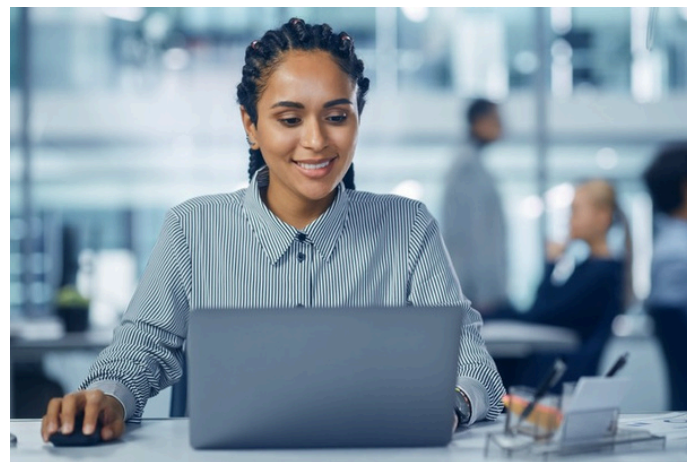


Developing an AI-powered curated solution to monitor the regulatory landscape

In the age of data and AI, the life sciences industry faces an information explosion. The surge in regulatory intelligence brings both opportunity and complexity. A recent survey by the Regulatory Affairs Professionals Society (RAPS) highlights key challenges:



The challenges

- 1 The information avalanche**

While the increasing availability of information is, without a doubt, a boon for the pharmaceutical industry, it paradoxically raises a series of critical concerns. The very data that has the potential to fuel informed decisions is often overwhelming. Timely uptake and the appropriate dissemination of this wealth of regulatory and pharmaceutical intelligence is a daunting challenge that businesses must confront.
- 2 The rise of regulatory professionals**

In response to this information explosion, the industry has reacted by dedicating more resources, both full and part-time, to the crucial task of monitoring and informing regulatory strategies. While this investment is a step in the right direction, it is clear that human resources alone cannot keep pace with the relentless influx of data and evolving regulations.
- 3 The emergence of cutting-edge tech**

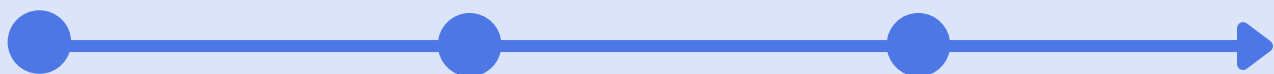
The escalating complexity of regulatory and pharmaceutical intelligence has prompted a pivotal shift towards innovative technologies to understand the holistic information picture and boost time to insight. Artificial intelligence is becoming an indispensable resource in this mission. These technologies empower businesses to not only manage the information deluge efficiently but also to extract meaningful insights and make data-driven decisions swiftly.

The background

The Regulatory team at a leading Biotech organization is responsible for monitoring, identifying and analyzing relevant updates to communicate to stakeholders companywide. However, faced with the time-consuming surveillance of endless third party regulatory sources via the internet, news alerts and emails, the team is overwhelmed. As a result, their processes lack efficiency, risking critical knowledge gaps due to expedited timelines, missed alerts and untimely communication.

Quantifying the problem

The process before Infodesk was implemented



10-12 hours / week

- Manually search several email sources to identify most relevant and critical updates.
- Analyze impact to company and industry.
- Review secondary research and analyses.
- Send key insights to team lead for further landscape and trends analyses.

10 hours / week

- Regulatory lead gathers recommendations from SMEs via email.
- Perform additional manual searches of various sources to complete briefing.

2-3 hours / week

- Add briefing to queue and triage.
- Manually search emails and sites to identify any last guidance for team meetings.



The objective

The goal was to integrate an available AI-powered digest, leveraging the company's current list of trusted information sources to extract key updates relevant to their regulatory priorities. This would reduce the time spent on manual work, increasing the efficiency and effectiveness of their activities.

The Infodesk solution

- **A one-stop shop** for triage, assessment and evaluation of all current and past policy and intelligence updates, streamlining the surveillance and monitoring of regulatory insights.
- **An AI-powered feed** of all health authorities, by region and functional area topic combined with premium content (e.g. Cortellis, DIA, PharmaIntelligence, Pink Sheet, RAPS, STAT News).
- **A searchable archive** to enable user-friendly searching by any predefined topic or region, simplifying the tracking of previous updates and the identification of emerging trends (especially in regions where the company's market is developing).



The Infodesk intelligence activation workflow

AI-powered intelligence drives efficiency across the entire workflow

Regulatory intelligence



- Regulations and guidelines monitoring and surveillance.
- Intelligence information management and dissemination.
- Global HA requirements monitoring and tracking.
- Newsletters and other targeted communications

Research and development



- Competitive intelligence.
- Compiling relevant regulatory information.
- Precedent information, including approvals, rejections and withdrawals.
- Topic area landscape analyses (e.g., US Congressional activity 2022).

Policy and strategy



- Commenting on HA and industry documents and positional statements.
- Advisory Committee, trade group and consortium participation or observation.
- Agency Request for/Solicitation of Information (policy).
- Therapeutic area or indication landscape and trend analysis.

The outcomes

- 1 | By incorporating an AI-powered regulatory intelligence feed tailored to their business needs, the client has seen manual surveillance time decrease by 55%.
- 2 | Consistent, accurate and targeted information allows the Regulatory Intelligence team to more efficiently identify and share high priority documents.
- 3 | The solution cross-references specialized coverage of niche topics and regions with industry standards for developing regions, preventing knowledge gaps to produce more accurate impact assessments
- 4 | Having seen the success and effectiveness of the curated briefing within the Regulatory team, other functions across the organization have also engaged Infodesk to produce solutions specific to their use cases and wider workflows, ensuring critical intelligence can be accessed, searched and shared effortlessly, companywide.

55%

Time saved on monitoring and analysis of regulatory intelligence

22

hours per week saved on regulatory intelligence monitoring

\$49k

saved per annum or used on higher value tasks and more strategic initiatives

About Infodesk

From intelligence to impact. Infodesk drives informed action. Infodesk gives you the clarity, confidence and proof to act, when action matters most. Infodesk is the SaaS solution that transforms intelligence into action. It helps teams identify what matters, embed insights into workflows and stay prepared for anything, with full traceability and design optimized for high-pressure environments.

Intelligence. Activated.

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