



Risk and Response: Chubb Life Sciences Risk and Insurance Survey



What losses do life sciences companies experience most often? What risks are they most concerned about? What are these companies doing to address their risks? Chubb's risk and insurance survey looked at these and other risk management issues facing life sciences firms.

Losses over the past three years

Nearly one in five (17%) of the companies surveyed has experienced a loss in the past three years. The average loss was \$140,233, with losses ranging up to \$26 million. The most frequent losses are shown below.

Loss event	Of respondents experiencing a loss, percentage experiencing this event
Injuries to third parties (e.g., products)	46%
Loss due to spoilage or change in temperature	32%
Employment practices liability lawsuit	25%
Loss of income due to a property loss at key supplier or customer	22%
Medical professional injury	15%



Concerns on the horizon

Companies that experienced a specific type of loss in the past three years were considerably more likely to cite that loss as a major concern in the year ahead—a clear reflection of the significant effect these past losses had on their companies.

Loss event	Companies citing as major concern during the coming year (total)	Companies citing as major concern (experienced this loss)	Companies citing as major concern (did not experience this loss)
Injuries to third parties (e.g., products)	24%	64%	20%
Loss of income due to property loss at key supplier or customer	21%	58%	19%
Employment practices liability lawsuit	19%	67%	17%
Spoilage or change in temperature to perishable property	15%	74%	12%
Losses due to financial injury to a third party	12%	50%	12%

Observations on these findings include:

- It is no surprise that customers who have experienced a third-party products loss understand the complexities and hardships that accompany these situations. Failure-to-warn allegations, coupled with improper sales and marketing practices, continue to be the most common areas of product litigation. Recent findings have shown that product litigation defenses such as preemption do not offer the protections once afforded.
- One likely explanation for the higher level of concern over a loss of income due to property loss at a key supplier or customer is that one in four companies in the survey import chemicals or other pharmaceutical raw materials from suppliers outside the United States and Canada. Geographic variations in transportation infrastructures, local regulations, and sheer geographic distances are among the circumstances that can complicate efforts to transport materials.
- The Equal Employment Opportunity Commission (EEOC) reports that discrimination, harassment, and other employment practices charges rose to their highest levels ever during 2008 and 2009—a period of high economic anxiety and increased layoffs for companies of all types. These employment-related exposures would be on the minds of life sciences company executives, as well.
- Spoilage or change in temperature to perishable property is all too often realized throughout the industry. Losses can range from vaccines spoiling due to mechanical compressor failure to an employee failing to properly secure cell lines in a freezer. Even small quantities of materials can have significant monetary value, based on their biochemical complexity and difficulty to reproduce. Without appropriate risk management controls, companies open themselves up to issues that affect many life science businesses.
- One key driver of financial injury concerns is the industry's increased reliance on third-party subcontractors in an effort to address the high costs of developing medical products. This outsourcing, particularly among R&D and manufacturing processes, reduces the control life sciences companies have over the ability of their products or services to perform to specifications.

Top threats: Signs of the times

A struggling economy, increasing government regulation, and growing dependence on electronic data storage and communications are reflected in respondents' top threats:

- **Intellectual property theft (42%).** A life sciences company's life blood is its intellectual property. A breach in security, through criminal cyber activity, could lead to financial devastation through lost business, lawsuits, or even bankruptcy. It's no wonder that protecting confidential information is a major concern.
- **Supply-chain failure (41%).** Heavy reliance on outsourcing, a complex and increasingly global supply chain, and a steady rise in bankruptcies combine to weaken supply chain links.
- **Government or regulatory investigation (38%).** The public's demand for increased safety is evidenced in new leadership and regulation. The sweeping drug safety changes imposed by the Food and Drug Administration Amendments Act (FDAAA) of 2007 places increased scrutiny on the drug approval process, including an increase in post-marketing studies and product distribution controls. In addition, medical devices have been the subject of increased regulatory focus amid calls for safety transparency between regulators, companies and the public.
- **Credit risk (37%).** The strong showing of credit risk as a threat indicates that more than 1 in 3 respondents may be worrying about their financial viability in today's tight credit environment.
- **Political instability (31%).** Life sciences companies that manufacture products at international locations or contract with third parties across geographic borders can be exposed to political upheaval, ranging from trade disputes (such as an embargo or import/export license cancellation) to outright war or civil war. Often a change in government, be it by democratic election or coup d'Etat, can change the operational, political and security risks of a company.
- **Major product risks, such as recalls, tamperings, and lawsuits (30%).** The cost of litigation continues to rise. A Jury Verdict Research report published in 2005 on jury verdicts showed that the median medical products claim was \$987,500, with 25% of jury awards in excess of \$1 million. Drugs and vaccines had a median award of \$1 million, and 77% of drug/vaccine claims were in excess of \$1 million. The magnitude of jury awards, coupled with the specter of recalls and regulatory actions, makes product safety a very real concern for life science companies.

Product recall plans prove valuable

Thirty percent of respondents identified product recalls, tamperings, and lawsuits as major threats to their companies. Of the companies having product recall plans, 1 in 10 (11%) have used their plan in the past year.

The larger the company, the more likely it is to have a product recall plan: 85% of respondents with 250+ employees have a product recall plan, compared with 57% of smaller companies. Twenty-nine percent of larger companies used their plan in the past year, compared with 9% of smaller companies.

Product recall plans encompass a broad range of activities, from required labeling changes to repackaging to removing potentially unsafe products from distribution. Without advance planning, even smaller-scale recalls can be difficult to manage and can potentially result in product shortages and customer dissatisfaction. For larger scale recalls, particularly those conducted in case of emergency, the results can extend to financial hardship and reputational damage.

Supply chain protection efforts on the rise

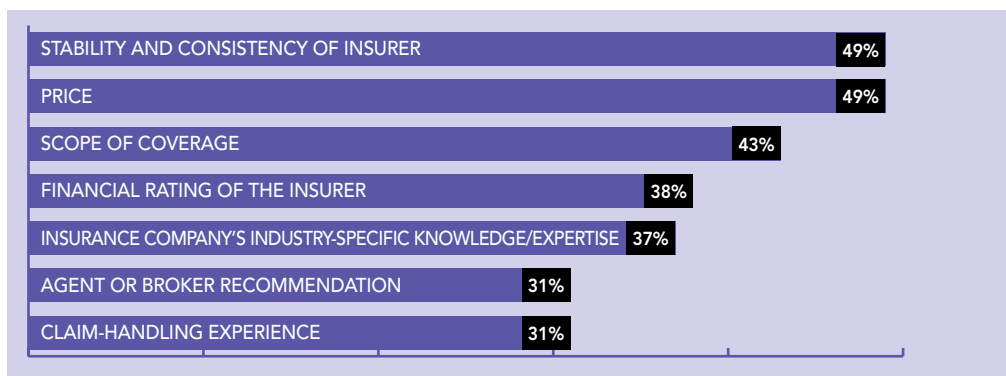
As mentioned, one in four companies import chemicals or other pharmaceutical raw materials from suppliers outside the United States and Canada, and respondents consider supply chain issues to be the second-greatest threat to their business. That's little surprise given the recent media attention over tainted materials sickening consumers.

Few respondents have stopped importing materials in response to concerns, but many have taken significant steps to maximize the reliability and safety of the supplies they import. Many of respondents' actions have been taken recently.

Step taken by companies that import chemicals and other pharmaceutical raw materials from suppliers outside the U.S. and Canada:	Percent taking this step within the past five years:	Of these, percent taking this step in the past year:
Implemented new policies and procedures to qualify suppliers	58%	70%
Implemented additional testing measures	53%	76%
Started requiring foreign suppliers to carry product liability insurance in the U.S. and/or Canada	47%	71%
Stopped doing business with certain suppliers	30%	61%
Halted importing certain chemicals or other pharmaceutical materials	16%	80%

Insurance: Decision drivers

When it comes to purchasing insurance, the respondents are as likely to be influenced by the stability and consistency of an insurer as by the price of insurance, with 49% of respondents saying each of these factors have a great deal of influence on their decision to buy. The survey revealed that several additional factors exert significant influence on the purchase decision.



About the survey

Chubb commissioned Pollara to conduct a telephone survey of the risk management practices of 500 insurance decision makers at biotech and life sciences companies in the United States. Chubb wishes to thank the Biotechnology Industry Organization (BIO) and Medical Device Manufacturers Association (MDMA) for their participation in and contributions to this survey.

The study, conducted between June 25, 2009 and July 20, 2009, is accurate to within +/-4.4% (19 times out of 20).



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