

Rx For Risk

Product Liability Risks for Emerging Life Sciences Technology Companies

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In today's litigious environment, most life sciences technology executives recognize product development gives rise to liability exposures. This issue of Rx For Risk reviews three types of product liability risks that are highly relevant to emerging growth healthcare technology companies and provides related detailed loss control checklists to help these companies develop sound product liability risk management practices.

Product Liability Risks and Emerging Companies

While product liability risks present a wide range of exposures for life sciences technology companies of all sizes, companies in the early stages of development, or "emerging companies," face challenges that make them particularly susceptible to product liability losses.

Typically emerging companies tend to focus on the benefits that their products provide, causing them to underestimate product liability risks and the potential severity of losses. As a result, when product liability claims arise, young companies are often taken by surprise. For emerging companies, financial concerns may be intensified due to constraints on resources and expertise, both of which affect new product development and clinical studies. At the same time, emerging companies are often under pressure by those who provide funding to launch new devices or drugs. Given these factors, product liability risks can be a problem for many emerging companies.

Three Categories of Product Liability Risks

Medmarc initiated a study of its historical claims data regarding product liability litigation to identify and categorize recurring product liability loss patterns. From the study, three categories of risk that are particularly relevant to early stage life sciences technology companies emerged: (1) Clinical Trial Risks, (2) Vendor/Supplier Risks, and (3) Management Failures.

Clinical Trial Risks

Clinical Trial Risks develop as a result of inadequate planning and preparation prior to beginning a clinical study and from the failure to identify and address complications that arise during and after the study. Failure to meet clinical milestones, fulfill regulatory submission requirements, and keep product development processes on time and within budget are symptomatic of Clinical Trial Risks. Additionally, emerging companies often face Clinical Trial Risks when

they misunderstand their insurance coverage or do not obtain sufficient post-study coverage. This type of risk, which is infrequent but severe, can significantly impair emerging companies.

The following are examples of Clinical Trial Risks:

- In a drug study, infections and allergic reactions were not anticipated and were poorly addressed as a result.
- Researchers failed to disclose to patients that the Food and Drug Administration (FDA) had not yet approved the use of the device being studied.
- Study patients were not properly pre-screened.
- Inadequate legal oversight led to hidden product liability exposures in clinical research documents.


As detailed in the attached *Checklist for Assessing Clinical Trial Risks*, emerging companies can mitigate against these risks by taking the following measures:

- ✓ Confirm that there is sufficient legal, regulatory, and investor support for the clinical study.
- ✓ Validate that sufficient disclosures and consent practices and procedures are in place.
- ✓ Confirm the adequacy of the study methodology.
- ✓ Determine the extent of insurance coverage available and the coverage needs and expectations of researchers, physicians, and clinical research organizations.

Vendor/Supplier Risks

Emerging companies commonly outsource some or all of their manufacturing processes to original equipment manufacturers (OEM) and contract manufacturers (CM). Limited due diligence during the vendor selection

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process, failure to appreciate vendor practices, and poor communication between emerging companies and vendors may result in the development of Vendor/Supplier Risks. For example, Vendor/Supplier Risks can develop when emerging companies are inexact or inaccurate when providing product specifications. Vendor/Supplier Risks may develop when emerging companies select inexperienced OEMs or CMs. Compounding these problems, OEMs and CMs sometimes believe erroneously that they are immune from product liability claims. As a result, OEMs and CMs may neglect proper quality and product safety or fail to obtain proper insurance, thus increasing the vulnerability of emerging companies when product liability claims arise.

The following are examples of Vendor/Supplier Risks:

- There is no written agreement between the OEM and CM, causing the parties to rely on a generic purchase order agreement.
- Raw materials or component parts are not evaluated before they are put into production.
- The emerging company fails to test the finished device to ensure that it works and was built to specification.

As outlined in the *Checklist for Assessing Vendor/Supplier Risks*, emerging companies can mitigate against these risks by taking the following measures:

- ✓ Verify that management understands the product liability risks presented by its vendors and suppliers.
- ✓ Confirm management's understanding of various legal and contractual issues associated with vendors and suppliers.
- ✓ Confirm the type and extent of insurance coverage of each vendor and supplier.
- ✓ Verify that the emerging company understands FDA and/or European Union (EU) requirements applicable to vendors and suppliers and the company's related duties and responsibilities.
- ✓ Confirm that the emerging company has validated the

quality management practices of its suppliers/vendors and has followed its own quality management standards.

Management Failures

Management Failures develop when managers fail to recognize or appreciate the potential for and severity of product liability problems. Oftentimes, managers do not anticipate or address unexpected variables that emerge during product development. Management Failures also arise when managers are unaware or uninformed of FDA or EU medical directives or regulations. In other instances, Management Failures develop when managers discount the potential for product liability problems in light of competing interests. The following are examples of Management Failures:

- Managers were unaware of mandatory FDA filings and the importance regulators would place on the type of information to be provided therein.
- Problems identified by researchers presented a conflict of interest or ethical dilemma and management's solution did not resolve the matter appropriately.
- Managers were familiar with the research and development of a drug but did not have the professional clinical competencies needed to lead and manage the clinical study.

As explained in the *Checklist for Assessing Potential Management Failures*, emerging companies can mitigate against the risks associated with these failures by doing the following:

- ✓ Determine that management reinforced product safety throughout the product life cycle.
- ✓ Confirm that patient and/or product safety information is fully documented and adequate analyses performed.
- ✓ Ensure that product warnings and instructions were adequate and properly tested.
- ✓ Validate the firm's training practices and procedures.
- ✓ Confirm that the quality policy and quality management system are adequate and meet and exceed FDA requirements.

Checklists for Risks

The attached checklists detail loss control measures that address the three types of product liability risk—Clinical Trial, Vendor/Supplier, and Management Failures—identified above. The checklists should be used as a general guide for assessing potential risks, which will vary according to the developmental stage of the company and its product(s).

CHECKLIST FOR ASSESSING CLINICAL TRIAL RISKS

Clinical trials present a unique set of liability risks. Each trial must be adequately supported by investors, as well as from a technological and regulatory perspective. Thorough methodologies and adequate disclosures and warnings are vital loss controls. In addition, insurance coverage and protections must be sufficient and meet the needs and expectations of clinical researchers, physicians, and clinical research organizations (CROs).

Confirm that there is sufficient legal, regulatory, and investor support for the study

- Do the science and techniques used in the clinical study or new product testing support the submittal for approval and marketing of the device or drug under study?
- Have the Food and Drug Administration (FDA) and/or European Union (EU) regulatory authorities approved the drug/device under study at this stage in its development? *If the device is not approved for use at this stage as an investigational device/drug, reconsider or revise the study under regulatory approval.*
- Are management and/or the CRO aware of the FDA and EU medical directives regarding the time required to satisfy post study requirements?
- Do the venture capitalists or other investors (who might withhold funds if project milestones are not met) economically support the emerging company?

Confirm the adequacy of the study methodology

- Do the criteria for initial pre-screening and qualification of study candidates follow a clearly articulated methodology? *The methodology should continue screening throughout the study and contains a strategy for following up on study participants.*
- Have communication avenues been developed between clinical researchers, physicians, the institutional review board (IRB), manufacturers' representatives, and insurers of the study to ensure open and prompt sharing of information?
- Has the IRB been made aware of the clinical risk potentials involved in the study to ensure that adequate oversight for the study is provided?
- Have unanticipated risks (*e.g.*, infections, toxic or allergic reactions, etc.) been built into the methodology of the drug or product testing and have clinicians been alerted to the potential unanticipated risks?

- Does the manufacturer or CRO have a protocol or procedure to follow-up with patient surveillance from the clinical studies?
- Have the clinical studies established a protocol or procedure for thorough investigation and analysis of post study medical device incidents or drug reactions?

Validate that sufficient disclosure and consent practices and procedures are in place

- Is the informed consent process perceived as an opportunity to inform each patient, rather than as a formality involving completion of necessary informed consent forms?
- Have the clinical risks been fully disclosed to patients?
- Have adequate information and instructions and warnings been made available to clinical researchers and their subject patients involved in product or drug testing?

Determine the extent of insurance coverage available and the coverage needs and expectations of researchers, physicians, and the CRO

- Were the clinical research documents and agreements reviewed by legal counsel familiar with clinical research, as well as by insurers or brokers for coverage limits, warranties, and indemnification clauses?
- What are the expectations of the researchers and CRO concerning professional liability exposures? *Are these being covered by product liability insurance or professional medical malpractice and/or errors and omissions liability coverage?*
- Do the clinical researchers/physicians involved in the study expect that they will be protected and indemnified from all liability potentials and acts that may occur during the clinical studies and have steps been taken to address these expectations?
- Does the company carry adequate and appropriate clinical trials insurance for the post study period?

CHECKLIST FOR ASSESSING POTENTIAL MANAGEMENT FAILURES

An informed and proactive management team can avoid potential products liability claims and mitigate risk. Management must set the tone for corporate policy and practices and assure that the quality management system is established and working properly. The management team is responsible for understanding, communicating, and maintaining compliance with regulatory requirements and must ensure that adequate training, documentation, and analyses are performed throughout the product lifecycle.

Determine that management reinforced product safety throughout the product life cycle

- Is management familiar with the basic principles of product liability avoidance?
- Did managers make a clear assignment of product safety responsibilities and accountabilities during early commercialization?
- Was the management team focused primarily on an exit strategy to reduce financial pressure, thereby disregarding critical product safety and product liability avoidance concerns?

Confirm that patient and/or product safety information is fully documented and adequate analyses performed

- Has the company's commitment to product safety been demonstrated by requiring documented methods, processes, or procedures for communicating product safety concerns during product development and product design?
- Has the firm documented its hazard analysis/risk analysis in its product design history files?
- Has the firm included an appropriate analysis of raw materials for biocompatibility with design specifications for raw materials and components?
- Has the firm investigated the state-of-the-art of its product compared to predecessor and predicate products and demonstrated evidence of the worldwide literature review of hazard potentials cited in their risk analysis files?

Ensure that product warnings and instructions were adequate and properly tested

- Were the warnings and instructions identified as necessary during the design phase of product development included in the final design and final design documents?
- Are the product's warnings and instructions adequate for all of the potential users?
- Were warnings and instructions tested for accuracy

during the design phase following a standard operating procedure or guideline?

Validate the firm's training practices and procedures

- Has management adequately established an infrastructure for product safety by hiring and training qualified in-house personnel and making them available to integrate product liability avoidance principles into the firm's quality management system?
- Was staff adequately trained in product safety as a component of the quality management system, and is training documented?
- Does management understand that quality managers do not always have the training to manage the system to affect product safety and patient safety?
- Does management understand that training personnel to address product and patient safety is not the same as training personnel to manage the quality management system?

Confirm that the quality policy and quality management system are adequate and meet and exceed Food and Drug Administration (FDA) requirements

- Were references to patient safety and/or product safety included in the firm's quality policy, and does management understand the product liability loss control reason for doing so?
- Has management taken steps to ensure that device/drug safety and patient safety are an integral part of the company's quality management system?
- Does management understand that its corporate quality statement should reflect the importance of patient safety? *Management must be aware that it will be necessary to address specific product and patient safety risks presented by their devices.*
- Does management understand how critical it is for life sciences technology firms to be in compliance with FDA regulations during early commercialization, as product liability claimants will use any and all negative regulatory information to prove their cases?

CHECKLIST FOR ASSESSING VENDOR/SUPPLIER RISKS

Understanding the potential risk associated with the use of contract manufacturers, vendors and suppliers is part of a comprehensive risk analysis. Life Sciences Technology companies should be knowledgeable about the regulatory requirements and legal agreements and arrangements applicable to vendors and suppliers. In addition, these companies should validate vendor quality control practices and ensure that quality management protocols are being followed.

Verify that management understands the product liability risks presented by its vendors and suppliers

- ❑ Is management aware of the potential product liability risks that contract manufacturer (CMs) and original equipment manufacturers (OEMs) share with one another, and is management knowledgeable about risk shifting and risk protection methods available to them?

Confirm management's understanding of various legal and contractual issues associated with vendors and suppliers

- ❑ When conducting product liability coverage reviews of OEM and CM agreements, does the firm rely on insurers and insurance brokers, rather than using legal counsel?
- ❑ Is management aware of written, pre-manufacturing agreements between OEMs and CMs, as opposed to the use of standard purchase order agreements?
- ❑ Does the company have an effective operating contract with its vendors and do they test incoming supplies to make certain that vendors meet contract requirements?
- ❑ Does the firm understand that it is necessary to have contractual manufacturing agreements appropriate to the legal jurisdictions in which they plan to do business?

Confirm the type and extent of insurance coverage of each vendor and supplier

- ❑ Do the firm's CMs and OEMs carry product liability insurance on products they supply?
- ❑ Has the CM acquired indemnity protection from the product designer by being named as an additional insured on the designer's liability policy, and has the designer been named as an additional insured on the CM's product liability policy?
- ❑ Does management understand the need to have

certificates of insurance in place before starting a project or venture?


- ❑ Does the OEM that supplies components carry adequate product liability insurance?
- ❑ Does the manufacturer/designer require the CMs and OEMs to obtain product liability insurance coverage?

Verify that the company understands Food and Drug Administration (FDA) and/or European Union (EU) requirements applicable to vendors and suppliers and the company's related duties and responsibilities

- ❑ Is the company aware of FDA Quality System Regulation requirements and guidelines for CMs?
- ❑ Is the firm fully aware of FDA requirements for CMs? *Under certain circumstances, the FDA could hold both the contractor and manufacturer jointly responsible for activities performed.*
- ❑ Is the firm familiar with and has it implemented FDA and EU quality management system regulatory requirements for purchasing and contract manufacturing?

Confirm that the company has validated the quality management practices of its suppliers/vendors and has followed its own quality management standards

- ❑ Has the vendor's product been tested by the vendor? *A vendor should not simply rely on a prior Certificate of Conformity issued to the vendor. The vendor should determine if its quality system procedures are being followed by its employees.*
- ❑ Has the firm conducted an appropriate hazard analysis concerning raw materials and biocompatibility and selected a vendor that can deliver the material specified?
- ❑ Does the firm follow its quality management procedures to select vendors and audit vendors in a timely manner?
- ❑ Does the firm maintain control over its vendor relationships, and is it receiving the correct materials for manufacturing?



In addition to product liability, emerging companies should assess all risks stemming from operations, including risks that may be associated with accidents, business interruption, employment practices and the activities of its directors and officers. Medmarc, in conjunction with its strategic partners, The Hartford and BioMedic Insure offers insurance protection to meet the needs of emerging companies.

Created in 1979 by the healthcare technology industry, Medmarc's purpose is to be the superior provider of liability insurance protection and related risk management services at consistently fair prices and to support the development, testing and delivery of products that save lives and improve the quality of life. Further, through a strategic alliance with The Hartford and Biomedic-Insure, Medmarc policyholders benefit from all-lines property and liability insurance protection, loss prevention services and claims management tailored to the needs of life sciences technology companies.

**From Ideas and Prototypes to the Reality of Commercialization,
We Can Meet the Changing Needs of Life Science Technology Companies**

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