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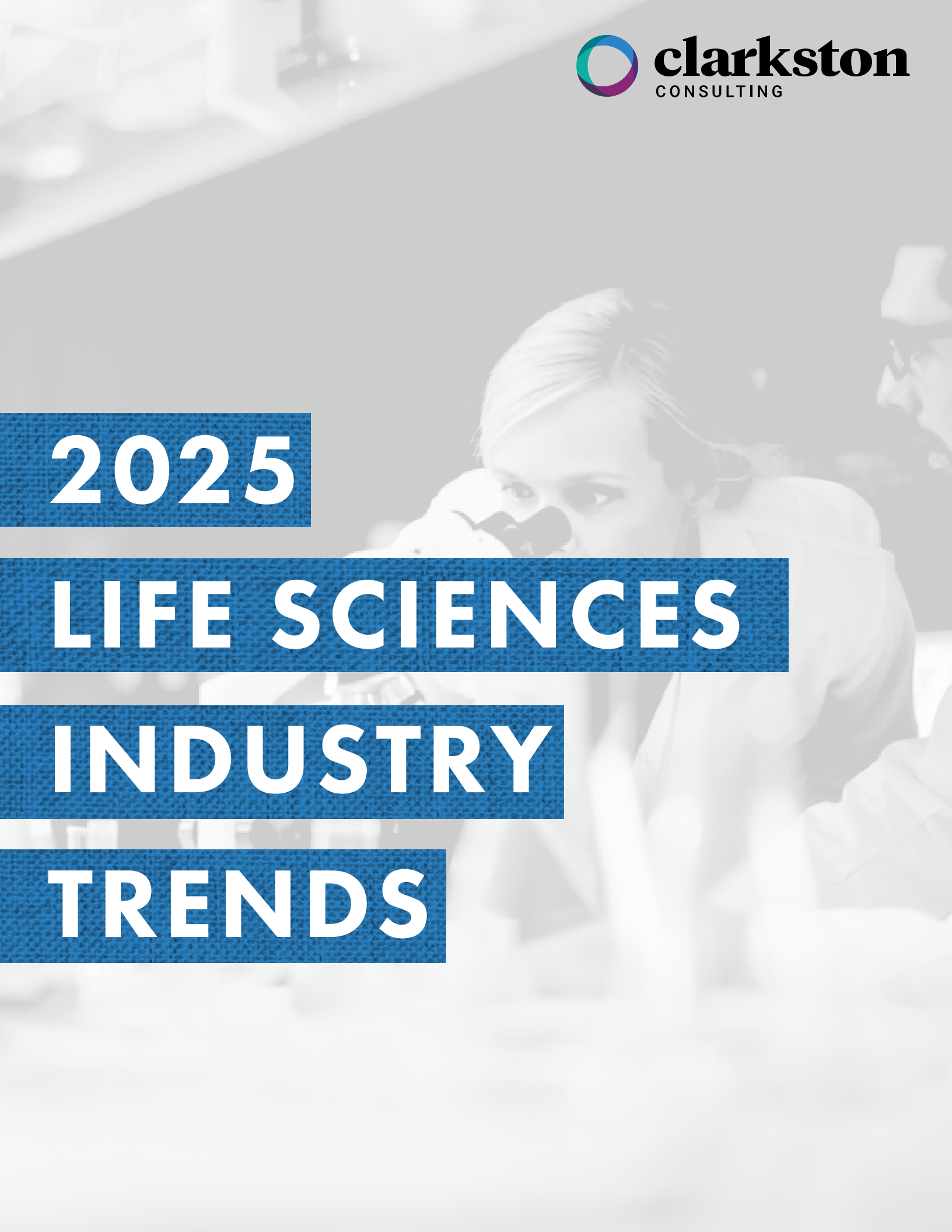

2025 LIFE SCIENCES INDUSTRY TRENDS

As geopolitical instability and economic uncertainties continue to shape the global landscape, life sciences companies have a unique opportunity to leverage sophisticated growth strategies and emerging technologies to thrive in 2025. With the integration of AI and ML, along with a surge in M&A activity, innovation is set to drive industry growth. At the same time, the increasing complexities of supply chains, dynamic geopolitical environment, and growing concerns about data integrity will require organizations to prioritize agility in order to remain competitive.

In this trends report, we outline the key opportunities that will define the life sciences industry in the coming year, offering insights to help organizations stay agile and well-positioned for sustained growth.

1 REVOLUTIONIZING R&D WITH ARTIFICIAL INTELLIGENCE (AI) & MACHINE LEARNING (ML)

2 INCREASED COMPLEXITIES IN MANUFACTURING AND SUPPLY CHAIN

3 GEOPOLITICAL ENVIRONMENT IS CREATING UNCERTAINTY

4 NAVIGATING THE CAPITAL MARKET

5 INCREASED NEED FOR DATA SECURITY AND MODERN ARCHITECTURES

1 REVOLUTIONIZING R&D WITH ARTIFICIAL INTELLIGENCE (AI) & MACHINE LEARNING (ML)

Artificial Intelligence (AI) and Machine Learning (ML) present significant opportunities to enhance efficiency in drug discovery, manufacturing, and clinical research; expand data analysis capabilities; and reduce operational costs for life sciences companies in 2025. While beneficial in R&D and data processing, scaling these technologies to meet cGXP standards remains a complex challenge for many organizations. In 2025, it will be essential for companies to begin integrating AI and ML throughout business units to stay competitive.

AI and ML have already started to revolutionize the R&D realm. With capabilities such as target identification, predictive protein folding, and candidate filtering, AI tools can act as virtual assistants, accelerating the drug discovery process. Predictive protein folding models can help identify patterns and drug candidates faster than ever, saving years of manual labor in the lab. The integration of AI and ML models has also led to the development of the "Lab in a Loop" concept. By training AI systems with data generated from laboratory and clinical studies, models like this can predict disease targets and therapeutics, which are then tested in the physical lab. The integration of complex AI algorithms with wet lab execution allows for more informed decision-making throughout the R&D process.

AI also has robust data management capabilities. Validation 4.0 leverages digitization and automation to link data with quality systems in real time, providing an integrated data validation approach. With AI and ML, traditional big data validation has shifted from document-centric to data-centric, creating a more holistic and efficient process. However, this model requires a strong foundation of data to be effective. Organizations must assess their data creation, usage, and access to have an accurate understanding of their current data landscape. Building an "AI-ready" data core through scalable, resilient pipelines and integration tools will provide the foundation for AI adoption.

Integrating these advanced technologies can be highly rewarding, though the process can be daunting. Companies are encouraged to take a risk-based approach when implementing automation systems in 2025. Establishing AI literacy programs in tandem will establish an effective hybrid workforce of human and technology that can drive innovation. While the process may never be flawless, starting with small use cases that deliver tangible value is key. As data is cleansed and becomes more accessible, additional use cases can be gradually added in. For instance, begin by implementing your AI model in a single business unit, site, or process to identify successes and areas for improvement. From there, the model can be scaled with confidence, knowing that core business operations remain unaffected.

AI in the life sciences is currently worth USD 3.61 billion and expected to reach USD 11.11 billion by 2030.

– SOURCE

2 INCREASED COMPLEXITIES IN MANUFACTURING AND SUPPLY CHAIN

The recent rise of novel therapeutic areas is highlighting pharmaceutical supply chain complexities more than ever. Emerging therapeutic areas such as cell and gene therapies, radiopharmaceuticals, regenerative medicine, and mRNA therapies are shaping the regulatory landscape in 2025 and beyond.

In response to the expansion of innovative therapeutic areas, CBER has introduced the Office of Therapeutic Products (OTP). With this introduction comes increased guidance on manufacturing and comparability studies for change management within the companies. As a result, there's an increased need for harmonization, standardization, and visibility throughout the supply chain. To prepare for the adoption of complex supply chain features, companies will now need to stress test their manufacturing process more than ever. Advanced technology tools, like a digital twin, can replicate real-world scenarios, simulate potential changes, and predict outcomes to increase crisis preparedness. Implementing automation systems in manufacturing will also improve accuracy and reduce human error to ensure precise and timely production.

New regulations surrounding the pharmaceutical supply chain are also expected to have a significant impact on processes in 2025. The BIOSECURE Act, passed by the House of Representatives in September 2024, prohibits life sciences companies from doing business with biotechnology companies of concern. In combination with proposed tariffs, these regulations will have wide-spread effects across the supply chain. Deadlines for compliance with the Drug Supply Chain Security Act (DSCSA) have also been extended into 2025, allowing manufacturers, repackagers, wholesalers, and dispensers to implement changes in phases through the end of 2026. Given these evolving guidelines, it's essential for businesses to prepare their supply chains for the uncertainties ahead in 2025 and beyond. We anticipate organizations will reassess their internal capabilities, with many pulling strategic

functions back in-house to leverage efficiencies, reduce risks, and maintain collaboration with external partners throughout the supply chain.

Despite these regulatory changes, cell and gene therapies (CGT) are rapidly gaining commercialization momentum, and this market is expected to grow by $111 billion from 2025-2033. CGT provides groundbreaking technology to treat a range of diseases; however, it also comes with additional supply chain complexities. For the therapy to be effective, patient chain of custody must be maintained across the entire process—from development to manufacturing and delivery. CGT developers must address logistics during the early stages of product development to prepare for scaling up.

CGT isn't the only complex therapy on the rise. Radiopharmaceuticals, mRNA therapies, and regenerative medicine each present unique manufacturing and supply chain challenges. Radiopharmaceuticals require a precise "just-in-time" supply chain due to the short half-life of the radioactive isotopes they contain. Similarity, quality raw materials with short lead times are essential to mRNA therapies and regenerative medicine, as these processes are highly dependent on the stability of materials.

With the continuous advancements of therapeutics and the changing environment, risks to the supply chain have never been more real. Companies must remain flexible to quickly assess impacts, evaluate risks, and mitigate immediate threats.

3 GEOPOLITICAL ENVIRONMENT IS CREATING UNCERTAINTY

2024 was marked by uncertainty surrounding the U.S. presidential election. However, now that we move further into 2025, it remains crucial for life sciences companies to stay agile in anticipation of any challenges and changes the new presidential administration may bring.

Robert F. Kennedy was confirmed as the next Health and Human Services Secretary in mid-February. Known for advocating preventative and holistic approaches to healthcare, Kennedy has also expressed skepticism around vaccines. As a result of his confirmation, we anticipate tighter oversight of the NIH and the FDA. At the NIH, funding is expected to be redirected toward preventive and holistic research focused on addressing chronic diseases and reducing chemical exposure.

Similarly, FDA priorities could shift toward a potential decrease in emphasis on fast-tracked approvals to support Kennedy's effort to improve public perception of the agency. Kennedy's stance on vaccines may also lead to stricter regulations, including increased transparency in clinical data, heightened safety studies, and more public disclosure of adverse events. As a result, we expect to see changes in the way vaccine trials are conducted in the coming years, with an emphasis on enhancing the science of vaccine safety.

Additionally, President Trump has imposed tariffs on the United States' largest trading partners – China, Mexico, and Canada. President Trump announced a 25% tariff on goods from Mexico and Canada, and 10% on goods from China. Life sciences companies that rely heavily on offshore suppliers or manufacturers may face economic pressures in 2025. While these tariffs are intended to support domestic industry, they could cause an inadvertent increase of drug prices due to the insufficient local manufacturing capacity. Based on President Trump's previous term, H1B visas may also become more difficult for skilled workers to obtain, leading to additional workforce disruptions.

As external uncertainty rises, life sciences companies must create certainty in their scope of control and increase agility across the organization. For example, maintain tight control over data and information while exploring the flexibility of your supply chain to capitalize on emerging opportunities, and create a commercialization roadmap for each asset in your portfolio to prepare for varying timelines and execute accordingly. By fostering this balance of control and adaptability, companies will be better prepared to navigate uncertainty and drive sustained success.

4 NAVIGATING THE CAPITAL MARKET

2024 was a year of smaller M&A activity, with the largest deal being Novo Holdings' $16.5 billion buyout of Catalent. Most other transactions were valued at less than $5 billion, reflecting an industry-wide shift toward smaller, more strategic deals. Looking ahead to 2025, we expect that this may change as M&A activity is anticipated to increase, driven by regulatory shifts, a favorable economic climate, and investment in innovative therapeutics.

With Republican control of both houses of Congress, we anticipate that larger deals will be completed with greater ease during the upcoming administration. The return of IPOs in 2025 should drive more acquisitions as the IPO market regains momentum following a two-year lull. Reduced anti-trust scrutiny will also support deal-making, allowing for smoother large-scale mergers and acquisitions in many life sciences sectors. However, market volatility and investor caution may still affect deal sizes and timelines. Venture capital funding increased in 2024, and investors are likely to continue focusing on cautious, risk-aligned deals in 2025. While anticipated Federal Reserve interest rate cuts are expected to support investment, inflationary pressures may still pose risks, potentially impacting deal values and timing.

Despite potential challenges, the expansion of novel therapeutics will drive M&A activity in 2025. Promising sectors such as radiopharmaceuticals, cell and gene therapy, ADCs, and specifically GLP-1 agonists are poised for sustained growth and continued investment as companies look to capitalize on innovative therapeutics that address unmet medical needs. The success of GLP-1 therapies in 2024 has already generated considerable investor interest, which is anticipated to continue long term. Given the growing demand for this treatment, this class of drugs is likely to dominate strategic M&A activity in the coming years. The GLP-1 agonist market is projected to maintain a 19.2% compound annual growth rate (CAGR) from 2023 to 2029, reaching $105 billion in 2029.

Given the industry's expected increase in M&A activity, now is the time to strategically assess your organization's position in the market and explore potential opportunities for collaboration, investment, and expansion.

5 INCREASED NEED FOR DATA SECURITY AND MODERN ARCHITECTURES

Life sciences organizations are increasingly confronted with the challenge of managing complex data while striving to maintain operational efficiency. To stay ahead, companies must adopt innovative strategies for system deployment, security, and implementation to ensure compliance and foster continuous improvement.

As big data continues to expand in 2025, data integrity is increasingly critical to quality operations in life sciences. To effectively implement the guiding principles of ALCOA++, organizations must adopt robust frameworks and controls to monitor and track data management. A strong data governance framework establishes clear standards and promotes a collaborative, sustainable approach to data integrity.

To meet this need, data governance platforms are progressively shifting to cloud-based solutions, offering a more flexible platform to enable data-centricity across an organization. Similarly, validated systems, like SAP and LIMS, are becoming increasingly cloud-based within life sciences. SAP's S/4HANA Private Cloud for GxP provides a flexible cloud solution compliant with FDA standards, while LIMS vendors are similarly shifting to cloud-based offerings to support accessibility and scalability of laboratory operations. It's essential to recognize the advantages of adopting cloud software in 2025: increased remote access to files, reduced hardware expenses, and enhanced file encryption will help organizations to be agile with their data in preparation for any uncertainties in the upcoming years.

Looking ahead, companies are expected to prioritize more efficient system deployments that leverage out-of-the-box capabilities, reducing the need for customization and additional services. A strategic focus on resource planning, effective use of vendor documentation, adoption of a CSA approach, and alignment with broader strategic initiatives will facilitate a phased implementation. By concentrating on small, targeted scopes, companies can yield immediate benefits and generate continuous ROI.

The adoption of a robust data governance framework is vital to maintaining data integrity throughout system deployments. Cloud-based platforms will enhance scalability while securing data in line with industry standards. Data governance is a complex, ongoing process that requires an understanding of organizational dynamics. Frameworks will evolve over time, and companies have the opportunity to take proactive steps now to support future growth.

LOOKING AHEAD

The trends highlighted above present life sciences companies with the challenge of maintaining agility in 2025. As advanced automation, economic uncertainty, and evolving regulations impact the industry, organizations must have a clear understanding of their current position and be prepared to adapt to change. For all life sciences companies, data integrity will remain at the core of operations, while a return to large-scale M&A is expected to drive further growth. These trends will not only shape success in 2025 but will also drive long-term innovation in the industry. To further explore these emerging trends, connect with our team today.

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For more information about how we can help your company, please contact us.

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