

Automating Pharmacovigilance workflows for compliance with Health Canada's Foreign Risk guidance

How the Pharmacovigilance team at a global pharmaceutical organization ensured auditing and proactive compliance with Foreign Risk communications, for products authorized by Health Canada under Section C.01.050 of the Food & Drug Regulations.

Main challenges



Information overload and the risk of incomplete information when reporting back to Health Canada.



Overspent resources, with regional Pharmacovigilance (PV) teams sharing the responsibility of identifying and sharing risk communications relevant to their products.



No systematic approach or process, increasing the risk of non-compliance with Health Canada regulations.

Business benefits



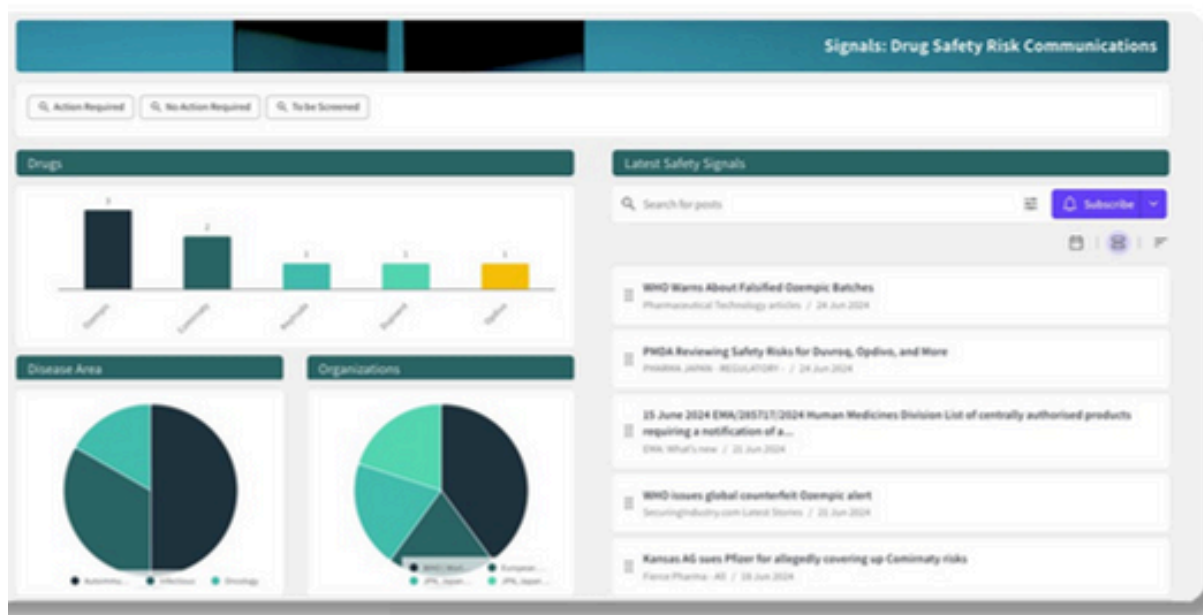
Provides a single source of truth, including a weekly update on safety/risk communications concerning their marketed products, to ensure ongoing compliance (with a readily available archive of intelligence for inspections).



Time and financial resources saved, across both the PV team at hand and other regional teams who shared the same responsibilities.

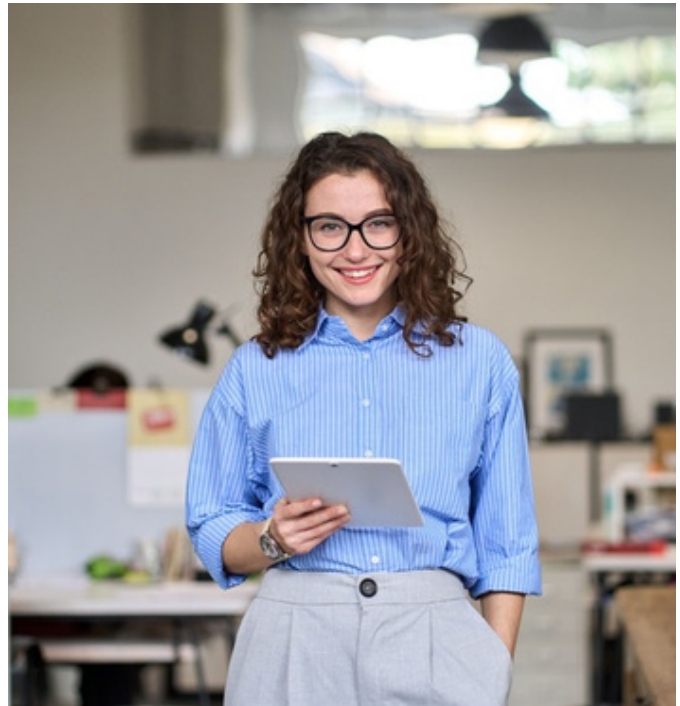


AI-powered platform enables quick access to risk communications, meaning stakeholders can make more effective and systematic decisions on the actions required.



The challenge

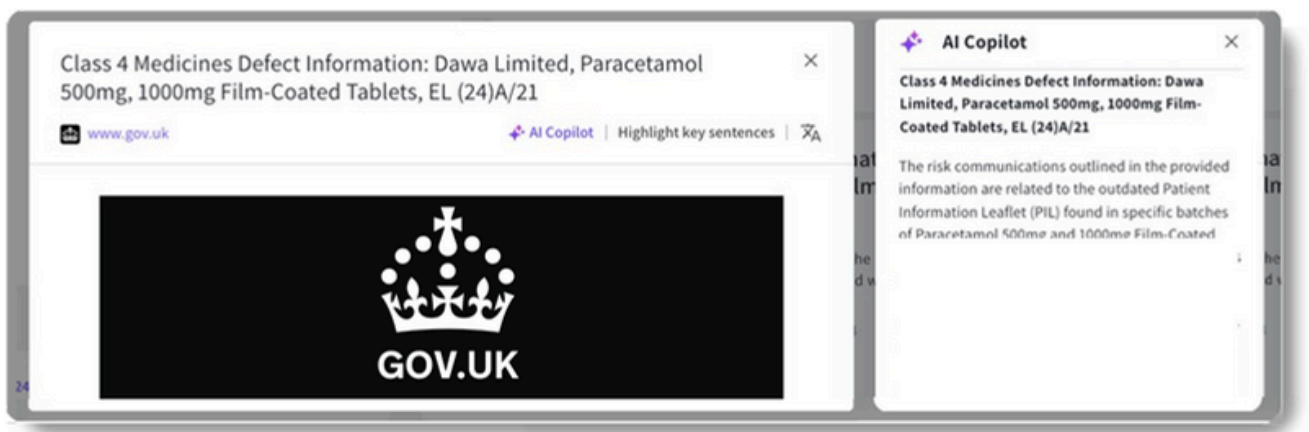
A global pharmaceutical organization develops products that require authorization by Health Canada. Their Pharmacovigilance (PV) team is responsible for reporting any risk communications on these specific products from the list of Health Authorities under Section C.01.050 of the 2018 Food and Drug regulations. This must be done within 72 hours of becoming aware of any adverse communications. The team struggled with the time-consuming task of manually monitoring all listed Health Authorities. What's more, PV teams in other respective countries shared the responsibility, adding to growing resource costs. Amidst the overwhelm, an inspection uncovered that a critical piece of intelligence had been missed. Without a formal auditing process in place, even more resource was then required to produce and distribute an inspection report.



The impact

The organization's QPPV had already cultivated a successful long-term relationship with Infodesk while working at a previous company, having held the same responsibility regarding this particular regulation. The QPPV therefore chose to implement the same solution, confident it would optimize auditing and surveillance. The solution would:

- 1 | Utilize Infodesk's **AI-powered technology** together with human expertise, to create a single source of consolidated intelligence delivered on an agreed frequency.
- 2 | Centralize all validated content in a **secure repository** with private AI search functionality, allowing quick, easy and trusted information retrieval.

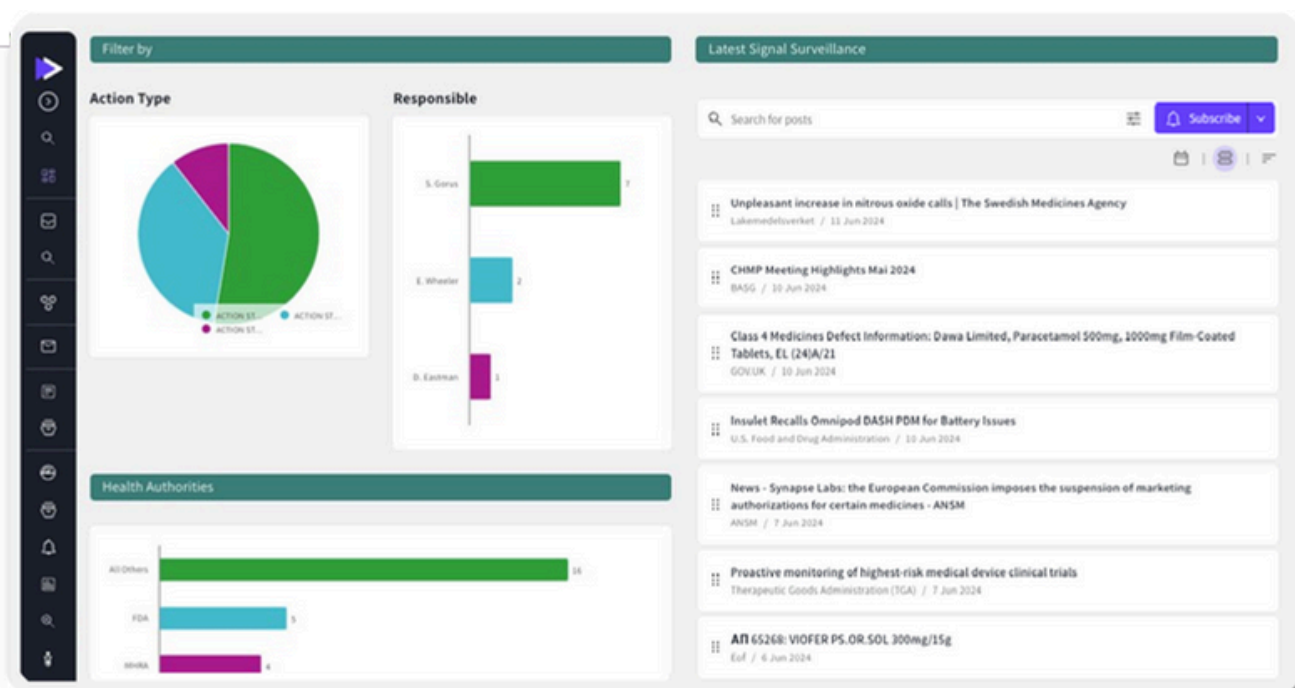
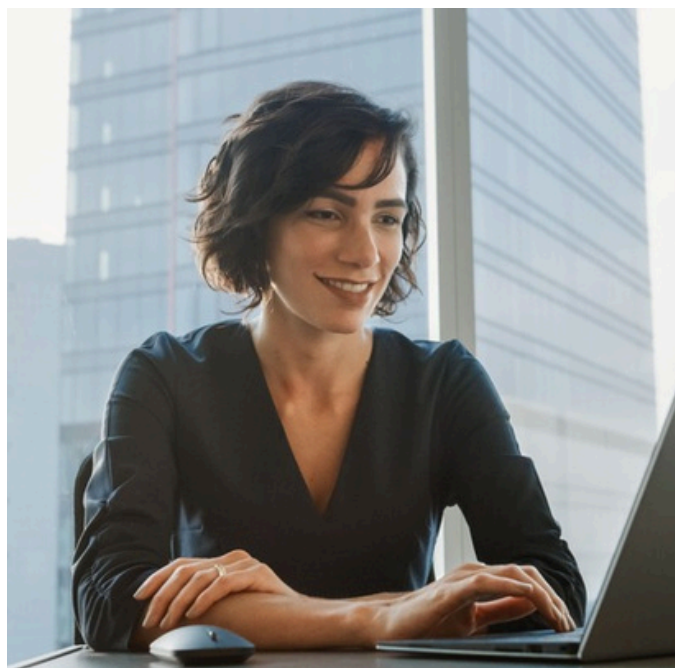


- 3 | Tag all intelligence with product names, relevant health authorities, and type of risk communication, displayed in an **interactive dashboard** for ease of information retrieval and collaboration on action items.
- 4 | Insure respective country representatives receive personalized alerts, empowering them with the right information to conduct **impact assessments** on relevant risk communications.
- 5 | Enable teams to report information back to Health Canada in a systematic manner using Infodesk's **reporting modules** (with all produced reports stored in the dashboard).

The result

The solution provided a user-friendly dashboard with curated information, empowering the team to overcome the challenges of information overload. Not only did this reduce time spent searching intelligence by 73%, but in turn the team could utilize the solution to identify relevant risk communications and safety signals in line with Health Canada's Notifying Health Canada of Foreign Action regulation.

The solution's flexibility and scalability allowed the team to expand their coverage to Health Authorities beyond the list initially provided, broadening the topics included to cover additional aspects of safety intelligence.



Intelligence. Activated.

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.

[Learn more](#)