What Could Go Wrong With Using a Third Party Vendor?
Potential Exposures
Part 1

Introduction

When your organization relies on a third party to conduct business operations, issues can and do arise. In this two part series, we will explore potential product liability and errors and omissions exposures that may occur in your relationships with third party vendors and how to best manage these issues through risk management techniques.

What could go wrong when contracting certain services from a third party? Consider these examples:

- A contract research organization has been hired to conduct clinical trials for a small life science company to develop clinical safety and efficacy data for their lead candidate drug. However, some of the key data for the trial is lost and delays the candidate drug's chances to move forward in the regulatory process and the research needs to be redone.

- A raw material supplier provides an ingredient to a dietary supplement manufacturer that does not match the certificate of analysis and this is not discovered before the final product goes out for distribution. There is a claim from the final customer for failure to provide the material that was noted on the label and that was required by their specifications.

- Final sterilization of a product was conducted by a third party and the product was then released for distribution. Post sterilization, a packaging issue has been discovered but the source of the defect is not known. This product is alleged to have caused an infection in the patient and results in bodily injury.

We will review what tasks may typically be outsourced to a third party by life science companies and what types of exposure these assignments may create for the organization.

Types of Third Party Vendor Relationships

Many life science organizations use third party vendors at some point during their product development and commercialization lifecycle. It can be difficult for a company to have the infrastructure and investments necessary to create a final product, whether a device, a drug or a supplement, and to manage the post commercialization process of that product. The importance of your organization's relationship has with your third party vendors can be vital to your business. Proper contracting procedures to ensure that each party clearly understands the parameters of the work contracted can help to protect your organization from potential product liability claims or loss.

What are some of the tasks that are outsourced by life science companies? The following are common types of third party vendor relationships that a life science organization may create through the life cycle of product development, manufacturing and distribution, and the types of exposures that may be created by such connections:

1. **Research and development**: The research that is developed can be the foundation for your organization's growth. If expectations are not set early (and updated as often as necessary) as to the direction of research and data needed from the CRO, your growth could be stunted.

- Contract research organizations (CROs): CROs are contracted by life science companies to assist in research and development work to help with preclinical and clinical data that FDA requires before these products can be released to the market.

2. **Supply chain**: Lack of specifications for what is to be provided by these supply chain vendors could expose your organization to materials that may not be usable.
    - Raw material or component suppliers: Some examples of raw materials or components that make up life science products are active pharmaceutical ingredients, herbs for dietary supplements, and precious metals for medical devices.
    - Quality control testing labs: Not all companies may have the resources to conduct the product testing required by the FDA. Therefore, there are third party testing labs that assist life science companies with testing raw materials, testing of work in process and evaluating finished product to ensure that the finished product meets all regulatory standards.

3. **Manufacturing**: The lack of clearly defined procedures, roles, and responsibilities for both the contract manufacturer and your organization can lead to missteps in the manufacturing process.
    - Contract manufacturing organizations (CMO): Commercializing a product for market may require equipment and processes so specialized that the manufacturing process itself needs to be outsourced to a vendor.
    - Temporary work agencies: Temporary employees contracted to work in manufacturing or other parts of the process to help get the product ready for distribution.
    - Information technology: Server and data management can be outsourced to store the information that is created by the organization, whether intellectual property, manufacturing orders, etc.

4. **Distribution**: Misunderstanding of who owns the products during distribution and storage can lead to an exposure if a loss occurs during this process.
    - Logistics/distribution vendor: Life science organizations may outsource the distribution of their products to ease delivery of their product to final customers. These vendors can also include freight companies that carry the products from one location to another.

5. **Post commercialization**: There are many moving parts in the post commercialization phase of the product life cycle and the management of this process is critical to the success of your organization. If this is mismanaged, it may expose your organization to a regulatory warning, lagging sales or more.
    - Adverse event management: Tracking and managing the reporting of adverse events is a key step in the regulatory process. There are firms that specialize in providing this service for life science companies.
    - Product recall firms: When a product recall occurs, a firm can be hired to manage various aspects of the product recall, from notifications to collection to destruction of the recalled products.
    - Marketing: Marketing can be outsourced to a marketing or media company to help create a consistent message that can include, but is not limited to, graphics, labels, and taglines.
    - Sales: Contract sales organizations assist life science organizations to increase the sales of their product in areas of the country/world where they may not have the presence to sell their products.
    - Customer service call centers: Life science organizations may not have the resources to manage customer service in house and turn to third party call centers to provide the customer service that is needed for their products.

Product Liability Exposures

There are different types of exposures that can result in a product liability loss for an organization. Product liability is the liability that a company may have for producing or selling a faulty product. This can be broken down further into bodily injury, property damage, or errors and omission financial loss. For companies utilizing third party vendors, it is vital to evaluate possible product liability exposures that these vendor relationships may cause and how each party could be held liable for a loss. By identifying and understanding these issues, your organization can create and utilize proper risk management techniques. The following are several exposures that are often seen in third party vendor relationships:

1. **Manufacturing Defect/Contamination** - If there is an issue with the product due to defects or contamination, the end user will likely allege that the manufacturer is liable for any injury. However, if a third party vendor was involved at any point during the manufacturing process, they could also be made a party of any litigation that occurs.

2. **Marketplace Safety Management** - Adverse events or product recalls can occur. If these are not managed correctly, it may create a liability for a life science company.

3. **Quality Deviation** – If there is a lack of quality control inspection when using materials supplied by a third party vendor as part of the supply chain, agreed upon specifications may not be met, which could affect the final product.

4. **Mismanaged Audits of Vendor Practices** - A third party vendor may not have the practices in place that meet the expectations of your organization. Without regular audits of these vendors, the services or materials that the vendor supplies may affect the final quality of your product.

5. **Missed Training Opportunities** - Third party vendors may not have had the training necessary to meet your organization's standards, which could affect, depending on the type of vendor relationship, how your product is manufactured, inspected or distributed.

6. **Roles and Responsibilities for Vendors are not Clearly Defined** - Without clearly defining the roles and responsibilities of your third party vendors, you potentially increase your liability for any issues that may arise.

7. **Incorrect Product Forecast** - A third party vendor may not correctly forecast the product mix they need to meet your demand, which causes your company to miss a key delivery with a customer.

8. **Loss of Intellectual Property/Data Breach** - The more people that can access your data and your systems, the greater the possibility of the loss of your intellectual property or other confidential information.

9. **Breach of Contract** – If there is a failure by your vendor to perform any part of the contract that was agreed upon at the beginning of the relationship, a financial loss to your organization could result.

10. **Reputational Damages** - If third party vendors are not properly vetted, their actions result in lost revenue or increased costs to your company.

Conclusion

The use of third party vendors can expose a life science company to potential product liability losses that affect the product's development and could result in post commercialization adverse events. A loss without

adequate controls in place may result in the company not having the necessary resources to continue operating.

Third party relationships are critical to the development and growth of many life science organizations, but the use of these vendors also presents increased exposures. In Part 2 of this series, we will discuss the risk management practices that life sciences organizations can put in place to control the exposures discussed in this article.

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