



## Insurance for the Pharmaceutical Industry

Trial Results Under Investigation in FDA Study

Fire Devastates Plant in India, Manufacturing Halted in U.S.

Cultures Contaminated, Months of Research Lost

These headlines don't foretell the future of the pharmaceutical industry — they reflect the risks facing pharmaceutical companies today. 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* portfolio. We offer pharmaceutical companies a range of innovative insurance products, including dual-trigger general liability, products and human clinical trials liability and change in controlled environment.

Pharmaceutical companies face new exposures to loss every day. Your company needs an insurance partner that can keep pace. With a unit dedicated to the life sciences industry, Chubb has unique expertise in helping companies manage risks with enterprise-wide insurance products supported by outstanding claim and loss control services.

### Property

Broad "all-risks" perils cover is available to respond to the needs of pharmaceutical companies.

**Research & development property** is defined as processes or cultures, prototypes, written or inscribed documents, plans, records or formulas produced and directly associated with research and development operations.

**Scientific animals** are defined as animals used for research and development operations, plus breeding animals, production animals and animals from which biologic products are harvested for production. Valuation consists of two key components: the cost of replacement animals and the accumulated research and development investment in the animals as of the date of loss. Protection is afforded at scheduled, unnamed and newly acquired locations, and can apply while animals are in transit.

**Broad "all-risk" property perils** are included, such as water damage, inundation, abrupt and accidental mechanical breakdown and surface water.



**Change in controlled** environment protection applies to loss or damage to perishable property due to spoilage, rapid decay or deterioration. Protection is also provided for scientific animals for changes in air quality, temperature, atmosphere or other environmental conditions. Insurance is afforded at scheduled, unnamed and newly acquired locations, and can apply while property is in transit.

**Contamination** from a wide variety of causes, including bacteria, mildew, mold microorganisms, viruses, pathogens, radiation or airborne microbes, can be included. Protection is afforded at scheduled, unnamed and newly acquired locations.

**Contaminant cleanup and removal** responds to costs incurred to clean up or remove contaminants, including radioactive contaminants, from land, water or air, either inside or outside of a building.

### **Business Income**

Chubb's Life Sciences sets the standard in business income protection. Regardless of the extent of your operations, your company needs this insurance. The following forms of Business Income protection are available:-

**Research & development income** provides recovery for continuing normal operating and payroll expenses for research and development operations, even when the company is not generating a profit. It can also respond to grants, endowments or other financial contributions that a company would have earned if the covered property loss had not occurred.

**Operational restoration** extends business income protection beyond physical restoration of property. A loss will be paid until operations are restored to the level that existed prior to the covered property loss. This continued protection is essential for facilities that must be validated by government authorities, such as the FDA, before manufacturing can resume. These procedures can take months, and in some cases go on for more than a year after the physical restoration.

**Dependent business premises** protection is available on a scheduled basis. Reliance on others, such as component suppliers and outsourced contract research, manufacturing and packaging organisations, creates susceptibility to business interruption from a loss at any of these firms.

**Extra expense** insurance pays expenses over and above the usual expenses a company would have incurred to continue operations had it not sustained a covered loss.

### **General Liability**

General liability has tailored definitions of your product and of the products/completed operations hazard. Further, lessors of leased equipment and volunteers are automatically included as insureds.

A **hybrid general liability** contract offers a dual trigger — an occurrence trigger for Premises/Operations and a claims-made trigger for Products/Completed Operations. This single form offers convenience and reduces potential for conflicts in the claims process.

An **extended occurrence period** of one year fills a potential gap for delayed occurrences from products that may still be in the hands of consumers after a recall or ban.

**Product withdrawal & crisis management expense** protection up to \$25,000 for Class 1 recall is offered to companies with a formal product recall program.

**Insured status** is granted for typical contractor relationships based on activities performed, as contractually required.

Customised **human clinical trial reporting conditions** offer greater efficiency by recognising the various roles and responsibilities associated with these activities.

**Notice of circumstances** condition provides the opportunity to preserve insurance for known circumstances that may result in a claim.

**Blanket protection** applies to human clinical trials initiated after the policy inception within the same drug or medical device family. Certain exceptions may require advanced underwriting approval.

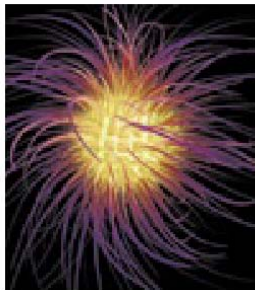
**Emergency medical expenses** are covered for bodily injury in connection with human clinical trials, including trial-related athletic activities.

#### LOSS SCENARIO #1

A pharmaceutical company used a subcontractor to manufacture its capsules. A custom soft-gel encapsulation machine suffered a mechanical breakdown and required extensive repairs. The repairs and FDA revalidation took six months. The existing inventory lasted only two months.

Chubb's *Life Sciences'*

Dependent Business Premises protection kicked in, covering the four months of lost income.



#### LOSS SCENARIO #2

A manufacturer of an over-the-counter cold medication withdrew the product in accordance with its product recall program. Not all consumers were aware of the recall. Six months later, a woman suffered a reaction when taking the medication for the first time and led a claim against the manufacturer. With Chubb's *Life Sciences'* optional Extended Occurrence Period, this company had the needed protection.

#### LOSS SCENARIO #3

A fire in a research facility was quickly extinguished by the building's automatic sprinkler system, but smoke from the fire killed a colony of fourth generation scientific animals.

Chubb's *Life Sciences'* protection for Scientific Animals responded by funding the purchase of new, pre-research and development animals and paying the full cost of recreating the research to its pre-loss state.

**Employees** who voluntarily participate in a human clinical trial are not excluded, as their participation is not deemed to be within the scope of their employment.

#### Errors & Omissions

For pharmaceutical companies that perform services for others, errors & omissions insurance is affordable protection against a significant threat to your company's financial well being. Errors & Omissions insurance helps protect your company from lawsuits claiming a financial loss resulting from a failure of your service to perform to specifications. General liability insurance does not protect you from these emerging vulnerabilities.

Errors & Omissions protection can provide financial injury compensation to a third party resulting from the need to stop using your product due the risk of future **bodily injury or property damage**.

**Oral & written contractual liability** insurance is provided for insured contracts and includes the obligation to defend an indemnitee where provided by such contract.

**Notice of circumstances** provision provides the opportunity to preserve insurance for known circumstances that may result in a claim.

Customised **human clinical trial reporting conditions** offer greater efficiency by recognising the various roles and responsibilities associated with these activities.

#### More Options

Round out your insurance program with additional products:

**Umbrella & Excess** — can be structured to include products liability on a follow-form basis

**Environmental** — protects against liability for first-party remediation costs as well as third-party bodily injury, property damage and remediation costs resulting from new or existing pollution incidents

**Commercial Automobiles** – includes nonowned and hired cars

**Workers Compensation** – includes protection for employees while travelling overseas

**Reputational Injury and Communication Liability** – offered in conjunction with General Liability and includes protection for product disparagement, copyright and trademark infringement, libel, slander and violation of the rights of privacy and publicity

**Executive Protection Liability** — includes Crime and Employment Practices.

**Political Risk and Trade Credit** — help protect your overseas investments

#### Global

You can easily expand your domestic property and liability insurance worldwide with a Chubb's global extension. Differences in conditions or limits that may exist between the domestic program and the local (admitted) insurance contracts are insured, subject to the terms and conditions of the policy. Where admitted insurance is required, Chubb can write primary policies through its network of wholly owned offices or affiliates, including the compulsory coverages for human clinical trials in many countries.

*Chubb's dedication to the life sciences industry is evidenced by its product innovation, quality of services, precision underwriting and depth of expertise.*

#### FIND OUT MORE

If you would like more information about Chubb's Life Science insurance, please contact your nearest Chubb office.

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Chubb refers to the insurers of Chubb Group of Insurance Companies: Federal Insurance Company, Vigilant Insurance Company, Great Northern Insurance Company, Pacific Indemnity Company, Northwestern Pacific Indemnity Company, Texas Pacific Indemnity Company, Executive Risk Indemnity Inc., Executive Risk Specialty Insurance Company, Quadrant Indemnity Company, Chubb Custom Insurance Company, Chubb Indemnity Insurance Company, Chubb Insurance Company of New Jersey, Chubb National Insurance Company, Chubb Lloyds Insurance Company of Texas. Not all insurers do business in all jurisdictions.

This literature is descriptive only. Actual coverage is subject to the language of the policies as issued.

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