Umesh Kurra, Manager – Global Regulatory Services, Freyr Solutions elaborates about the right approach to regulatory intelligence and explains how it will benefit in faster time to market while taking proactive regulatory decisions for global implementation, and improved operational excellence

Launching innovative products across global markets is an effective revenue generation method for life sciences companies. Regulatory compliance and approvals being the driving factors behind any successful launch, inadequate regulatory information can trigger an increase in costs and time-to-market. The role of a comprehensive regulatory intelligence (RI) approach is paramount in the launch process.

The life sciences industry is governed by continuously evolving regulations requiring industry players to stay informed and stay compliant. Keeping up with the ever-changing regulatory landscape can be challenging for life sciences manufacturers.

Furthermore, collation of the enormous amount of information, understanding and interpreting all the regulatory updates available on the Health Authority (HA) websites, third-party databases, and adapting to the new regulations puts an additional burden on the company resources. To counter these challenges and hurdles, an increasing number of organisations prefer to rely on RI tools and services. These tools and services assist in creating a compliant strategy and execution plan thereby avoiding any mishaps throughout the product lifecycle. For over a decade now, large and enterprise companies have been investing in a dedicated RI function. Despite the integration of RI tools, solutions, or support, organisations still face difficulties in decoding the regulations and complying with them. This could partly be due to the inefficiency of existing tools to tackle end-to-end RI on a global scale.

In this digital era, information is infinite. In fact, with so much information on hand, companies struggle to segregate useful information. Not all data is relevant to the companies and there can be a significant amount of noise that regulatory professionals need to filter. The information needs to be processed effectively for regulatory compliance and even the filtered-out information can also prove to be useful, with an effective approach for RI.

Moreover, as described in *Table 1*, different stakeholders responsible for regulatory compliance have different requirements. RI helps in meeting all these diverse needs.

TABLE 1: STAKEHOLDERS' REQUIREMENTS FOR REGULATORY COMPLIANCE

Manufacturer Requirements	Health Agency Requirements	Regulatory Intelligence
◗ Focused view on the therapeutic segment of interest ◗ Regulatory Intelligence data pertaining to competitor/precedence products ◗ To get it right-the-first time of Regulatory approach and avoid any regulatory blockades in the product life cycle	◗ A holistic view on the developmental landscape ◗ New technological advancements in each therapeutic segment ◗ Monitor the advancements to understand the need for more stringent regulations and data requirements ◗ Identify the need for new policies, laws, and directives	◗ Understand new technologies and build internal capabilities ◗ Identify applicable regulations ◗ Track and be updated on new advancements in regulations ◗ Understand and identify test requirements and optimum data requirement for Regulatory submissions ◗ Regulatory pathways for registration ◗ Optimise data and documentation forglobal registrations

So, what then constitutes the requirements for an ideal RI approach? An ideal 3600 RI support must encompass and support regulatory functions of Global Regulatory Affairs, Quality Assurance, CMC, Submissions, Labeling, Artwork and Packaging, Pharmacovigilance, Supply Chain, Technology and IT, Regulatory Policy, and Marketing.

From a bird's eye view, the RI process seems effortless – gathering data, analysing information, and creating a regulatory strategy. RI is the key to unlock superior regulatory submission strategies and new market decisions. However, each step in this process includes a multitude of steps and brings with it its own set of challenges.

A comprehensive approach to RI

A wholesome approach for RI includes:

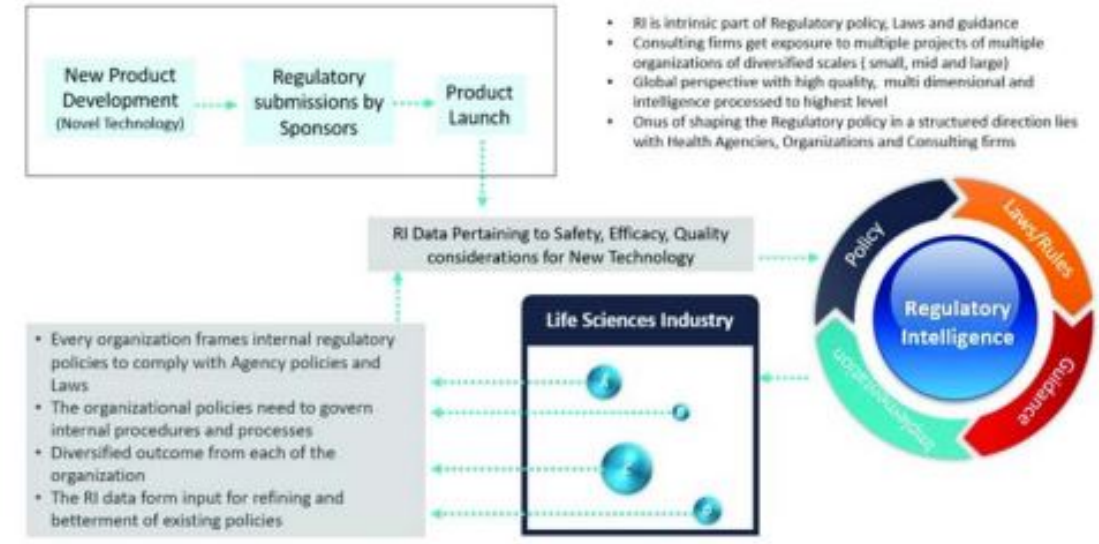
- **Primary research** that covers data sources across country updates, regulatory updates, congress coverage, trade associations coverage, authority and ministry coverage, key opinion leaders, and key influencers.
- **Secondary research** that encompasses data about country/product regulatory landscape, ongoing literature review, regulatory updates, clinical intelligence, HA updates, news and research, regulatory precedent of the policy, impact on the policy, lead countries and follow up countries.
- **A technology** solution that is a web-based, metadata-driven RI platform, real-time tracking and update, multiple information sources, actionable, auditable, collaborative social, and compare documents, regulations, and requirements globally.
- **GRX Framework** – IMPACT integrated with other technologies, in-house integration with DMS, PLM, submissions and other software, reusable content.
- **Real-time** distribution and action, real-time impact assessment of regulations and changes assign activities across departments for timely action

- **Reporting and audit** – Country/product specific comprehensive analysis, Newsletters and periodic reports, real-time news updates, on-demand reports, audit actions for compliance with changing regulations.

Another key aspect of regulatory compliance for organisations is being synchronous with regulatory policy and unmasking the gaps between regulatory policy and RI. Paving the way for the synchronous functioning of an organisation demands relentless efforts and support – both technological and functional.

As shown in *Figure 1*, every organisation should create an internal regulatory policy to comply with the HA policies and laws. Organisational policies need to govern internal procedures and processes. The RI data form the input for refining and enhancing existing policies.

FIGURE 1: BRIDGING THE GAP BETWEEN RI AND REGULATORY POLICY



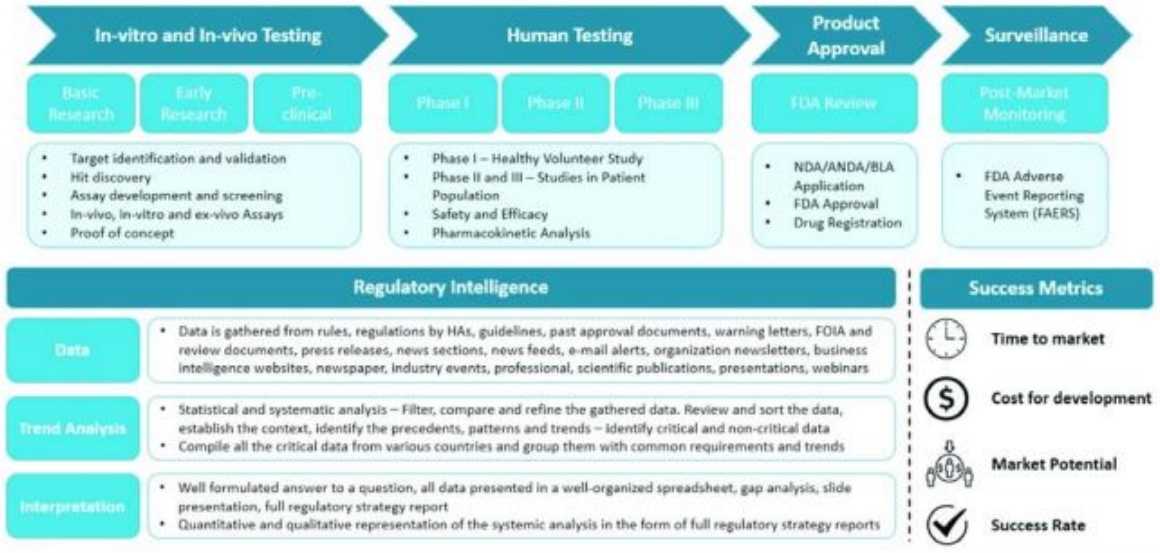
Value proposition of RI

RI can be gathered, assessed, and used across various stages of the product life cycle. Its value proposition is immense in understanding the current trends and taking necessary actions for addressing both; functional and business needs of an organisation. As described in *Table 2* and *Figure 2*, the value proposition of RI is multi-faceted and is significant throughout the product life cycle.

TABLE 2: BRIDGING THE GAP BETWEEN RI AND REGULATORY POLICY

RI Trends	Description	Value Proposition
Competitor Intelligence	Regulatory status or Regulatory evaluation of a competitor product.	Determines the likelihood of success of own strategy and gauges launch time if need to be 'first in line'.
Environmental Intelligence	Existence, implementation and use of legislation, regulatory frameworks, tools, or initiatives on a specific pharmaceutical topic.	Enables identification of requirements, rewards, and incentives, as well as regulator acceptability and competence.
Due Diligence Support	Scenario and risk management planning in relation to an in-licensing opportunity.	Enables identification of potential risks that may impact regulatory success. Aids go/no-go decision-making.
Procedural Intelligence	Practical experience in the interpretation or application of regulatory provisions that relate to a regulatory procedure.	Clarifies whether the situation falls within known instances. Shapes dialogue with regulators if required; to justify the position.
Regulatory Precedents	Known instances of a novel regulatory approach or deviation from normal practice (success or failure).	Helps determine the likelihood of success and any key differentiators that might persuade regulators to accept the client's position.
Metrics	The mathematical occurrence of a regulatory event or time span for a regulatory procedure.	Aids submission and launch planning and internal benchmarking against industry standards.

FIGURE 2: RI ACROSS PRODUCT LIFE CYCLE (US FDA EXAMPLE)



Regulatory strategy

A regulatory strategy is an authorised approach that coordinates with regulatory affairs to launch an overhauled pharma product/ device into a market, backed with a brilliant marketing plan. A regulatory strategy defines the plan for developing a product with the goal of obtaining regulatory approvals without any hassles in the desired markets. It also includes a plan for life cycle management/maintenance.

The regulatory strategy process aims at offering a comprehensive elucidation of the project, apart from distinguishing the relevant regulatory elements that need to be addressed to promote the product.

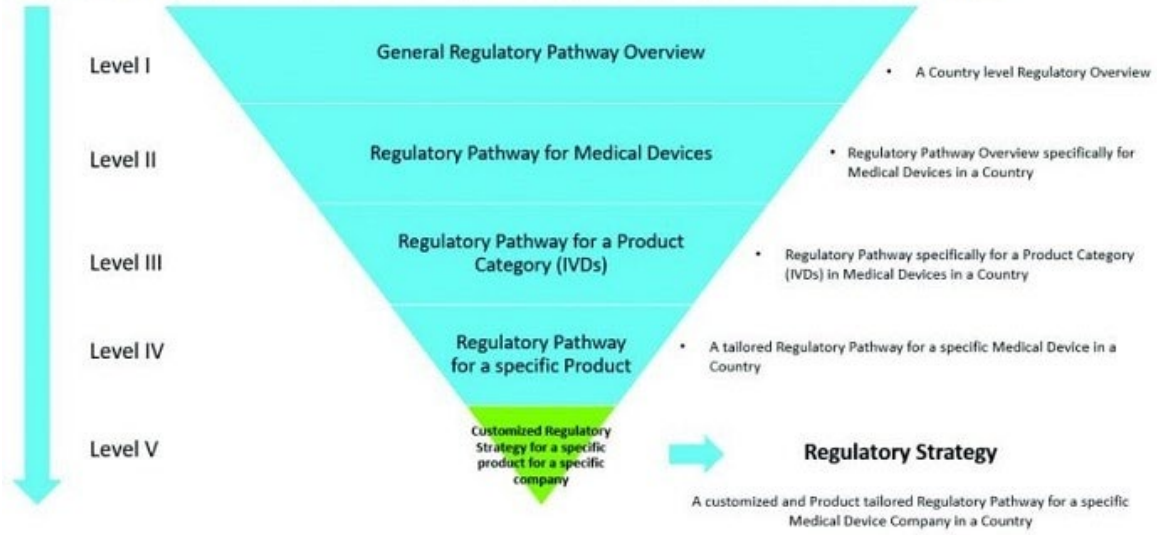
A global regulatory strategy program must fulfil the following criteria:

- **Fundamental target product profile** – The marked analytical implications alongwith predictable labelling petitions of the product should be configurated with the fundamental target product profile
- **Changing regulatory environment** – The program shall determine the continuously evolving regulatory environment that further involves the pursuit of a revived legislation and standards for requirements
- **Facilitate new development tools** – The program should leverage newly acknowledged development tools that save time and expense. Those tools should also ardently enhance compliance of foreign data to access global markets
- **Predictable future approval requisites** – The program shall determine predictable future approval requisites aligning with present approval prototypes and progressing clinical programs. The requisites may include comparisons, deadlines, statistical paradigms etc.
- **Proactively recognise challenges** – The program should ardently recognise challenges that are responsible for delaying analytical development. It should also explain the creative approaches initiated to circumvent these challenges.
- **Distinguish key opportunities** – The program should be able to distinguish key opportunities to engage global Regulatory authorities to assist these discussions.
- **Eliminate developmental risk** –The program should be able to eliminate the developmental risk if any, whilst boosting the potential for commercial success.

Multi-level approach for a product and country-specific regulatory strategy

In parallel to having a global regulatory strategy, it is equally important to have a country-specific regulatory strategy as companies tend to simultaneously start the registration process in multiple desired markets; particularly in emerging markets, to expedite the overall registration process and reduce their time to market. As shown in *Figure 3*, there are multiple levels in devising an effective regulatory strategy. A country-specific regulatory strategy is the most advanced level of RI and it must be specific to a particular product and company.

FIGURE 3: MULTI-LEVEL APPROACH FOR PRODUCT AND COUNTRY SPECIFIC REGULATORY STRATEGY



The key outcomes of RI and regulatory strategy:

- Timely and consistent submissions across global markets
- Effective approval process
- Uniform versions of documents
- Better planning for turnaround time and quality metrics
- Compliance
- Market-specific process adherence
- Harmonised documentation and quality standards across markets
- Policy and strategy
- Proactive product/market strategy
- Policy adaptation and internal/external influence
- Supporting business as usual
- Support day-to-day intelligence needs for micro and macro decisions
- Real-time knowledge support
- Accelerated training
- Impact on patient safety and brand image
- Consistency across markets impacting brand image
- Accelerated response to changes in regulations
- New regulatory opportunities and portfolio maximization
- Market-specific process adherence
- Harmonised documentation and quality standards across markets
- Centralised intelligence delivery platform
- Global submissions, dossier preparation, CMC management, artwork and label management
- Global intelligence-driven approach
- Compliance monitoring and business risk management
- Productivity, efficiency, and cost
- Informed decisions
- Improved compliance
- Intelligence-driven approach
- Internal links

To conclude, the right approach to RI will benefit in faster time to market, lesser cost for development, greater market potential, higher success rate, proactive regulatory decisions, global implementation, and improved operational excellence. What is your approach towards RI? Define it carefully and in a compliant manner. Stay informed. Stay compliant.