6 Regulatory Trends in the Pharmaceutical Industry to Be Aware of in 2024

No industry stands still, including the pharmaceutical industry. Therefore, it's important that companies in the pharmaceutical industry don't stand still either as standing still effectively means you are going backwards. You need to stay up to date with the trends and developments taking place in the industry. For this blog, we are going to focus on the main regulatory trends in the pharmaceutical industry for 2024.

Trend 1: The Need to Remain Agile as Regulations Change and Are Updated

The regulatory landscape across all major jurisdictions is constantly in a state of flux. Changes are always on the horizon as regulators and lawmakers react to technological advances, grapple with new product innovations, and seek to enhance protections for patients and consumers.

As a result, there is a growing need for pharmaceutical companies to remain agile and adaptive to the evolving regulatory landscape. This includes staying on top of guidance documentation that is released by regulators, particularly in the US and EU, as well as legislative and regulatory proposals.

To underline the importance of remaining agile and reacting quickly, both the FDA and the EU Commission have published new guidance and proposals that will impact compliance and quality control in pharmaceutical manufacturing facilities in the short term. Here are a few examples:

- The FDA has announced plans to publish in 2024 a guidance document on the basic safety and essential performance of medical electrical equipment, medical electrical systems, and laboratory medical equipment.
- The EU Commission has published its Reform of Pharmaceutical Regulations. It is being billed as the biggest change in EU pharmaceutical legislation in 20 years.
- The International Recognition Procedure is being implemented by the UK's MHRA. It is a new regulatory approval route for medicines in the UK that involves the MHRA recognising approvals from another regulator on the MHRA's Reference Regulators list. With this approval route, medicines can be approved for the UK market in as little as 60 days.
- Already published guidance from the FDA on Benefit-Risk Assessment for New Drug and Biological Products. This guidance explains how the FDA assesses the risks and benefits of an application based on the evidence submitted in the application, the therapeutic context, uncertainties, and how to reduce uncertainties with the available regulatory options.

Trend 2: Skills Availability and Adapting to Skills Shortages

The availability of staff with the required regulatory skills will continue to be a challenge for the pharmaceutical industry throughout 2024. There are many reasons for this, including the industry being a victim of its own success whereby the number of people achieving relevant third-level qualifications is not keeping up with ~~the~~ staffing requirements ~~of the industry~~.

As with other industries, today's staff are more likely to move more frequently from company to company for career advancement opportunities and to gain additional experience.

One solution to this problem (which will also be an ongoing trend in 2024) is to enhance the promotion of the pharmaceutical industry and, in particular, regulatory and quality specialisms to young people in third-level education or who are about to enter third-level education.

Adapting to skills shortages also presents opportunities, as you can partner with companies like us at Westbourne IT. Having a reliable partner will enable you to fill your skills gaps as required. You will also be able to tap into a much wider range of skills, experience, and expertise when needed.

Trend 3: Digitalisation and Automation

Companies in the pharmaceutical industry will continue with their digital transformation strategies throughout 2024. This includes increasing the digitalisation and automation of compliance and quality control processes.

Increased digitalisation and automation improve accuracy, productivity, and efficiency, as well as helping to alleviate some skills availability pressures.

Trend 4: Increased Use and Importance of Data

Data is becoming more and more important in pharmaceutical operations, including regulatory compliance and quality control. Over the coming year and beyond, we will see companies increasing their data capabilities through enhanced equipment and platform integration. Enhanced integration will eliminate any remaining remnants of data capture and storage being paper-based while enabling fully digitalised processes.

That said, the real benefits of data for compliance and quality control in the pharmaceutical industry come from putting data to use. Those benefits include:

- Achieving productivity gains
- Increasing transparency
- Reducing compliance costs
- Reducing product recalls and adverse events
- Improving patient/consumer confidence
- Developing new production and business insights

Trend 5: Health Equity in New Drug Development and Existing Medicines

There is a growing emphasis in the pharmaceutical industry on equity, ethics, and responsibility.

One of the first focus areas that is already being discussed, and will be further developed in the near future, is the need to ensure medicines are effective and beneficial for everyone, regardless of ethnicity or race. This specific measure is being driven by FDA research that found that nearly 80 percent of patients participating in clinical trials are white, while less than 20 percent of drugs approved for sale in the US have data on the side effects or benefits for black patients.

Trend 6: AI

Any review of trends in the pharmaceutical industry is likely to include a mention of artificial intelligence (AI). AI technologies have experienced an explosion of interest in the past 12 months. In the pharmaceutical industry, we are likely to see AI technologies being used more and more in areas like product development, sales forecasting, and marketing.

There are also use cases and exciting applications for AI technologies in pharmaceutical manufacturing and supply chain management process optimisation. Medical devices, including combination devices with pharmaceutical components, are also being developed with AI capabilities.

AI technologies will also become increasingly important in the world of regulatory compliance and quality control over the coming years. For example, AI algorithms developed to handle tasks such as documentation management and reporting, as well as AI

technologies that can predict potential quality deviations so adjustments can be made before any manufactured batches are impacted.

An Industry Moving Forward

Some of the main regulatory trends in the pharmaceutical industry over the coming year and beyond are entirely predictable, such as changes in regulations and published guidance from regulators. The potential landing point for others is less clear, such as exactly how AI technologies will be used as part of compliance and quality control processes.

What we have learned over recent years with experiences like the COVID-19 pandemic, supply chain challenges, and geopolitical upheaval is the importance of staying on top of current and emerging trends. This knowledge will help your organisation react, adapt, and improve while staying on-side with regulators and delivering products that are not just profitable, but transformative to patient care.