TATA ELXSI

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TEDREG: GLOBAL REGULATORY INTELLIGENCE PLATFORM

Consolidated | Validated | On-Demand

TEDREG
Global Regulatory Intelligence Platform

Trending

Pharmaceuticals, biotech, and medical device manufacturers struggle to maintain their compliance in the dynamic regulatory environment

There has been a strong trend towards companies having a dedicated Regulatory Intelligence (RI) function

- Expert knowledge of information sources/data mining tools
- Insights to position trends across internal projects/ lessons learned
- Unique perspective across therapy areas, regions, functions, and project teams

With increasing competition, cost pressure, and constantly shifting expectations of regulatory authorities, companies are looking for RI technology solutions.

Moreover, this technology enables companies to build an agile and proactive regulatory function capable of anticipating and responding to changes across the value chain.

Opportunities & Challenges

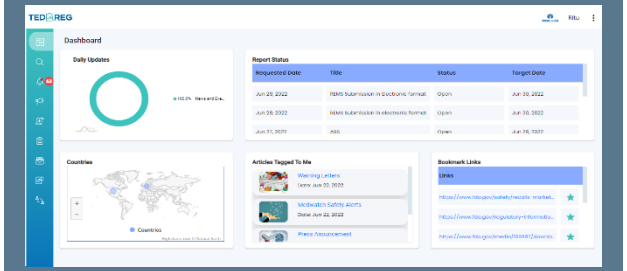
To contain the cost of compliance, a business must monitor and analyze multiple sources for regulatory requirements information across various regions.

Key challenges:

- Constantly increasing growth of information
- Regulatory Authority transparency initiatives
- EMA sharing information on medicines during various stages of MA process; meetings and workshops; other outcomes
- Regional requirement is different for clinical, pharmacovigilance, and regulatory requirements
- Information flow- reaching the right people in your company
- Companies face difficulties in comprehending regional regulatory requirements due to language barriers, multiple data sources, low awareness about regional regulatory updates

Opportunities

- Rapidly identify and communicate significant changes in the regulatory environment to key internal stakeholders
- Conduct and deliver unique and insightful analyses that facilitate strategic decision-making
- Serve as regulatory consultants and respond to ad-hoc intelligence requests
- Facilitate access to high-value and frequently referenced regulatory intelligence sources



Benefits for the manufacturers

70%
Manual effort reduction for searching insights

70%
Time saved in information dissemination

40%
Faster information availability compared to transitional methods

40%
Cost savings in regulatory intelligence operations

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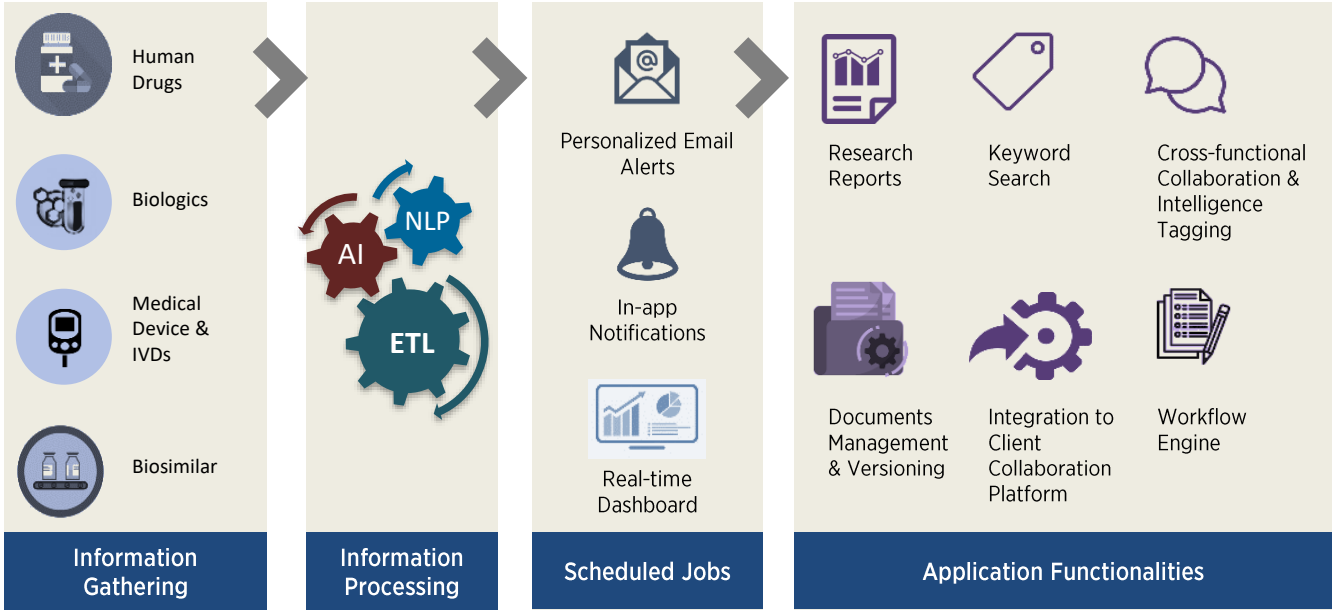

Key Features

- Meticulous and regular monitoring of local, and global regulatory information
- Documents repo management and comparison
- Rule-based automated update alerts and notifications
- Customized report on specific topics e.g., regulatory submission, GVP, GCP, GMP through RI consulting services
- On-premises or cloud-based based deployment
- Cross collaboration for enabling discussions with peers
- 21 CFR part 11 compliance

Differentiators

- Validated Insights – Curated intelligence validated by in-house/external regulatory experts
- Flexibility for “on-demand” or “periodic & structured” reports
- Access to local insights through localized consultants and regulatory experts
- On-demand consulting with regulatory experts
- Commercial models configured for subscription-based, demand-based, and functional service outsourcing

Application Scenarios

- Tracking regulatory updates for drugs and medical devices
- Local, regional, and global Health Authority updates report
- Ready-to-use information on country-specific and regional compliance requirements
- Guideline line search and quick referencing when creating regulatory & safety submissions
- Insights on drug-drug interactions for monitoring compounds compared to competitor products, indications of interest, and therapeutic class

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