IDENTIFICATION OF MEDICINAL PRODUCTS (IDMP) COMPLIANCE MADE SIMPLE

EU legislation requires pharmaceutical companies to submit their product information in conformance with a set of ISO standards called `identification of medicinal products'. This rollout is being enabled by multiple regulatory organizations such as EMA and FDA, among others, and makes it of utmost importance to have an effective pharmacovigilance and improved patient safety.

5 ISO Standards

Each of these standards define data element structures for unique identi-fication of details pertaining to various aspects of a medicinal product

ISO 11615
Medicinal product

ISO 11616
Pharmaceutical product

ISO 11238
Substances

ISO 11239
Unit of presentation

ISO 11239
Unit of measurement

Substances, specified substances

Units of presentation, dose form, route of admin, packaging

Unit of measurement

Pharmaceutical product

Medicinal product

Our proposition

At Infosys, we are helping various pharma clients chart their roadmap to compliance providing an end-to-end offering that is not just low on cost but also accurate to ensure success. We recognize that identifying, sourcing, qualifying, and curating the data required for IDMP is the most critical part of the implementation and therefore leveraging the master data management system, a key success factor. Here are some salient features of our offering:

Readiness assessment utilizing proprietary offerings like IDMP mapping toolkit, inventory of processes, etc.

Preconfigured data model and business rules relevant to IDMP can be deployed out of the box minimizing implementation time and cost.

Provide an early bird view into solution roadmap for choosing and deploying a long-term solution leveraging existing investments in SAP.

- Long-term solution in alignment with organization's overall architecture
- Deep relationship with SAP helping in solution implementation
- Unmatched expertise in SAP solutions as well as domain under consideration for forming of a formidable team
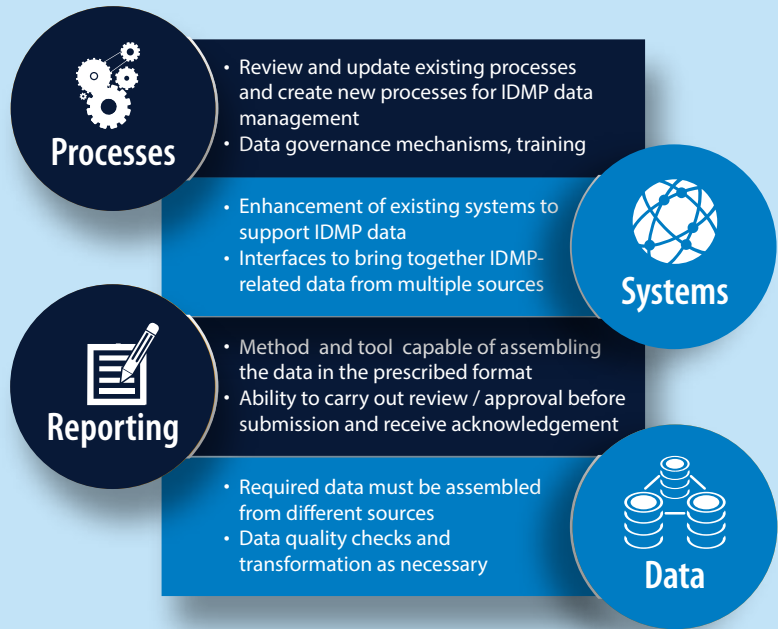
Impact on your organization

IDMP compliance requires a corporate-wide, cross-functional effort alignment on the standards, identification of source systems and data, master data management and data governance, and associated interfaces with electronic gate.

Primary impact

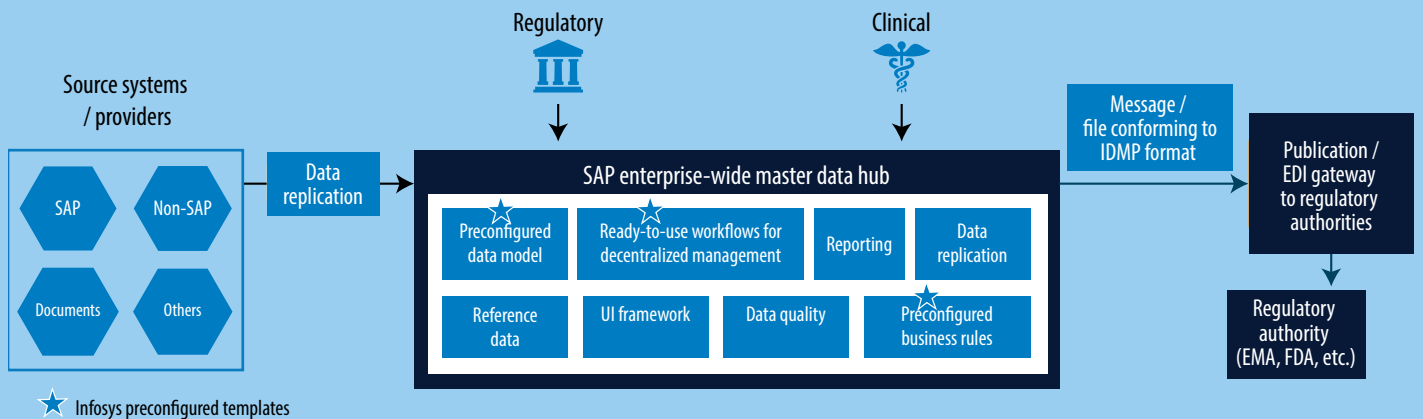- Regulatory affairs
- Manufacturing
- Pharmacovigilance
- Clinical

Downstream impact

- Indirect data sources
- Software vendors
- Supporting functions
- People

Processes
- Review and update existing processes and create new processes for IDMP data management
- Data governance mechanisms, training

Systems
- Enhancement of existing systems to support IDMP data
- Interfaces to bring together IDMP-related data from multiple sources

Reporting
- Method and tool capable of assembling the data in the prescribed format
- Ability to carry out review / approval before submission and receive acknowledgement

Data
- Required data must be assembled from different sources
- Data quality checks and transformation as necessary

IDMP compliance is to be achieved by addressing processes, systems, data, and having a method to report product information to the health authority in the prescribed format

Solution outline

Regulatory   Clinical

Source systems / providers

| SAP | Non-SAP |
| Documents | Others |

Data replication

SAP enterprise-wide master data hub

| ☆ Preconfigured data model | ☆ Ready-to-use workflows for decentralized management | Reporting | Data replication |
| Reference data | UI framework | Data quality | ☆ Preconfigured business rules |

Message / file conforming to IDMP format

Publication / EDI gateway to regulatory authorities

Regulatory authority (EMA, FDA, etc.)

☆ Infosys preconfigured templates

An IDMP solution addresses key requirements such as:

- Sourcing and extracting data from various organizational systems having both structured and unstructured content
- Transformation and loading alongwith aggregation of the data in a data hub capable of supporting data cleansing and curation
- Ability to publish the product data in IDMP-specified submission format and send it electronically to the regulatory authority

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Navigate your next

For more information, contact askus@infosys.com

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