

Medmarc *Protect*™

Risk management solutions for the medical technology and life sciences industry



Integrated Risk Management Services: Products Liability and Regulatory Compliance

A medical technology and life sciences company should build its quality management system to meet both products liability risk management and regulatory compliance objectives. Through Medmarc *Protect*, we offer medical technology and life sciences companies **products liability risk management and regulatory compliance assistance** designed to improve quality management systems.

What are “integrated” risk management services?

Companies typically build their operational infrastructure to meet the regulatory requirements of the Food and Drug Administration (FDA). A company that does so without also considering products liability risk mitigation is missing an important opportunity to minimize the potential for costly litigation. Medmarc’s integrated risk management services are designed to assist companies with incorporating products liability risk management into FDA-required quality management systems.

How do you determine the scope of a project and develop a work plan?

Medmarc can assist a company with rebuilding a single function, such as its recall infrastructure or compliant handling system, should the company discover that the function is not meeting its needs. Medmarc also can help a company implement improvements throughout its quality management system.

Our integrated risk management services are designed to be tailored to a company’s particular needs. We work closely with a company’s management team to identify project requirements and then develop a customized service proposal.

Who performs your integrated risk management services?

Depending on the project requirements, we use the expertise of attorneys, engineers, regulatory compliance, and insurance specialists. After we identify a company’s particular needs, we assemble a team of industry experts best suited to develop and implement tailored solutions.

Can you conduct “mock” FDA audits?

Yes. By law, the FDA must audit medical technology and life sciences companies every two years. Many companies seek the assistance of regulatory compliance specialists who conduct audits similar to those conducted by the FDA as a means of identifying and correcting potential weaknesses before they emerge during actual FDA audits.

Medmarc can provide its policyholders with mock FDA audits at a discounted rate. Medmarc also can provide mock FDA audits to companies it does not insure on a fee-for-service basis.

The services provided through Medmarc *Protect* are available to Medmarc’s policyholders on a complimentary basis or are offered at a discount, depending on the company’s specific needs. We also provide our services to companies not insured by Medmarc on a fee-for-service basis. **Contact your broker or our Loss Control Department for more information.**

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