

## **Managing Risk in Life Science Firms Contractual Risk Transfer using Terms and Conditions**

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When managers of companies talk about business insurance - perils, price, and limits - they usually assume they are engaged in a discussion of Risk Management. Strictly speaking, they're wrong.

Risk Management consists of procedures firms adopt to evaluate, manage, reduce, or avoid risk. Think of Managing Risk as one of a company's many goals for success. In that context insurance is one of many strategic tools that can help to reach the goal. Specifically, it is a device for transferring risk to an insurance carrier.

Insurance underwriters who really know their business want to insure firms who first adopt good Risk Management processes before choosing to buy protection. Put another way, a basic tenet of Risk Management is "never substitute insurance for good Risk Management."

As an important Risk Management strategy, Contractual Risk Transfer should be an area of special interest to Life Science firms. Don't confuse this with purchasing an insurance policy. Rather, it is using routine contracts to shield your company from loss and, in some cases, have someone with whom you do commerce pick up your defense. For Life Science firms just starting out, a point at which this contractual barrier should most certainly be instituted is when products or services are ready for distribution.

Putting your technology in the hands of others - particularly when it is specified "for research only"- may seem benign insofar as attracting lawsuits. But in fact, anytime you relinquish your work product to someone for their use, there is the potential for it to cause Bodily Injury or Property Damage. If you wanted insurance for these losses, the policy you would purchase is referred to as Products/Completed Operations Liability Insurance.

However, start-ups are often reluctant to spend several thousand dollars on Products/Completed Operations Coverage. And even if they do, the fundamental rule "never substitute insurance for good Risk Management" precludes buying insurance as a first step.

Firms should use their Terms and Conditions document as one of many shields against claims and lawsuits. Along with the many IP, price, acceptance, delivery, warranty, returns and other subjects often addressed in Terms and Conditions, the following Contractual Risk Transfer features should be prominently displayed.

Limitation of Liability If your product does not perform as represented, your customer may expect compensation. Limitation of Liability language generally stipulates the maximum your customer can receive as damages. Many times this equals the amount paid, or repair or replacement of the product and no more. It is often important to have a statement in this limitation that it is the sole and exclusive remedy, especially if the Terms and Conditions have an indemnification provision (discussed below).

Hold Harmless When you transfer your product to someone for their use, there is a risk it may cause damage to them, their property, and employees. When that person also uses it to aid in development of their own product, your risk extends further. Here's how. Should someone using a customer's product incur damages, that injured person (referred to as a third party) may

allege you contributed to their loss. Since a third party isn't bound by the contract you have with your customer (via your Terms and Conditions), a third party is free to seek remedies however they choose, including filing suit. Plaintiffs' attorneys are criticized for "suing everyone" who might have played some role in their client's loss. But in doing so, they are only ensuring the right people will, in the end, share blame. Hold Harmless agreements can create a barrier, protecting you against claims from these sources. In effect, the buyer agrees to absolve you from any responsibility for damage or other liability arising from the transaction. This includes protecting you against lawsuits by third parties.

Indemnification Agreement This provision is used in concert with the Hold Harmless agreement. Your customer uses your work product to develop their goods. Distribution of those goods in-turn create exposures for you with third parties, exposure for which you have no control. Should a customer's operations create liabilities that generate expenses to you, including attorney's fees, your customer agrees to reimburse you those costs.

Complete Contract This provision in a contract, sometimes referred to as a merger clause, says regardless of other information or circumstances to the contrary that were discussed prior to the contract being formed, your agreement (Terms and Conditions) is primary and shall prevail, superseding all prior oral or written communications, negotiations, and discussions. Typically this provision also includes a related sentence that states any changes to your contract must be made in writing, signed by an authorized representative of each organization.

These and other Contractual Risk Transfer techniques should begin at the earliest stages of a start-up. Doing so creates a culture of good contract management, shields the organization from loss, and reduces or delays the need to spend scarce research dollars on Products/Completed Operations Liability insurance. At the point coverage is purchased, good Contractual Risk Transfer strategies will make your company more attractive to the insurance marketplace since underwriters prefer insuring those least likely to have claims.

Always consult an attorney. Complications arise relating to particular states in which you operate, protection of your IP, confidentiality issues and more. You must seek competent professional advice to ensure all these are addressed correctly. A good attorney will help you strike the right balance of risk mitigation and efficient business contracting.

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