Informatica

Executive Brief

Data-Driven Digital Transformation in Regulatory Affairs

"The bottom line is that medical information teams now need to be able to provide highly specialized answers to a broader set of inquiries more frequently than ever before."

—McKinsey

"There's an opportunity for us to have a strategic advantage by bringing together diagnostics and pharma with data management. This triangle is almost impossible for anybody else to copy."

—Severin Schwan, CEO Roche

Regulatory compliance touches most departments within the pharmaceutical company, not just Regulatory Affairs. Recent trends demonstrate that the regulators continue to ask for more data, more frequently. McKinsey accurately sums up the situation by stating "The bottom line is that medical information teams now need to be able to provide highly specialized answers to a broader set of inquiries more frequently than ever before."[1]

Traditionally, regulatory submissions have been done in isolation – duplicating efforts in collecting, cleansing and submitting data, as well as raising questions should data not match across submissions. With the increase in both the breadth and depth of data required to be submitted, this approach is no longer sustainable. For example, the broad data set required by the full ISO IDMP standards draws on data from Regulatory Affairs and other departments such as manufacturing, including data that is required for the Good Manufacturing Practices (GMP) guidelines.

Simultaneously, the pharmaceutical industry is at the forefront of the global trend toward greater data-driven processes. Global pharmaceutical executives increasingly acknowledge that future competitiveness depends on the ability to manage data most effectively and efficiently. Often, regulatory requirements are a key driver of improving the quality of data assets for submission purposes. The ability of pharmaceutical companies to reuse this data within other business processes and departments can lead to significant, measurable benefits beyond more efficient and timelier compliance.

A Master Data Foundation for Regulatory Affairs

The European Medicines Agency (EMA) is leading the way with its approach to IDMP oversight. The agency has embarked on creating a master data foundation for the four domains covered by IDMP – Substance, Product, Organization and Referentials. Starting with Organisational and Referential domains, this foundation will reduce the overall effort required to manage submission data by creating a single version of each data entity for use across multiple submissions. Data quality is also expected to improve. A single version of each entity ensures new records and changes to existing records will be distributed rapidly for use throughout the organization. It will also enable data on individual entities (e.g. organisation or product data) submitted under different regulations to easily be cross-checked for anomalies or inaccuracies.

[1]How pharma manufacturers can enhance their medical information teams, McKinsey&Company, 2018

By following this lead, the opportunity is real for pharmaceutical companies to lower the cost of compliance by reducing data management tasks that are currently replicated to support compliance across organizational silos. Additionally, a foundational data layer for compliance can benefit the entire organization by providing trusted data that's ready for all regulatory requirements and beyond. Deloitte finds that "life sciences companies who make investments in unifying data, resources, departments, and technology are expected to realize benefits throughout the organization – not just for compliance purposes."[2]

These additional benefits come from breaking down barriers between departments and processes to find synergies which contribute directly, or indirectly, to the bottom line. This principle has been proven by leveraging Informatica's Master Data Management (MDM) technology to comply with the Sunshine Act in America. Many pharmaceutical companies created a single view of health care providers in Informatica MDM to ease the burden of submitting a consolidated spend report by individual at an organizational level. These Informatica customers went on to enjoy many tangible benefits beyond compliance from the trusted HCP data set curated in MDM. These benefits included revenue uplift between 5 to 7%, and reduced marketing communication costs by 30%.

Informatica counts major regulators among our customers, including the U.S. Food and Drug Administration (FDA). The FDA relies on Informatica MDM to build visibility of the global drug supply chain, product ingredients, suppliers, sites, and facilities - bringing them into one trusted view and empowering the agency to trace any potential harm, save lives, and respond to changes in supply and demand more quickly.

Data Governance

The majority of pharmaceutical regulations are largely based on the timely submission of accurate, trusted data. In order to comply, a pharmaceutical company has to demonstrate that it is in control of its data. The higher the degree of internal data control, the lower the cost and effort of compliance across all regulations.

Merck's Science Information Management Group has already made progress in this area. The group needed a data governance program that would drive better visibility into how processes, systems, and information connect. Using Informatica Axon Data Governance, they have developed a holistic understanding of the data landscape and improved the efficiency of support for regulatory and strategic programs.

Introducing data governance into a pharmaceutical company requires commitment and contributions by both business and IT teams. Informatica's unique approach to data governance reduces the overhead of governance, and provides tools and automation for business and IT users to consistently and collaboratively improve the trustworthiness and quality of their data. By leveraging AI for data discovery, cataloging, and reporting, the most talented people in the organization are empowered to focus on deeper analyses and higher-value processes. Their time is better spent and they're motivated to constantly move things forward.

[2]2018 Global life sciences outlook, Deloitte

About Informatica

Digital transformation changes expectations: better service, faster delivery, with less cost. Businesses must transform to stay relevant and data holds the answers.

As the world's leader in Enterprise Cloud Data Management, we're prepared to help you intelligently lead—in any sector, category or niche. Informatica provides you with the foresight to become more agile, realize new growth opportunities or create new inventions. With 100% focus on everything data, we offer the versatility needed to succeed.

We invite you to explore all that Informatica has to offer—and unleash the power of data to drive your next intelligent disruption.

Informatica Axon Data Governance seamlessly integrates with the Informatica Enterprise Data Catalog to assist in classifying and organizing data assets across multi-cloud and on-premises environments. Informatica Data Quality provides Axon Data Governance with data quality scores for data assets, based on business rules that are easy to define and adapt. Together they lessen the workload of data governance, increasing the control of pharmaceutical companies over the quality of the data that is required across all regulations.

Summary

A trusted foundation of clean, governed and authoritative data offers the benefit of reducing the overall effort of regulatory compliance, and delivers value to the enterprise across multiple business processes. With Informatica solutions, pharmaceutical companies can actively manage all data that is subject to regulatory oversight. Our customers that have built mulit-purpose data foundations to increase compliance efficiency, have also enjoyed a repository of trusted data that has been repurposed internally to deliver business value across the organization.

Informatica's large pharmaceutical user base includes multiple use cases in increasing the efficiency of regulatory compliance. Given our broad customer base within the pharmaceutical sector, your company may already have Informatica data management tools and skills available which can be leveraged to support regulatory compliance.

Visit Informatica.com to find out more about our data management capabilities for pharmaceutical companies.

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