

Employee Training: Developing Warnings & Instructions to Reduce Products Liability Risks and Communicate Effectively

It is important for manufacturers to understand that while they must comply with FDA requirements related to warnings and instructions, manufacturers do not receive an absolute defense in products liability cases when they do. The FDA may find a particular warning or instruction to be adequate, but the standards for what constitutes an adequate warning or instruction under products liability law are different from the FDA's requirements, meaning that **FDA compliance does not prevent products liability exposures from arising from warnings and instructions.**

Manufacturers, have considerable flexibility when it comes to the development of warnings and instructions and should ensure that they are designed to minimize products liability risks. This course provides participants with **key information about products liability law as it relates to warnings and instructions.** It covers the fundamentals of failure to warn claims, describes the characteristics of adequate warnings and instructions, and suggests “**best practices**” that manufacturers can use to reduce products liability risks and improve the information they provide to health care professionals and patients.

Course Overview: This course:

- Explains **common law and state products liability law**, including a manufacturer's duty to warn and the importance of an “adequate” warning;
- Describes the relationship between **regulatory requirements, industry standards, and products liability**;
- Discusses **case studies** about warnings and instructions that have been deemed inadequate and the related products liability consequences;
- Identifies the **common mistakes** that manufacturers make when developing warnings and instructions;
- Describes how a **label's format and appearance** can impact its products liability risk;
- Emphasizes the need to **integrate** the development of warnings and instructions **into the product design process**;
- Teaches participants to **recognize** the characteristics of **effective and “adequate” warnings and instructions**; and
- Provides “**best practices**” for **writing effective warnings and instructions** that may reduce products liability risks and enhance communication with health care professionals and patients.

Course Format: PowerPoint presentation, group discussion, small group break-out sessions and exercises, questions and answers.

Contact your broker or our Loss Control Department to schedule a training session. Our Loss Control Department offers a variety of educational programs designed to assist medical technology and life sciences companies with reducing their potential products liability exposures. Our training programs may be included as a complementary service to our policyholders or are available on a discounted basis, depending on the specific needs of the company. We also conduct these programs for companies that are not insured by Medmarc on a fee-for-service basis.