

5 BIGGEST CHALLENGES FOR LIFE SCIENCES IN 2024: HOW TO OVERCOME THEM WITH INNOVATIVE TECHNOLOGIES

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Organizations in the life sciences sector faced many difficulties in 2023: a drop-off in fundraising, low market valuation, higher costs for capital expenditures, unstable supply chains, ongoing federal negotiations over drug prices, pharmaceutical shortages, and costs eroding profitability, among other issues.

While some of these challenges continue to impact life sciences, there are five issues in particular that have become a priority for life sciences leaders in 2024.

This article explores the top five obstacles facing life sciences companies this year and how they can be resolved.

5 TOP LIFE SCIENCES CHALLENGES AND HOW TO RESOLVE THEM

A core element of combating the difficulties life sciences leaders are currently facing, will be the proper implementation of innovative technologies.





Effectively leveraging generative AI (genAI)

The life sciences industry has been leveraging artificial intelligence (AI) long before its current popularity. However, generative AI (or genAI), which utilizes models to generate new data based on pattern and structure training, has emerged with great promise. GenAI's traction in the marketplace is largely the result of improvements to large language models (LLMs) that have accelerated training and compiling with vast amounts of complex data.

These new capabilities enable genAI to support life sciences by developing new content and optimizing processes. This can range from novel chemical compounds and patient simulations to identifying novel drug candidates and automating chemical reactions. GenAI can also increase the efficiency of clinical trial designs by selecting ideal candidates and predicting trial outcomes, which can translate to higher success rates in drug development.

The ability to bring new therapies quickly to market, improve diagnostic accuracy, and reduce research and development costs are helping to transform and accelerate drug discovery and personalized medicine.

However, navigating the deployment of advanced and emerging technologies, requires life sciences organizations to engage in collaborations, and enter partnerships to drive performance by sharing expertise and skill sets, as well as resources, capital, and complementary technologies.

As a result, consultants play a vital role in helping life sciences companies comply with a growing body of regulations and establish guidelines for the ethical use of AI and data access. Technology partners in AI, cybersecurity, and data analytics, to name a few, can work together to ensure the security, reliability, access, and quality of data, as well as the diversity, unbiased nature, and comprehensiveness of datasets.

Partners can also support ongoing training alongside rigorous testing and monitoring. Life sciences companies need to work with all their partners to ensure that they are leveraging AI responsibly and to its full potential while upholding regulatory compliance.

Demand for drug pricing transparency

The Inflation Reduction Act's (IRA) drug negotiation provision has drawn fierce industry opposition, with some life sciences companies proactively restructuring their licensing and partnership agreements to decrease royalty payments should price negotiations affect drugs entering the market.

While lawsuits challenging the provision's constitutionality are likely to delay compliance, life sciences companies can lessen the impact of drug negotiations on revenue by deploying innovative technologies.

Such technologies will help to increase speed to market and lower the cost of developing drugs in the long term. GenAI, among other digital tools, and advanced smart automation and data analytics technologies, can drive workflows and cost efficiencies by increasing accuracy. This empowers life sciences companies to enhance their decision making across the drug development lifecycle. Ultimately, these applications will help increase patient safety and access to therapeutics.



Supply-chain upheaval

A myriad of factors, including climate change and geopolitical events have highlighted the current weaknesses of supply chains, and an overreliance on overseas suppliers or single manufacturing sites. This, coupled with the impact of regulations, necessitates life sciences companies to reconsider their supply chain strategies.

Indeed, <u>The Drug Supply Chain Security Act</u>, which went into effect in November 2023, requires all pharmaceutical supply chain stakeholders to "achieve interoperable, electronic tracing of products at the package level to identify and trace prescription drugs as they are distributed in the United States." This is to ensure that patients are protected from compromised drugs by improving detection and removal from the market.

However, despite these challenges, <u>only 44% of life sciences companies</u> are currently leveraging technology to calculate how scenarios such as these will impact their supply chains and outcomes (Supply Chain Management Review, 2024).

Utilizing innovative technologies and technology solution partners is therefore critical, to benefit from their cybersecurity, data analytics, AI, robotic process automation, and performance tracking/visibility capabilities:

- Cybersecurity: To protect data and assets
- Agility/adaptability: To withstand unpredictable environments
- **Sustainability:** To reduce environmental impact and enhance long-term resilience
- Transparency: For regulatory compliance
- **Robust, forward-looking partnerships:** To foster innovation and speed to market





Enabling new innovative modalities

In 2023, 30 gene therapies, 29 RNA therapies, and 65 non-genetically modified cell therapies were approved globally for clinical use, while 3,951 therapies are currently in development, ranging from preclinical to pre-registration (**Technology Networks, 2024**).

Emerging technologies such as genAI are rapidly empowering the development of these new modalities. However, life sciences companies need to ensure that they have the right infrastructure (including supply chain and manufacturing sites), policies, and resources to effectively bring new therapies to market. Technologies will also need to be appropriately managed and harnessed as they are developed in order to yield the best results.

These complexities require life sciences companies to work closely with their technology providers and other partners. This is critical for ensuring that the speed of their drug discoveries is equaled by their ability to protect data and assets, enhance patient safety, meet regulatory compliance, and manage the drug discovery lifecycle in a cost-effective and efficient manner.

5 The regulation of laboratory-developed tests (LDTs)

Both the U.S. Food & Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS) have emphasized that the proposed rule to regulate LDTs as medical devices was designed to ensure the consistency and accuracy of diagnostic tests.

Specifically, it addresses concerns that LDTs have led to inappropriate or ineffective therapies, incorrect diagnoses, and over- or undertreatment of diseases. In response, laboratories argue that the proposed rule will slow innovation and hinder access to vital tests.

Despite more than 7,000 comments, the proposed rule is on the fast track toward finalization, and despite litigation surely to follow, impacted laboratories should consider developing a blueprint for compliance. As a medical device manufacturer, laboratories need to comply with reporting requirements, manufacturing practices, and standardization, to name but a few.

With AI, data analytics, electronic batch records systems, and robotics likely already deployed, laboratories should work with their technology partners to enhance and customize those capabilities. This may include innovative solutions such as genAI to improve the speed of risk assessment and documentation by streamlining new workflow processes for analyzing data and generating information required for FDA reporting.



THE IMPORTANCE OF CYBERSECURITY

With the excitement and promise of innovative technologies powering discoveries in the industry, life sciences companies need to prioritize cybersecurity to avoid the impact of cyberattacks on progress.

Embedding cybersecurity in every aspect of the technologies and processes of life sciences is therefore essential. By working closely with their cybersecurity partners, life sciences companies can focus on the development of novel therapeutics and innovative medical devices, with greater peace of mind.





KEY TAKEAWAYS

Consider the following takeaways when approaching the top challenges facing life sciences this year:

- Leveraging innovative technologies can help life sciences companies navigate challenges and capitalize on opportunities
- The impact of regulations can be lessened by leveraging technologies to adjust strategies
- While emerging technology has the potential to drive meaningful optimizations, cybersecurity must be prioritized to mitigate risk

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