What Could Go Wrong With Using a Third Party Vendor?
Risk Management Techniques
Part 2

Introduction

Part 1 of this article explored the potential product liability exposures that could arise when your life science organization uses a third party vendor. In Part 2, we will examine how to manage these exposures through risk management techniques.

Risk Management Techniques

A life science entity is well versed in understanding their product life cycle and managing the various risks found throughout this cycle. It is crucial that any third party vendor also understand the product's life cycle. When a third party vendor is used, your organization can be exposed to different risks. These risks need to be managed in a similar fashion as the risks found in your company. Conducting a risk exposure analysis of the third party will assist you in understanding what types of claims are possible.

The risk management process starts with an inventory listing of your organization's third party relationships and conducting an individual risk assessment of each vendor to understand the specific risk each stakeholder could present. There are many risk management techniques to choose from when managing risks. The following techniques are not all-inclusive but can guide you as you develop a more comprehensive risk management program for managing the potential exposure from your third party vendors.

Management of third party vendors starts with your organization's selection process. It is essential to have a list of characteristics that your organization would like to see in a vendor. Some organizations use a questionnaire that each vendor has to complete, others conduct onsite walkthroughs, and still, others have a checklist of the required characteristics.

Once a third party vendor is selected, a key part of the relationship is to ensure that a written agreement is completed. There are two types of written agreements: contracts and purchase orders. Purchase orders are often used in the procurement of goods and will include certain simple conditions such as terms of product delivery and carriage as well as which party bears the risk of the product being lost. These terms will become legally binding once accepted. A purchase order is most often used for short, perhaps one-time, relationships such as a single delivery. Contracts are generally used for longer term relationships and will include additional terms and conditions beyond what is normally contained in a purchase order, including, but not limited to, the following:

- a full description of the scope of work
- representations and warranty statements
- limitations on liability
- remedies
- dispute resolution mechanisms
- force majeure
- severability
- confidentiality provisions
- terms of contract length
- roles and responsibilities defined
- change order methods
- indemnification clauses
- performance standards including QA/QC procedures or protocols as well as requirements for adherence to applicable regulations

Both your standard purchase order template as well as all vendor contracts should be reviewed by legal counsel to protect your organization from potential disputes.

Once the contract is established, then an onboarding process should be conducted. Onboarding is important so that your organization can conduct training as needed. The onboarding process will also allow your company to provide procedures that are to be followed by the third party vendor to ensure compliance with the agreement. Once the vendor is on board with the contracted task, it is up to your organization to provide adequate oversight and conduct regular audits of each vendor to ensure that they are meeting expectations and following the developed procedures.

Information is regularly passed back and forth between your organization and the third party vendor and much of this information and data might be confidential or include intellectual property that has to be protected. To ensure that your data and confidential information is protected, there should be clear procedures on how any third party vendor protects your data and how to transfer it securely between organizations.

The last risk management technique to consider is a business interruption plan. If something were to happen that affected your vendor operations, how would this affect your organization? Understanding this and creating a plan to address such an occurrence will assist your organization in keeping your business operational even if a catastrophic event occurs.

Conclusion

There are many exposures that result from using a third party vendor but if managed properly, third party vendors can be a vital part of making your life science organization successful. Extending your risk management program to include your organization's third party vendors is a key part of protecting yourself from increased liability. If your organization needs further assistance in conducting a risk management gap assessment or is interested in a general products liability discussion with Berkley Life Sciences Risk Management Resources, please feel free to reach out to us at blsrmr@berkleyls.com.

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