

Life Sciences: Where Innovation Meets Risk

The life sciences industry, long known for its innovation and complexity, continues to evolve at a remarkable pace. From AI-powered diagnostics to wearable monitors and at-home genetic testing kits, today's technologies are changing the way products are developed, distributed and used. This introduces new exposures to an industry that many carriers are still learning how to manage.



Technology and emerging risks

Pricing and capacity in the life sciences insurance marketplace have remained generally stable. However, carriers are increasingly focused on understanding the nuanced risks that come with new technologies. These risks can include cyber vulnerabilities, diagnostic inaccuracies driven by algorithms and liability concerns tied to consumer-facing platforms.

AI and machine learning are transforming diagnostics, clinical trials and patient monitoring. These tools can improve accuracy, cut costs and shorten development cycles. But with advancement comes uncertainty. AI-enabled platforms used to interpret scans, predict outcomes or flag patient risks carry the potential for misdiagnosis—and with it, the possibility of bodily injury claims or professional liability allegations, especially in failure-to-warn scenarios. Even a false negative from a home testing kit can delay treatment and lead to costly, high-severity claims.

The same technologies that streamline care can also create points of failure. Many direct-to-consumer (DTC) platforms collect large volumes of personal health data, making them attractive targets for cyberattacks. A data breach that exposes genetic or biometric information could trigger HIPAA violations, class action suits or long-tail reputational harm.

Meanwhile, the lines of medical liability are becoming harder to define. When a consumer uses a wearable or home testing kit, who is responsible for the outcome? The device manufacturer or the data platform or the healthcare provider? These questions are testing the limits of traditional product and professional liability policies.

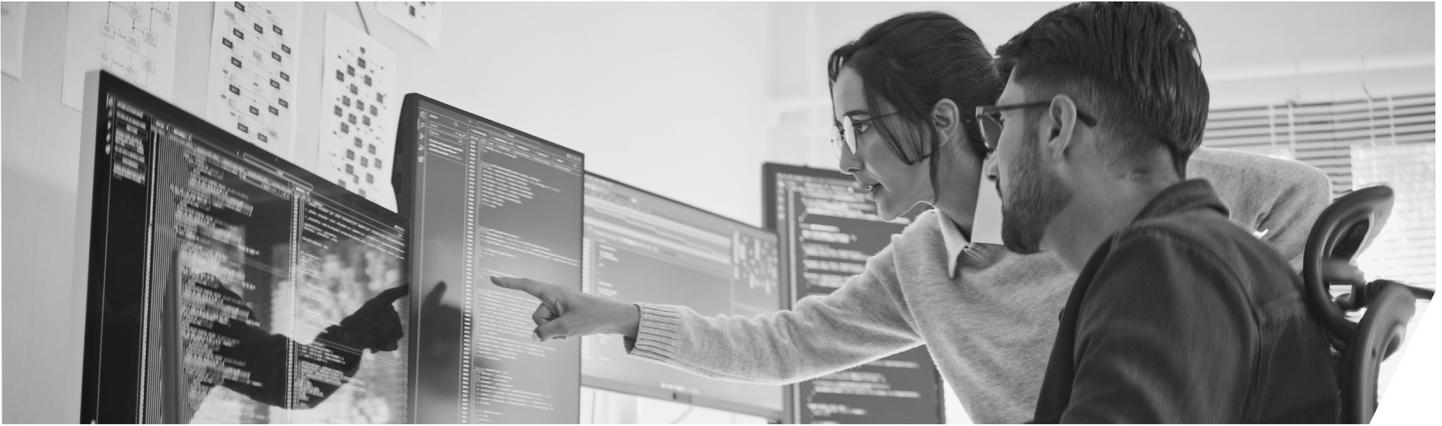
[Read more about the importance of cyber security and liability coverage in healthcare here.](#)

Data privacy pressures

As this sector leans into digital-first delivery, data protection must keep pace. HIPAA remains the foundational framework when it comes to privacy, but many new platforms, especially DTC diagnostic tools, operate in regulatory gray zones without the oversight or safeguards common in clinical settings.

The healthcare and life sciences industries have always been ripe for cyber attacks and the stakes are growing. Consumers expect both accuracy and security when using digital health platforms, and regulators are increasingly holding companies to those expectations. Breaching one of these, even unintentionally, could result in claims that blend cyber, professional and product liability.

According to the 2024 Ponemon Institute Report, 92% of surveyed US healthcare organizations experienced at least one cyber attack in the last 12 months.



Classes under pressure

Certain product categories remain under heightened scrutiny, not only for their medical risk but for the technological ecosystems they operate within. Biologics, mesh implants and weight-loss drugs like semaglutide have drawn increased litigation due to uncertain long-term effects, off-label use and rising demand.

Other fast-evolving categories include:

- AI-based diagnostic software: often integrated into hospital systems or sold as decision-support tools for providers
- Wearable health monitors: capable of real-time data transmission and intervention alerts
- At-home testing kits: offering genetic analysis, hormone tracking or chronic condition screening

These tools present overlapping exposures, from software failure and user error to data security. Coverage concerns span bodily injury, data security, E&O exposures and compliance with evolving FDA and privacy standards.

Even with clinical validation, the legal and regulatory frameworks are still catching up, and underwriters are paying close attention.

Pricing and capacity

Although the life sciences insurance market remains broadly stable in terms of pricing and available capacity, carriers are exercising more caution. Accounts involving high-profile products, emerging technologies or past losses may face tighter terms or higher retentions. As the life sciences industry becomes more technologically centered, underwriters will have to change with it.

Coverage now depends on how well the insured can demonstrate controls not just in a lab or clinical setting, but digitally as well. Proven data governance, secure systems and transparency in how AI or algorithms are used all help mitigate underwriting concerns.

Reframing risk

The life sciences industry is advancing quickly, and the insurance solutions supporting it must evolve just as fast. Brokers and carriers who understand both biotech and health tech will be best positioned to navigate this changing landscape.

That means staying ahead of regulatory changes across AI and digital health, building policies that reflect multi-layered exposures, and forming deep relationships with underwriters who understand these nuances.

We help you win

When it comes to work as vital as developing and distributing health products, companies deserve more than just insurance – they deserve a lifeline. That’s where Amwins steps in with bespoke insurance solutions that keep pace with your client’s innovations.

It’s critical to partner with a wholesale broker with deep knowledge of exposures, insurance coverages, and carriers operating in the life science and nutraceutical industries to ensure your clients are properly protected. Amwins is that partner.

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To learn more about how Amwins can help you place coverage for your clients, reach out to your local Amwins broker.

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