

Loss Scenarios for Products and Services, Property, Spoilage, Errors and Omissions and Employers Liability

Many businesses within the Life Science industry face a series of unique exposures and complex risks, so what can you expect if you need to file a business claim with us?

We understand that businesses need to get back up and running as soon as possible, so we ensure that claims are managed by a Chubb claims professional who has a solid knowledge of the Life Science industry.

Chubb’s Liability insurance for Life Science companies can help mitigate the financial risks associated with a number of loss scenarios.



Faulty Packaging Compromises Clinical Trial

Coverage	Commercial Errors & Omissions
Cause	Faulty packaging
Type of organization	Contract Manufacturing Organization
Number of employees	More than 100
Annual revenue	More than €25 million

Description of event

A contract manufacturing organization (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.

Resolution

The claim was valued at circa **€1,700,000**



Insufficient Radioactivity Produces Unsatisfactory Results

Coverage	Commercial Errors & Omissions
Cause	Manufacturing error
Type of organization	Contract Manufacturing Organization
Number of employees	22
Annual revenue	€20 million

Description of event

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.

Resolution

The claim was resolved for **€400,000**



Alleged Copyright Infringement

Coverage	Commercial Errors & Omissions
Cause	Advertising Injury
Type of organization	Biotech/Pharma Manufacturer
Number of employees	More than 25
Annual revenue	More than €13 million

Description of event

A medical device company's advertisements were alleged to infringe on another company's registered trademark and slogan. Most of the cost of the claim was for extensive discovery and litigation expenses.

Resolution

The claim was valued at **€1,225,000**



Product Misuse Turns Fatal

Coverage	Products and Services Liability
Cause	Failure to Advise
Type of organization	Pharmaceutical
Number of employees	More than 500
Annual revenue	More than €175 million

Description of event

A teenage boy was prescribed an oral antibiotic to treat acne, even though this was an "off-label" use for which the product was not approved. He developed rash, fever and inflammation of internal organs. He was in intensive care for four months before dying from the adverse reaction. His medical expenses were more than €2.5 million.

Resolution

Damages exceeded **€4,000,000**



Manufacturing Error Causes Bodily Injury

Coverage	Products and Services Liability
Cause	Failure to Advise
Type of organization	Biotechnology Company
Number of employees	Fewer than 125
Annual revenue	More than €10 million

Description of event

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

Resolution

Damages exceeded **€2,500,000**



Broad Allegations Limit CMO's Mutual Indemnification Protection

Coverage	Products and Services Liability
Cause	Product Defect
Type of organization	Contract Manufacturing Organization

Description of event

A contract manufacturing organization (CMO) manufactured orthopedic implants to a customer's specifications. After the product began causing bodily injury, the parties looked to their contract to define each party's responsibilities. While the contract included mutual indemnification language, allegations from claimants cross over to both parties' contractual obligations, thereby making it difficult for the CMO to extract themselves from the litigation.

Resolution

Claim estimated at **€4,000,000**



Contaminated Syringes Cause Patient Illness

Coverage	Products and Services Liability
Cause	Contamination
Type of organization	Medical Device Manufacturer
Number of employees	100 - 250
Annual revenue	€50 to €175 million

Description of event

Patients filed suit against a medical device company alleging that the company's pre-filled syringes were contaminated with bacteria, causing the patients to become violently ill. The syringes were manufactured by a third party contract manufacturer.

Resolution

The claim resolved for more than **€1,000,000**



Power Outage Contaminates Drugs

Coverage	Property Damage
Cause	Contamination
Type of organization	Biotechnology Company
Number of employees	Fewer than 25
Annual revenue	Less than €13 million

Description of event

A power outage from vehicle damage to a nearby utility pole disrupted a manufacturer's in-process batch of biologic drugs. The disruption resulted in some contamination, diminished production in the affected bioreactors and a loss of revenue from the inability to meet market demand for the drug.

Resolution

The claim was valued at **€750,000**



Water Damage Floods Facility

Coverage	Property Damage
Cause	Water Damage
Type of organization	Biotechnology Company
Number of employees	More than 100
Annual revenue	More than €50 million

Description of event

An incubator in the claimant's second-floor lab caught fire, triggering the sprinkler system. The fire was contained and the building was evacuated. Sprinklers continued to run for 45 minutes because the fire department refused to enter the bio-hazard facility, being unfamiliar with the potential hazards to firefighters. Water pooled on the floor and leaked down to the first floor, damaging equipment, personal property and research and development property, and triggering significant extra expense to move production to another facility.

Resolution

The claim was valued at **€750,000**



Power Surge Destroys Samples

Coverage	Property Damage
Cause	Change in Controlled Environment
Type of organization	Biotech/Pharma R&D
Number of employees	Fewer than 25
Annual revenue	Less than €13 million

Description of event

The refrigeration system in a pharmaceutical company's research department failed due to a power surge. The back-up power unit was not self-starting, and personnel did not re-start the unit in time to maintain the controlled environment. Specimen samples that took weeks to develop were destroyed.

Resolution

Damages sought exceeded **€450,000**



Small Fire Causes Income Loss

Coverage	Property Damage
Cause	Fire
Type of organization	Device Manufacturer
Number of employees	More than 250
Annual revenue	More than €13 million

Description of event

After a small fire in a medical device production facility, it took three weeks to repair the damage, but more than four months to re-certify and re-validate the clean room for production. During that time, continuing normal operating expenses were incurred at a rate of €375,000 per month.

Resolution

The claim was valued at **€2,325,000**



Broken Capsule Lead to Lost Income

Coverage	Property Damage
Cause	Machinery Breakdown
Type of organization	Biotech/Pharma Manufacturer
Number of employees	More than 100

Description of event

A pharmaceutical company used a subcontractor to manufacture its capsules. A custom soft-gel encapsulation machine suffered a mechanical breakdown that required extensive repairs. The repairs and FDA revalidation took 6 months. Their existing inventory lasted only 2 months, resulting in 4 months of lost income.

Resolution

The claim was valued at **€375,000**



Product Contaminated by Raw Material

Coverage	Property Damage
Cause	Contamination
Type of organization	Biotech/Pharma Manufacturer
Number of employees	More than 500
Annual revenue	€125 - €250 million

Description of event

Contaminated raw material was incorporated into a pharmaceutical company's product. The damage was not discovered until a number of batches were produced, affecting a large volume of finished product. Although only 10% of finished stock was directly contaminated, the FDA condemned all product batches.

Resolution

The claim exceeded **€225,000**



Employee Burned by Exposure to Chemical Reaction

Coverage	Employers Liability
Cause	Employee Injury
Type of organization	Biotech/Pharma Manufacturer
Number of employees	Fewer than 25
Annual revenue	Less than €13 million

Description of event

A pharmaceutical employee was working with chemicals under a fume hood when a fire started as a result of a pressure gauge that was closed. The employee sustained facial, hand and arm burns.

Resolution

The claim was resolved for about **€85,000**