



Regulatory Intelligence Search

AI-powered semantic search across 120+ markets; surfaces relevant regulations, standards, and guidance instantly.



Document Comparison

Automated diff between two regulatory document versions; identifies additions, deletions, and structural changes.



Submission Builder Autofill

AI maps product data to eSTAR / submission wizard fields; reduces manual entry by up to 80%.



Market Gap Analysis

Compares published regulatory content vs agency sources; flags missing or outdated tiles across markets.



Labeling Requirements Research

AI-generates country-specific labeling requirements (UDI, symbols, language, authorized rep, etc.).



Scanned PDF Translation

Translates regulatory PDFs from any language to English while preserving formatting.



Regulatory Reporting & Analytics

Auto-generates trackings reports, status dashboards, and submission activity analytics.



AIS Data Manager AI Chat

Conversational AI assistant for internal team queries, data lookups, and report generation.

AI Agents — What We Can Build Next

Agentic AI workflows to transform regulatory operations



 **Submission Drafting Agent**

End-to-end agent that takes a product brief, selects the right pathway, fills the submission form, and validates against current FDA/EU requirements.

 **Regulatory Change Monitor Agent**

Continuously watches agency websites for new guidance, standards updates, and regulatory changes; auto-notifies impacted submissions.

 **Pre-Submission Review Agent**

Acts as a virtual regulatory reviewer; checks submissions for completeness, consistency, and common deficiency patterns before filing.

 **Market Entry Strategy Agent**

Given a device and target markets, generates a prioritized market entry roadmap with timelines, costs, and regulatory pathway recommendations.

 **Compliance Audit Agent**

Scans existing registrations and product data against current requirements; generates risk-ranked compliance gap reports.

 **Multi-Market Dossier Agent**

Adapts a core technical file for multiple jurisdictions simultaneously; generates country-specific appendices automatically.

 **Client Regulatory Copilot**

Embedded AI assistant for RegDesk clients; answers regulatory questions, explains requirements, and guides users through submissions in real time.

 **The Future of Regulatory AI**

These agents represent the next frontier of RegDesk's AI roadmap — transforming regulatory teams from manual processors into strategic orchestrators.

Each agent is buildable today using RegDesk's existing data infrastructure, AI pipelines, and regulatory intelligence platform.

