad enough to encompass the whole company," says Young. "The more people you can engage, the better the discussion will be."

JETTISON INSURANCE

While boards and investors are pushing companies for more extensive risk management, trends in the insurance industry are also forcing companies into looking at new ways to address risk (see "Four Ways to Save Money and Your Business," p. 44). Insurance premiums have climbed to unprecedented levels, and significant coverage restrictions have combined to force companies to reexamine the value of insurance. It is now not uncommon for premiums to equal 10% of the limit of liability purchased, i.e., a $50 million limit could cost $5 million.

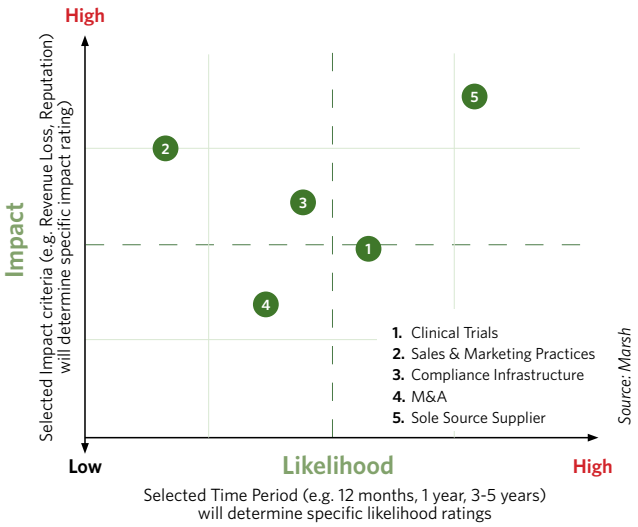
"Commercial insurance is not going to be readily available to cover risks," says Gary Nelson, vice president of risk management ▶

at Medtronic, a medical technology company based in Minneapolis, Minn. "Industry has had huge losses, so underwriters are walking away or getting too expensive," he says. "So some pharmaceutical companies and medical device companies are self-insuring exposures such as product liability, which has traditionally been covered by insurance."

Medtronic is one of a growing number of companies that have made the decision to either entirely self-insure or to self-insure its product liability exposures, because purchasing such insurance no longer makes economic sense. This growing group of self-insurers also includes most major pharmaceutical companies, which have enough money to do this; they are betting that they are big enough to absorb a big loss. For them, it's probably a good bet: The likelihood of having a huge loss in, say, seven years, is low, and a company saves money over that time by not paying insurance premiums. Moreover, insurance probably wouldn't cover a catastrophic loss because of the reduced limits of liability and underwriters excluding a number of drugs from coverage.

The majority of life science companies continue to buy insurance, however, because their balance sheets do not allow them to

Sample Life Sciences Inherent Risk Map



Prioritize your list so that your company does not put too many resources against low-probability risks or risk that won't significantly affect a company's bottom line, and not nearly enough against risks that could bring a company to its knees.

CASE STUDY:

BUSINESS CONTINUITY PLANNING

By Fred Klapetzky

CLIENT: Therapeutic protein manufacturer

CHALLENGE: A fire started in IT operations controlling the therapeutic protein production facility. The center had a fast response and recovered the data before the production line could be affected. If the response hadn't been quick and appropriate, production could have been affected, causing a drop in the supply of the therapeutic protein and/or a tainted product.

EVALUATION: Here, a small-scale event – a fire that threatened the loss of IT – could have caused a business interruption. Other trigger events might include the loss of air conditioning in the lab, or the loss of one or two critical scientists or other employees (e.g., through an automobile accident, heart attack, or influenza). Most organizations don't do a very good job of identifying all their key people. Sure, a top scientist might be obvious, but what about key technical people? The consequence of a loss might be data collection, organization, and/or access. Without investing a lot of money, you can accomplish the business continuity processes internally (it will take some of your time and effort, of course).

If you employ an outside consulting firm, costs can range from tens of thousands to several hundred thousand dollars, depending on the size of your organization. Either way, make sure a process is created so that a loss of a physical plant, data, or personnel doesn't cause an outage. It's a straightforward process of understanding the impact of an outage, considering the tolerable level for that impact, and then determining what can be done to recover operations under that limit. Consider implementing the following strategies.

1. Perform stability testing. How long will the business last at status quo if various interruptions occur? What steps need to be taken to insure business continuity? All possible scenarios need to be tested. For example, what happens if a fire causes sprinklers to go off in the entire building? Water damage means your labs are no longer certified. Do you have alternative work space in a certified lab? If you can recover lab space, what about lab notebooks if your computers are not working? Or, what happens if a key supplier of reagents or equipment has a crisis and cannot make deliveries? What are your alternatives? We lay out the business process first. We would then cover up one of the processes. For example, if you were to experience an outage during production of a master sample, what alternatives would be available? These alternatives provide the strategies for plans to be built.

2. Evaluate and select alternatives. The strategies are evaluated and business leaders should select the alternatives that meet the business' needs and its ability to implement. Plans should then be created around these initiatives, and technology for implementation put into place.

3. Focus on the impact, not the cause. This approach to planning enables you to look at the impact of an outage and not be overly concerned with the causes. There are many causes, and writing a

self-insure. While it is expensive for smaller companies to buy insurance, they can't afford to not buy it, as a major loss would put them out of business. So what they are doing, typically, is buying less insurance or moving to buy more catastrophic coverage. In the end, the decision comes down to your balance sheet and how lucky you feel.

Medtronic decided to put its money into increased risk identification and loss prevention rather than insurance. By focusing more deeply on risk in various business units, it hoped to prevent problems and ultimately save money, says Nelson. For example, when Medtronic was expanding its operations in Puerto Rico in the 1990s, the risk management department convinced facilities management to consider design improvements that provided better protection. They evaluated the cost benefit of meeting the local building codes or exceeding them. By making a relatively small additional investment, the company could build the facility in a way that would not only provide protection against exposure to high winds, but also gain protection against seismic events. Exceeding local building codes turned out to be a good business decision as evidenced when hurricane George swept right over the facility but left little damage.

Human-caused accidents also threaten a company's continued operation. In the Business Continuity Planning case study (see p. 42), see how even a small fire, the loss of air conditioning, or a heart attack can halt your business, and what you should do to uncover and prepare for such risk.

BUILD FLEXIBILITY

Protecting your physical plant from weather or trespassing may seem obvious, but what about the threat of animal activism? Many biotechs would not consider this an issue if they weren't using animals on-site, but while the risk may be small, the harm can be great. Confrontation can interrupt administrative processes, R&D operations, and manufacturing, and publicity may make employee recruitment and retention more difficult. Smaller firms in particular are vulnerable to controversy because of smaller cash reserves, and being targeted can compromise venture capital funding. Moreover, activist organizations may operate under an inaccurate perception, seeing a link between animal testing and a life science or biotech company. Or, as groups have done in the past, they target ▸

plan focused on just a few specific causes may not provide enough flexibility to respond to an actual emergency. Generally speaking, all plans will contain some common items. Start with making sure the contact information for key people is up-to-date, and build in a process to audit that information.

Next, brainstorm every possible point of disruption in your business. To do so, first focus on the critical processes, and then determine what actions are needed to implement the strategy that management approves. Often these include manual procedures that can be followed if an IT disruption occurs, alternative work sites or locations that can complete the process steps, and outsourced laboratories that could continue the development process. This planning approach enables you to respond to the impacts of an outage (which you can manage) rather than the cause(s) of the outage (which you often can't control).

4. Do tabletop exercises around crisis. This can often be accomplished over a lunch meeting with the team members that have a role in the recovery process. Build a scenario (this could be a fire, a flood – caused by rain or a burst pipe, a weather event such as a hurricane, or a natural event such as an earthquake). Don't forget events such as accidents or targeted acts of terror against your company (perhaps by someone opposed to animal testing). These scenarios should be varied and complete enough to use during an actual event. We recommend this be done at least annually once you have an established plan, and more frequently if you are still building your plans.

Continuity plans are not considered complete until you can demonstrate they will work. Make sure your plans have backups and alternates designated for key roles and responsibilities. Workplaces that change as new staff are brought onboard requires that you keep the teams updated, trained, and ready to respond.

5. Maintain your plan and update it annually. You can either devote two full days yearly to updating it, or do so in weekly or monthly increments. In many cases, working incrementally can mean devoting less than an hour per week to keeping the plan up-to-date. We like the latter approach, because it keeps managers and staff thinking about it.

Continuity planning is a process, not a project. Completing one and placing it on the shelf so you can point to it when asked doesn't get you far. So keep the planning updated and continuous. This will enable you to deal better with a crisis, as well as make you a better investment risk (which could improve your funding prospects). The plan also might improve your insurance-risk profile, providing you with more opportunities or higher insurance limits (see "Four Ways to Save Money and Your Business," p. 44). It will also provide you with a better understanding of the expected impact of an actual disaster from a financial and operational perspective.

OUTCOME: The company had prepared well and acted quickly. Production was not halted, and manufacture of the therapeutic protein was not stopped. If the company had not been prepared to respond, customer's lives might have been endangered, as well as brand reputation and the company's revenue.

Fred Klapetzky is a practice leader for business continuity management at Marsh Risk Consulting.

Four Ways to Save Money and Your Business

An underwriter reveals the must-do items he looks for when evaluating a company for coverage.

By Philip W. Fiscus

Underwriter scrutiny is like a dose of preventive medicine: You may not like the taste of it, but it's good for you. Life science companies that partner with an insurance carrier and manage risk may qualify for higher limits of insurance at lower rates. For those companies that do not take these steps, affordability of insurance may be the least of their problems: They may not be able to purchase insurance at any price and can expect to be a vulnerable target in the event of litigation. Here are issues to consider when evaluating your company's potential risk. Checking off each one might not only lower your premiums, but also save your business.

1. **Use "best practices" rather than just following the letter of the law.** Commitment to safety and security should be so pervasive in the culture of the organization that it's as apparent in the most senior managers as it is to hourly maintenance personnel. For example, to help ensure best practices for participants to understand a clinical trial, companies could include readability testing of informed consent documents, use information videos, and test participants on their understanding of the document.

2. **Protect your energy source.** One biotech firm's cell culture, representing an accumulated investment of $1.7 million over 22 months, spoiled after a power outage cut electricity to the facility and the backup diesel generator failed. The company lost both the critical cell line and the opportunity to earn a $1 million milestone payment from a sponsor. California is home to 25% of US biotech firms, and the state's energy crisis in 2001 ruined experiments and damaged costly equipment at the many organizations that lacked sufficient backup power. This past summer's heat waves have again put pressure on the power grid; usage was as much as five times greater than during the 2001 electricity crisis. Is your company better equipped to weather brownouts or power interruptions today as a result of risk management improvements since 2001?

3. **Minimize physical threats to your R&D facility.** Underwriters look for safety measures that help protect not only the building and the expensive equipment inside, but also research, documents, lab animals and other property that is difficult to replace. A "good risk" will have effective duplication procedures (for lab books, electronic data, samples, cell lines, and cultures) and ensure that the duplicates are securely stored offsite. Underwriters also look for a prudent facility-protection philosophy: proper storage and use of flammable chemicals; controls to protect clean rooms from potential breaches; alarms and a backup supply of electricity or refrigeration; systems that detect both heat and smoke; and sprinkler systems designed to reduce the chance of water contamination in a lab. Highly sensitive lab instruments are particularly susceptible to smoke damage.

In one example, a contract manufacturer sustained smoke damage from a small oven fire. It took five weeks of round-the-clock work for specialized cleaning contractors to get clean rooms back to the required standard, and only then could regulatory authorities begin the process of revalidating the rooms. In many such cases, a fire or other damage will invalidate equipment warranties and service contracts, making the cost of third-party warranties and service contracts a factor in the claim adjustment. These types of exposures could be eliminated (for example, by using infrared thermography cameras to identify hot spots that could develop into fires); mitigated through identification and segregation in a separate fire area; or alleviated through the design of dedicated heating and air conditioning systems with smoke dampers.

4. **Protect against information theft.** Start by conducting thorough background checks on employees and contractors, requiring nondisclosure agreements, and restricting access to facilities and sensitive information to those who need such measures. Identity theft is also a concern, especially for companies that conduct human clinical trials and need to collect personal information on a large number of individuals. Safeguards should be in place to ensure that this information is not accessible. For example, the information should not be stored on discs or laptop computers that are taken home by employees, and access to such information should be limited to those who need to see it.

Philip W. Fiscus is worldwide product manager for Chubb & Son's life science practice.

companies along the supply chain that may lead to an animal-testing company.

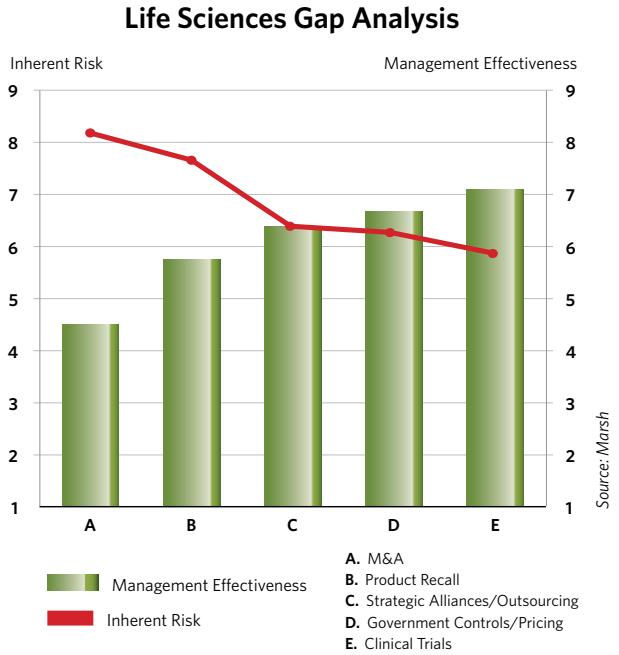
For such a risk, a small investment could have a big impact, and risk preparedness can be based on a changing level of risk. For example, once a basic plan is in place and an increased threat arises, consider your response if a demonstration occurs outside or if somebody comes through the door. Also consider protection at special events, including public events you may sponsor. Brief all employees on the appropriate response, which for many would be to do nothing other than clear out of the area. Advocacy groups want the pushback, because it provides grist for controversy, a way to get new members, and more funding so they can stay in business.

Review your standard security procedures and your response plans to be sure they match up to the threat. As with many forms of risk, it is important to establish a basic plan and have the flexibility to adapt different parts, depending on the threat. If a specific activist-related threat exists or periodic intelligence says your company is a more likely target, it's time to consider enhancing these procedures, maybe even conducting exercises to be certain employees understand the plans and procedures. If you are at a life sciences lab that works with animals (or may be perceived as working with animals), stay abreast of a particular group's actions and plans. You can get a somewhat biased view of most of the groups from their Web sites.

DIG DEEP

Of course, risk is not limited to physical attack or accidents. ERM strives to examine risk to your business model as well as potential opportunities. Risks that may seem analogous often are very different once you begin a deeper analysis. For example, in the Product Risk Assessment case study (see p. 41), a company was hesitant about supplying components for an implantable device, because it had become embroiled in a lawsuit by supplying a previous implantable device with components. On the surface, the company was managing risk in a reasonable way. Once a thorough risk analysis was done, however, things looked very different.

Even when a company performs significant risk management beyond items typically checked off (worker safety, safeguarding data, and issues covered under insurance) – and thus also covers strategic, financial, operational, hazard and regulatory issues – it may wind up with a list but little prioritization (see "Life Sciences Inherent Risk Map," p. 42). In this way, a company may end up putting too many resources against low-probability risks or risk that won't significantly affect a company's bottom line, and not nearly enough against risks that could bring a company to its knees. Thus, the company has bought itself a false sense of preparedness. Doing an analysis to rank risk (see "Life Sciences Gap Analysis," p. 45) will help guide the best use of resources. It is also important to reassess a company's risk annually as external and internal variables are constantly changing. And a company needs to conduct exercises at least once a year to test its reaction to possible risk scenarios.



Large gaps between inherent risk and risk management effectiveness indicate the potential need to address the over/under-managed gap.

Risk management aimed at both operations and strategy yields increased results when a company can more deeply evaluate specific areas while involving as many staff throughout the company as possible. The goal, says Nelson, is to condense "why should I care" topics so that everyone understands why they should be worried. In this way, responsibility is distributed throughout the company in a grassroots effort. When implemented, a good risk program will look at not only "what can go wrong," says Young, but also "what can go right, and are we taking advantage of it?" ■

Bruce Belzak is managing director of the life sciences practice at Marsh.

RESOURCES:

D. Apgar, *Risk Intelligence: Learning to Manage What We Don't Know*, Boston: Harvard Business School Press, 2006.

Development and use of risk minimization action plans:
www.fda.gov/cder/guidance/6358fnl.htm
Pharmacovigilance practices and pharmacoepidemiologic assessment:
www.fda.gov/cder/guidance/6359OCC.htm
Premarketing risk assessment:
www.fda.gov/cder/guidance/6357fnl.htm

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REPRINTED FROM

TheScientist
MAGAZINE OF THE LIFE SCIENCES

NOVEMBER 2006
VOL. 20 | NO. 11
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