The Future of Pharma Regulations

Yogi Raj, Associate Vice President, Fryer Solutions, India

The future of pharma regulations is challenging with diverse and complex regulations globally. It will be challenging for industry to adapt to regulated and semi-regulated markets alike while attempting to develop a harmonised strategy with ever-growing cost pressure on off-patent products for both small molecules and biologics. Differentiating new and legacy products with established safety profile and evolving a new compliance paradigm that shifts from traditional methods to a new, global, intelligence-driven regulatory compliance structure along with a judicial mix of centralised and localised regulatory teams is the key to reducing the cost burden and achieve global compliance in a timely manner.

The Pharma industry at large is faced with challenges due to fast changing global regulations and many countries moving towards adopting a tighter control over drugs. The patent cliff has pushed the industry to maximise their revenue from the existing portfolio in the past few years and thus resulted in expanding their market in emerging markets. This thought process, however, is not limited to off-patent or soon to be off-patent drugs, but companies with the product under development are also adopting a global strategy for trials either to address niche therapeutic indications or maximise their drug's commercial potential. Both the scenarios pose a common challenge of understanding, assessing and implementing a global regulatory strategy in a timely manner. While global ICH guidelines and countries moving towards CTD/eCTD format offer a way of harmonised regulatory strategy to these markets, regional regulatory complexities largely continue to pose a challenge and despite certain commonalities, each country is handled individually impacting the subsequent timelines and cost of compliance significantly. The region-specific challenges span across the local GMP requirements(as not all the countries follow a lead country model), semi-regulated, unstandardised documentation, multi-agency interactions, requirement of intensive health authority interactions, language nuances, export and import licenses, need for local applicants or representation, regulations on biological samples, and ICF requirements, to name a few.

Adopting a centralised regulatory strategy

It will be ideal if global markets could adapt to harmonised regulatory standards and procedures; however, it is unlikely to happen anytime sooner, due to socioeconomic and political factors that play a key role in countries' applied regulatory frameworks.

Nevertheless, the industry is diligently identifying areas across the regulatory value chain that can potentially be centralised and harmonised to achieve compliance faster using cost-effective methodologies. Pharma companies are increasingly investing in global regulatory strategies using a two-pronged approach, including comparative assessment of global regulations and formulating template-based strategies to address the regulatory gaps across markets while also integrating technology-enabled intelligence frameworks to tap on potential changes in regulations in these markets that can impact existing procedures and thus the regulatory strategies at large. The ever-increasing pressure with R&D costs will lead to the evolution of new business models where traditional ways of regulatory aspect of global clinical trials will shift from localised/nationalised to a combination of a centralised and localised model. The model already exists for regulatory operational functions such as publishing, labeling, and artwork. However, this approach will expand to regulatory affairs functions such as dossier preparation and chemistry, manufacturing and control (CMC) functions that are traditionally supported locally.

Regulatory information management transformation

The way forward for pharma industry will be to bring efficiency and boost productivity through comprehensive global regulatory information management and achieve compliance in a timely manner by reducing costs. Over the past few years industry has been seeking transformation in regulatory information strategies and solutions across the value chain i.e., regulatory data management as per the HA standards (XEVMPD, IDMP and UDI), submissions planning, dossier management, product registrations, label management, submissions management, HA interactions and product lifecycle management among others. It will take another few years for companies to have implemented validated systems for end-to-end regulatory information management; however, this strategy is the key for centralisation of key regulatory activities focusing on core portfolio to enable better control and ensure key challenges are addressed. The challenges include Compliance Monitoring and Business Risk Management, Inconsistency across markets impacting brand image, Non-traceability of information, Slower response to changes in regulations, Ineffective approval process, Non-uniform versions of documents, Undefined turnaround time, quality metrics and focus on reusability of documents.

Integrated regulatory intelligence

Existing regulatory frameworks within the Pharma companies are often fragmented, except few centralised functions, with diverse products and markets and respective product and market representatives. Cross-functional teams located in different regions often slow down the information exchange process and further change assessment and implementation. Hence, the industry is realising the potential of agile solutions and strategies that can enable faster change assessment and implementation. Current processes and vendor landscape allow less flexibility to innovate, thus offering greater opportunities for aggressive processes, frameworks, and technology solutions to evolve. As these challenges become part of major discussions, industry will look towards solutions that change the current landscape. Effectively integrated intelligence-driven regulatory frameworks will be one of the key elements possibly to drive the change with desired flexibility complimented by flexible and scalable technology solutions. An integrated regulatory intelligence system will not only provide access to global regulations, but such systems can also provide a real-time

notification of changes in global regulations that can potentially impact organisations' regulatory strategies, regulatory processes, and even operational frameworks. Collaborative models where the system-enabled teams can assess the impact and implement the change efficiently can save huge cost for organisations while ensuring compliance.

Identify and focus on growth functions

Increasing cost pressure, reducing margins, and growing competition including that from counterfeit products, pose significant operational challenges for regulatory teams. While regulatory professionals in different regions spend about 60-70 per cent of their time in life cycle maintenance activities against 40-30 per cent on growth activities (where growth activities include those supporting innovation, R&D, new product roll outs, market expansion etc.), the organisation focus is diluted leading to reduced growth rate and shareholders value. It will be imperative for organisations to identify and clearly differentiate these activities and implement alternative models that can centralise the non-growth operational activities (often routine and scripted) for legacy products versus growth activities driven by innovation. Centralisation of such operations not only bring efficiency, and consistency across documents and document types, but also reduce the costs significantly if combined with low-cost operations and delivery centers. During the past couple of years, organisations have invested increasingly on assessing their regulatory organisation landscape for assessing the opportunities that can impact their bottom-line and realign their focus towards boosting the topline through innovation. This trend will continue and will potentially give rise to a combination of models, integrating global, centralised, uniform, process driven, and fast-paced low-cost models to address the margin gap. The industry is also trying to implement those models for R&D programs to reduce the cost of development programs across regions.

Cross-functional, cross-market excellence

The supply chain of pharma continues to grow globally, posing greater challenges to track compliance. While leading agencies such as the Food and Drug Administration (FDA) is working with regional authorities to distribute the sheer number of registrations assessments and audits, pharma companies will have to soon align with comprehensive data management and traceability of drug products to ensure they manage their global registrations in a timely manner. Guidelines such as UDI for devices and IDMP for drugs in the USA and Europe respectively designed to ensure medicinal products and devices can be traced and can be held accountable for any adverse event. This also aims at addressing the challenges from counterfeit products that are increasingly gaining market share in the multi-billion dollar industry worldwide. This requires smarter tracking systems and cross-functional, cross-market integrated applications to ensure uniformity across the board and the global compliance monitoring. Global registrations management traditionally has been handled in silos. The entire ecosystem including the pharma companies and vendors are evolving towards an end-to-end submissions management structure where there is a visibility across the board on the current status of documents and document components, submission timelines, deviations across countries and proactive measures driven by real-time intelligence. This means cross-functional stakeholders will have to work using centralised systems as well as work closely with stakeholders and regional market representatives to maintain the uniformity.

To summarise, it is unlikely in near future to have harmonised global regulations on medicinal products and devices alike. The country-specific socioeconomic and political situations might pose challenges in managing different documentation standards for a product across markets, managing submissions timelines, quality and compliance and further gaining visibility of overall status. An all-round regulatory affairs and operations management strategy, driven by regulatory intelligence, coupled with significant transformational technology intervention for information management is a way forward to address the regulatory needs of the pharma industry.

Author Bio

	**Yogi Raj** is a seasoned competitive, clinical, market and regulatory intelligence professional with over ten years of multi-disciplinary experience within the life sciences industry. A science driven, entrepreneurial and resourceful professional with hands on experience in building processes, systems and solutions ground up solving critical industry needs.