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TATA ELXSI

Automating Regulatory Intelligence for the $10 Trillion Global Healthcare Market

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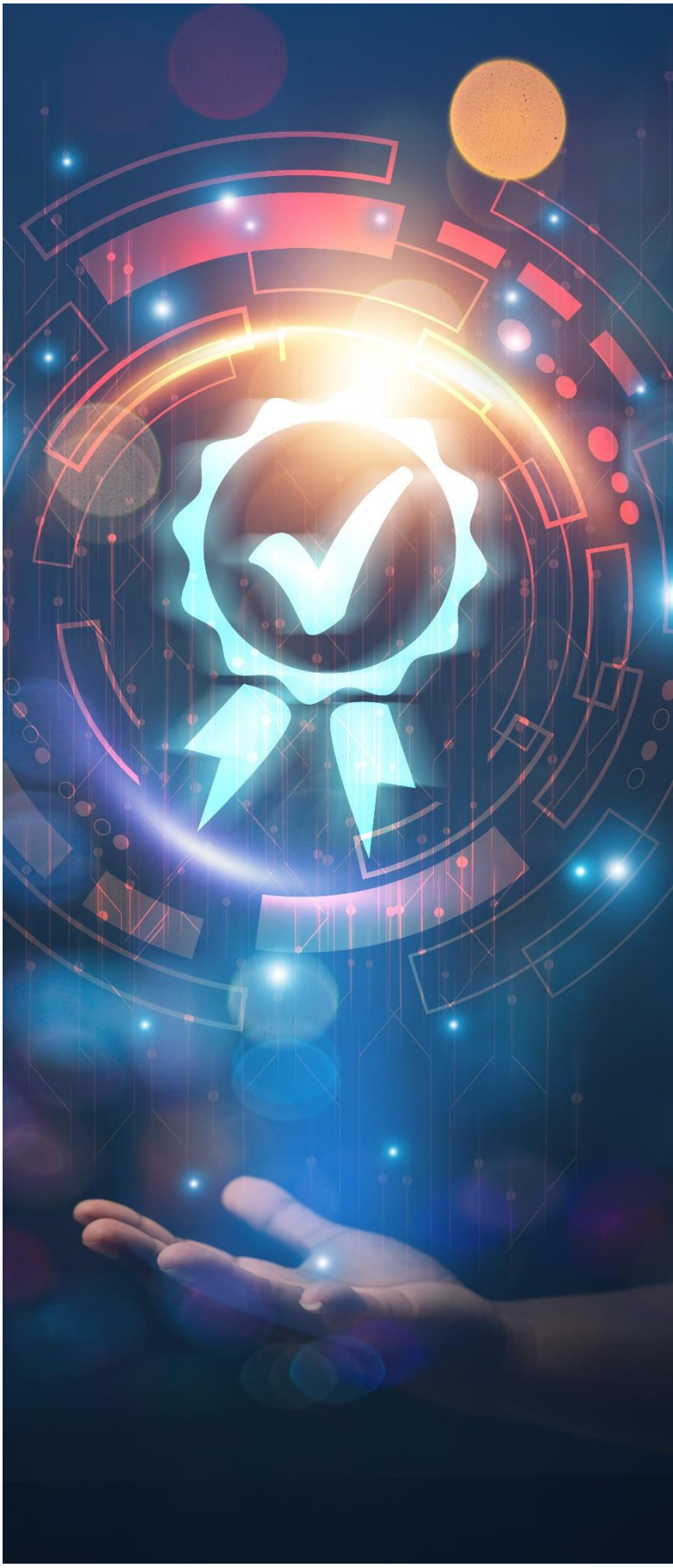
ABSTRACT

Pharmaceuticals, biotech, and medical device manufacturers spend millions of dollars annually in compliance costs across regulated and semi-regulated markets. The number and complexity of laws that the healthcare sector must follow have grown over the past few years. With the evolving regulatory landscape and increasing competition and cost pressure, organizations are shifting their focus to building sustainable business processes relevant to current times. Manufacturers are already using regulatory intelligence technology to address complex compliance requirements. Several factors, such as the vast amount of unprocessed information, complex clinical development and trial workflows, stringent regulatory requirements, etc., call for advanced automation technologies such as robotic process automation (RPA), artificial intelligence (AI), and machine learning. Automating regulatory intelligence can not only help streamline time-consuming processes but can eliminate the inevitable manual errors as well.



INTRODUCTION

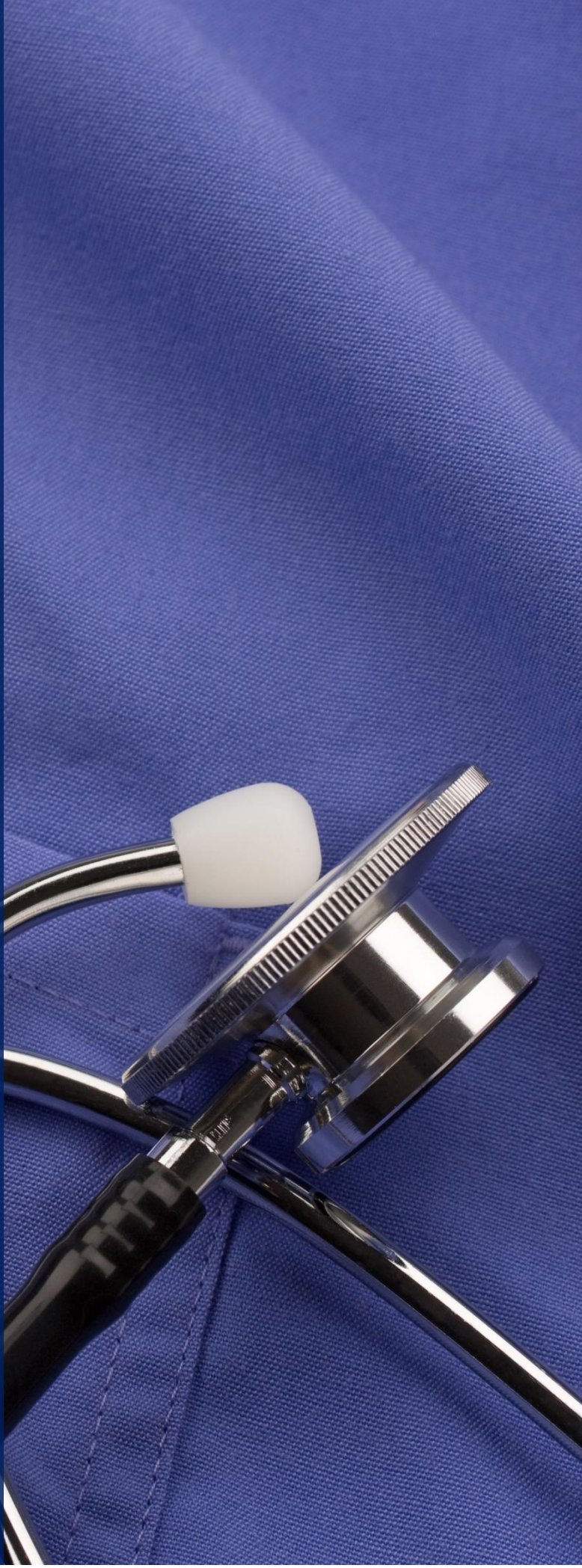
For businesses to remain compliant with the healthcare industry's ever-changing regulatory requirements, it is imperative to gain a comprehensive understanding of global regulatory updates and information to determine the best course of action. Organizations have to assess the impact of regulatory changes on the organization, report to the board, and put appropriate plans in place to stay compliant with the evolving regulatory landscape.

Many healthcare organizations have reorganized their financial and resource allocation models to invest more in adhering to compliance. In the past decades, there has been a massive growth in compliance requirements around the globe. Each country has differences in safety standards, and global businesses have to ensure they meet the regional requirements. Healthcare businesses were further encouraged to comply with regulatory guidelines while developing therapeutics and vaccines at an unprecedented pace during the COVID-19 pandemic.

Regulatory Affairs (RA) professionals play a crucial role in demonstrating the safety and effectiveness of drugs, biologics, and medical devices to regulatory bodies and health authorities. From conception and development through approval and launch, each stage requires specialized experts to collect clinical data and gather

experts to collect clinical data and gather and report safety events. Therefore, RA professionals need to keep abreast of new trends and changes in the industry. Understanding how regulations are changing and how they impact the industry is crucial to reducing time to market and gaining a competitive edge.

With the help of a smart Regulatory Intelligence (RI) solution, the burden of manual work can be reduced and businesses can stay updated on the latest trends in the industry. The RI solution can ease the burden of multiple submission queries received from different regulatory authorities, improve response time, and centralize all the information, which can be beneficial for the entire organization. The rapid discovery of information can be helpful in identifying key factors during an unforeseen situation, like the COVID-19 pandemic. On the basis of these findings, healthcare organizations can choose to suspend or continue an ongoing study or initiate an entirely new one.



CURRENT CHALLENGES

In the healthcare industry, regulatory assessments encompass all operations, including clinical, sales, and marketing, product pricing reporting, patient privacy, and medical device testing and manufacture. Consequently, regulatory compliance becomes the primary concern for businesses as failure to address any compliance issues may result in severe repercussions, such as significant financial penalties or even civil and criminal charges. Therefore, pharma and medical device organizations must be aware of the risks associated with non-compliance and keep it a top priority at the organizational level.

Recent Regulatory Landscape: FDA Warning Letters

More than 900 warning letters have been issued to drug makers by the FDA in the last ten years.[1] The majority of the violations cited in warning letters are related to documentation.

Considering observational trends, the categories of warning letters that have been on the rise in the last decade are listed below:

- Absence of written procedure
- Problems with Data Integrity
- Failure to investigate the discrepancy
- Failure of the quality unit to investigate critical deviations
- Unauthorized access to electronic systems and data manipulation

The most common observation in the agency's Form 483 report is a failure to document quality department duties and processes and the trend continues to remain the same over the last decade. This estimate is the highest in over ten years and often makes a big difference.

The following are typical reasons for these failures:

1. Sheer number and complexity of regulatory changes
2. Being compliant with the constantly evolving regulatory landscape
3. Maintaining an up-to-date regulatory repository
4. Availability of information in local languages in some countries

Noncompliance can have a significant negative impact on a company's profits, reputation, and clients. Nonetheless, leading healthcare organizations and manufacturers continue to struggle with generating innovative ideas while maintaining a focus on compliance, risk mitigation, and management. Therefore, in order to ensure compliance, it is imperative for companies to create an organization-level view of all regulatory updates, rather than segregate regulatory affairs into individual teams.

SOLUTION APPROACH

In the heavily regulated healthcare industry, digitizing information gathering and document management is paramount to preventing unnecessary communications from health authorities. This is where regulatory intelligence can save the day.

Regulatory intelligence involves gathering and analyzing publicly available regulatory information, collaborating on its implications, and monitoring the current regulatory environment. In addition to understanding industry trends, competitors, and regulations that govern the industry, RI gives healthcare businesses a comprehensive market view. A well-formulated report must present appropriate information in an easily readable format. Therefore, an ideal solution shall take advantage of digitization in monitoring and gathering the information while the subject matter experts curate the gathered information to create a well-informed intelligence report. An agreed-upon template can be used for generating the RI report to meet the requirements.

Regulatory intelligence encompasses several screened areas and includes:

- Product development life cycle
- Developmental product applications (e.g. IND, CTA, IMPD)
- Labeling & variation management
- Marketing authorization applications (e.g. ANDA, NDA, BLA, MAA)
- Individual Case Safety Reports (ICSR)
- Periodic Safety Update Reports (PSUR)
- Risk Management Plans (RMP)
- Pharmacovigilance System Master File (PSMF)

Benefits of Regulatory Intelligence

Regulatory intelligence reduces the potential for errors within the organization by providing information that has been stringently tracked, monitored, and analyzed and helps organizations manage and mitigate risk. Discussed below are a few of the benefits:

- Assists in prioritizing risk-based assessments based on key performance metrics to boost the efficiency and quality of the regulatory function.
- Proactive regulatory intelligence may accelerate a new product launch by enabling manufacturers to disseminate information that can affect the ongoing regulatory programs.[2]
- Robust regulatory intelligence drives efficiency in regulatory processing, improves stakeholder collaborations, promotes transparency, provides ease of requirement prediction, and enables quality with data-driven submissions.
- It facilitates product and service quality improvements through the integration of internal and external information sources.
- It enables businesses to employ a single system to forecast and manage changes in global regulatory requirements.

TECHNOLOGY PLAY IN RI SOLUTION IMPLEMENTATION

Technology plays a crucial role in automating regular regulatory intelligence-gathering chores and making the entire process more cost-effective. Automation and natural language processing innovations have made it possible to delegate several repetitive tasks to machines.[3]

The typical challenge for regulatory intelligence teams is that, in today's digital world, there are numerous information channels and sources that must be scanned, and the information is presented in different structures and formats on these channels. Additionally, it is crucial for companies planning worldwide product launches to monitor region-specific updates from respective regulatory authority websites. The sheer volume of data that must be accessible and tracked on a regular basis is a significant issue.[4] An average regulatory intelligence team member spends 3 to 4 hours per day researching relevant information in their domain area and records or updates this information periodically. Internet robots have essentially taken over routine tasks such as monitoring dozens of regulatory websites for updates. The following technologies can play a key role in regulatory intelligence solutions:

Internet bots

Internet bots are extremely effective at gathering relevant data from numerous websites. This has resulted in a 25% decrease in manpower and a significant reduction in search time, thereby improving productivity and freeing up time for other crucial endeavors. There can be a variety of search objectives, such as keyword searches, API-based information retrieval,[5] finding the latest documents, or selecting a piece of specific information, such as the most recent updates to the website.

Internet bots also present a number of challenges for developers. Selecting the right technology for reaching a site and deploying the most appropriate methodology to extract relevant content is the first hurdle to overcome. Scaling up bot production necessitates additional considerations such as automated application maintenance. This is critical in minimizing the disruptions to information availability caused by changing page structure. It is also necessary for the program to have built-in measures to avoid blocking access attempts by internet bots.

Intelligent Bots

AI-enabled technologies make web crawlers more powerful and intelligent by extracting information from unstructured formats such as images and literature. Image analysis and Optical Character Recognition (OCR), for example, enable the reading of information in non-textual formats, enhancing it further.

AI-driven insights

In addition to automated bots and OCRs, AI technologies are used in regulatory intelligence to create summaries, categorize information, make interest-based recommendations, extract information from unstructured formats, and analyze collected data to generate actionable insights.

Natural Language Processing (NLP) facilitates the extraction of targeted information and the generation of intelligence from it. Sentiment analysis of a drug or policy is a very simple use case, where various social networking, product, and regulatory websites are crawled to fetch information on users' opinions and create a trend of sentiments over a period of time.

Digitization

Bringing all the information onto a single platform allows for the digitization of workflows and information dissemination. Alerts from websites can be analyzed and converted into action items to update existing regulatory SOPs (standard operating procedures). The action item undergoes the automated review and approval process before being added to the database.

Integration with new sources of information and with the preferred methods of dissemination becomes much easier with digitization. The collection of information is automated and the flow of information becomes seamless. With digitization, manual tasks can be automated, they can be made more efficient with workflow automation and information is managed in a harmonized centralized way making its consumption and analysis very easy.

CHALLENGES ADDRESSED BY DIGITIZED REGULATORY INTELLIGENCE SOLUTIONS

The advances in technology, as mentioned above, allow for a digital solution to efficiently address some of the challenges faced by regulatory intelligence teams. There is a need for tools to centralize and harmonize the information for better analysis by humans and machines as the number of accessible information increases daily. A meticulously designed architecture can quickly address the following issues:

A single platform for all updates: A digitized solution automates the gathering of updates from various countries on the same platform and organizes them for easy consumption. No need to remember websites and check for updates regularly. The information in different languages can be automatically translated, making it available for a quick check for relevance. Receive alerts and notifications regarding what's new in the region of interest, regulatory updates on the product of interest, and trend monitoring. If, for example, a product identical to yours receives FDA approval, you will be notified on the platform and in your inbox so that you may initiate the next steps to obtain additional information.

Proactive and simplified RI operations: Automated alerts provide actionable insights, allowing the team of specialists to proactively update the procedures in accordance with new regulatory guidelines. Any organization-specific workflows for change management can be digitized and the process can be made web-based with automated task assignments as per workflow and email notifications. The entire RI operations thus become more efficient and cost-effective, with manpower costs reduced by up to 25%, consequently, improving productivity and freeing up time for other critical innovative endeavors.

Classified, categorized, filtered, and harmonized information:

Using AI training models, the information presented to users can be personalized based on a user's activity and is more likely to align with the user's interest areas. Hence, the flooding of information can be avoided. Information from different sources can also be put together in a way that makes it easier to understand and compare.

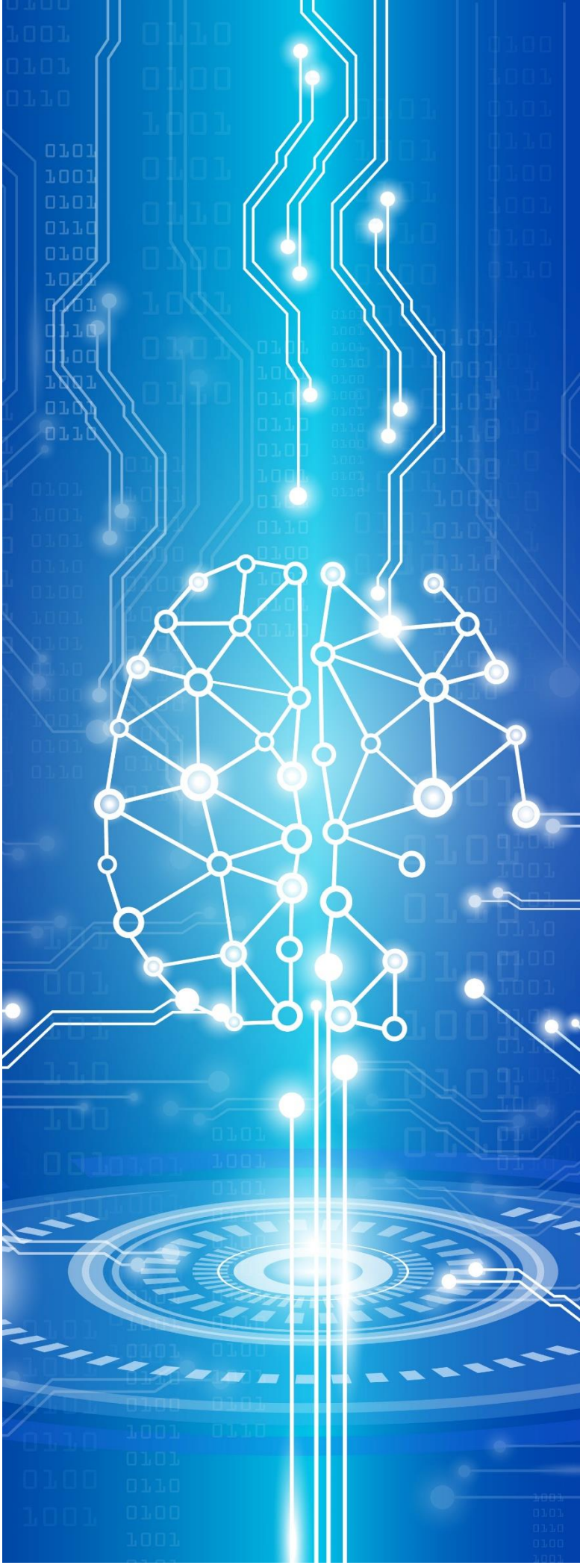
Centralized documentation of all regulatory procedures and versions: The regulatory guidance documents are spread across multiple websites. A digitized RI solution maintains a central archive of regulatory documents, classified according to their subject and version.

It also lets users compare new and old versions of a document visually to find changes that need to be fixed right away.

Improved information sharing and collaboration: Digital solutions inherently improve user experience through multi-channel presence, intuitive designs, and dashboards, and allow cross-functional collaboration between R&D and regulatory stakeholders, making the RI solution very engaging. The platform allows for faster sharing and discussion of regulatory news and accelerates the availability of actionable insight to responsible stakeholders, resulting in increased ownership and hence better decision-making.

Customizable frameworks to cope with the dynamically changing landscape of IT solutions and information sources: Digital solutions allow seamless integration with existing processes and collaboration solutions in the enterprise. Once the base platform is ready, a digital solution can be customized for an organization's workflows and with the ability to track pre-selected regulatory authority websites. A customizable digital framework provides a solution at a lower cost of ownership compared to COTS products.

Secure solution and controlled access: The digital frameworks allow you to control access to documents and rights to update them to a granular level. Each and every action performed can be recorded.



Access to servers is secured by network security protocols and authorization modules. Personal Identifiable Information (PII) is encrypted to maintain anonymity as per HIPAA requirements. This addresses unauthorized access and security concerns of the operations teams.

The integrated platform for expert reports: The analysis and impact of changes in regulatory procedures may need assessment by experts. The digitized framework provides a platform to request and receive such reports and maintain them all in a common version-controlled repository.

Analytics and trends: A company's regulatory strategy is based on a thorough examination of the competition. In order to speed up the time-to-market, it is important to have access to information about competitors' products, such as the current status, area of indication, recent market authorization approvals, drug warning letters, etc.

The information is dispersed across several websites, such as regulatory authority websites, company web portals, and scientific publications. A regulatory intelligence framework allows organizations to effectively gather and process the information to highlight the lessons learned from the successes and failures of rival products.[6] [7] Furthermore, capturing vital information such as recalls, audits, inspections, approvals, etc., and displaying it visually in a flexible chronological order enables the critical analysis of the data.

All pharmaceutical, biotech, and medical device manufacturers are going to benefit from such a framework by having a proactive and cost-effective approach toward regulatory affairs and the lifecycle management of their products. It’s up to the organizations to deploy and customize for their specific needs in products and markets.

CONCLUSION

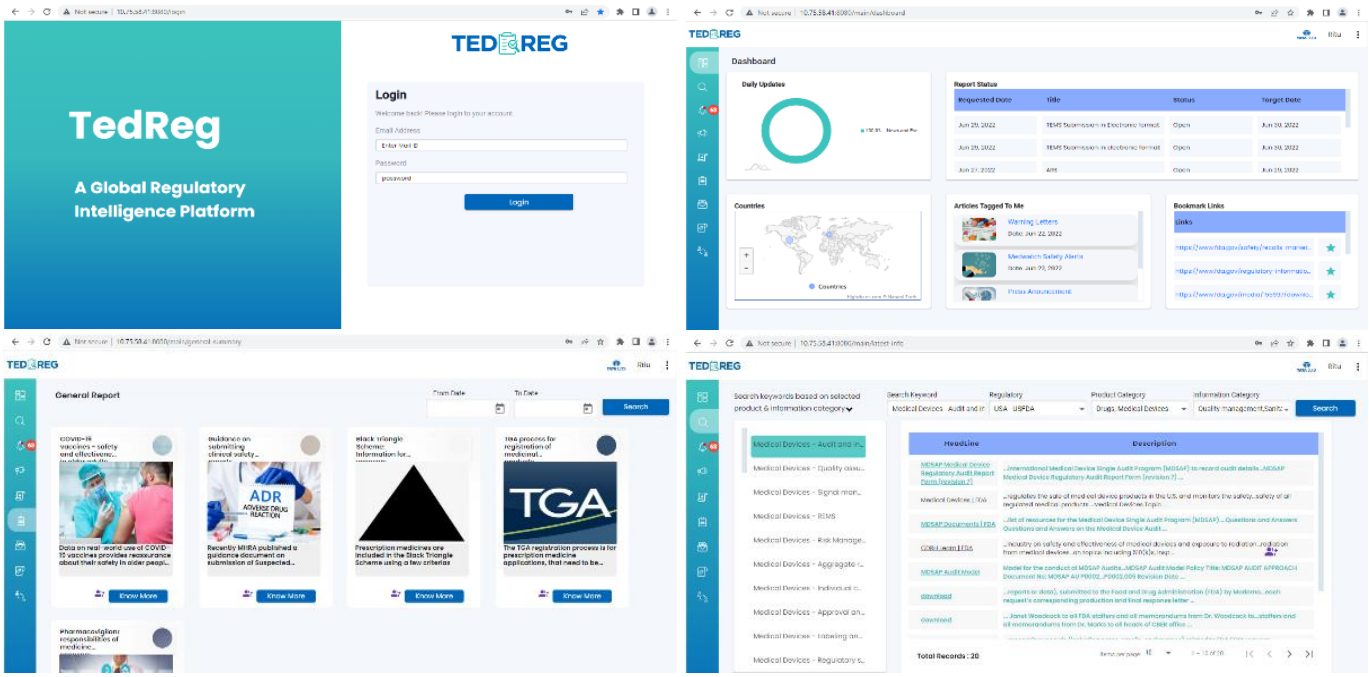
An optimal regulatory intelligence approach enables faster time-to-market, lower development costs, and better market potential with high success rates. It also facilitates proactive regulatory decisions, global implementation, and overall operational excellence.

Regulatory intelligence platforms streamline the process of automating and maintaining regulatory activities and ensure compliance with constantly evolving regulatory requirements. With well-structured RI platforms, regulatory, quality, and safety data can be combined for rapid reference and utilization, thus reducing manual work.

ABOUT TATA ELXSI'S GLOBAL REGULATORY INTELLIGENCE PLATFORM - TEDREG

Tata Elxsi understands the need for modernizing compliance management and harnessing regulatory intelligence. Our global regulatory intelligence platform, TEDREG, effectively aggregates and organizes the data and provides actionable insights for manufacturers to stay compliant with the latest regulatory requirements. The solution can be tailored to meet the compliance needs of pharmaceutical, biotech, and medical device organizations.

Moreover, as technology evolves, TEDREG will become more powerful and will be able to assist the RI team with predictive analysis and provide strategic recommendations. TEDRED is well-positioned to serve as an ideal regulatory intelligence partner with a unique combination of design, domain, and digital capabilities backed by a strong team of regulatory intelligence experts.



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Avinash heads the Pharmaceutical business practice at Tata Elxsi. He comes with a robust experience of 18+ years in pharma and life sciences with domain expertise largely in drug safety & risk management, medical information services, patient assistance programs, and quality assurance services. He manages accounts across various geographies and oversees large scale outsourcing deals that include business transformation initiatives, regulatory affairs & compliance, audits & inspections, etc. His current interests lie in exploring novel technologies such as data analytics, AI/ML, RPA, etc. to transform and streamline regulatory processes in organizations.

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Digital Solutions Delivery Head – Healthcare & Life Sciences

Mani heads the delivery of digital solutions for the Healthcare & Life Sciences business at Tata Elxsi. She comes with over 22 years of experience in developing and deploying software solutions for major players in the healthcare space.

Most of her expertise is in the design and development of cloud, web, and mobile software solutions that involve the application of the latest technologies like artificial intelligence, automation, and OCR. Additionally, she oversees delivery and innovation for several accounts across various geographies.

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Dr. Ritu works as a project manager and subject matter expert for the Healthcare & Life Sciences business at Tata Elxsi. She has over 13 years of experience in scientific, clinical, and regulatory roles in the healthcare, pharmaceutical, and medical device industries. Her main expertise is in pharmacovigilance (ICSR management), patient assistance programs, safety contact services, quality assurance, and regulatory pharma services operations. She is experienced in leading several pharmacovigilance initiatives within cross-functional processes and teams, including regulatory affairs, marketing, business development, and quality assurance.

TATA ELXSI

Tata Elxsi, a part of Tata Group, is among the world's leading providers of design, engineering, and regulatory compliance services. With 20+ years of experience in catering to healthcare & life sciences businesses, Tata Elxsi has built a comprehensive services and solutions portfolio that adds value at every stage of the customer's product development lifecycle. Tata Elxsi is an established name in technology consulting, new product design, development, verification and validation, and regulatory compliance services.

Tata Elxsi also provides solutions and services for emerging technologies such as IoT (Internet of Things), Big Data Analytics, Cloud, Mobility, Virtual Reality, Cognitive Computing, and Artificial Intelligence (AI). Tata Elxsi has a global presence and is supported by a talent pool of over 10,000 employees, a network of ISO 13485 certified design and development centers, and a robust ecosystem of technology, manufacturing, and internationally accredited testing partners.

For more information, please visit www.tataelxsi.com click here

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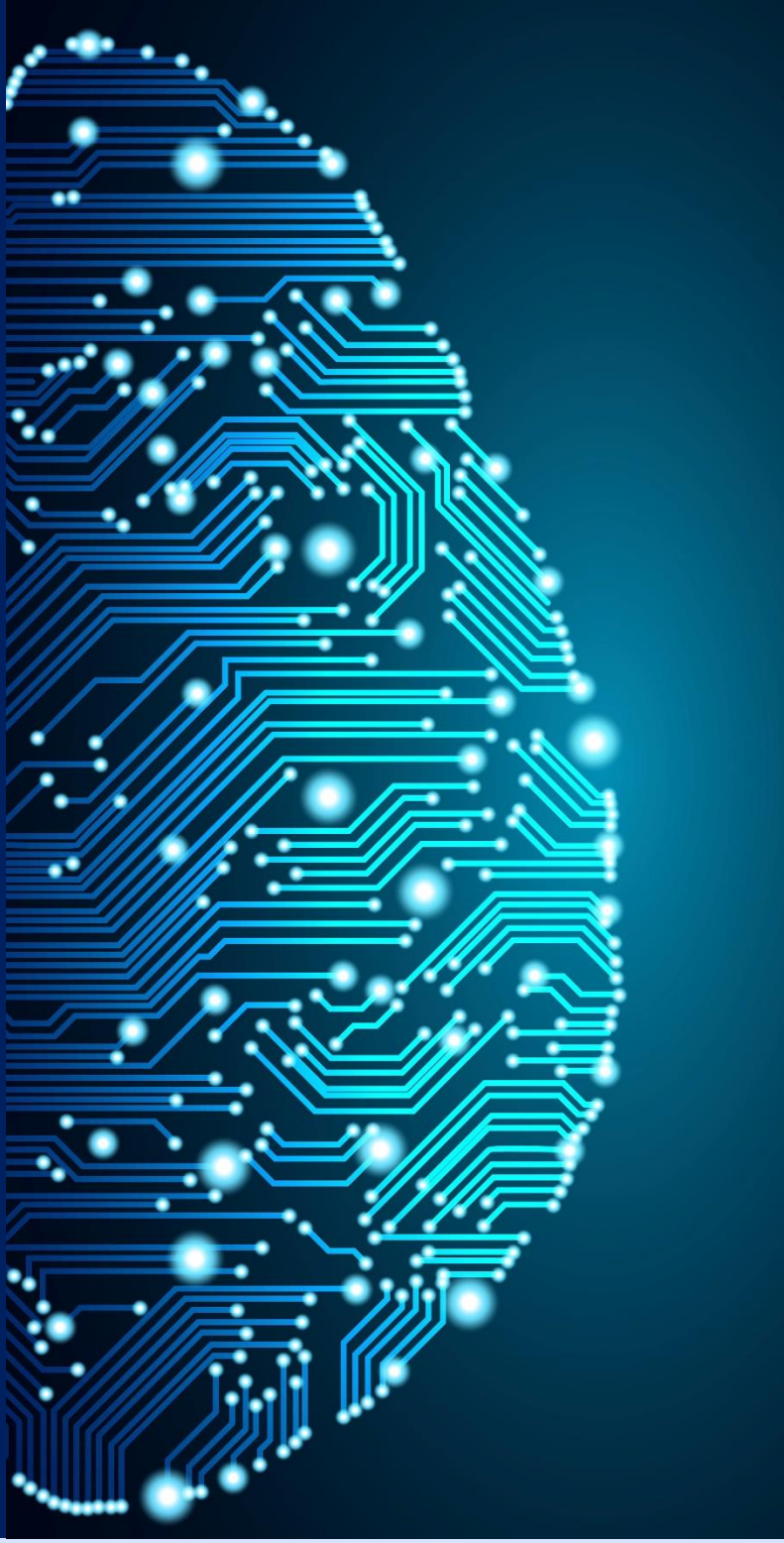

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