

By Steve Schoenberger, VP & Technology Liability Practice Leader

The Insurance Lifecycle Guide for Life Sciences Companies

When and what insurance coverage is needed to protect your emerging business

Property and Casualty

Stage 1

Companies in their infancy • Typically no outside funding other than state or federal grants • Ideas/Patents coming out of Universities • Research and Development only organizations

Business Owners Package Policy – coverage include:

- **General Liability Insurance** – this coverage will be mandatory to lease space and begin research. This coverage protects against bodily injury and property damage to third parties arising from the operation. Product liability coverage is specifically excluded for companies at this stage.
- **Property insurance** covers your fixed assets that have been purchased or for which you have a duty to insure via lease requirements. Property values will be low at this point but nonetheless it is prudent to insure. Items to protect: laboratory equipment, laptops, scientific animals, and servers.
- **Business Interruption/extra expense coverage** helps replace operating income from grants, endowments, and other sources of public funding. Coverage must be specifically added to the property policy otherwise there will be no coverage for an interruption in your revenue stream following a property loss. Extra Expense will cover additional expenses incurred to get your business up and running as fast as possible after an insured loss. For example, extra rental expense to find comparable wet lab facilities, added expense to expedite the replacement of critical laboratory supplies.
- **Automobile hired and non-owned liability** will protect the entity from liability arising from the use of rental vehicles on company business. It will also protect the corporation against liability arising from the use of other non-owned vehicles. We strongly recommend this coverage given the minimal cost and potential liability. Hired Car Physical Damage coverage insures damage to the rented vehicle and may also be elected. However, this coverage is usually not cost effective in the early stage and companies instead often chose to buy the physical damage waivers offered by the rental companies.

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Workers Compensation and Employers Liability coverage

In most states, required by state law when a corporation is formed. In some states, including MA, coverage is required even if the entity has no employees. Will cover medical expenses as well as indemnify employees for time off work as a result of a work related injury. Executive Officers may opt out of this coverage in most states. *Uninsured independent subcontractors may be entitled to collect workers compensation benefits from an entity with no employees.*

Umbrella coverage

Layers of catastrophic protection that sit above third party coverage's such as general liability, employer's liability, auto liability and international liability. Written in million dollar increments. Umbrella coverage is often used, at this stage, to build limits that are needed if lessors require liability limits in excess of those provided in the primary general liability.

Stage 2

Companies receiving Venture or Angel funding • Companies who have organized a Board of Directors

Directors and Officers liability

When money is raised the directors, officers and board members have a responsibility to oversee the prudent use of these funds. D&O insurance offers protection to those making decisions. Early investors are often asked to sit on the board. These individuals will require that D&O insurance be in place before they will accept a board seat. If D&O coverage is not purchased, the personal assets of the directors and officers are exposed to any suits that name them individually. Privately held company's need this coverage just as publicly held companies do.

Employment Practices Liability

Protects the directors and officers, and the corporation against lawsuits as a result of improper hiring, firing and/or advancement. EPL will also cover allegations of racial discrimination and sexual harassment. EPL coverage can provide a critical transfer of liabilities if a situation arises at this early developmental stage. Proper human resource management is becoming vital to the continued growth of the organization. There can be both frequency and severity of claims in the EPL arena. Key Man Life Many times part of the funding requirements is to secure this coverage for the key people of the organization in case of death. For example, payment of the policy precedes go to the corporation to find a replacement for the key person.

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Stage 3

Companies Entering Clinical Trial Testing • Product development beyond clinical trials • Partnerships with larger organizations are becoming a reality • Additional rounds of outside funding

Clinical Trials coverage

Specially designed policies written by a handful of insurance companies who understand the drug/medical device regulatory process. A typical general liability policy is not designed to pick up clinical trials exposures. Trials may be conducted either in the USA or overseas. If trials are taking place overseas, the terms and limits of the policies must meet mandated country guidelines. For example, Germany and France have very strict guidelines for insurance covering clinical trials being conducted in their countries. There are certain documents required by the insurance companies that provide them the necessary information to evaluate and underwrite the risks. Be prepared to provide:

- Protocols
- Informed Consent Forms
- Clinical Agreements

Local language translation of the above may also be required for foreign trials

Each Phase of a clinical trial typically increases in premium as a result of an increase in trial participants and an increase in the risk of someone being injured.

International Insurance Coverage

Companies at this stage are seeking global partnering and /or funding opportunities. When employees leave the borders of the USA to transact business, insurance does not follow them. Specialized coverage must be put in place. International coverage will cover employees who may be injured while traveling, who may rent cars or who may enter into contractual arrangements. Property such as computers and exhibit booths will be protected by an international policy. Depending on the extent of the foreign activities and coverage desired, US policies may be endorsed to provide worldwide coverage or a separate foreign package policy may be issued.

Internet Liability coverage

Liability associated with the Internet is one of the fastest growing areas of litigation. Many companies are choosing to share their data via the Internet and setting up large databases containing trial results. Companies are extremely vulnerable to the wrongful manipulation of data and invasion of privacy. Insurance coverage has been developed to protect against unauthorized access, unauthorized use and destruction of data. Companies involved in bioinformatics have a higher susceptibility to risk due to privacy laws and the possibility of decisions being made based on corrupted data.

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Even companies whose only Internet presence is a website are being brought into copyright and trademark infringement suits brought domestically and internationally.

Owned or Leased Automobile

Coverage applies to owned automobiles and/ or for automobiles which are hired or non-owned. This coverage will protect employees from liability and/or physical damage to the car while renting vehicles on company business. The liability portion of the coverage may protect employees driving their own vehicles on company business (after their personal insurance is exhausted). If your company frequently rents vehicles this coverage will quickly pay for itself.

Stage 4

Product being sold to the public • Pre –IPO / IPO / Additional Rounds of Funding • Company becoming more established • Upper Management in Place including Human Resources

Stable staff of core employees while still aggressively hiring Research and Development activities are in full swing Possible expansion of work sites to incorporate manufacturing of product Revenue generation from product sales or services offered.

Products Liability

Protects against third party bodily injury and property damage suits arising from use of your product. Be prepared to supply the underwriters with your various FDA filings and in turn the FDA's comments. Once products are released into the stream of commerce there are significant liabilities that should be transferred to an insurance policy.

Employment Practices Liability (if not purchased previously)

Protects the corporation against lawsuits as a result of improper hiring, firing and/or advancement. Will also cover allegations of racial discrimination and sexual harassment. Proper human resource management is becoming vital to the continued growth of the organization. There can be both frequency and severity of claims in the EPL arena.

Enhanced Property Coverages

FDA approved facilities add significantly to the cost to replace a building or set up operations elsewhere. Operations may be shut down after a loss and may remain closed until and acceptable replacement facility is located. Insurance limits will need to be increased to not only reflect higher replacement costs of buildings but also to account for time to find specialized facilities.

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- Pollution enhancements
- Boiler and Machinery – refrigerators, ovens, autoclaves that break down can cause significant damage
- Research and Development Property – cost to recreate/replace cell lines, cultures, and lab books
- Radiation Contamination
- Evaluation of extra expense limits and disaster recovery plans.
- Temperature sensitive property – requires special attention

Umbrella coverage

Layers of catastrophic protection that sit above the general liability, employer's liability, international liability and auto liability. Written in million dollar increments. Note that in the Life Science sector, umbrella coverage often excludes products liability and additional products liability protection is secured by increasing the products liability policy limit. Review contracts to see if there are minimum limits of liability requested. The umbrella can help fulfill contractual requirements.

Steve Schoenberger is the VP and Technology Liability Practice Leader at Mason & Mason Technology Insurance Services Inc. Prior to joining Mason & Mason, he managed AIG's Technology & Professional Liability underwriting for the Boston Region. Steve works with a broad range of life science and technology companies from pre-funded to mid-cap public companies and can be reached at sschoenberger@masoninsure.com or 781-447-5531 x140.

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