RELTIO

SOLUTION BRIEF

Simplify IDMP compliance with modern data management

Identification of Medicinal Products (IDMP) is a regulatory requirement consisting of five ISO standards to facilitate the unique identification of medicinal products in the context of pharmacovigilance and the safety of medications throughout the world.

EU member states must comply with these standards, as must marketing authorization holders of the EU (that is, US-based pharmaceutical companies selling in the EU) by April 2023. The FDA supports the global implementation, and it is expected that this regulation will come to the U.S. soon after its launch in the EU.

This internationally accepted framework can be achieved by following ISO-mandated standards and guidance. Most pharma companies will need to undergo a transformation of processes to support this regulation. Data is at the center, yet fragmented data and inflexible, outdated systems can get in the way, making compliance more difficult and costly.

Modern master data management (MDM) helps connect, cleanse, and enrich data to ease compliance and pave the way for increased safety.

Consistent data drives global data exchange

The IDMP master data initiative, led by the European Medicines Agency (EMA), outlines a phased approach with four master data domains—substance, product, organization, and referential data (acronym "SPOR").

The five standards facilitate the exchange of medicinal product information with unique identifiers for:

- Medicinal product information (MPID)
- Pharmaceutical product information (PhPID)
- Substances (Substance ID)
- Pharmaceutical dose forms, units of presentation, and routes of administration
- Unique identification and exchange of units of measurement (UoM)

These standards provide an international framework everyone can follow to facilitate global data exchange. The use of modern master data management for IDMP provides enterprise-wide benefits for improved data quality, insights, operational efficiency, and ultimately better safety outcomes.

Benefits of global IDMP

- Safety surveillance and improved pharmacovigilance
- Data quality improvements
- Building trust in medicinal product quality and safety
- Mitigation of drug shortages by identifying pharmaceutically equivalent products
- Consistent product data enabling a better exchange of information
- Transparent communications throughout product lifecycles
- Tracking end-to-end lineage of product definitions

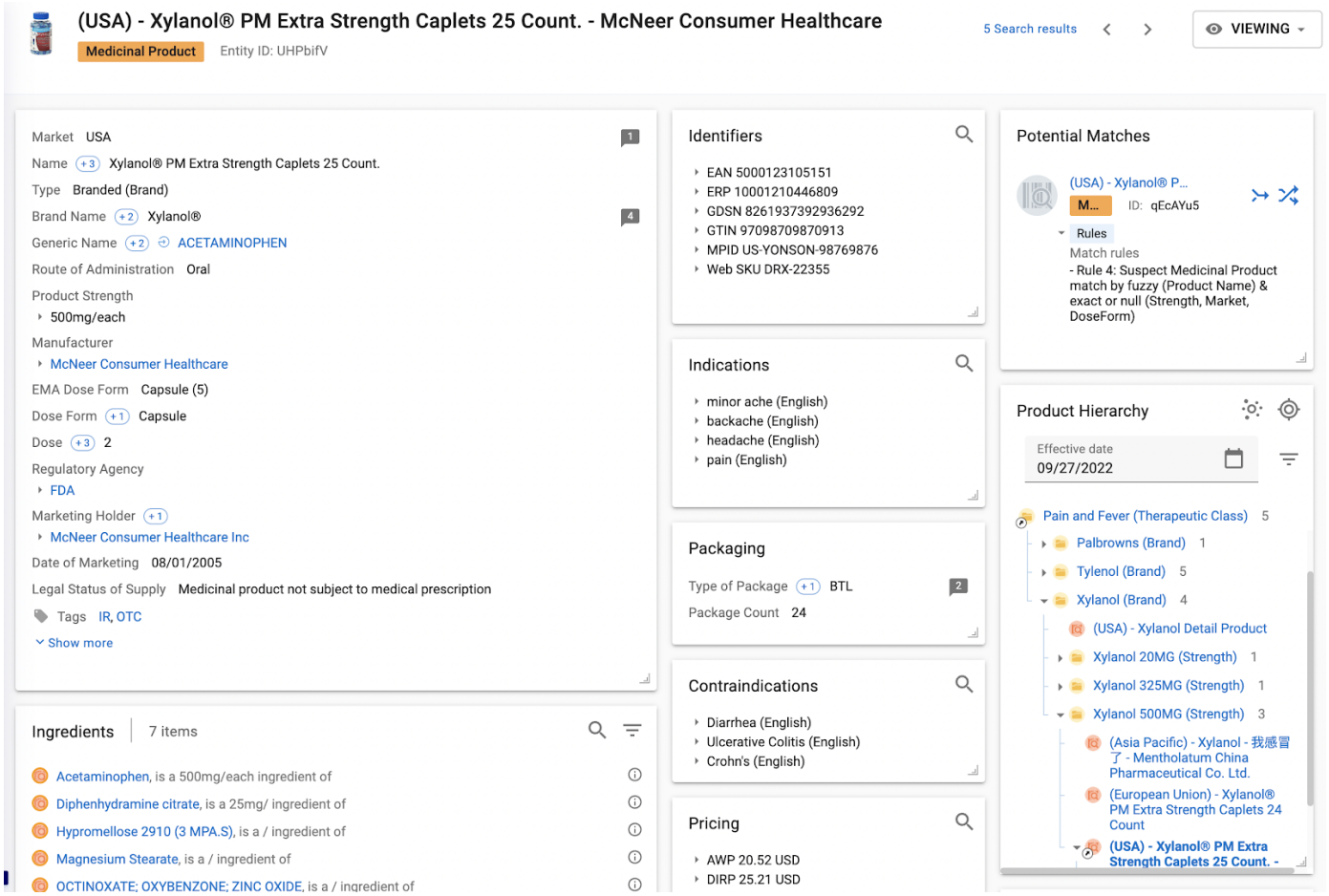
How we simplify IDMP compliance

IDMP requires input from many departments and systems to integrate product, substance, and organization data domains. But many organizations are challenged by data residing in disconnected systems with different technologies.

To comply, you need access to cross-functional data using master data management. MDM uniquely identifies medicinal products and substances across the enterprise—and ensures that they do not stay limited in view to the regulatory function alone. Unlike other approaches, MDM eliminates cumbersome manual maintenance as it increases data quality, reducing your compliance overhead.

Reltio Connected Data Platform—our modern, cloud-native, SaaS MDM solution—provides key capabilities to support IDMP compliance:

- **Integration of data sources** for substances, product definitions, organizations, and reference data to create a 360 view of the product for IDMP purposes
- Ability to create **unique identifiers and master data frameworks** for the exchange of data
- **Alignment of that data with reference data** that is approved and provided by the regulatory bodies
- **Blending that organized product perspective with regulator-provided data** such as approvals and corresponding IDs to establish a feedback loop
- **Continuous and automated data quality management** and data security to provide accurate, consistent data so you are confident in your operations and reports to regulators
- Delivery of **unified, up-to-date information** across the organization—critical for adverse event tracking and pharmacovigilance—enabling increased safety
- **Visual representations** of relationships between equivalent medicinal products across the globe
- **Configurable workflows**, so that the inputs and approvals of your various teams can be coordinated



Ease IDMP compliance and go beyond

Our Reltio Connected Data Platform makes compliance with IDMP easier, faster, and less complex. But we also go beyond compliance to deliver significant productivity gains and cost savings to your wider organization by fueling processes—as well as operational and analytical systems—with high-quality, timely data. And increased productivity and efficiency enables your teams to focus on innovation and other value-added business initiatives to improve business outcomes.

Continuous, automated data quality capabilities—along with our intuitive dashboards—ensure that you can find and fix data quality issues before they cause difficulties downstream. And reference data management, an integral part of our platform, adds to your data governance practices to ensure consistent data.

Our cloud-native, SaaS solution delivers low TCO and fast time to value. It also provides flexible data models to adapt to your changing data needs—and regulatory requirements. And it enables you to cost effectively scale your data storage while delivering the high performance you require to support large data volumes.

Reltio benefits

- Accelerate IDMP compliance with minimized effort
- Streamline operations to drive significant productivity gains and cost savings
- Go beyond compliance to bring efficiencies and faster innovation
- Enhance data quality and data governance practices
- Eliminate manual data preparation work for compliance and other processes
- Ease change management with a modern, flexible solution
- Scale data storage easily, quickly, and cost effectively

With Reltio Connected Data Platform you can cleanse, integrate, and enrich your data to simplify IDMP compliance, ultimately leading to improved patient safety. And use standardized, trusted data to streamline your operations—from R&D and safety to clinical and commercialization. So you can go beyond compliance to produce better business outcomes.

At Reltio, we believe data should fuel business success. Reltio's cloud-native master data management (MDM) SaaS platform unifies—in real time—core data from multiple sources into a single source of trusted information. Leading enterprise brands—from more than 140 countries spanning multiple industries—rely on our award-winning solution to turn data into their most valuable asset.