CHUBB®

Loss Scenarios for Life Science Companies

Whether you're a biotech, medical device or service organisation, your complex products and devices have volatile financial and liability risks that could put you out of business.

In a competitive commercial environment, Life Science firms are increasingly challenged to meet customers' expectations, regulatory requirements and the pressures of bringing product to market in a timely and cost-efficient manner. Companies are faced with a diverse range of loss scenarios ranging from errors or flaws in the product design causing bodily injury to contamination arising during production.

No matter how stringent a company is with their quality control procedures, these errors are often not discovered until the end-product has been distributed. Rectification expenses, damages, compensation and of course legal costs along with reputational damage, are just some of the ramifications of these errors that manufacturers can face. The costs can be significant.

These risks can seem daunting and their effects devastating without a quality insurance program. That's why Chubb has developed the next generation of insurance protection with its Life Sciences liability and property insurance portfolio.

Consider the following loss scenarios and then ask yourself whether you have adequate insurance protection in place.

Product Liability

Manufacturing error

Potential Cost: $8M

A Contract Manufacturing Organisation (CMO) manufactured orthopaedic implants to a customer's specifications. After the product began causing bodily injury, the CMO and their customer were involved in litigation relating to the injuries caused by the quality of the implants. Both parties were found to be liable.

Hearing aid causes hearing loss and facial paralysis

Potential Cost: $1.2M

A medical device company manufactures hearing aids. A patient's ear infection led to a brain aneurysm, allegedly because the stem of his hearing aid was too long. The patient underwent multiple ear and brain surgeries, suffering severe headaches and bleeding from his ear, complete loss of hearing, and loss of memory.

Device blamed for injury to artery

Potential Cost: $225,000

A patient sustained injury to the arterial wall of his femoral artery when a medical device manufacturer's product allegedly failed. The artery had to be surgically repaired.

Class action against contract manufacturer caused by contaminated mouthwash

Potential Cost: $900,000

A contract manufacturer of mouthwash was sued when injuries to hundreds of patients were traced back to a bacterial contaminant in its mouthwash. The patients made claims for damages for both bodily injury and financial injury.

Class action alleging drug company failed to warn of neurological risks

Potential Cost: $5M

Frequent long-term use of a generic product was linked to a disorder that causes uncontrollable repetitive body movements. The pharmaceutical manufacturer was sued by a consumer who allegedly suffered those side effects, and who claimed that the manufacturer failed to warn of those side effects. The case resulted in significant defence expenses and a negotiated settlement for the alleged injuries. Subsequently, a "black box" label was issued for the product that explicitly warned of this potential side effect.

Patient injured ingesting product after its withdrawal from the market

Potential Cost: $1M

Contamination in a batch of cold medication led a pharmaceutical manufacturer of over the-counter products to issue a Class 1 recall of the medication. Unfortunately, not all consumers were aware of the recall and, three months later, a woman suffered an adverse reaction when taking the medication for the first time.

Clinical Trials Liability

Clinical trial patient suffers nerve damage

Potential Cost: $175,000

A healthy volunteer developed facial nerve damage during participation in a trial to test the safety of the pharmaceutical company's investigational drug.

Failure to fully disclose bodily injury risks

Potential Cost: $1.3M

The plaintiff was part of a clinical trial for a new drug, and experienced liver toxicity. He alleged the pharmaceutical manufacturer did not fully disclose the risks of the study drug in the informed consent document. Although there was a general warning of potential adverse effects, this specific effect was not addressed, despite some animal studies showing the potential for liver toxicity.

Financial Loss (E&O) Liability

Clinical trial delayed due to contract packager's improper choice of packaging

Potential Cost: $1.7M

A contract manufacturing organisation (CMO) was contracted to make a drug to be used in a clinical trial. The CMO's customer claimed that an error on the part of the CMO compromised its product, and its failure to meet contract specifications regarding product quality led to a delay in the clinical trial and subsequent financial loss. Investigation revealed that the CMO's packaging design possibly contributed to degradation of the trial product.

Failure to keep enrolment promises results in claim from sponsor

Potential Cost: $4.5M

A contract research organisation (CRO) was contracted by a large pharmaceutical company to handle clinical trial activities, including patient enrolment. The CRO failed to meet recruitment goals, made numerous data errors, and the business model they set up for the sponsor's trial was allegedly flawed in multiple ways. The sponsor charged the CRO with negligence and breach of contract that caused them to lose millions of dollars in potential revenue due to delays.

Interactive voice response system developed by CRO compromises clinical trial data, forcing study to be repeated

Potential Cost: $3.8M

A Contract Research Organisation (CRO) was responsible for recruiting 500 subjects for a late-stage clinical trial. After most of the participants were recruited, the CRO's voice-response system experienced a problem that resulted in the invalidation of much of the trial data. The recruitment process had to be repeated, and the sponsor filed a breach of contract allegation against the CRO.

Software glitch invalidates clinical trial data

Potential Cost: $8.2M

A contract research organisation (CRO) was contracted to provide clinical trial services in Europe. An error in the CRO's software program failed to properly randomise participants in one of the trials. As a result, the trial deviated from its intended design, rendering the data unusable and costing their customer millions of dollars to repeat the trial.

Insufficient radioactivity produced unsatisfactory results

Potential Cost: $400,000

A contract manufacturing organization supplied to its customer radioactive sulfate that was less radioactive than indicated on the label. This produced unsatisfactory results in the client's experiment, forcing the client to repeat their work.