State of the Market

Life Sciences Insurance Market Update

2024 Outlook

BRP

OVERVIEW

In 2024, the life sciences landscape remains deeply shaped by changes that occurred in response to the COVID-19 pandemic. As a means to nurture continued growth and innovation, the strategies and initiatives that entities adopted out of necessity have fostered unprecedented growth in the industry. Like in 2023, the market remains focused on several key areas, including decentralized clinical trials (DCTs), psychedelic drug therapy research, gene therapy and editing, wearable devices, and artificial intelligence (AI).

In addition to these continued areas of focus, looking ahead at 2024, life sciences companies will need to stay abreast of the significant regulatory changes that came into effect the second half of 2023. These include the SEC's new cybersecurity rules and updates to the FDA's 510(k) program. This year, the industry also remains focused on the impacts of growing geopolitical conflicts like the Russia-Ukraine war and Israel-Hamas conflict and their impact on critical dependencies like employee safety, clinical trial viability, and supply chain stability.

For life sciences companies, the commercial P&C insurance market remains stable, with most lines seeing healthy capacity and competitive pricing. Property and stock throughput do remain challenging due to sustained loss patterns driven by natural disaster and geopolitical exposures. Because of the complexity of these companies' exposures, partnering with a dedicated team of insurance advisors embedded in the life sciences industry can help organizations protect their operations for continued innovation and success.

KEY CONSIDERATIONS AND INSURANCE MARKET TRENDS

Regulatory Landscape

New SEC reporting requirements

In July 2023, the SEC adopted new requirements for companies to address cybersecurity risks. These new rules increase board members' and executives' responsibilities regarding cybersecurity and have two main components Firstly, all U.S.-listed companies must disclose material cybersecurity incidents within four business days of determining that a cybersecurity incident is material, with materiality not yet defined by the SEC. Companies must also disclose their cybersecurity risk management, strategy, and governance on an annual basis. To ensure compliance and gain clarity, companies should monitor these new requirements for any new developments and guidance from the SEC.

FDA modernizes 510(k) program

There were several significant changes to the FDA's 510(k) program in late 2023 that will impact the way life sciences conduct business in 2024. The FDA unveiled a trio of draft guidances in September 2023 which modernize the 510(k) program.

The three draft guidances are:

- Best Practices for Selecting a Predicate Device to Support a Premarket Notification 510(k) Submission [1]
- Recommendations for the Use of Clinical Data in Premarket Notification 510(k) Submissions [2]
- Evidentiary Expectations for 510(k) Implant Devices [3]

In addition to these draft guidances, the FDA also issued final guidance on informed consent for IRBs, clinical investigators, and sponsors on August 15, 2023. [4] On September 27, 2023, the FDA unveiled final guidelines for cybersecurity in medical devices, providing recommendations on how to make medical devices more resilient to cybersecurity threats. [5] Finally, the FDA announced that as of October 1, 2023, all 510(k) submissions (unless exempted) must be submitted as electronic submissions using virtual platform eSTAR, whereas before all submissions had to be filed on paper. [6]

Key Coverage Lines

Property

For life sciences companies, property insurance remains the most challenging coverage. Sustained losses due to weather events, inflation, supply chain issues, and reinsurance capacity market have contributed to continued rate instability. Buyers can expect heightened underwriting scrutiny over the proper valuation of facilities and equipment. Geographic location, asset class, and loss history will be the primary drivers of rates.

Stock throughput and transit

Globally in 2024, the geopolitical environment is seeing mounting instability, with conflicts worsening and amplifying one another. These events shape trade policy, economic growth, and supply chains in ways that pose great operational risks to life sciences companies. For the life sciences industry, supply chain delays disrupt project timelines and can cause spoilage.

Just as supply chains began to stabilize in 2023, conflict broke out in the Middle East. Consider this: due to the disruption from attacks by the Houthis, in the first week of January 2024, the number of container ships at the mouth of the Red Sea on their way to or from the Suez Canal was down 90 percent compared with the start of 2023.[7] These types of events have led to increased losses in the stock throughput insurance and transit insurance markets. From an insurance perspective, companies with geopolitical and supply chain exposures need to be able to demonstrate to underwriters what steps they are taking to strengthen their operations by finding alternate suppliers to reduce the likelihood of claims.

Builder's risk

With supply chains impacting the availability of raw materials and goods, recent conflicts have created delays and hurdles in construction project completion. As a response to losses, insurance companies have raised rates and reduced capacity. Insurers will continue to monitor the developments of global events and how they impact loss patterns in builder's risk.

Pollution

Throughout 2023, there were over $700 million in jury awards and settlements related to ethylene oxide litigation. [8] Ethylene oxide is used to sterilize medical devices and some foods and spices and is a known carcinogen. Due to increased litigation involving the use of ethylene oxide, there is now increased demand for pollution liability coverage. In spite of increased claims activity, there is still capacity in the pollution liability market.

Product liability

In 2024, the product liability market is currently seeing softening. For the life sciences industry, there is healthy capacity and competitive rates for product liability for this line due in large part to new market entrants.

Cyber

The cyber liability market is currently coming off a year of rate stabilization. Insurance companies remain focused on the security controls and policies companies have in place when determining the pricing, terms, and conditions of coverage. Throughout 2023, several cybersecurity laws and regulations came into effect at both state and federal levels, including the SEC's new guidelines. Organizations should focus on investing in strong cross functional processes to meet regulatory obligations and cybersecurity best practices, which will also improve outcomes in cyber liability market.

Clinical trial liability

The clinical trial liability market is also currently softened because of new entrants that have created abundant capacity.

Directors & Officers (D&O)

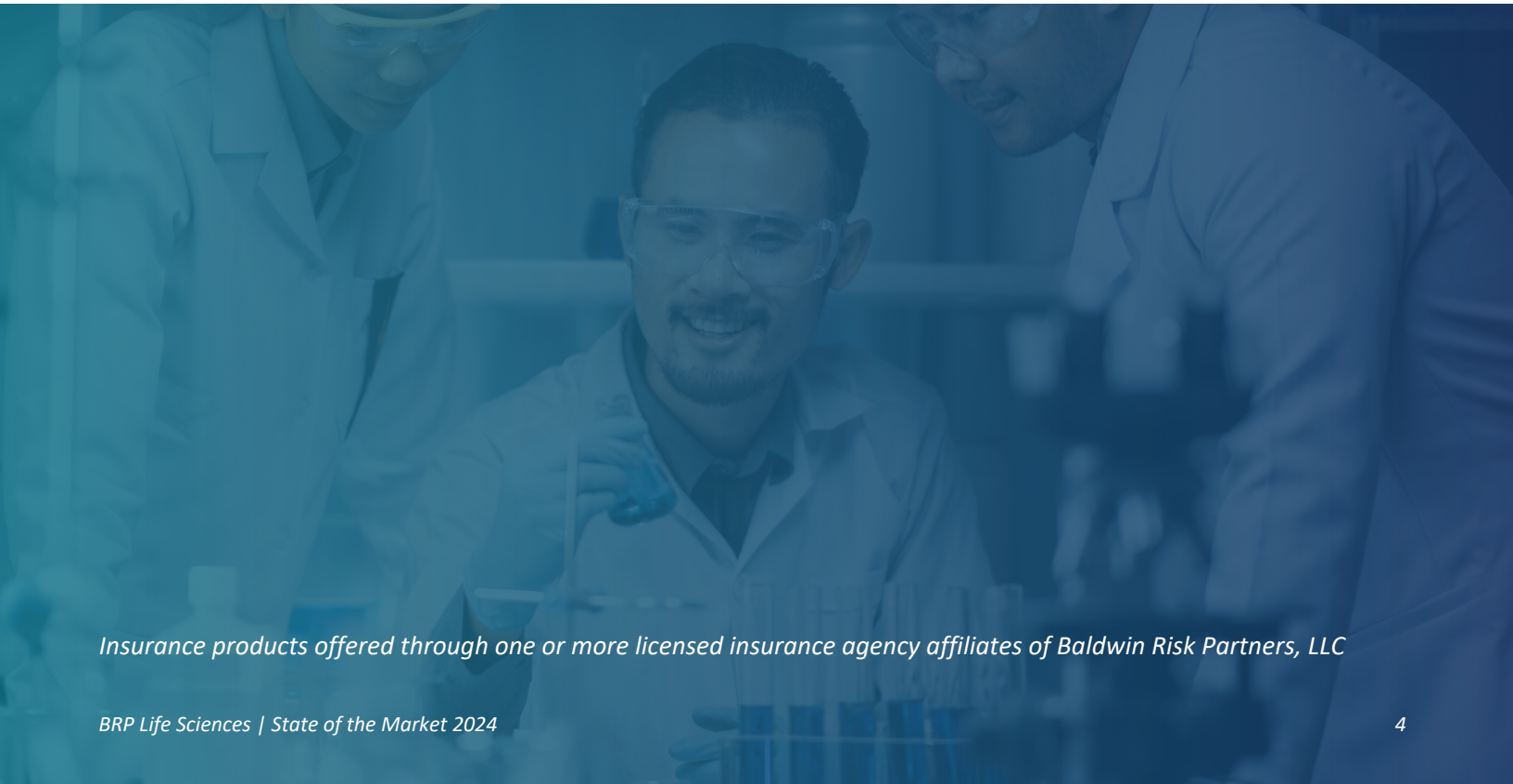
Environmental, social, and governance (ESG) initiatives and policies will continue to influence the life sciences companies and their executives, with its impact only growing. Because there is no one clear definition of ESG, reporting standards and expectations are inconsistent. Additionally, different stakeholders' positions on ESG can vary greatly. To avoid D&O claims, life sciences companies need to stay abreast of claims that may arise from stakeholder's sentiments on ESG and allegations of wrongdoing. Additionally, failure to comply with regulations like the SEC's and FDA's new guidelines could lead to claims.

In spite of these developments, the D&O market for both public and private companies has generally softened due to increased competition and great capacity from new market entrants.

YOUR PARTNER FOR SUCCESS

As you navigate the challenges and opportunities in the life sciences industry and insurance market, partnering with a specialized insurance advisor who understands and speaks your language will help you stay ahead of risk so that you can pursue your goals and innovate. Our dedicated team of experts have expertise in all areas of the life sciences industry, and the insurance products that best support these complex operations. Working as an extension of your organization, your advisory team will help you find the right coverages for your specific business needs, be prepared for renewal, and best represent you in front of underwriters.

Discover a partnership with us to innovate with confidence.



1 U.S. Food & Drug Administration, "Best Practices for Selecting a Predicate Device to Support a Premarket Notification [510(k)] Submission: Draft Guidance for Industry and Food and Drug Administration Staff," September 7, 2023

2 U.S. Food & Drug Administration, "Recommendations for the Use of Clinical Data in Premarket Notification [510(k)] Submissions: Draft Guidance for Industry and Food and Drug Administration Staff," September 7, 2023

3 U.S. Food & Drug Administration, "Evidentiary Expectations for 510(k) Implant Devices: Draft Guidance for Industry and Food and Drug Administration Staff," September 7, 2023

4 U.S. Food & Drug Administration, "Informed Consent: Guidance for IRBs, Clinical Investigators, and Sponsors," August 15, 2023

5 U.S. Food & Drug Administration, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions: Guidance for Industry and Food and Drug Administration Staff," September 26, 2023

6 U.S. Food & Drug Administration, "510(k) Submission Process," October 3, 2022

7 FCIA Trade Credit & Political Risk, "Major Country Risk Developments January 2024," Byron Shoulton, January 2024

8 Verisk, "A Primer on Ethylene Oxide for P/C Insurers," Greg Scoblete, January 25, 2024