

Health Authority



Global Life Sciences Company



Life Sciences



Regulatory

Background & objectives

This global pharmaceutical company focuses on developing and delivering innovative medicines across various therapeutic areas. Responding to Health Authority (HA) inquiries or HAIs is an integral part of their regulatory process to ensure the safety, efficacy, and quality of their product portfolio. The client was looking to create an efficient, effective and consistent global solution by automating the intake process, streamlining the response workflow, and providing a user-friendly solution that provides intelligence from previous HA interactions.



Client challenges

- Limited visibility into the end-to-end process due to departmental and regional silos.
- Inconsistent approaches to ingest, assign ownership and track HAIs
- No ability to leverage previous responses to both streamline future responses & improve consistency
- Insufficient reporting, making it difficult to realize compliance with regulatory requirements



KPMG response

Scope and approach

- Led workshops with SMEs to assess current state processes, define future state workflows, define data requirements, and drive standardization
- Worked across technical teams to architect technical requirements and map integrations with dependent systems
- Designed and developed an integrated solution to streamline HAI process, driving toward more efficient, effective and consistent HAI responses globally

Solution highlights

- Automated AI-enabled ingestion, creating a digital entry from a forwarded HAI email
- Streamlined workflow to organize response ownership and tracking HA deadlines
- Automatically generated draft responses based on response templates
- Intelligence repository that can be leveraged for identifying similar questions and their responses

Integrations

- Regulatory Product Master Data through APIs to retrieve Product and Application data
- Documentum based authoring system through APIs to create draft response documents and ingest approved response documents
- Integrations with KPMG's Ignite AI/ML engine and associated vector database to facilitate query and response ingestion and smart searches



Outcomes

- Streamlined technology-enabled process to provide transparency into HAI processes with role-based approvals and clear audit trails
- AI-enabled ingestion, reducing effort to intake, identify, and track HA queries
- Smart search capability to generate regulatory insights and intelligence from past questions and responses
- Ingested over 3,500 queries in the first 3 months after go-live, supporting ~1,000 Regulatory users globally



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