TATA ELXSI

Customizable Cloud-based Global Regulatory Intelligence Platform

CASE STUDY

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CUSTOMIZABLE CLOUD-BASED GLOBAL REGULATORY INTELLIGENCE PLATFORM

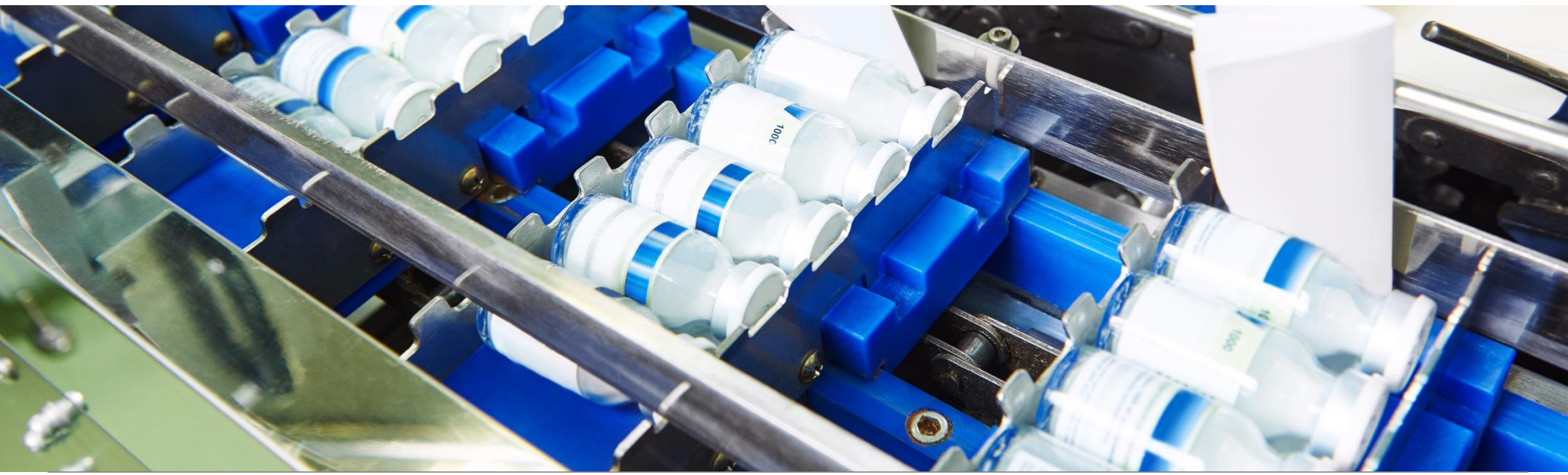
Customer Challenges

Our client is one of the top 20 global pharmaceutical companies with a product portfolio of prescription and OTC drugs, IVD, medical devices, and a significant presence across India, Europe, the US, the Middle East, and African markets.

The customer had been gathering Regulatory Intelligence (RI) manually and was experiencing challenges in generating actionable insights through cross-functional collaboration.

Scope

- Deploy Tata Elxsi's global regulatory intelligence platform - TEDREG, on cloud
- Customize the platform for cross-functional collaboration within existing client systems
- Enable chat module feature for stakeholder collaboration
- Validate customized solution as per 21 CFR part 11 compliance
- Create on-demand reports based on client's requirements



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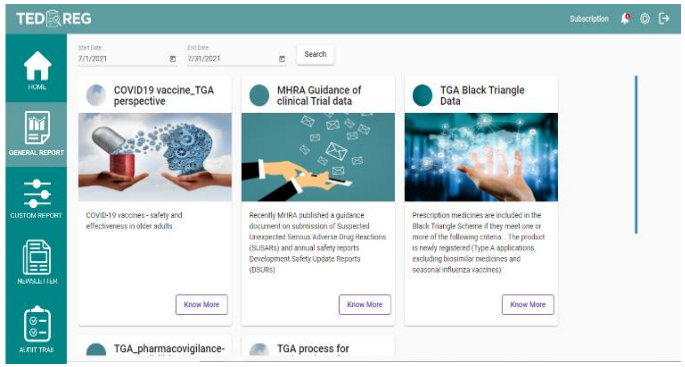
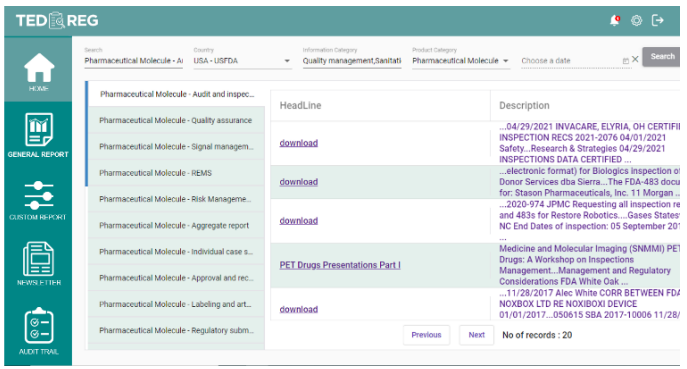
Approach

Tata Elxsi's team conducted a full-scale requirement understanding in collaboration with customer's regulatory, IT, clinical, manufacturing, and quality teams. TEDREG was curated to facilitate cross-functional collaboration through MS suite and integrated chat module.

The platform was deployed on the cloud with multi-regional access and unlimited access time to the stakeholders.

The platform was also integrated with the active organization directory for insight dissemination through e-mail and SharePoint. The entire standard package was validated, documented, and customized as per 21 CFR Part 11 compliance.





Impact

- Increased compliance index through readily available latest updates across regulatory, clinical, manufacturing, and quality teams
- Increased efficiency by 70% due to automated insights gathering from numerous health authority portals
- Delivered cloud-ready platform for round-the-clock and remote information access
- Reduced creation time for the monthly newsletter to less than 10 business days through ready-to-use template and information capturing parameters
- On-platform chat module enabled easy cross-functional collaboration to brainstorm and determine actions on the gathered insights