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2024 INDUSTRY TRENDS:

QUALITY +

COMPLIANCE

The life sciences sector remains committed to its mission of improving existing [quality systems](#) to ensure drug effectiveness and patient safety. Regulatory agencies and pharmaceutical companies are steadfast in their efforts to minimize disruptions in the supply chain and expedite clinical trials through the ongoing advancement of technological systems. This has spurred trends in 2023, including the introduction of quality management initiatives, the growing adoption of quality 4.0, the incorporation of Artificial Intelligence and Machine Learning for data analytics, the embrace of the virtual pharmaceutical model, and the leveraging of Real-World Data.

As we move into 2024, these trends will remain pivotal in shaping the future of advanced quality management practices and ensuring reliability and compliance across industries.

1

**FOSTERING A
QUALITY-DRIVEN
CULTURE**

2

**INCREASING
RECOGNITION OF
QUALITY 4.0**

3

**AI CONTINUES
TO SHAPE DATA
ANALYTICS**

4

**THE RISE OF THE VIRTUAL
PHARMACEUTICAL
MODEL**

5

**ADVANCES IN
REAL-WORLD DATA
(RWD)**

1 FOSTERING A QUALITY-DRIVEN CULTURE

Effective use of quality metrics is imperative in assessing the health of a quality system. However, the dialogue concerning quality has evolved toward a more comprehensive approach that considers the behaviors and characteristics of a successful PQS (Pharmaceutical Quality System). This past year, the FDA initiated the [Quality Management Maturity \(QMM\) Program](#), signifying a transformation in the assessment of quality management practices. This is a result of the agency realizing the benefit of taking a more proactive approach in its [assessments of quality systems](#), marking “a move away from focusing solely on negative outcomes and one that will move the FDA closer to performance-based regulation.”

The program aims to surpass the current Good Manufacturing Practices (CGMP) requirements, introducing a five-level rating system to inform manufacturers and purchasers about facility performance. The QMM Program emphasizes fostering a robust quality culture, recognizing high-quality management practices, identifying growth areas, and reducing supply chain risks, all with the overarching goal of enhancing drug quality.

Historically, the FDA didn’t incentivize manufacturers to adopt mature quality management systems, leading to minimal modernization and investment in quality. As a result, life sciences companies can benefit from the program’s incentives. Participation in the program presents the potential for increased market share, owing to the program's transparency, which provides a competitive edge. This transparency grants purchasers, patients, and health professionals valuable insights into and confidence in the drug manufacturing process, ultimately enhancing the participant's reputation and reducing their share price volatility. Moreover, the program promotes a high level of [quality maturity](#), enabling early detection of quality issues and reducing the risk of drug supply disruptions.





2

INCREASING RECOGNITION OF QUALITY 4.0

Quality management has undergone a significant transformation, evolving into what is now known as Quality 4.0. This evolution is essential to the larger concept known as Industry 4.0, which is the integration of cutting-edge digital technologies with established quality norms. While [Quality 4.0](#) isn't a novel concept, its prominence is steadily growing, and it's gaining recognition across various industries. Quality management has been developing over time, and as businesses look to modernize and stay competitive in the ever-evolving business landscape, this approach is becoming more generally recognized and adopted.

Through the integration of the Internet of Things (IoT), artificial intelligence (AI), and data analytics, Quality 4.0 presents a myriad of opportunities. Enhanced product and service quality can be achieved through the ability to monitor and control production processes with unprecedented precision. Efficiency gains become substantial as data-driven decision-making and process optimization become the norm, benefiting the pursuit of continuous quality improvement through real-time feedback and analysis.

One of the most significant advantages of Quality 4.0 is its ability to foster collaboration by breaking down organizational silos and enabling a holistic approach to quality. This is achieved through the utilization of digital tools and technology, which promotes seamless data and insights sharing among teams and departments, facilitating real-time collaboration and cultivating a more harmonious and well-coordinated working environment. Furthermore, Quality 4.0 reduces defects, streamlines processes, and mitigates risks while simultaneously making compliance with regulatory requirements more manageable and efficient, further enhancing an organization's reputation and credibility.

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3

AI CONTINUES TO SHAPE DATA ANALYTICS

The ever-evolving landscape of [artificial intelligence \(AI\)](#) and machine learning (ML) has had a profound impact on data analytics, particularly within the realm of pharmaceuticals and drug development. These technologies have opened doors to new possibilities, including the ability to conduct experiments through computer simulations. This innovation presents a promising avenue for substantial cost savings and can significantly expedite the drug development process.

Data analytics plays a pivotal role in this context. It involves the systematic examination of data to identify patterns, trends, and relationships, enabling the extraction of valuable insights and informed decision-making. In the pharmaceutical industry, one key use of data analytics is to expedite the identification of potential safety concerns associated with drugs and medical products.

Furthermore, the development of [synthetic data](#) has emerged as a groundbreaking solution to train AI algorithms in the medical field without compromising patient privacy. This approach allows for the creation of realistic yet entirely artificial data sets, which can be used to enhance the capabilities of AI systems in tasks such as diagnostics and drug discovery.

One prominent example of how these technological advancements is being put into practice is the utilization of cloud-based software platforms like [Veeva Vault Safety](#). This innovative platform empowers pharmaceutical companies to efficiently capture, process, and manage adverse event reports and safety cases. By streamlining the collection and assessment of safety data, it simplifies the process of identifying potential safety issues related to drugs and medical products, ultimately contributing to the creation of safer and more effective healthcare solutions.

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- SOURCE



4 THE RISE OF THE VIRTUAL PHARMACEUTICAL MODEL

The emergence of the "[virtual pharma model](#)" is significantly reshaping the life sciences industry, raising questions about its impact on quality systems. This dynamic approach to drug development has the potential to revolutionize the future of the pharmaceutical sector, affecting quality systems in a multitude of ways.

Virtual pharmaceutical companies, also known as "virtual pharma," entail pharmaceutical companies outsourcing various elements of their drug development process to Contract Development and Manufacturing Organizations (CDMOs). By doing so, they can concentrate on their core competency, which is research and development, while CDMOs handle manufacturing, quality control, and distribution. This model can enhance quality systems by allowing pharmaceutical companies to access the specialized expertise and cutting-edge technology of CDMOs. These partners are often at the forefront of manufacturing and quality assurance, which can lead to higher quality standards and more robust systems. By focusing on their core R&D strengths, pharma companies can dedicate more resources to improving product safety and effectiveness.

Alternatively, the virtual pharmaceutical model may introduce challenges in maintaining consistent quality control. With multiple partners involved, ensuring standardized processes and quality management across the supply chain can be complex. The need for effective communication, information sharing, and risk management becomes crucial to prevent lapses in quality systems.



5 ADVANCES IN REAL-WORLD DATA (RWD)

The pharmaceutical industry has long grappled with a significant challenge: striking the delicate balance between implementing cost-saving measures and ensuring the quality of drugs. This challenge continuously places demand on the healthcare sector to nurture innovation and explore novel solutions to strike this equilibrium. As a result, the utilization of [real-world data](#) (RWD) has emerged as a cost-effective alternative to aid in the research and development of drug treatments.

RWD is comprised of patient data collected from various sources in real-world, non-clinical trial settings, typically drawn from electronic health records (EHRs), medical claims data, and emerging technologies like wearable devices and mobile health applications. Regulatory agencies are increasingly recognizing the value of RWD as real-world evidence (RWE) to support drug approvals. In recent developments, [international regulators](#) have made substantial progress in incorporating RWD to enhance decision-making concerning the safety of marketed drugs.

RWD empowers life sciences companies to make [patient-centric](#), well-informed decisions throughout the drug development process. It enables the identification of real-world patient needs and challenges, thereby guiding the development of safer and more effective drugs for diverse populations. This is especially vital as pharmaceutical companies face persistent barriers in [conducting clinical trials](#). However, life sciences companies can leverage data from clinical trials in conjunction with RWD to inform their decisions regarding clinical trial designs and procedures, ultimately expediting the drug development process.

Effectively harnessing RWD can also support post-market surveillance, enabling early detection of safety concerns and adverse events, thereby safeguarding patient safety. This can potentially yield substantial cost savings as companies mitigate expenses associated with adverse outcomes, allowing them to redirect financial resources toward implementing technologies that can realize the full potential of real-world data.

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These trends reflect the resilience and adaptability of the pharmaceutical and life sciences sector in the face of global challenges, emphasizing the importance of quality, innovation, and data-driven decision-making in ensuring patient safety and drug efficacy. Undoubtedly, the future longevity of life sciences companies hinges on the adoption of quality-driven cultures that prioritize transparency and place significant importance on improving processes to reduce the risk of drug shortages and deliver high-quality products.

ABOUT CLARKSTON CONSULTING

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