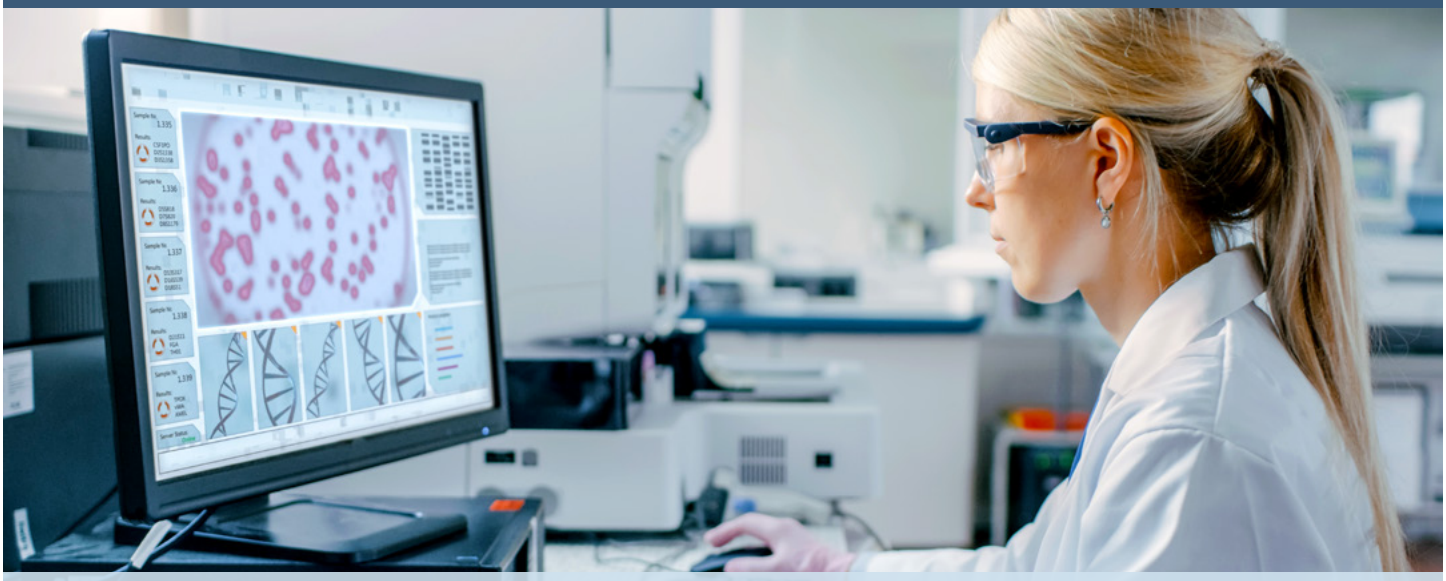

CONTRACTUAL RISK TRANSFER – A LIFE SCIENCE PERSPECTIVE

INTRODUCTION

Every day companies complete many transactions, from the mundane to the essential, to keep their operations productive, efficient and competitive. For a life science company, these transactions may be with a supplier of critical components or raw materials, a subcontractor that performs contract research or sterilization and a wholesaler/distributor that sells to the end user. These business partners are essential to your reputation as a provider of a safe, quality product or service. Unfortunately, the use of contracts in these transactions is an underutilized risk management mechanism. A well written contract clarifies the contracting parties' roles and responsibilities, improves outcomes and manages expectations between the contracting parties. Due to the nature of product liability law, potentially costly liabilities can exist regardless of fault. Entering into a mutually agreeable and fair contract can help define the parameters of risk to the company and financial responsibilities in the event of an unforeseen loss.

WHY IS CONTRACTUAL RISK TRANSFER IMPORTANT?

Product liability for a design, manufacturing or warning defect usually flows upstream to the designer or manufacturer where the product, component, raw material or software originated. However, product liability laws will allow a claimant to bring suit against all entities in the stream of commerce from the retailer to the distributor or contract manufacturer back to the designer. It is common for a product liability lawsuit to name all entities; and to this end, the terms and conditions within the contractual agreement will act to shift or apportion the risk to the responsible party. Favorable contractual provisions form an important part of your risk transfer strategy and can materially impact which party is ultimately responsible for legal defense costs and indemnity risk.

continued

THE HARTFORD

WHAT ARE SOME EXAMPLES OF A CLAIM?

For illustrative purposes, take a fictitious medical device company (MEDCO) that designs and fabricates durable medical goods that are used in a home environment. MEDCO has written sales agreements with dealers and contract installers who are responsible for the exclusive sales, service and repair of MEDCO's products. These sales agreements did not have any definition of responsibilities in the event of installation failure and no provision requiring the dealers and installers to indemnify MEDCO for the bodily injury, property damages or legal expenses arising from errors committed by the dealers' field installer and service technicians. The contract did require both the dealer and contract installers to obtain and maintain liability insurance coverage, however, MEDCO failed to include specific limits of liability or require that it be added as an additional insured on these policies. The absence of the risk transfer language in the agreement resulted in MEDCO being unable to shift ultimate responsibility to the negligent party for the costly installer errors.

In the case of a U.S. distributor of an Asian pharmaceutical manufacturer, the applicable supplier agreement clearly defined the roles and responsibilities for both companies. The U.S. entity was also named as an additional insured on the Asian pharmaceutical liability policy. During a routine inspection by the FDA, several violations were noted and not addressed by the Asian manufacturer. A 483 Warning Letter was issued and the FDA banned the import of all drugs, however, a purity issue with the product in the stream of commerce resulted in a voluntary U.S. recall. A multidistrict lawsuit was filed against the U.S. distributor by the retailers that sold the drug to hospitals and consumers. Unfortunately, the supplier agreement did not require the manufacturer to defend, hold harmless or indemnify the U.S. distributor for manufacturing or regulatory compliance failure. The Asian based liability coverage has not responded and the company has been unable to seek redress for the significant costs of the recall and litigation defense.

WHERE ARE THE VULNERABILITIES IN A RELATIONSHIP?

- Missing or deficient indemnification provisions in agreements exposes the company to liability for a loss that occurs due to the negligent acts or omissions of a vendor, contractor or supplier.
- Not specifying insurance coverage limits on the vendor's insurance policy, failure to request additional insured status, and not demanding proof of compliance to these conditions with actual endorsements.
- Agreeing to exculpatory provisions as part of terms and conditions without fully assessing the potential loss impact.
- Assuming a foreign company will provide financial protections against harm due to an adverse judgment.

WHO SHOULD BE ENGAGED IN THE PROCESS?

Being named in a lawsuit is expensive even when it is just pending a determination of no responsibility in the suit. The absence of a contract review by a product liability attorney can be a costly mistake as the company may be unable to access funds for reimbursement of defense related expenses.

To avoid costly legal errors, company leadership should engage the services of a competent product liability attorney firm. As identified in the above scenario, product liability attorneys provide a greater measure of protection against contract omissions that can be adverse in a litigation scenario. Once the formal contracts, master vendor agreements and purchase orders have been fully reviewed by competent product liability counsel, the company procurement staff will need to become familiar with the terms and conditions of these documents and make sure that clear escalation procedures exist for approval of documents that are returned with changes to the language.

Here's an example that shows the need for product liability specialist legal advice: a fictitious company that was involved in M&A activity of a life science product line, performed the necessary due diligence on the product life span and the potential for litigation. Based on the research, the company demanded that an escrow account be established by the seller for payment of future losses. An M&A law firm that was responsible for managing the transaction unknowingly missed the need to include provisions to account for potential product litigation expenses and did not craft the terms and conditions to allow access to the escrow account for reimbursement of legal defense costs.

RISK MANAGEMENT CHECKLIST FOR GOOD CRT PRACTICES

☐	Appropriate legal representation with product liability expertise prepares or reviews formal contracts, master service agreements and purchase orders. The documents are in use with all relationships.
☐	Use Indemnity Provisions that comply with the law of the applicable jurisdiction to shift or apportion risk in a contract.
☐	Request Additional Insured Status with vendors to list the other party as an "additional insured" on its insurance policy. With these provisions, the insurer is obligated to indemnify and defend the additional insured in accordance with the policy terms and conditions. Additional insured provision to a vendor contract should require the vendor to provide proof of compliance.
☐	Require that vendor insurance only be purchased from carriers with a certain financial rating as part of the contract as the financial solvency of the insurance carrier is critical to the effectiveness of this provision.
☐	Establish a responsibility matrix in the contract as a means for laying out which party in the agreement is responsible for every contemplated procedure, eventuality and allocate responsibility for each among the contract parties according to their mutual understanding. In addition to the basic functions involved in the product manufacture, the entities responsible for product testing, record keeping, complaint handling, and recall coordination should also be identified.
☐	Include language in the contract with suppliers to inform of all changes or modifications to the component part designs, processes, equipment, raw materials, or third-tier suppliers. Without the notification and transparency requirement, it will be the subjective judgment of the supplier to provide the notice on a change that may ultimately affect the performance of the finished product.
☐	Identify the Term of the contract (duration) and express it clearly in the agreement. It should include a provision for the termination of the agreement, how and when will the agreement end, whether or not the contract can be renewed and under what terms.
☐	Require the contractor or supplier to report any event such as a FDA inspection or enforcement action, or when their product or process has been the subject of an adverse event or user complaint that could be serious in terms of injury severity or likelihood of a frequency/repeat issue.
☐	Contract for independent review of Merger & Acquisition contract by product liability counsel to verify the language in the contract provides necessary protections for the company.
☐	Require severability provisions that state if parts of the contract are held to be illegal or otherwise unenforceable, the remainder of the contract will apply.
☐	Establish dispute resolution language for use of arbitration in lieu of litigation.
☐	Require legal review of any deviations to the standard approved language of the contracts.

CONCLUSION

Legal actions involving life science products and services have increased significantly as more complex products are launched including medical apps on smartphones. Since compliance with FDA requirements is not a full defense in a products liability action, it's critical for all life science companies to proactively evaluate their contractual risk management mechanisms.

LEARN MORE.

For more information, contact your Risk Engineering consultant from The Hartford today or visit us at **TheHartford.com/riskengineering**

THE HARTFORD

Business Insurance
Employee Benefits
Auto
Home