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How the Right Liability Insurance Carrier Can Protect Your Life Sciences Business

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Introduction

Major corporations get the most attention in medical technology (medtech) and life sciences, but many new products and therapies come from small and medium-sized companies, some of which are bringing their first innovations to market. And those players often don't know what they don't know about risk management and products liability.

This playbook will help equip company leaders to understand the essential features of a liability policy, select the appropriate liability insurance carrier and broker for their needs, and protect their businesses if something should go wrong. With insights from experts at Medmarc, this playbook provides a clear roadmap for any company innovating in medtech and life sciences.

SECTION 1:

Overview of Life Sciences Liability Insurance

Every industry faces some level of liability risk. That's why every appliance manual starts with page after page of safety warnings and why every other billboard seems to advertise a personal-injury attorney.

Life sciences companies face unique challenges. Their products interact closely with the human body and can lead to unpredictable or disappointing outcomes. The best drug or medical device, even when used as directed, may not always result in expected or desired results. The stakes are high whether the company is in clinical trial phase or commercialized.

Products liability coverage is an essential tool for safeguarding your business's balance sheet and reputation. From the start-up stage through commercialization and success, it helps you manage risks that could otherwise doom your business to failure.

> *"You want to have coverage for any clinical trial because people are going to be exposed to your product. And once you're ready for commercialization, you should have a policy in place on day 1."*
>
> Kate Klaus
> Senior Risk Management Attorney, Medmarc

What's Covered

Life sciences policies are tailored to each business, but they can cover a vast array of medical devices and in vitro diagnostic, biotechnology and pharmaceutical products. That can include everything from syringes to prescription drugs to artificial limbs.

What's covered is important. So is who's covered. A policy should cover additional insureds such as:

- Vendors
- Scientific advisory boards
- Sales reps, service techs, and product training and support staff
- Clinical research organizations
- Institutional review boards
- Independent engineers and consultants
- Medical staff members

In short, you should seek coverage that accounts for every potential liability. Your business's future could lie in the balance.

COUNTING THE COST

How much a policy costs depends on many factors. To start, most underwriters will base their initial pricing on your type of product and your global sales figures, and for clinical trial stage companies, the number of enrolled participants in the trials. Underwriters review the company's track record and safety practices, then compare what its history of adverse events looks like compared to those of competitors. Underwriters also look at similar products and any issues they've had.

SECTION 2:

Identifying a Liability Insurance Carrier

In most industries, an insurance provider is just that: a provider. In life sciences, the best insurance providers are more like risk management partners. They offer liability coverage, of course, but they also work with clients to minimize potential risks and support them through any litigation or arbitration that arises. That requires a good understanding of both insurance and the medical products field.

"What you're purchasing is not just the policy itself; you're purchasing the institutional knowledge and the services that come along with the policy," Klaus says. "So look for a company that can be a good partner to you as you're building your business and putting your products out there."

While some carriers support companies in many industries, others, like Medmarc, specialize in medtech and life sciences. In fact, Medmarc was founded by the medical technology and life sciences industry in 1979. That year, 31 companies that were members of the Healthcare Industry Manufacturing Association (the predecessor of AdvaMed), created Medmarc to be a permanent solution to the volatile products liability insurance market.

> ***"We have employees who've been here for over 30 years, and bring their deep knowledge and experience to work every day.***
>
> Andy Hall
> Executive Claims Specialist, Medmarc

As you're considering risk management partners for your business, here are 6 questions to ask:

1. How long have you covered life sciences companies, and what expertise do you have?
2. Does coverage extend to newly acquired or formed organizations?
3. Does coverage extend to new clinical trials initiated during the coverage period?
4. What technical support do you offer?
5. What legal support do you offer if we're sued?
6. Do you offer worldwide coverage and support if claims are brought overseas?

COVERAGE OVERSEAS

Every country has its own rules around products liability and litigation. If you're selling into or conducting a clinical trial in another country, make sure your carrier has networks that can help you get locally admitted coverage there.

"Worldwide coverage is a key feature," Hall says. "And on the claims side, be sure your carrier can get you quality help in a foreign country when you need it."

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SECTION 3:

Identifying a Life Sciences Insurance Broker

A licensed insurance broker can help you find the right carrier—and a whole lot more. "The brokers we work with especially are not really trying to sell you things as much as advise you on what you need and when you need it," says Lynn Carney, Director of Agency and Alliances at Medmarc. "They do a great job of educating clients and then using our risk management department for services such as reviews of contracts with customers or informed consents in clinical trials."

Brokers can help companies obtain many forms of coverage, including workers' compensation, auto, and cyber insurance. As with carriers, the best brokers tend to have expertise in medtech and life sciences. Some even have science backgrounds.

If you aren't sure where to start, Carney recommends contacting Medmarc first. Different brokers have different size requirements for their target customers, so some may not want to service start-ups. Others may not specialize in life sciences and therefore not understand the ins-and-outs of your company's products and services.

"Since we specialize in medtech, we have curated a list of brokers across the country that work with medtech companies of all sizes and technologies."

Lynn Carney
Director of Agency and Alliances, Medmarc

SECTION 4:

How to Keep Yourself Out of Court

Benjamin Franklin famously said there's nothing certain but death and taxes. Many business owners would probably add litigation to Franklin's list. However, there are steps your company can take—beyond having good liability coverage—to reduce the chances you'll end up in court.

Here are 6:

1. **Benchmark your competitors.**

Klaus recommends studying how the competition addresses safety. "Are you meeting or bettering what they're doing?" she asks. "Are they using safeguards that you've decided not to employ? If so, is there a good reason?"

2. **Rely on your insurance carrier.**

"We can provide guidance on regulatory strategy and look at risk shifting in contracts," Klaus says. "I spend a lot of time doing site visits with our policyholders to evaluate their risk management practices and give them suggestions based on the 45 years of data Medmarc has on companies that are operating in this space."

3. **Carefully craft informed consent documents.**

"The informed consent document should be written in a really clear manner that's easily understood by a layperson," Klaus says. "Are they doing the informed consent on video so they have proof of exactly what questions were asked and how they were answered?"

4 **Police your partners.**

Ensure that your additional insureds aren't putting you at risk. "With clinical trials, we want to ensure that the sites and the investigators are assuming responsibility for the actions of their own people," Klaus says.

5 **Go overboard on safety and documentation.**

"If you do those things, if you're creating a safe product, you may not be able to avoid a lawsuit, but we're going to be in a much better situation than if you don't," Hall says.

6 **Heighten your focus on product safety.**

Previously, juries were more inclined to trust companies that adhered to FDA regulations and obtained their approval. Nowadays, many jurors view FDA approval as merely a basic safety benchmark.

SECTION 5:

What to Do When Things Go Wrong

Despite your best efforts, problems can occur—anything from isolated injuries to massive lawsuits. (That's why you have products liability coverage, of course.) If the worst happens, you should take steps to mitigate the damage to your company.

The first step is to reach out to your insurance carrier. This may be the first incident your company has faced, but it's most assuredly not theirs. "This is what we do every day," Hall says. "It's hopefully something the insured doesn't encounter very often."

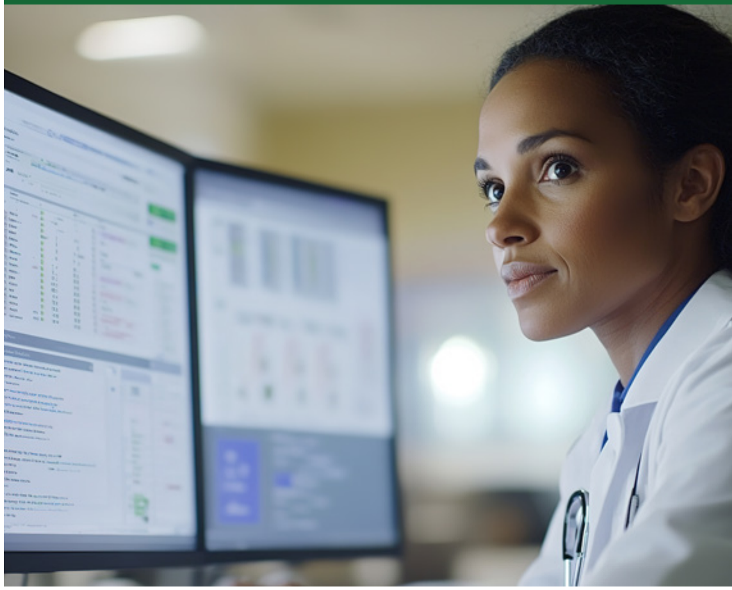
"We'll ask if they're pulling back product as needed, if they've contacted FDA, if this is the kind of problem where they need to hire a crisis-management team," Klaus says.

It's also important to take every incident seriously. For example, even if the number of incidents is statistically insignificant—say 2 in 200,000—you should still investigate and take appropriate action. "At the end of the day, if you're facing a jury, they're just people trying to figure out if you're a good company or not," Hall says.

Medmarc often takes additional steps, such as counseling clients to train employees who may be deposed with some frequency. "We'll work with you to make those folks good witnesses who are familiar with the process," Hall says. "We see that kind of thing as a long-term benefit to both the insured and Medmarc."

WHY DOCUMENTATION MATTERS

Hall believes many large verdicts, including so-called nuclear verdicts (exceptionally high jury awards typically $10 million or more) happen when defendants appear to have cut corners to save money. "There are many other considerations, but that's the way folks look at it," Hall says. "By documenting your decision-making, you can defend your actions in a way that makes you look the most credible."



SECTION 6:

Liability Coverage Checklist

As we've noted throughout this playbook, liability coverage is essential for medtech and life sciences companies. Here are 6 key actions every company should take to protect itself.

- [ ] 1. Select a broker and an insurance carrier with expertise in medtech and life sciences.
- [ ] 2. Obtain coverage for the appropriate people, sites, and markets.
- [ ] 3. Ensure that trial protocols are solid and that everyone involved is adhering to them.
- [ ] 4. Ensure that informed consents are truly informed and that there are no red flags (such as inordinately high compensation for trial participants).
- [ ] 5. Document your decisions, especially those related to safety.
- [ ] 6. Inform your carrier if issues arise.

Conclusion

You've invested countless hours in the products you've created. While you don't have to spend that much time thinking about products liability coverage, you do need to select a carrier that can help you protect yourself and your company so you can continue delivering life-changing innovations to the patients who need them.

We hope this playbook has given you the resources to get started. And we look forward to talking with you about your needs. At Medmarc, your success is our success.

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Founded by the industry in 1979, Medmarc is the leading expert in the product liability risks facing medical technology and life sciences companies. We understand the unique risks these companies face and specialize in providing insurance and risk management solutions designed to respond to the industry's particular needs.

Learn More

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