Streamline compliance, minimize risk and accelerate time to market

Smarter workflows for regulatory documentation

Automate content creation and document quality checks, ensuring submission accuracy while significantly reducing manual effort with AI.

No matter your company's size or the stage of product development, regulatory submissions are complex and demanding, requiring strict adherence to data accuracy, consistency and compliance standards. Preparing these submissions is time consuming and labor intensive, with errors or rejections causing costly delays in bringing new treatments to market.

Manual tasks like data extraction, formatting and review introduce inefficiencies and increase the risk of inconsistencies. By leveraging a Hybrid AI approach, EIX-Submission Readiness automates these critical steps, detecting discrepancies, generating compliant content and accelerating submission reviews to reduce the operational burden and speed approval times.

Part of EidenAI Suite – the expert.ai suite that delivers comprehensive, ready-to-deploy enterprise AI solutions tailored to each industry – EIX-Submission Readiness streamlines source data verification, study report generation, quality review, regulatory approvals and other critical processes to reduce effort and improve accuracy.

KEY CAPABILITIES

EIX-Submission Readiness is built on a framework designed for document generation and comparison for life sciences and regulatory operations. It uses Hybrid AI—a powerful combination of symbolic AI, machine learning and LLMs, alongside curated life sciences data and deep domain expertise.

Multimodal comparison
Automatically detects discrepancies between summary reports and supporting studies.

Automated content generation
Uses Agentic AI to generate content from reference materials.

Intelligent review & validation
Identifies misalignments and ensures compliance with submission standards.

BENEFITS

Improved productivity and efficiency.

Accelerated research and submission timelines through intelligent automation.

Reduced inconsistencies across submission materials.

Empower regulatory teams with AI-driven tools that support seamless compliance.

Scalability for growing pipelines.

Better submission accuracy by comparing regulatory documents with source study reports.

Expert.ai

Expert.ai is a company specialized in the implementation of enterprise artificial intelligence solutions to create business value. Through EidenAI Suite, expert.ai supports companies and public administrations in their AI adoption journeys by offering a suite of ready-to-use solutions tailored for vertical markets.

Expert.ai brings over 30 years of AI expertise to transform Pharma and Healthcare. Our Hybrid AI capabilities empower researchers, clinicians, and regulatory leaders to accelerate discovery, optimize clinical trials, streamlining regulatory submissions and harness real-world data – reducing risk, boosting efficiency, and enabling smarter data-driven decisions.

Learn more: www.expert.ai