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## Regulatory Intelligence: It's More Than Just Compliance

**By Manan Ambani, Freyr Solutions**

Almost every life science company — in particular, every pharmaceutical company — is under pressure to monitor the changes that are taking place in the regulated landscape and respond to them accordingly. Deep insight, quick, accurate data analysis, and timely publication are critical to an incisive regulatory intelligence function that ultimately leads to a multitude of business benefits.



Compliance should never be an afterthought. If intelligence toolkits are cascaded throughout the organization, everyone is made aware of potential issues and how they should be handled. More importantly, they know exactly what the rules are.

You can't afford to move forward with the regulatory intelligence momentum without first understanding the layer cake of global regulations. Industry pundits predicted that the production of globally regulated and complex pharmaceutical products would double between 2011 and 2021 and eventually would increase exponentially as the years pass by. At this juncture, the industry requires appropriate market entry strategies to remain competitive. Pharmaceutical regulatory intelligence is about understanding the trends, players, the regulations themselves, bureaucracies that regulate the industry, an entire market map, and the regulatory forces that impact the business. The perspectives of regulators, trade associations, and major players in the sector and understanding the market access issues provide essential insights to the practitioner. This information helps decode the market entry challenges in the target market. Once the regulatory landscape is mapped, the practitioner can make strategic decisions and informed choices to minimize regulatory risks and increase success. A regulatory intelligence plan includes an analysis of the global regulations and the key variables of every ecosystem of an organization. Domestic or global companies expose themselves to organizational risks without a regulatory intelligence plan, as they fail to understand the true risks.

When a company monitors and gathers information about regulations affecting its business, it is cognizant of specific risks. Regulatory intelligence includes a lot of information that must be collected, evaluated, analyzed, and summarized. Data pertaining to filings, publicly available material, confidential material, technical information, political information, economic analysis, and media analysis is part of the intelligence. The practice of analyzing data and identifying trends for decision-making is key here.

## Roles And Responsibilities

Regulatory intelligence professionals work in different roles, including as in-house analysts, consultants, and independent practitioners. They serve in positions ranging from entry-level analysts and specialists to senior managers, directors, and vice presidents. Regulatory intelligence consultants typically specialize in an industry or a specific regulatory area (e.g., healthcare), have deep knowledge of that industry or regulatory area, and understand the fundamental concepts of regulatory intelligence. Every aspect is addressed, from gathering, analyzing, and delivering advice or intelligence on the activities to plans, intentions, and performance of organizations and individuals operating in a regulated industry. Most regulatory intelligence professionals serve in one or more of the following roles:

- Research identifying trends, patterns, and opportunities
- Identifying, analyzing, and interpreting regulatory information
- Writing reports, articles, and white papers
- Communicating information effectively
- Consulting and/or serving as expert advisors
- Developing strategic recommendations
- Developing and delivering training
- Supporting business development, etc.

The regulatory environment is complex and dynamic. Regulatory intelligence analysts must accurately comprehend vast amounts of information, translate it into insight, and communicate it in an actionable form. Regulatory intelligence is information about regulatory activity, such as impending changes, filing requirements, and enforcement actions. It is different from regulatory risk analysis, which requires a rigorous assessment of the potential impact of a regulatory change on an organization.

## Regulatory Intelligence Approaches

There are two primary approaches used by regulatory intelligence professionals to collect, analyze, and disseminate information – passive and active, a combination of which is ideally the best way forward.

**Passive approach** – The passive approach involves monitoring, analyzing, and disseminating publicly available information. This approach can be completed relatively quickly and does not require the analyst to have specialized knowledge or access to confidential information. Passive approaches are best suited for monitoring broad and general trends (e.g., regulatory trends, industry trends), monitoring emerging risks, and identifying significant developments (e.g., emerging legislation, landmark regulatory filings, etc.).

**Active approach** – The active approach involves the identification and collection of confidential information, specialized knowledge, and personal relationships. This approach is best suited to situations where an organization needs situational awareness, early warning of regulatory developments, or specific information about a target organization. The active approach is based on identifying contacts, conducting information interviews,

acquiring confidential documents, establishing confidential sources, and conducting surveillance activities.

Regulatory intelligence can help your company go global as well as reduce regulatory risks, achieve faster approvals, and help manage the cost and time impact of global regulatory changes. Regulatory intelligence thus allows companies to identify issues and trends and manage compliance proactively. It identifies and eliminates high-risk areas so you can prevent fines and expensive delays. It increases profitability through faster time to market, thus resulting in improved outcomes and increased revenue. It also empowers businesses to make faster and better business decisions. Having a continuous feed of knowledge helps your organization respond to market, legislative, and competitive demands in a timely manner.

With a regulatory intelligence team available on demand, you can isolate data points, define sources, use monitoring platforms, watch for changes in legislation, and record information onto dashboards. Simultaneously, you can track internal, external, and third-party data, so you have a complete picture of your business.

Regulatory authorities have shown an increase in interest in reporting of quality metrics, typically a role satisfied by a regulatory intelligence team member. That team member can use various tools for this, such as dashboards, event monitoring, data visualization, data mining, predictive analytics, artificial intelligence, and machine learning. If your reporting is cost effective, timely, and focused, your regulatory intelligence team's efforts can help your company identify opportunities, defend existing positions, and help you define and implement strategic changes to catapult your firm to global markets.

### **About The Author:**

**Manan Ambani** is a senior associate in Freyr Solutions' Medicinal Products Division. A pharmacist . and MBA graduate from Narsee Monjee Institute of Management Studies (NMIMS) Mumbai, he believes that there is a place for innovation in the everyday lives of all stakeholders, internal as well as external. He holds experience across the pharmaceutical and healthcare value chain, ranging from formulation development and R&D to healthcare advertising and communications.

