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Compliance evolving - becoming more global, tech-driven

DR SANJAY AGRAWAL

THE pharmaceutical industry is one of the most regulated sectors in the world - and for good reason. Unlike other industries where mistakes may mean financial losses, in pharmaceuticals, errors can cost lives. Every pill, injection, or vaccine that reaches a patient must not only be effective but also safe and consistent in quality. This assurance is made possible through regulatory compliance.

Regulatory compliance in pharmaceuticals refers to adherence to the laws, standards, and guidelines laid out by governing bodies across the globe. It is the invisible safety net that ensures scientific breakthroughs translate into trustworthy medicines. Yet, in today's dynamic world, compliance is also evolving- becoming more global, technology-driven, and intertwined with corporate reputation.

This article takes a deep dive into what regulatory compliance means for the pharmaceutical industry, its frameworks, challenges, and the way forward.

Understanding Regulatory Compliance in Pharma

At its core, regulatory compliance ensures that pharmaceutical products meet the highest standards of safety, efficacy, and quality throughout their lifecycle. This includes every step:

- Drug discovery and pre-clinical studies
- Clinical trials on human volunteers
- Manufacturing and packaging
- Distribution and market authorisation
- Post-marketing surveillance

Non-compliance at any of these stages can result in delayed approvals, product recalls, financial penalties, reputational harm, and, most importantly, risks to patient health.

Key Global Regulatory Bodies

Pharma operates in a global marketplace, meaning compliance often spans multiple geographies. Some of the most influential regulatory authorities include:

- **USFDA** (United States Food and Drug Administration): Oversees drug approvals, inspections, and post-market monitoring in the US. Its guidelines are often considered the gold standard.
- **EMA** (European Medicines Agency): Centralises medicine approval across EU member states and ensures pharmacovigilance.
- **CDSCO** (Central Drugs Standard Control Organization, India): Regulates clinical trials, approvals, and drug quality in India, one of the largest producers of generic medicines.
- **MHRA** (Medicines and Healthcare products Regulatory Agency, UK): Supervises medicines and devices post-Brexit.

- **ICH** (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use): Works globally to align technical standards.

- **WHO** (World Health Organization): Provides international guidelines and prequalification, especially critical for global health programmes.

For multinational pharma companies, navigating this regulatory maze is a strategic priority.

Pillars of Pharmaceutical Compliance

1. Good Manufacturing Practices (GMP)

GMP ensures that drugs are consistently produced and controlled under quality standards. It governs facility design, equipment validation, process monitoring, and personnel training. A lapse here can lead to contamination, recalls, and even loss of licences.

2. Good Clinical Practices (GCP)

GCP sets the ethical and scientific standards

At its core, regulatory compliance ensures that pharmaceutical products meet the highest standards of safety

for clinical trials. It ensures participant safety, informed consent, and reliability of clinical data. Regulatory agencies scrutinise adherence to GCP before approving any drug.

3. Good Laboratory Practices (GLP)

GLP ensures the reliability of non-clinical studies supporting drug applications. It addresses documentation, calibration of instruments, and reporting of results.

4. Data Integrity

Agencies like the FDA stress on ALCOA+ principles- data must be Attributable, Legible, Contemporaneous, Original, Accurate, Complete, Consistent, Enduring, and Available. With digital adoption, maintaining unaltered, transparent records has become both vital and challenging.

5. Pharmacovigilance

Even after approval, drugs must be continuously monitored for adverse effects. Pharmacovigilance systems ensure real-world safety, often leading to updates in labelling or, in rare cases, withdrawal from the market.

6. Labelling and

Packaging

Compliance extends to how drugs are labelled and packed. Labels must provide clear, accurate, and regulatory-approved information on dosage, warnings, and expiration dates. Packaging must ensure safety and integrity during distribution.



Challenges in Achieving Compliance

1. Globalisation of Supply Chains

Most pharmaceutical companies today rely on global supply networks. Ensuring compliance across suppliers and third-party manufacturers is a complex task. A single weak link can disrupt entire operations.

2. Evolving Regulations

Regulatory frameworks constantly evolve with new scientific discoveries, safety concerns, and global crises such as pandemics. Keeping pace requires dedicated compliance teams and continuous monitoring.

3. Technology Integration

AI, IoT, and digital health tools are transforming pharma, but they also introduce new compliance questions around data integrity, cyber security, and ethical use.

4. Compliance Costs

Maintaining high standards requires significant investment in infrastructure, audits, and training. For smaller companies, compliance can feel like a heavy burden.

5. Drug Shortages and Recalls

Non-compliance can trigger recalls that not only damage reputation but also disrupt patient care. Regulators often hold companies publicly accountable, making prevention critical.

Why Strong Compliance is an Asset, Not a Burden

While some view compliance as a regulatory hurdle, forward-thinking pharma companies see it as a strategic advantage:

- **Protecting Patients:** The ultimate purpose of compliance is safeguarding lives.
- **Market Access:** Only compliant companies gain entry into global markets, widening business opportunities.
- **Reputation and Trust:** In a sensitive industry, reputation is everything. Compliance builds trust with regulators, physicians, and patients.
- **Operational Excellence:** Standardised processes and quality checks often translate into efficiency and cost savings.

In essence, compliance is not just about fol-

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Compliance becoming predictive

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lowing rules- it's about embedding a culture of quality and accountability.

The Future of Regulatory Compliance

The next decade will witness compliance becoming more predictive, harmonised, and technology-driven. Key trends include:

- **Artificial Intelligence & Machine Learning:** AI will predict quality issues before they occur, enabling proactive compliance.
- **Blockchain:** A transparent, immutable way to track the drug supply chain, preventing counterfeiting and ensuring traceability.
- **Remote Audits & Digital Inspections:** Regulators are increasingly adopting digital audits, especially post-pandemic.
- **Global Harmonisation:** Organisations like ICH are pushing for unified global standards to reduce duplication and accelerate approvals.
- **Sustainability Compliance:** Environmental and social governance (ESG) standards will

integrate into regulatory frameworks, shaping greener pharma practices.

Conclusion

Regulatory compliance is the backbone of the pharmaceutical industry. It ensures that innovation in labs translates into safe, reliable, and effective medicines for patients worldwide. While the regulatory landscape is complex, embracing compliance as a core value- not just a requirement empowers pharmaceutical companies to thrive in a competitive and highly scrutinised environment.

As the industry marches forward with AI, biotechnology, and globalised production, compliance will remain the anchor that balances innovation with trust. For patients, regulators, and companies alike, regulatory compliance isn't just about rules- it is about responsibility, resilience, and respect for human life.

(The author is scientific advisor, Alkomex GBN Pharma Group USA)

Enhancing efficiency

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Pharmaceutical contract manufacturing has become vital to the global pharmaceutical industry, enabling companies to enhance efficiency, reduce costs, and accelerate product development. While it offers numerous advantages, including cost savings, expertise access, and scalability, it also presents challenges such as dependency on third-party manufacturers and regulatory risks.

As the market grows rapidly, pharmaceutical companies must strategically choose the right CMOs to ensure product quality, regulatory compliance, and long-term success. With the industry projected to reach US\$319.6 billion by 2029, pharmaceutical contract manufacturing will remain a key driver of innovation and efficiency in the healthcare sector.

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Steady growth driven by regulatory requirements

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followed by India at 8% and Germany at 7.4%. The United Kingdom records a growth rate of 6.1%, while the United States shows the slowest growth at 5.4%. The varying growth rates reflect the unique needs and developments within each market. Emerging economies like China and India are seeing higher growth due to increasing pharmaceutical production capacities, modernisation efforts, and government support for domestic manufacturing. In developed markets such as the US and UK, steady growth is driven by regulatory requirements, advancements in automation, and the continued focus on improving efficiency and product quality. This report includes insights on 40+ countries; the top markets are shown here for reference.

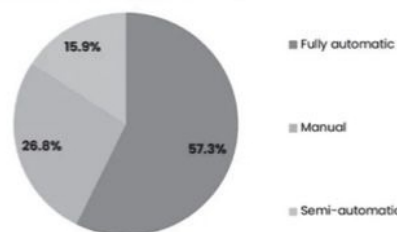
India's strong presence in the global pharmaceutical manufacturing industry, particularly in generic drugs production, is fueling the demand

for pharmaceutical machinery. The country's focus on increasing self-sufficiency in drug production and exports is a significant factor driving market growth. As India modernises its manufacturing facilities and embraces more automated and efficient production processes, the demand for advanced machinery is on the rise. Additionally, government initiatives such as "Make in India" are expected to further stimulate the adoption of advanced pharmaceutical machinery for both domestic and international markets.

The pharmaceuticals machinery market is experiencing strong growth, driven by the need for advanced manufacturing technologies that ensure efficiency, precision, and regulatory compliance. Rising global pharmaceutical output— fueled by population growth, higher healthcare spending, and increasing cases of chronic disease— is accelerating investment in modern machinery. Automation, robotics, IoT, and AI integration are transforming production, reducing errors, and improving consistency. Modular and compact de-

Pharmaceuticals Machinery Market

Global Analysis by Mode of Operation



signs are also gaining traction, offering greater flexibility to adapt to evolving drug formulations and production scales.

The market is segmented by machine type, including processing, solid dosage, capsule filling, analytical instruments, packaging, printing, and others. By operation mode, it is divided into fully automatic, semi-automatic, and manual systems. Applications span filling and packaging, formulation, sterilisation, quality control, and storage. Although high operational costs and strict compliance requirements present challenges, advancements in technology and rising demand for biologics and personalised medicines continue to strengthen long-term market prospects.

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Pharmaceuticals Machinery Market

Global Analysis by Machine Type

