

# Rx For Risk

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## CHECKLIST TO IMPROVE YOUR PRODUCT LIABILITY LEGAL DEFENSE POSITION THROUGH CAREFUL DOCUMENTATION PRACTICES

By: Timothy J. Budacki, MS, CHCM, CEP, CPSM, Karen M. Murphy, J.D. and Sara E. Dyson, J.D.

Prudent document management can improve your product liability legal defense position. Your firm should ensure that its document standards, quality processes and internal and external documents and communications demonstrate a commitment to patient welfare and product safety. Carefully constructed documents and documentation of your processes and procedures are not only best practices but can assist your firm in defending itself should it ever become involved in product liability litigation. Poorly crafted documents—or lack of documentation altogether—can be a costly mistake. To protect your firm from potential liability, carefully and critically review your documents and create a document strategy. This checklist can serve as a guide for your review and analysis in the following areas:

PATIENT AND PRODUCT SAFETY  
 QUALITY MANAGEMENT SYSTEM  
 COMPLIANCE WITH FDA AND EU REQUIREMENTS  
 PRODUCT ASSESSMENTS AND TESTING  
 INSTRUCTIONS, LABELS, WARNINGS AND ADVERTISING MATERIALS  
 OTHER RECORDS, DOCUMENTS AND AGREEMENTS

### PATIENT AND PRODUCT SAFETY

Demonstrate a commitment to patient and product safety throughout the product development process. Begin with a well-crafted Quality Policy Statement, thoroughly document all processes and procedures, and provide clear assignments of responsibility. Consider the following...

- ❑ **Does the firm's Quality Policy Statement describe a commitment to patient and product safety?** *Quality policy statements should reflect a genuine commitment to patient welfare and product safety. Plaintiffs' attorneys have successfully argued that the absence of such a statement signifies that a firm is not committed to patient and product safety.*
- ❑ **Has the firm documented methods, processes and/or procedures for communicating its commitment to product and patient safety?** *Problems may arise when there are no documented methods, processes or procedures for communicating concerns about product and/or patient safety. Including these methods in the firm's business processes demonstrates the firm's commitment to product safety and patient safety; thereby, improving its legal defense position.*
- ❑ **Has the firm clearly assigned responsibility for product safety? Is the assignment documented?** *The lack of a clear assignment of product safety responsibilities and documentation of those responsibilities may have adverse consequences when defending a products liability claim.*
- ❑ **Has the firm included the principles of safety integration in the product development process for all phases of the device/drug technology life cycle and does the firm have documentation to verify its efforts?** *Firms cannot ignore the principles of safety integration in the product development process for all phases of the device/drug technology lifecycle and must ensure that there is sufficient documentation of its safety practices. A failure to do so may inadvertently open the firm to potential liability.*

## QUALITY MANAGEMENT SYSTEM

Establish that your firm abides by its Quality Management System (QMS) and ensure that the QMS incorporates product liability avoidance principles. Ask yourself...

- ❑ **Is the firm consistently following its QMS? Does it audit and document the results?** *The firm, through its documentation, should be able to prove that it is following its QMS. At trial, the firm's QMS documents and quality manuals could readily be used against the manufacturer if the firm does not follow, audit and/or document its QMS.*
- ❑ **Has the firm developed product liability avoidance principles, documented those principles and integrated them into their QMS?** *It is important to be able to establish an infrastructure for product safety. The lack of qualified persons in-house and available to integrate documented product liability avoidance principles into the firm's quality system documents may impede the firm's ability to do so.*

## COMPLIANCE WITH FDA AND EU REQUIREMENTS

Validate that U.S. Food and Drug Administration (FDA) regulations and the requirements of the European Union (EU) Medical Device Directive have been studied and compliance sufficiently documented. Documented training in FDA and EU requirements, as well as patient and product safety, demonstrates the firm's commitment to compliance and consumer protection. Consider the following...

- ❑ **Is the firm in compliance with FDA regulations and EU requirements and has compliance been adequately documented?** *Compliance must be documented in accordance with FDA regulations and the EU Medical Device Directive. Management failures that lead to product liability issues frequently occur due to noncompliance with FDA regulations, the EU Medical Device Directive and other regulations and requirements for clinical research.*
- ❑ **Is management aware of FDA regulations and EU Medical Devices Directive concerning requirements for the length and time involved in post study and has compliance been documented?** *Management must be aware of and understand the requirements imposed by the FDA and the EU Medical Devices Directive for the length and time involved in post clinical studies to ensure that there is adequate documentation to demonstrate compliance.*
- ❑ **Does the firm have a design control protocol that complies with FDA's Quality System Regulation (QSR) and the EU's EN ISO 13485:2003? Have the design steps been documented for each device manufactured?** *Ensure that the QMS includes all aspects of design control required by FDA's QSR 820.30 and the EU's EN ISO 13485:2003. In addition to a written design control protocol, there must be documentation demonstrating that the required design steps were followed when designing new products.*
- ❑ **Has the firm documented training of management staff in compliance with FDA and EU regulatory requirements? Does the firm conduct and document training on product safety?** *A firm leaves itself vulnerable to liability if there is a lack of documented management staff training as required by FDA's QSR and the EU's EN ISO 13485:2003 and documentation of production employee training. Ensure that there is proper product safety training.*
- ❑ **Has the firm established a clear, documented design protocol meeting FDA and EU regulatory requirements and appropriately documented its review of the sciences relating to human factors potentials?** *Some firms in early commercialization fail to establish hazard analysis stage gates in the firm's product development and design review processes and, as a result, cannot demonstrate an appropriately documented review of the sciences relating to human factors potentials.*

## PRODUCT ASSESSMENTS AND TESTING

Product assessments and product testing must be comprehensive, thoroughly documented, and in accordance with regulatory standards. Conformity with design specifications for raw materials and components also must be adequately documented. Failure to do so will leave your firm open to potential product liability issues. Ask yourself...

- **Does the firm conduct documented state-of-the-art technology assessments as part of its product development process? Were the firm's historic claims, past product litigation experience, customer complaints, medical device adverse event reports (MDRs) and warranty and Corrective and Preventive Action (CAPA) data integrated into the assessment?** *To satisfy FDA regulations, firms must clearly document how state-of-the-art technology assessments were conducted as part of the product development process. If the firm's historic claims, past product litigation experience, customer complaints, MDRs, and warranty and CAPA data are not integrated into the technology assessments, the firm can open the door to product liability exposure.*
- **Has the firm fully documented its product testing and included the information in the product history design files?** *While a firm may complete exhaustive testing of its product, the product design history files may inadequately document the hazard analysis; thereby, failing to demonstrate adherence to regulatory requirements imposed by the FDA and/or EU Medical Device Directive.*
- **Has the firm documented its analysis of raw materials for biocompatibility and for conformity with design specification for raw materials and/or components?** *A firm must conduct and document an appropriate analysis of raw materials for biocompatibility. It also must document conformity to a design specification for raw materials and/or components.*

## INSTRUCTIONS, LABELS AND WARNINGS

Adequate labels, warnings and user instructions are essential when it comes to patient and product safety and cannot be overstated when it comes to product liability litigation. Adequate instructions with comprehensive warnings must accompany a product if a product hazard is known or should be known. The firm also may be held liable for injuries associated with foreseeable misuses of its product, including abnormal uses that could have been protected against. This requires the firm to identify the hazards associated with its product and ensure that it has fully researched and documented them. Additionally, advertisements must be subjected to the same hazard analysis and critical review as the firm's labels, warnings and user instructions. Consider the following...

- **Does the firm have standard operating procedures (SOPs) or guidelines to document how they developed their warnings, labels and instruction?** *Firms must stand ready to defend the adequacy of its warnings and user instructions should they be questioned by the FDA and/or challenged by plaintiffs' attorneys. Product warning label instructions must be supported by adequate documentation of the testing of the warnings or instructions in order to demonstrate their adequacy. Establish standard operating procedures (SOPs) and/or adopt guidelines for documenting how the firm developed its warnings, labels and user instructions.*
- **Has the firm fully documented its warnings and user instructions in relationship to its hazard analysis documents and has it followed up in its final design documents?** *Ensure that warnings and user instructions are itemized as a control method in hazard analysis documents. Additionally, make certain that they are followed up on in the final design and/or design documents.*
- **Has the firm's advertising materials been subjected to the same level of documented hazards analysis and critical review as labels, warnings and user instructions?** *Product warranty claims and liability allegations also can arise from advertising materials. The firm should ensure that its product works as claimed in its product advertisements.*

## OTHER RECORDS, DOCUMENTS AND AGREEMENTS

The firm should establish a records retention policy and have sufficient internal controls in place to guard against the possibility that its own documents will be used against it in a legal matter. Clinical research documents and agreements should be reviewed for potential product liability exposures. The firm should have written agreements with its original equipment manufacturers (OEMs) and contract manufacturers (CMs) to avoid compliance and legal issues. Ask yourself...

- **Has the manufacturer exercised effective control over the quality and content of its written records?** *Plaintiffs' attorneys rely on the defendant manufacturer's own poorly conceived written records to win their cases. Document retention policies and training programs can mitigate "smoking gun" documents retained in a firm's own records.*
- **Do the clinical research documents/agreements contain any hidden product liability exposures? Were the documents reviewed by legal counsel familiar with research, insurers or brokers for coverage limits and indemnification clauses?** *Clinical research documents/agreements may contain hidden product liability exposures. Too often these documents/agreements are not reviewed by legal counsel familiar with clinical research or by insurers or brokers for issues related to coverage limits and indemnification clauses.*
- **Does the firm have written pre-manufacturing agreements with its OEMs and CMs?** *Avoid potential problems by creating written agreements between the firm and its OEMs and CMs. The lack of written pre-manufacturing agreements between OEMs and CMs leaves the firm to rely on the less effective terms and conditions of a standard purchase order agreement.*

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.

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Inquiries regarding Medmarc should be directed to:

**Eastern & Midwestern States**

Bill Igoe  
(800)-356-6886 ext. 330  
bigoe@medmarc.com

**Western & Pacific States**

Cindy Melocik  
(800)-356-6886 ext. 337  
cmelocik@medmarc.com

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