Ensuring Patient Safety & Beyond

Pharmaceuticals companies can keep patients safe and enhance supply chain efficiencies by embracing an IDMP-compliant product hub approach.

Executive Summary

Identification of medical products (IDMP) standards are under development by the International Standards Organization (ISO) to ensure all medicinal products have a unique international identifier. IDMP will provide a universal ID for drugs that can be referenced in individual case safety reports (ICSRs). Currently, ICSRs use national identifiers for the drugs. Since every national authority has different identification systems, it is difficult to track patient safety issues related to the same approved drug in different countries. IDMP solves this problem by specifying international identifiers for each drug, substance and generic version of the pharmaceuticals product.

Beyond its ability to improve patient safety, IDMP presents pharmaceuticals companies with an opportunity to get their houses in order and obtain a comprehensive view of all products and substances with which they deal. Having such a unique, enterprise-wide view can lead to operational efficiencies and effectiveness across the entire pharmaceuticals value chain. For example, inventory costs can be reduced as the organization gains a clear view of the availability of products across all global locations and makes decisions accordingly.

This white paper discusses the challenges and benefits of complying with IDMP and highlights our approach for helping pharmaceuticals companies improve organizational efficiency and effectiveness while meeting IDMP's compliance objectives.

Ensuring Patient Safety Using IDMP

Patient safety is among the biggest concerns for regulators worldwide. It is estimated that up to 20% of discharged patients in the U.S. alone have an adverse event post discharge, about 72% of which are caused by drugs.[1] Regulators seek to take credible action based on reported adverse drug reactions (ADRs). The ISO IDMP standards provide a universal

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identifier for drugs that can be referenced in ICSRs – which currently include national identifiers – used for ADR reporting. IDMP improves on this by including international identifiers for the substances and generic formulations of pharmaceuticals products. This makes it possible to classify similar items and drill down and cross-reference products where there are safety issues.

The European Medicines Agency (EMA) has taken the lead in mandating the use of ISO IDMP standards for the regulatory submissions made by European pharmaceuticals 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. (See Quick Take below for IDMP high-level compliance considerations.)

Embracing IDMP Compliance: A Move-Forward Plan

It is the organization's choice whether to view IDMP as merely a compliance requirement or as a strategic project that can transform the entire pharmaceuticals supply chain.

We recommend that pharmaceuticals organizations maintain a central repository of product information in a standardized format, making that information available for the overall improvement of business processes. This can greatly benefit the global supply chain, reducing time to market and improving operating margins. (See Quick Take on the next page for more insights.)

However, some smaller companies may not be well-positioned to embrace this approach and may instead choose to transform data from existing sources and utilize the existing regulatory information management system (RIMS) to meet

Quick Take

IDMP Compliance: Immediate Priorities

Based on our engagement experience, we suggest that decision-makers consider the following:

- Prepare the organization for the new mind-set of using IDMP.
- Identify data sources for the multiple data elements needed in IDMP.
- Collect and organize data from various unstructured and structured sources.
- Initiate reengineering of business processes to leverage IDMP-compliant product definitions.

IDMP Standards

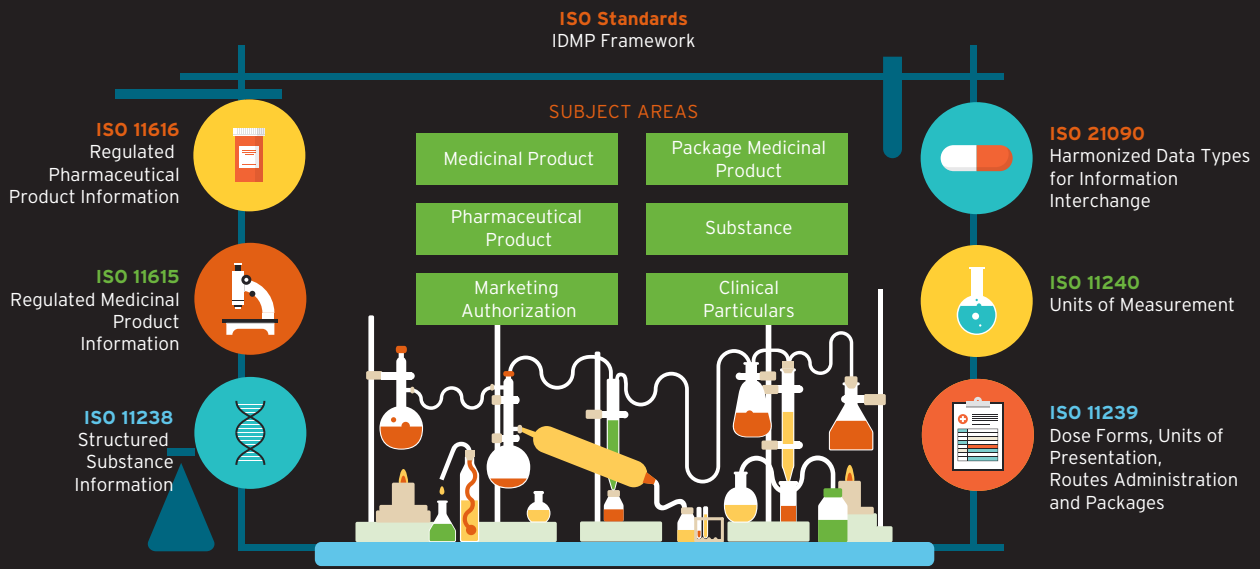


Figure 1

Quick Take

Key IDMP Success Factors

In our view, organizations need to consider the following to increase the odds of a successful IDMP implementation:

- **Change management:** Instill organizational awareness about the benefits of IDMP and secure commitment from all stakeholders.
- **Process reengineering:** Identify processes affected by IDMP and restructure as needed.
- **Data governance:** Define data ownership and data lifecycle process to ensure data quality.
- **Product hub roadmap:** Define the product hub needs and leverage IDMP during implementation.

the IDMP compliance target. A proper assessment of the organization's strategy, resources and technological landscape is therefore critical to determine the most appropriate approach.

Enter the Product Hub

We have worked with pharmaceuticals majors to create a standardized central repository of all products and substances in the organization. Our Product Hub (see Quick Take below) can import structured and unstructured product data from various sources and store it using an IDMP-compliant data model. It provides an easy-to-use data stewardship user interface and workflows to enable proper data maintenance.

As a central repository, our solution enables the propagation of product data into enterprise systems such as ERP, CRM, etc., thereby improving organizational efficiency and effectiveness. For example, we worked with a pharmaceuticals major to help define its IDMP compliance strategy and build a product hub with data sourced from various internal and external sources. The engagement covered the subject areas of medicinal product, package medicinal product, pharmaceuticals product, substance and marketing authorization.

Benefits Beyond Patient Safety

Once an organization has a product hub that is IDMP-compliant, it will be better able to streamline its manufacturing and distribution processes. Together with the implementation of product serialization, it can help ensure patient safety by enabling proper traceability of drugs and substances. In addition, the organization will reap the following benefits:

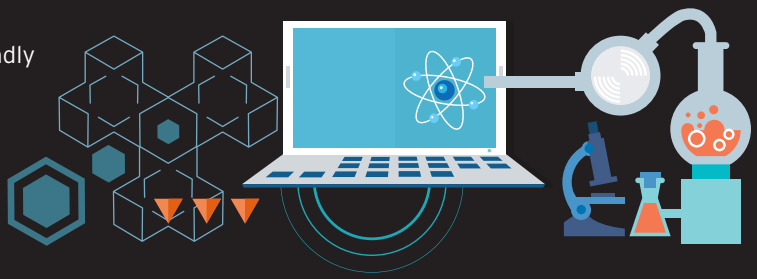
- A single definition of all product data to enable different departments/geographies to work more collaboratively. One common vocabulary

Quick Take

A Product Hub Walk-Through

Key features of our environment include:

- Easily import structured and unstructured product data.
- Auto-cleanse product data.
- Perform data stewardship with a user-friendly front end.
- Investigate data issues using hierarchical product views.
- Govern product data with defined roles and workflows.
- Store product data using a scalable IDMP-compliant data model.



and source of product information will enable the entire organization to collaborate better and reduce cross-references.

- An enhanced brand image in the eyes of end consumers.
- Reduced working capital through better inventory management. Ability to view availability of products and substances across global locations based on common product definitions will reduce the usage of inventory.
- Faster time to market with a consolidated product view.
- Improved decision-making through the provision of trusted product data.
- Greater support of various organization-wide IT and business initiatives related to product data.
- Heightened product margins through support of health economics and outcomes analysis. The demonstration of superior treatment outcomes for a given cost by leveraging detailed product and substance information as one of the inputs (in conjunction with real-world evidence data on outcomes) can help pharmaceuticals companies command better pricing.

Moving Forward

With multiple factors influencing the choice of approach for IDMP compliance and the need to get it right within the stipulated timeline, it is essential for pharmaceuticals companies to find a partner who can help steer their IDMP journey and derive the true benefits out of it while meeting the compliance norms. Our Product Hub is just the solution designed to address this and help pharmaceuticals companies meet their compliance and long-term business objectives.

As a first step, organizations should immediately start an IDMP readiness assessment, if they have not embarked upon it yet. This can yield a report that:

- Identifies the complexity and amount of data entities that need to be submitted.
- Identifies source systems for IDMP data.
- Provides input for an IDMP implementation charter and costs.

This assessment should culminate in a comprehensive IDMP adoption roadmap for the organization. Once the roadmap is in place, one of the first tasks in building the product hub is to collect a variety of data across various systems within the enterprise. A proper data collection approach is therefore critical. The data sources for IDMP will include many sources that have unstructured information (PDF reports, ZIP files, etc.). This information must be converted and made available in a structured format. Possible sources are:

- Regulatory information management systems.
- Product information systems.
- ERP.
- Document management systems.

Our IDMP Data Mapping Tool and the associated data extraction and coding services can help customers achieve this with ease and accuracy.

Footnote

[1] Stephanie N. Schatz and Robert J. Weber, Adverse Drug Reactions, https://www.accp.com/docs/bookstore/psap/2015B2.SampleChapter.pdf.

About the Authors

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