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2024 INDUSTRY TRENDS:

LIFE SCIENCES

Against the backdrop of both global challenges and innovative opportunities – ranging from ongoing geopolitical instability and economic uncertainties to the accelerating pace of technological innovation and R&D – life sciences companies are continuing to navigate a complex and rapidly evolving landscape.

In this trends report, we outline the key trends driving this growth and acceleration in the life sciences industry, focusing on how companies are responding, adapting, and innovating, all while maintaining lean operations.

1

AN INDUSTRY SHIFT TOWARD AUTOMATION

2

INCREASED M&A ACTIVITY

3

OPTIMIZING THE LIFE SCIENCES SUPPLY CHAIN

4

OPERATIONAL COST REDUCTION AND CAPITAL TIGHTENING OF BUDGET

5

AN INCREASED EMPHASIS ON DATA INTEGRITY FROM THE FDA

6

NAVIGATING THE COMPLEXITY OF SUPPLY CHAIN MANAGEMENT

7

A FOCUS ON DECENTRALIZED CLINICAL TRIALS

1 AN INDUSTRY SHIFT TOWARD AUTOMATION

In recent years, we've seen a conspicuous shift toward the integration of automation technologies within the rapidly evolving life sciences industry. Machine Learning (ML), Artificial Intelligence (AI), and data analytics are revolutionizing processes on the shop floor, offering unprecedented opportunities for optimization and efficiency within pharma. In fact, it's expected that the life sciences market size for AI investments is predicted to reach nearly $9 billion before 2032. These advancements streamline process monitoring by correlating vast datasets with critical quality attributes, thus minimizing the need for extensive quality control (QC) tests on bulk drug substances and further accelerating drug discovery.

By reducing human error and enhancing data integrity, automation not only ensures consistent product quality but also mitigates the risk of delays and waste, leading to substantial financial benefits for pre-clinical or commercializing companies where every dollar (and minute) counts. Take, for example, liquid handling – a process that involves the transfer of liquid from one place to another and is a critical step in the biological process. Normally, the method for this process is extremely manual, which can lead to an increased risk of process errors. Automatic liquid handling machines integrate automated injection modules – usually, a motorized pipette or syringe attached to a robotic arm – to dispense the designated volume of liquid. This automated process is a suitable alternative to reducing the human error that can come with manual liquid handling.

The emergence and continued integration of these intelligent solutions and systems is a larger reflection of Industry 4.0 principles, where the industry is embracing new tools and technologies that enable smarter, more digitized operations from end to end. However, with the promise of greater efficiencies, enhanced productivity, and faster drug production through the use of AI and ML also comes the need for specialized talent in data analytics, data science, and data engineering to help ensure and maintain data integrity – particularly with the incredibly vast amounts of data that can be processed and analyzed with these technologies. Essentially, the promise of this automated technology can't reach its full potential without the human element. Targeted training, in addition to upskilling and reskilling, will become crucial across pharmaceutical operations as the presence of AI and ML shifts the working landscape.

The life sciences market size for AI investments is predicted to reach nearly $9 billion before 2032. – SOURCE

2 INCREASED M&A ACTIVITY

The life sciences industry has been experiencing a surge in merger and acquisition (M&A) activity over the past year – and that trajectory is expected to continue to climb. These strategic decisions are about more than just acquiring products; companies are also interested in acquiring the manufacturing capabilities associated with the product as a pivotal component of their growth strategy. Novo Nordisk's acquisition of Alkermes is an example of this trend, as it sought to expand production of GLP-1 through access to Alkermes' development and manufacturing assets.

More recently, the Catalent acquisition by Novo Holdings created a ripple effect in how companies perceive and leverage Contract Development and Manufacturing Organization (CDMO) capabilities. Novo Nordisk continues to expand their manufacturing capabilities as part of their larger CDMO strategy, putting them in a competitive position in the market. While this particular deal is significant for the CDMO market, we expect this acquisition to accelerate a larger shift in how pharma companies think about risk management and partnership agility, emphasizing the need for flexibility and agility for sponsors as they move between contract partners.

M&A activity serves not only as a means of acquiring assets but also as a strategic maneuver to fortify core areas and address gaps in pipelines. Investors are increasingly drawn to companies with clear specialization rather than those aiming for portfolio diversification. Moreover, looming patent expirations are prompting larger entities to pursue deals to bolster their pipeline offerings. However, this surge in M&A is not without its challenges, as regulatory scrutiny, including heightened antitrust measures, and FDA rejections, adds complexity to future deal-making. Despite these hurdles, the trend toward increased M&A reflects the industry's continued consolidation of innovation and growth, which may set the stage for transformative developments in the years to come.

3 OPTIMIZING THE LIFE SCIENCES SUPPLY CHAIN

Supply chain visibility and resiliency continue to be critical focal points in the life sciences sector, with companies increasingly recognizing the need for robust risk management strategies to mitigate disruptions swiftly and minimize their impact. As the demand for life-saving treatments and products continues to outpace supply, there's a growing imperative to optimize the supply chain, ensuring efficient and reliable delivery to patients in need.

Possible loss or damage can be difficult to spot until it's too late; however, when it comes to these treatments and products, there's little room for error. As such, transportation giants like FedEx and DHL have been evolving to meet the unique requirements of the pharma industry's "cold chain," investing heavily in temperature-controlled logistics solutions to safeguard the integrity of sensitive products during transit. However, maintaining quality control in a global supply chain presents significant challenges, necessitating stringent auditing of suppliers and adherence to regulatory standards.

Navigating the complexity of the life sciences supply chain ultimately requires a multifaceted approach, encompassing diverse vendor management, regular audits for quality control, and contractual risk transfer mechanisms. However, this may be easier said than implemented. Take diverse vendors, for example. In the life sciences, backup suppliers may come with costs other industries don't have to worry about, and companies must take action to make sure those backup suppliers are just as well-vetted as their primary suppliers. Additionally, there can be a significant threat to quality control when dealing with a global supply chain.

One consideration for organizations looking to optimize their supply chains includes nearshoring – or moving manufacturing closer to the U.S. This not only allows for significant cost savings

but also helps to secure supply chains and facilitate access to diverse skill sets and specialized expertise available in emerging markets. We've seen an uptick in nearshoring due to ongoing political and economic uncertainty, particularly in the pharmaceutical sector. The U.S., for example, has leveraged Mexico as a reliable partner for these operations, as the country has one of the most developed pharmaceutical industries in the region (400+ companies). Pharma companies have also looked to other Latin American and Caribbean countries like Brazil, Puerto Rico, and Costa Rica, for nearshoring operations.

Pharma supply chains are also moving toward localizing as a way to cut operational costs. "Localizing," or moving away from globalization and toward regional hubs, is a way that organizations can optimize their operations while also establishing greater supply chain reliability. This involves prioritizing lower-cost and lower-complexity options, such as localizing finished goods distribution rather than the entire manufacturing process itself. By leveraging regional hubs, pharma companies can mitigate supply chain risks and improve product supply reliability through localized stockpiling and distribution – saving time and resources in the short and long term.

Looking ahead, life sciences companies must also be aware of the impending implementation of the Drug Supply Chain and Security Act (DSCSA), which will take effect November 27, 2024. While the Act places additional pressure on businesses and their suppliers by mandating unit-level traceability for manufacturers, wholesalers, re-packagers, and dispensers, it also serves as a catalyst for enhancing supply chain visibility from end-to-end, enabling companies to develop deeper insights for better decision-making and operational resilience.

From intentional risk management to enhancing end-to-end visibility, companies will need to incorporate strategies and implement systems that can empower them to make informed decisions and proactively address potential challenges in the ever-evolving landscape of the life sciences supply chain.

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4 OPERATIONAL COST REDUCTION AND CAPITAL TIGHTENING OF BUDGET

One trend emerging in the life sciences industry is a strategic shift toward operational cost reduction and capital tightening of budgets, particularly as venture capital funding for life sciences has returned to pre-pandemic levels after spiking in 2020-2021. Rather than embarking on large-scale capital investments, companies are increasingly opting for incremental improvements aimed at optimizing expenses while upholding quality, safety, and compliance standards. This approach is not merely a cost-cutting measure but a pivotal strategy for enhancing financial sustainability, profitability, and competitiveness in the industry – it's also helping to further drive R&D efforts and innovation.

One potent avenue for operational cost reduction lies in leveraging advanced technologies such as AI to optimize supply chain and business processes. Pharmaceutical giants like Novo Nordisk and Pfizer have already realized significant cost savings by adopting AI-driven demand forecasting and inventory management solutions. Novo Nordisk achieved a 50% reduction in forecast errors and significantly reduced overstock, leading to estimated cost savings of $20 million annually, and Pfizer achieved a 25% increase in supply chain efficiency and substantial cost savings with more accurate demand forecasting and improved inventory management.

AI also enables predictive maintenance programs that use real-time data to preemptively identify equipment failures, thus minimizing unplanned downtime and associated costs. Further, in a climate where available capital for biotech investment is limited and market competition for funding is fierce, companies are adopting a more conservative spending approach, including restructuring – and in some cases, laying off employees – to save costs; investing in innovative technologies like AI to save time and resources; and only pursuing required, incremental investments.

These actions all serve to maximize their overall efficiency and resilience, further underscoring the industry's commitment to financial discipline and strategic resource allocation in today's economic landscape.

5 AN INCREASED EMPHASIS ON DATA INTEGRITY FROM THE FDA

Data integrity is critical within the life sciences sector, and we're continuing to see industry emphasis on ensuring data integrity, particularly in laboratory settings and around manufacturing equipment. With the FDA raising alarms over drug manufacturing data integrity issues in the medical device industry, there's a renewed emphasis on collecting accurate and complete data to prevent shortages and ensure the availability of essential medications. This emphasis extends to the pharmaceutical sector, where guaranteeing the integrity of records generated during production processes is paramount to compliance and patient safety; however, companies often struggle to interpret and comply with these standards.

To meet data integrity requirements, organizations must establish robust quality systems based on continuous monitoring, system validation, and adherence to ALCOA+ metrics (Attributable, Legible, Contemporaneous, Original, Accurate). Every activity within the pharmaceutical sector, including transportation and outsourcing, generates data whose integrity is vital to ensure the quality of the final medicinal product. Selecting pharmaceutical quality system vendors that meet data integrity requirements is essential for maintaining compliance and upholding patient safety standards. As the industry continues to evolve, a steadfast commitment to data integrity will remain paramount in ensuring product quality, regulatory compliance, and ultimately, patient well-being.

Organizations navigating the complexities of launching commercial products must have a laser focus on data integrity as well as have a complete understanding of and comply with data integrity regulations. Partnerships with experienced firms can aid in creating document systems that fully comply with industry regulations, guiding companies through the intricacies of regulatory requirements and system needs and facilitating a smooth commercialization roadmap.

6 NAVIGATING THE COMPLEXITY OF SUPPLY CHAIN MANAGEMENT

News coverage of the need for temperature-controlled transportation and storage of COVID-19 vaccines brought the challenge and complexity of cold chain to the public eye. Proper storage conditions (temperature, humidity, etc.) are critical to safely deliver therapies to patients with properly preserved efficacy. However, storage space and particular transportation technology can be limited and result in difficulties accessing and storing life-saving treatments. Technology-driven automation and biological advancement are changing the course for specific storage conditions for therapy inventory in warehouses, transportation vehicles, hospital freezers, and beyond.

Technology-driven automation will become increasingly important to driving efficiency, accuracy, and speed within cold chain distribution and supply chain management. One key example is robotics assisting with inventory management to improve accuracy in moving products from a warehouse to the shipping zone. Additionally, innovation of biological materials is underway and expected to continue to expand in 2024. Biomaterials such as mRNA, enzymes, and antibodies are highly sensitive to ambient conditions during storage. If not stored properly, they can become inactive and significantly affect the efficacy of the treatment. American scientists have developed a novel method for storing biological materials like RNA and proteins in a solid state. This storage method enables them to be stored at room temperature and dissolved in water for immediate use. This kind of innovation could lead to biologics, like insulin, to be able to be taken orally in pill form instead of injected.

7 A FOCUS ON DECENTRALIZED CLINICAL TRIALS

In May 2023, the FDA issued a draft guidance with updated recommendations for implementing the International Council for Harmonization's (ICH) guidelines on good clinical practice (GCP), acknowledging Decentralized Clinical Trials (DCTs) and providing recommendations for sponsors, investigators, and other stakeholders regarding the implementation of DCTs. The use of decentralized elements, such as obtaining laboratory tests at a local facility (rather than requiring a participant to travel to an academic medical center) or conducting follow-up visits in a participant's home or via telemedicine, increases the convenience of such activities for research participants and can assist in diversity efforts.

Such increased access and convenience offer a more patient-centric approach to clinical trials. FDA Commissioner Robert M. Califf, M.D. specifically highlights the value of DCTs in regard to enhancing diversity and states: "As we seek to improve our evidence generation system, decentralized clinical trials may enhance convenience for trial participants, reduce the burden on caregivers, expand access to more diverse populations, improve trial efficiencies, and facilitate research on rare diseases and diseases affecting populations with limited mobility."

Additionally, the use of digital health technology (DHT) as a function of DCTs to gather and record health activity (e.g., glucose levels, blood pressure, etc.) will provide greater access to real-time real-world data, which will enable researchers to pursue additional questions and perform "meta-analyses." Into 2024 and beyond, there is consensus that the "D" will eventually be omitted from the DCT acronym altogether as decentralization becomes the industry standard.




LOOKING AHEAD

The above trends shaping the landscape of the life sciences industry in 2024 represent a strategic evolution toward greater efficiency, resilience, and global collaboration. From an increased emphasis on automation to the strategic movement of laboratory resources to more cost-effective global locations, companies are leveraging innovative approaches to speed up R&D and drive innovation – all while remaining lean. We're also seeing the industry continue to navigate challenges with maintaining regulatory compliance, protecting and optimizing the supply chain, prioritizing data integrity amidst increased AI/ML usage, and increasing accessibility and diversity within clinical trials.

These trends aren't just disparate factors within the life sciences, but rather trends that will continue to drive transformative innovation and ensure sustained growth and success in the years to come. To chat more about these emerging trends or challenges in the life sciences space, connect with our team today.

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