

The Adoption of Artificial Intelligence and Big Data in the Sector

The Life Science Sector has been undergoing an immense transformation, driven by the adoption of artificial intelligence (AI), machine learning (ML), natural language processing (NLP), and big data. These new technologies are enabling companies to restructure their business models, reduce human error, increase efficiency and performance, and bring innovative products to the market much faster. This has led to the emergence of a new “pharmaceutical intelligence” that has allowed the industry to move away from traditional, slow-moving, and costly processes. AI is increasingly important in drug discovery and development as well as clinical trials, operations, pharmacovigilance, and many other areas.

The life science sector is increasingly leveraging technology across its operations and this trend will continue in 2023 with increased collaborations and partnerships between pharma, biotech and medical device companies and IT vendors. Through these collaborations, advanced technologies such as AI and big data are being employed to develop personalised and targeted medicines, ultimately leading to more effective treatments for diseases like cancer and immune deficiencies. This technology will also allow companies to utilise advanced computational models to find better treatments more quickly while also reducing costs associated with drug development. This trend has already begun and is only likely to grow as companies continue to invest in advanced analytics and data-driven decisions.

Blockchain Technology: The Future of Data Transparency

Blockchain technology is quickly becoming one of the most important trends in the sector, offering a secure and easy way to share data across organisations. This technology provides all parties with an up-to-date and accurate view of the supply chain and other data sets, which is essential for maintaining robustness in the manufacturing process. While blockchain is commonly connected to cryptocurrencies, its uses extend far beyond financial transactions, and the technology is

being adopted across the sector to increase transparency and security.

One of the most valuable aspects of blockchain is that transactions on a blockchain network are stored permanently and are viewable by all participants, making it difficult for fraudulent activities to go unnoticed. This helps to ensure that sensitive data, such as patient information or drug safety standards, remain secure and trustworthy. The technology also offers a more efficient and cost-effective way to handle transactions confidentially. In addition, increased R&D in personalised medicines is driving more demand for blockchain technology. With personalised medicines, the need for data accuracy and integrity is paramount, as decisions are made with individual patients' health in mind. These factors highlight that the need for secure data sharing has become more important than ever in the sector.

Bringing Innovations to Market

The digital revolution in the sector is poised to take a huge leap forward in 2023. We have already seen how the adoption of digital technologies into clinical trials enables decentralised readouts and mobile phone applications for patient participation, allowing for more efficient and cost-effective clinical trials that span multiple regions. This could drastically reduce the time, cost, and resources associated with clinical trials. At the same time, Industry 5.0 will build upon the principles of Industry 4.0 to take production processes to a new level of human-centricity. This could lead to more personalised medicines tailored to individual patient needs and help companies develop more effective treatments for certain patient groups.

At the same time, the sector is closely following advancements in digital health technology and its applications in healthcare. Wearable technologies such as fitness trackers, heart rate monitors, and smartwatches are becoming increasingly popular and allow users to track their health more accurately than ever before. Wearables also have the potential to revolutionise healthcare in clinical trials, providing data that is more accurate and reliable than traditional methods of monitoring patients.

Another component is “connected health,” which refers to the use of digital technologies for healthcare, including mobile health (mHealth) and telehealth applications. Connected health has a wide range of potential applications, from providing patients with more convenient access to care to enabling healthcare providers to better monitor patients' health. In 2023, technologies that power wearable devices and support connected health are likely to become increasingly popular as companies continue to invest and explore the possibilities of leveraging them for healthcare purposes from remote monitoring to clinical decision support.

Ensuring Safety and Efficacy with CSA and CSV

Computer Software Assurance (CSA) and Computer Systems Validation (CSV) are two distinct areas of compliance that companies must consider when developing new computer systems for use in drug manufacturing and other related processes. CSA is a set of standards that ensure the safety and efficacy of computer systems used in drug manufacturing, while CSV involves validating the computer systems themselves. We expect to see a rise in CSA and CSV as companies continue to invest in computer-based technologies and strive towards meeting regulatory standards.

The adoption of cloud computing has also enabled companies to bring their products to market quickly while maintaining compliance and quality standards. This has allowed for the acceleration of innovation in the sector and is expected to become even more prominent in 2023.

An Evolving Regulatory Landscape

The regulatory environment is becoming increasingly interdependent and globalised. Companies are looking to leverage overseas approvals to increase efficiencies while ensuring quality and safety standards are met. This is especially true as the trend toward incorporating AI, cybersecurity, and data analytics into healthcare products is rapidly growing. In response, new regulations have been created to evaluate the quality, safety and efficacy of these products.



In particular, companies must pay attention to Medical Device Regulation (MDR) and In Vitro Diagnostic Regulation (IVDR). For example, the IVDR sets out specific requirements for software used as a medical device. These regulations stipulate the necessary steps for the design, development, and fulfillment of Software as a Medical Device (SaMDs), from product concept to market entry.

The release of new guidance from the Medical Devices Coordination Group (MDCG) and any transitional arrangements must also be considered. The US Food and Drug Administration (FDA) has introduced an electronic Submission Template And Resource (e-STAR) program to support companies in developing and reviewing new medical devices, which provides an interesting opportunity.

New Requirements for Safety and Quality

The continued interest in RNA-based therapies such as gene therapy and nano-extracellular vesicles is driving innovation within CMC biologics. CMC, short for chemistry, manufacturing, and control, defines the characteristics, safety, and consistency between batches of a pharmaceutical product. Ultimately, the goal of CMC within the biologics space is to ensure that pharmaceutical products can meet or exceed specifications throughout any step of the production process.

This goes hand in hand with revisions to EU pharmaceutical legislation are providing opportunities to improve the supply chain and reduce drug shortages. The use of electronic Product Information (ePI) and the web-based Human Variation electronic Application Form (eAF) on the Product Lifecycle Management (PLM) portal is also becoming more prevalent, particularly for Centrally Authorised Products (CAPs). Finally, the mandatory use of the Clinical Trials Information System (CTIS)

for clinical trial applications in the EU is increasing, ensuring that safety standards are met.

At the same time, the newly revised EudraLex Annex 1, published in August 2022, has brought a much-needed shift in regulatory expectations. Instead of simply providing what is considered acceptable and not acceptable, companies must now provide risk-based rationales for decisions made with patient safety when it comes to manufacturing processes. This brings with it several challenges for organisations that are not at the same level of maturity when it comes to Quality Risk Management (QRM) systems.

To ensure readiness by the August 2023 deadline, companies should first evaluate their current level of compliance with Annex 1 regulations and identify any gaps between current status and the regulatory expectations. This assessment should include all areas of sterile manufacturing and should involve a cross-functional team to ensure everyone involved is aware of how the new Annex 1 will impact their areas of expertise.

Early Phase Modeling to Inform Strategic Decisions

By 2023, early phase modeling (EPM) is expected to become a standard component within companies' development process. The EPM process involves key evidence gathered from the early stages of product development to support and inform decisions around pricing and reimbursement as well as market positioning. This helps to ensure that companies understand their product's potential before releasing it to the public, increasing the chances of successful reimbursement and anticipated pricing.

EPM not only helps to keep companies informed of their product's potential but also allows them to become more aware of any

gaps that may need attention. The process provides information on how a product will be accepted in the market, helping to predict whether or not there are likely to be any regulatory or health technology assessment (HTA) questions or concerns. This is especially helpful for the developers of more complex therapies and medical devices, as timely evidence gathering can help to demonstrate a product's potential to investors and encourage further investment in ATMPs.

Preparing for 2023

The rise of advanced technology such as AI will revolutionise how the life science sector manages supply chains in 2023. Companies will be able to leverage AI-driven analytics to predict customer demand and proactively adjust supply chain operations. Companies must prioritise sustainability in their supply chain operations. This means investing in green production methods and ethical sourcing – an area where PharmaLex can provide guidance and assistance.

In 2023, the sector will be shaped by advances in technology, globalisation, and quality compliance. Companies that fail to prepare for these challenges will find themselves left behind by their more nimble competitors. With its unique expertise in compliance-related services, PharmaLex is ideally positioned to help companies navigate these changes and be on the cutting edge of trends within the sector in 2023.



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