

Case Study

Big Pharma: Catching Potential Risks before the Regulators Do

Snapshot

A global pharmaceutical manufacturer needed to understand whether there were potential compliance issues before introducing a new drug to the market. The company turned to Conduent to design and implement an electronic communications and monitoring solution to catch potential issues before they turned into legal liabilities. Conduent's eCommunications monitoring and audit solution helped the client:

- Identify previously undetected sources of liability in employee email communications, allowing the company to remediate before investigations or litigation took place
- Avoid a formal regulatory investigation, costly penalties and fines
- Achieve ongoing, proactive compliance with regulatory standards through proactive identification of electronic communications potentially posing risk to the company



eCommunications Monitoring and Audit Solution Helps Big Pharma Legal and Compliance Teams Proactively Identify Risk Associated with Bringing New Drug to Market

A global pharmaceutical company was faced with a challenge when introducing a new drug to the market: identifying internal communications and documents between employees and doctors, vendors, patient populations and other third parties. In an industry that faces some of the strictest regulations and harshest penalties for breaches of compliance, with recent fines in the hundreds of millions or billion dollar fines, the company wanted to proactively mitigate risk that could result in regulatory investigations, litigation or a Corporate Integrity Agreement (CIA).

The company's in-house legal and compliance department had exhausted its internal resources, technology and capabilities. Specifically, the client faced the following challenges:

- A lack of insight into potential areas of liability—for the new product and for potential

issues occurring as far back as five years (a source of citation by regulatory agencies)

- A large, unstructured and decentralized data sources that needed to be searched
- Inability to consolidate, analyze and review internal communications, often a primary source of evidence against pharmaceutical companies

Pinpointing Indicia of Compliance Risk with A Holistic Data Analytics Approach

Believing that the most efficient and cost-effective way to identify potentially risky communications was to search across the myriad disparate sources of unstructured employee communications and other data—but lacking the technology, resources and expertise to do so—the company engaged Conduent. Working in close collaboration with the client's legal and compliance teams, Conduent met the challenge by providing technology, subject matter, data science and legal review experts, and an optimized process:

- Centralized the company's data into the Analytics Hub, a proprietary big data analytics platform for consolidating, categorizing, analyzing and reporting on data

Conduent coordinated all technical aspects of the analysis instead of dealing with disparate sources, locations and vendors for review of information, resulting in a streamlined process and enhanced data security.

- Partnered with the client to identify areas of liability and generate search terms for the analysis
- Applied advanced linguistics, statistics and sampling expertise to expand the search scope to identify areas of concern and create search filters
- Refined search mechanisms and performed granular analysis of the data
- Applied search filters and algorithms within the Analytics Hub to identify patterns and refine results
- Reviewed findings using Conduent in-house team of attorney and subject matter review experts
- Delivered the small subset of documents, less than 1% of the starting document collection, to the company, which identified several areas of previously undiscovered risk related to the new drug

Measurable Results: Avoidance of Litigation and On-Going Detection of Risk

Our findings allowed the company to make internal corrections before they turned into legal matters, saving the organization measurable expenses, time and resources. Results included:

- **Risk mitigation:** Sources of liability that were previously undetected were uncovered, allowing the company to address and remediate the issues before investigations or litigation occurred.

- **Cost-savings:** In addition to providing the company with outsourced technology they otherwise would have had to invest in or build themselves, the company avoided costly litigation and potential fines.
- **Process optimization:** Conduent coordinated all technical aspects of the analysis instead of dealing with disparate sources, locations and vendors for review of information, resulting in a streamlined process and enhanced data security.
- **Defensible process:** Conduent technology, along with comprehensive management of the process, documentation and audit trails, resulted in a defensible process.
- **Proactive compliance:** Being proactively compliant not only prevented litigation, but also defensibly positioned the company in case any issues arise in the future because self-discovery and reporting often reduces penalties.
- **Regular eCommunications monitoring:** Now, on a regular basis, Conduent works with the company to monitor its data and address high-risk issues at the formative stages.



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