Getting IDMP Ready via Modern Product Data Management

Pharmaceuticals companies can keep patients safe and enhance operational efficiencies by embracing an IDMP-compliant product master approach built on a modern data management platform.

Executive Summary

Most major life sciences organizations have already embarked on their identification of medicinal products (IDMP) journey. They are now defining their data collection and preparation strategies and determining the technological ecosystem that will best serve the needs of IDMP submission in 2018 and beyond.

The European Medicines Agency (EMA) has already defined a master data management strategy around substance, product, organization and referential (SPOR) that life sciences organizations must follow to curate and maintain product master data under its IDMP submission mandate.

As and when the U.S. Federal Drug Administration (FDA) and other regulatory agencies around the world make IDMP submission mandatory, it will require organizations to scale their IDMP solutions to meet global norms. Doing so will require a product hub that can import structured and unstructured data from various sources, and store information using an IDMP-compliant data model.
A modern data management platform is essential to pharma companies seeking to comply with the IDMP mandate of Iteration 1 (Q4, 2018), while creating the foundation for an enterprise product hub.

This white paper discusses what a modern data management approach means for pharmaceutical companies seeking to improve organizational efficiency and effectiveness while meeting IDMP’s compliance objectives. In our view, the best way to accelerate this process is to implement a solution using an existing IDMP-compliant product hub framework, such as the one discussed in this white paper.
IDMP should not be seen just as a compliance or a pharmacovigilance reporting challenge but as an operational improvement opportunity.

IDMP COMPLIANCE: THE INDUSTRY’S STANDING

EMA has taken the lead in mandating the use of ISO IDMP standards for the regulatory submissions made by European pharmaceutical companies. The initial IDMP submission to EMA is expected in 2018.

Outside of Europe, the U.S. is the next country expected to adopt IDMP standards. To comply with the regulation, life sciences companies are collecting and organizing product data residing in various structured and unstructured sources and building an IDMP-compliant product hub to facilitate submission.1

Embracing IDMP: An Opportunity Beyond Compliance

IDMP should not be seen just as a compliance or a pharmacovigilance reporting challenge but as an operational improvement opportunity. It is a strategic project that can transform the entire pharmaceuticals value chain. Greater integration across multiple functions and systems such as regulatory, labeling, safety, manufacturing, clinical and quality can offer impressive ROI. Any pharmaceuticals company that wants to operate more efficiently and nimbly in a rapidly changing world needs a central way for understanding product data inside and outside of the enterprise.

When pharmaceuticals organizations maintain a central repository of all product information in a standardized format, they can leverage that information to improve overall business processes. This can greatly benefit global operations, thereby reducing time to market and improving profit margins. Also, a central approach to product data management can help companies in various other regulatory submissions (e.g., eCTD) and reduce the overall cost of regulatory affairs.

Getting IDMP-Ready With a Modern Data Management Platform as a Service

Leading pharmaceuticals companies are creating a central repository of all products and substances used by the organization. This requires importing structured and unstructured product data from various internal, external and third-party sources, matching and merging, and storing it using an IDMP-compliant data model. Building such a reliable data foundation also requires creating multilevel product hierarchies and understanding product relationships with other data entities.

As a central repository, the solution enables the propagation of reliable product data into various downstream applications (e.g., CRM, ERP, etc.), thereby improving organizational efficiency and effectiveness. The challenge is how to bring
together this information and build true Product 360 data-driven applications for business users.

**Complete Product Understanding**

A Product 360 data-driven application, built on a modern data management platform² as a service (PaaS), brings together data from multiple internal, third-party and public sources − regulatory information management systems, product information systems, ERP and document management systems − and stores the information in a commercial graph. The graph is a single repository for not just all of a company’s master reference product data but also its relationships with manufacturers, suppliers, locations and competitors to create a complete and accurate picture (see Figure 1).

**Quick Data Modeling & Dynamic Integration**

It is easy to write metadata-based definitions of IDMP objects in an agile, real-time, configurable, modern data management platform. This starts by defining the objects according to the evolving IDMP standards, and then extending these definitions to the organization’s future business needs.

Reference data management (RDM) helps integrate master reference data from multiple systems. As an example, Global Substance Registration System (G-SRS) is one of the major source systems that implements and supports the ISO-11238 substance types and controlled vocabularies (CVs).

**Data as a Service for Real-Time Data Acquisition & Augmentation**

It is critical to integrate medicinal product data with various data sources for standardization and enrichment such as Global Ingredient Archival System (GiNAS), Unified Code for Units of Measure (UCUM) and Medical Dictionary for Regulatory Activities (MedDRA). Historically, identifying and blending premium data sources with internal data has been painful and costly.
The advent of data as a service (DaaS) built into a modern data management platform dramatically changes the game, not just for acquiring external data from multiple sources, but for sharing data internally as well. Such pre-built integration and ongoing support saves organizations time and money.

**Integrated Workflow Capabilities**

A modern data management platform provides integrated workflow capabilities for line of business (LoB) and data stewards to manage any data changes with proper traceability for IDMP compliance. Appropriate data governance and stewardship processes can be established to validate and approve changes to product data that is stored as the single source of truth. Given that product data originates from multiple structured and unstructured sources, it is vital to have well-defined approval processes to maintain data reliability (see Figure 2).

![Match & Merge Approval Workflow](image.png)
Instead of buying servers, installing and patching software, and constantly wrestling with how to handle the relentless growth and diversity of data, IT teams can focus on delivering relevant, operational information and intelligence to business users.

**Delivering Business Agility**
A cloud-based modern data management PaaS requires no on-premises installation, hardware or maintenance. Instead of buying servers, installing and patching software, and constantly wrestling with how to handle the relentless growth and diversity of data, IT teams can focus on delivering relevant, operational information and intelligence to business users. This is key to deploying an IDMP-compliant product hub on time to meet regulatory compliance.

**MOVING FORWARD**
As pharmaceuticals organizations ratchet up the data collection exercise to be IDMP-compliant, it is vital that they conduct proper due diligence and choose a data management platform that can meet their needs effectively and power the organization’s business operations over the long term. It is imperative to define processes, and choose platforms and partners so that they get it right and within the stipulated timeframe. The key next steps are:

- Identify the data sources and finalize the data collection approach.
- Define the data extraction approach to derive key data elements.
- Define the roadmap for product hub implementation with particular focus on Iteration 1 submission.
Reltio delivers reliable data, relevant insights and recommended actions so companies can be right faster. Reltio Cloud combines data-driven applications with modern data management for better planning, customer engagement and risk management. Reltio enables IT to streamline data management for a complete view across all sources and formats at scale, while sales, marketing and compliance teams use data-driven applications to predict, collaborate and respond to opportunities in real-time. Companies of all sizes, including leading Fortune 500 companies in healthcare and life sciences, media & entertainment, hospitality, distribution and retail rely on Reltio. For more information visit www.reltio.com.

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FOOTNOTES


ABOUT THE AUTHORS

Ranjit Agarwal
Associate Director, Master Data Management Practice, Cognizant

Ranjit Agarwal is an Associate Director with Cognizant’s Master Data Management Practice, a group within Cognizant’s Analytics and Information Management business unit. He has over 15 years of experience in consulting and delivering projects in a diversity of industries such as life sciences, medical devices and insurance. Ranjit is currently focused on providing solutions and thought leadership to life sciences customers in the areas of data governance, data quality and master data management. He holds a bachelor’s of engineering degree from Visvesvaraya National Institute of Technology, Nagpur, India and an M.B.A. from Indian Institute of Management, Ahmedabad, India. Ranjit can be reached at Ranjit.Agarwal@cognizant.com | https://in.linkedin.com/in/ranjit-agarwal-0313336.

Ankur Gupta
Product Marketing Manager, Reltio

Ankur Gupta is the Product Marketing Manager at Reltio. Prior to joining Reltio, he worked at Krux Digital and Yahoo to drive various data monetization and go-to-market initiatives. Ankur has more than 10 years of diverse experiences across strategy, analytics, product management and product marketing. He holds bachelor’s and master’s degrees in biochemical engineering from IIT Delhi, and an M.B.A. from Cornell University. Ankur can be reached at Ankur.Gupta@reltio.com | www.linkedin.com/in/ankurgupta002/.

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