

## RISK CONSULTING FOR PHARMACEUTICAL INDUSTRY



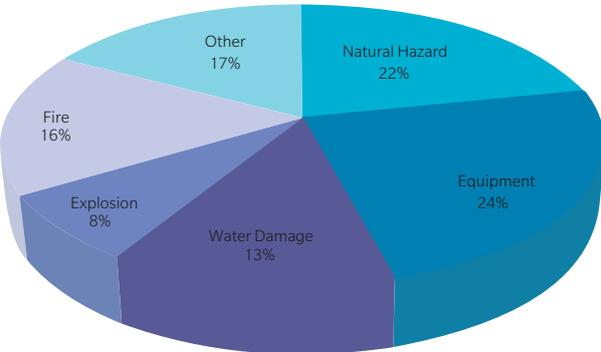
### RISK OUTLOOK

The pharmaceutical industry continues to change, especially given the industry trends that are reshaping its future.

However, with growth the risks associated with fire and explosion in the industry are rising, especially given the nature of its operation (complex chemistry, exothermic reactions, and flammable liquids). Risk to property from contamination, liquid damage, and natural catastrophe is also high.

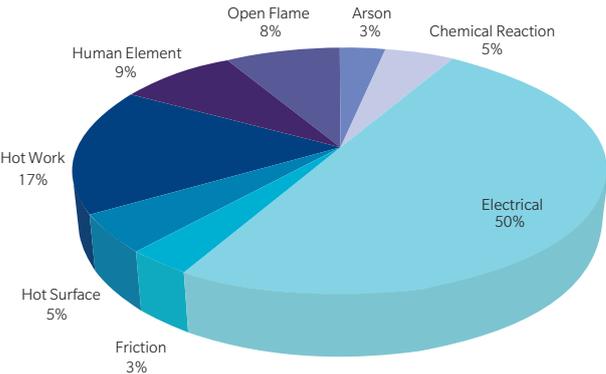
There are also the risks of utility or equipment breakdown and supply chain as well as dependency on toll manufacturers.

Pharmaceutical losses by peril



Source: FM Datasheet 7-36

Pharmaceutical losses by ignition source



Source: FM Datasheet 7-36

### MAJOR RISKS

Fire: Hazards in the active pharmaceutical ingredient (API) chemical processes, which are found in the pipes and process vessels are difficult to identify. The interaction of reactive chemicals under normal or unusual conditions can also become an issue without proper analysis.

Process safety management (PSM) program helps evaluate the different hazards and helps prevent or minimize a loss. Also, given that these companies manufacture drugs, they receive licenses to produce these products only in specific locations under certain conditions.

The process requirements also affect the materials used to construct these facilities. An effective PSM program helps with fire protection, housekeeping and management, and security.

**Liquid damage and contamination:**

Manufacturing medicines and drugs requires a complex process with different equipment and ancillary systems. Each equipment and system poses a contamination risk. A few of the common sources are pathogens and physical contamination. Other contaminants include smoke and liquid damage.

Power outages and issues beyond an organization’s control can cause contamination of process or batches of drugs, which can affect the business. Liquid damage from water lines used for fire protection, or for cooling is often overlooked contaminants. These have caused large damage to many companies in the industry.

Similarly, smoke damage due to a controlled fire in one area can spread to other areas, if the plant is poorly designed. An effective equipment maintenance program together with proper building materials can minimize this risk.

**Explosion:** After a fire, explosion is another large risk in the pharmaceutical industry. There is danger of explosion during the handling, storage, and processing of pharmaceutical raw materials and finish goods. Powders can form dust clouds that linger in the atmosphere and act as a fuel for a primary explosion that may be ignited by a small spark. Suspended dust ignites and rapidly burns causing a secondary explosion.

When such an explosion occurs in a closed space, such as fluidized bed dryer, mixing vessel or storage vessel, the subsequent rise in explosive pressure can cause devastating damages.

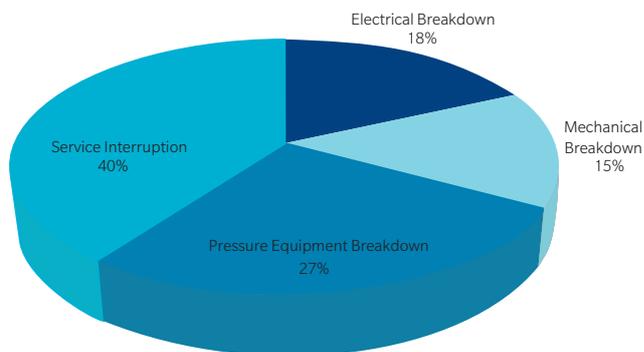
**Equipment breakdown:** Pharmaceutical companies use reactors, dryers, and sterilizers in their plants, a breakdown in one of them can stop production.

The lack of an effective maintenance system can lead to:

- Excessive machine breakdowns.
- Shortened life-span of the facility.
- Sub-standard products.
- Delay in delivery dates.
- Disproportionate investment in spare parts and maintenance materials.

All these contribute to high costs of production and loss of profits.

Pharmaceutical equipment losses



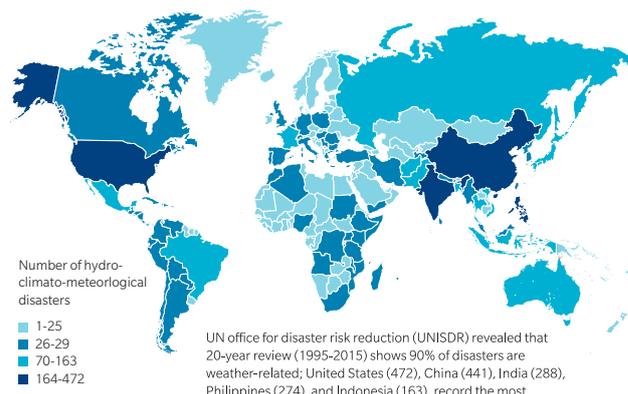
Source: FM Datasheet 7-36

**Supply chain risk:** Pharmaceutical companies manage complex supply chains as well as the operational challenges of working with large number of suppliers. The supply chain can be affected by many factors, including adverse weather, infrastructure issues, price increase, and damage to a supplier location.

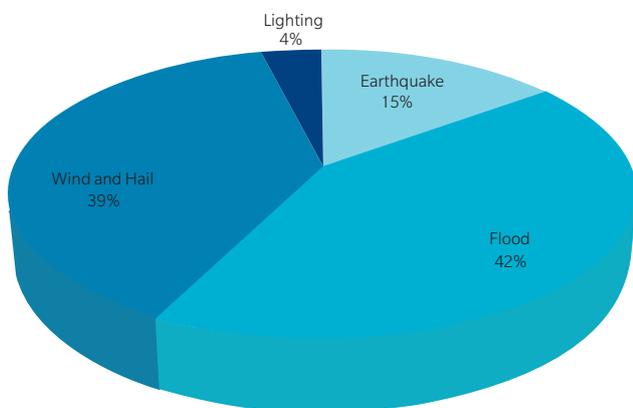
The loss of one dependable supplier can lead to a loss of income, and can affect the quality, consistency, and service of a food service provider. Supply chain study helps companies understand the cause of delays and the measures needed to mitigate risks.

**Natural hazard:** Natural hazards are one of the most severe disrupters of business and supply chain. A natural calamity event can also threaten economic growth. Natural disasters usually occur with little warning. However, the risk of such occurrences can be predicted. Knowing the likelihood of a natural calamity event allows companies to take steps to mitigate such risks.

Number of weather-related disasters reported per country (1995-2015)



Pharmaceutical natural hazard losses



Source: FM Datasheet 7-36

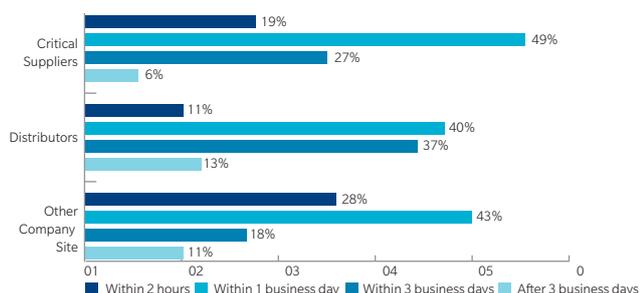
In addition to loss from direct damage, natural disasters may also cause losses arising from business interruption, and pose a threat to a company’s finances.

**Contingency plan:** Risk management and business continuation planning are critical components of a competitive strategy. Organizations need a business contingency plan to protect market share and brand reputation as well as for regulatory compliance, maintenance of cash flow, protection of vital records, and protection of assets and employees; In fact, the survival of the company.

**Companies don’t plan to fail, they fail to plan:** Most organizations do not have a fully tested contingency plan, thereby jeopardizing their assets and employees’ lives. The business contingency plan is the survival document that determines what needs to be done and who is responsible for implementation.

According to a study conducted by Price Waterhouse Coopers, many companies failed to get the information for critical supplier and distributor within two hours.

Pharmaceutical losses by different categories



Source: PWC Pharma 2020 Supplying the Future

## LOSS EXAMPLES

- In North India, a fire in a solvent recovery plant at a pharmaceutical company in the evening spread to the other sections of the unit and destroyed raw materials and finished goods as well as the building. Fire fighters took about three hours to douse the fire.
- In another incident, a private pharma company, in Hyderabad, was completely destroyed in a fire. The fire was triggered while a methyl tanker was unloaded. The fire, which started at around 11 am, destroyed the unit causing Rs. 20 crore in losses, as reported in the media. However, all the workers at the unit escaped safely and no one was hurt or killed.
- A fire in a pharmaceutical company injured 10 workers at one of the manufacturing facilities in South India. Two workers were seriously injured. The fire occurred when a tank containing ammonium nitrate exploded. Two workers were severely burned. A wall also collapsed and injured eight other workers.

## INDUSTRY FOCUS

Marsh Risk Consulting (MRC) practice can help clients understand their risk profiles. The services that we offer are:

- Review of the PSM program from a property loss prevention perspective.
- Assessing risks from natural hazards, including wind, flood, and earthquake exposure.
- Evaluating measures to store and handle flammable liquid and gas.
- Review of construction features, which include sandwich panel, which is essentially the plastic used in the construction.
- Review of facility design from the perspective of fire and smoke contamination.
- Review of vapor and dust explosion hazards.
- Review of ignition source control.
- Review of mechanical refrigeration system using Ammonia.
- Review of ignition source control measures.

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- Review of installed fire protection systems for local/international standard.
- Conduct annual pump tests as per NFPA 25.
- Conduct loss prevention training program and prepare the loss prevention manual.
- Help with property risk engineering evaluation, with loss control visit.
- Help in managing logistic risk, including cargo loss minimization, journey risk management, and vehicle and driver safety programs.
- Evaluate business continuity plans.
- Help with project risk engineering :
  - Adequacy of fire protection system for green field and brown field projects.
  - Evaluation of construction materials for fire stability.
  - Evaluation of natural hazard exposures: Flood/earthquake/storms / hail.

## SUCCESS STORIES

Consultants from India are involved in conducting loss prevention audits for a few of major pharmaceutical companies. The MRC team has helped companies understand the level of risks they face. The reports that the MRC team provides supports the organizations decision making, including allocation of resources to improve the fire protection system in their properties.

In another project, MRC consultant helped clients by conducting loss prevention training for their employees, including for key element of process safety management. The MRC perspective on property loss prevention for their PSM program was well appreciated.

For more information about Marsh Risk Consulting and other solutions from Marsh, visit <http://marsh.co.in/service/riskconsulting/> or contact [riskconsulting.india@marsh.com](mailto:riskconsulting.india@marsh.com) or contact your local MRC representative.

## THE MARSH DIFFERENCE

As the world's leading insurance broker and risk advisor, Marsh offers the experience, knowledge, and insight required to identify and manage property exposures in the current risk environment. Marsh was the first in the field to establish specialized industry practices for property risk consulting.

Marsh's and Marsh India's risk professionals are knowledgeable about the regulatory, technical, and business challenges of the pharmaceutical industry. The risk professionals continually monitor research developments, building codes, and local regulations to ensure that the risk solutions reflect the current local codes and best practices. They can help a pharmaceutical organization understand its risk profile and recommend cost-effective strategies for mitigating property related risks.



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