Navigating Compliance and Regulatory Readiness with Medical Information

Post-market regulations have grown significantly more complex over time. As populations have become broader and more diverse, the risk of off-label use or misuse has increased, and navigating local regulatory nuances, cultural differences, and varying healthcare practices has become more difficult. Global expansion, particularly for mid-sized pharmaceutical companies, can be challenging due to limited resources and a lack of in-house expertise needed to navigate regulatory and operational requirements across diverse markets.

No single team can be expected to navigate every regional law, culture, and evolving technology alone. This is where a trusted Medical Information (MI) partner becomes invaluable. This article outlines the critical operational areas where pharmaceutical companies must maintain compliance and highlights how the MI team can serve as compliant hubs for scientific exchange with the public.

Regulatory Frameworks around the Globe
Pharmaceutical companies are expected to operate across borders while staying aligned with each region's expectations for data protection, marketing practices, digital transparency, and safety communication. Here's a summary of some of the most critical compliance challenges currently impacting the industry, along with ways MI can provide valuable support.

EU Falsified Medicines Directive (FMD) and the U.S. Drug Supply Chain Security Act (DSCSA)
Many countries have implemented strict drug tracking regulations, but the most notable developments occurred in the early 2010s, when both the EU and the U.S. established regulatory frameworks to combat counterfeit drugs in circulation. These frameworks introduced requirements such as unique identifiers (serialisation) and more rigorous record-keeping. Together, they help prevent harmful drugs from entering the supply chain and enable quicker responses to remove them, ultimately protecting public health.[2,3]

Improving Clarity with MI Support
Pharmaceutical companies must ensure their packaging, distribution, and reporting systems comply with these regulations. Serialisation expertise within MI supports faster reporting of supply chain issues and enables clearer communication during recalls or when addressing product authenticity concerns.

Personal Information Protection Law (PIPL) of the People's Republic of China
China, the country of a 1.4 billion population, enacted the PIPL and Data Security Law (DSL) in 2021, which is widely regarded as one of the strictest data security and privacy laws in the world.[4] PIPL requires data to be collected with consent, stored within China, and restricts cross-border data transfers. These rules apply to both domestic and foreign organisations that process personal information of individuals in China.

Local Presence Matters for MI
Pharmaceutical companies need to comply with personal data processing regulations when handling product inquiries, complaints, and adverse event reports. To ensure compliance in China, it is essential to partner with a MI provider that has a locally established entity, secure documentation platforms, and expertise in local data governance.

EU General Data Protection Regulation (GDPR)
GDPR is one of the strictest privacy laws in the world,[6] enacted by the EU in 2018, imposing obligations on organisations anywhere in the world collecting data related to people in the EU. The data protection principles guide organisations on how to handle personal data responsibly and transparently. GDPR also outlines the rights of individuals, such as consent, access, and request for their data. Non-compliance can result in a high fine, up to 20 million euros or 4% of global revenue, whichever is higher.[5] Beyond financial impact, reputational damage can lead to further business loss.

Embedded Compliance in Front-End Communications with MI
As the primary point of contact for customers seeking product information or reporting adverse events, MI plays a critical role in ensuring compliance. MI specialists receive GDPR training to ensure all customer interactions are handled appropriately and all systems used for communication and documentation are fully GDPR compliant.

Health Insurance Portability and Accountability Act (HIPAA)
HIPAA is a U.S. federal law that defines which types of health information are protected and outlines how protected health information (PHI) may be used and disclosed by healthcare providers and related entities. It also grants patients specific rights over their health data, including access and control over how it is shared. Non-compliance with HIPAA can result in civil penalties and lawsuits, as well as criminal penalties, including imprisonment, for wilful violations.[6]

Upholding HIPAA Compliance Through MI Expertise
In the U.S., many MI specialists are healthcare professionals with strong HIPAA expertise. They ensure that all processes involving product inquiries and adverse event reporting comply with legal requirements, including proper handling of protected health information (PHI). Their guidance helps pharmaceutical companies maintain HIPAA compliance, along with other regulatory requirements, across all MI activities.

EU Artificial Intelligence Act (AIA)
EU AIA is the first comprehensive legal framework to regulate artificial intelligence in the EU. Enacted in 2024, its enforcement will roll out in phases by 2027 to ensure safe, transparent, and fair use of artificial intelligence (AI) based systems.[7] The act classifies AI according to its risks, prohibiting systems that may cause harm to individuals or society. AIA places the majority of obligations, such as risk assessment, audit trails, and transparency, on developers and deployers. Penalties for non-compliance are higher than the General Data Protection Regulation (GDPR), up to 35 million euros or 7% of annual turnover, whichever is greater.

Aligning AI with Compliance through MI
As AI tools like chatbots and virtual assistants become more prevalent, MI plays a critical role in supporting compliant

implementation. MI can help ensure these tools are designed to be unbiased and transparent, while also defining appropriate practices for data capture, storage, and oversight. MI's involvement is essential in aligning AI-enabled solutions with regulatory expectations and safeguarding patient trust.

U.S. Artificial Intelligence (AI) Regulation Development

While the U.S. does not yet have federal AI legislation, states and institutions are stepping in. An Executive Order titled 'Safe, Secure, and Trustworthy Development and Use of Artificial Intelligence', issued in October 2024, was revoked in January 2025, signalling a shift toward decentralised regulation.

National Institute of Standards and Technology (NIST): Artificial Risk Management Framework (AI RMF)

NIST worked with public and private sectors to develop AI RMF, first released in 2023 and last updated in July 2024. It is designed for organisations to voluntarily use to incorporate trustworthiness considerations into the development and use of AI systems.[8]

Food and Drug Administration (FDA): Software as Medical Device (SaMD)

Artificial Intelligence (AI) and Machine Learning (ML) are inclusive of SaMD risk-based pathways for approval. In January 2025, the FDA released a draft guidance titled Artificial Intelligence-Enabled Device Software Functions: Lifecycle Management and Marketing Submission Recommendations. The guidance outlines how to manage ongoing modifications to AI algorithms, with a focus on transparency, data quality, and performance monitoring expectations.

Federal Trade Commission (FTC): Operation AI Comply

In September 2024, the FTC launched a broad crackdown on the deceptive use of AI, taking enforcement action against five companies involved in misleading practices such as false claims about AI-powered legal services, the generation of fake consumer reviews, and AI-driven business scams.[9] This marked a significant step in the agency's commitment to protect consumers and maintain market integrity as AI technologies become more widespread. In addition to these actions, the FTC is actively investigating other instances of AI misuse reported by consumers, pursuing them on a case-by-case basis.

Supporting Ethical and Compliant AI Through MI

The integration of AI into medical communication presents immense opportunities to enhance efficiency, personalisation, and access to information. However, in the absence of comprehensive federal legislation and amid a patchwork of evolving agency-level regulations, the risks are equally substantial. This is where highly experienced MI professionals bring the regulatory and operational expertise needed to responsibly evaluate AI tools before implementation.

Beyond vetting, the MI team is instrumental in developing detailed use-cases, defining appropriate boundaries for AI deployment, and identifying potential risk points. Most importantly, they serve as the essential layer of human oversight, ensuring that AI-driven communication remains accurate and ethical.

The Value of Medical Information as a Strategic Regulatory Partner

Maintaining regulatory readiness is a crucial operational requirement in today's rapidly evolving, technology-driven pharmaceutical industry. With targeted medicine and the use of smart devices reshaping the treatment model,[1] pharmaceutical companies are facing challenges to keep up with increasingly complex and fragmented regulations, from healthcare authorities to data security and privacy. The pressure to innovate and customise has never been greater, yet even the slightest oversight can have negative consequences for companies.

Post-Market Expansion and Compliance with Medical Information

After product launch, the right regulatory partner and highly experienced communication hub, MI, can support companies navigate the complexities of applicable laws and industry standards; not only in healthcare, but also in areas such as data security and emerging technologies.

Benefits of the Right Partner

- **Regulatory Foresight –** Effective compliance requires anticipating regulatory shifts before they become urgent matters. A proactive partner continuously scans the global landscape, identifies emerging trends, and prepares

your team to adapt early, reducing risk and ensuring uninterrupted operations.

- **Global Presence and Local Expertise –** Staying ahead of evolving global regulations requires a deep understanding of how these changes translate at the local level. The right partner brings cross-regional expertise to help interpret, adapt, and implement regulatory requirements.

- **Implementation and Operation Support –** Implementing compliant workflows or systems within MI requires both regulatory knowledge and practical expertise. The right partner not only understands the requirements but also brings the frameworks, technology, and operational insight to optimise and scale processes that meet global standards, ensuring compliance is embedded in daily operations.

- **Innovation with Compliance –** Innovation can be challenging within strict regulatory frameworks. The right partner drives compliant innovation by collaborating with cross-functional experts, while MI professionals ensure that compliance requirements are clearly defined and integrated. True innovation is sustained through ongoing research, thoughtful design, continuous adoption of new solutions, and rigorous oversight.

Achieving Compliance Through Strategic Alignment with Medical Information

Post-market pharmaceutical compliance continues to evolve, with increasingly divergent global and local requirements. Yet, this complexity can be proactively managed by leveraging MI as a strategic compliance partner.

MI plays a critical role in ensuring regulatory readiness by:

- Adapting content to meet local regulatory nuances without losing global consistency
- Ensuring consistent, compliant, and medically accurate communication
- Supporting audit preparedness through regulatory-compliant, traceable processes
- Monitoring inquiry trends for early signal detection and safety insights
- Guiding the responsible implementation of advanced technologies and AI in medical communications

By embedding MI into compliance strategies, companies can shift from reactive approaches to proactive readiness. With the right systems and experts in place, compliance becomes a continuous state instead of a crisis response.

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