FreshGravity™
Driving Digital Success®

MDM Driven Identification of Medicinal Products (IDMP) Compliance

Fresh Gravity's comprehensive Master Data Management solution helps Pharma companies achieve compliance for Identification of Medicinal Products (IDMP) global regulation in an uncomplicated and time-efficient manner.

Background

New global regulation-IDMP has made it mandatory for pharmaceutical organizations to maintain product information in a systematized manner and submit it to the regulatory authorities using standard messaging protocols.

The IDMP definition allows for standardization and unique identification of medicinal products across the globe and facilitates exchange of product information between pharma companies and global regulators, ultimately leading to improved patient safety. This internationally accepted framework can be achieved by following ISO mandated standards and guidance.

Overview

IDMP necessitates that input from multiple functions (R&D, Clinical, Commercial, Regulatory, Pharmacovigilance) and systems from across the organization (Regulatory Information Management System (RIM), Clinical Trial Management Systems (CTMS), systems of record for Reference Data, Supply Chain Systems , Labelling Management System, Manufacturing ERP Systems , Adverse Event Reporting and Safety Monitoring Systems along with Unstructured data sources) are brought together in order to track attributes required to stay consistently compliant. This definition ensures that all the medicinal products and substances are uniquely identifiable across the enterprise, and do not stay limited in view to the Regulatory function alone.

Fresh Gravity has extended its Medicinal product master to build a complete solution that includes ISO mandated attributes for IDMP compliance. It encompasses integration for standard Reference data sets, workflows for data governance and stewardship, processes to de-duplicate data across multiple systems and provide a single source of truth for the product entity.

Fresh Gravity's Implementation Approach:

Fresh Gravity views the IDMP compliance requirement as a unique opportunity to:

- Build a repository of enterprise-wide Data Assets
- Identify opportunities to bring efficiencies including Data Quality and Data Governance practices
- Create an Enterprise Architecture view for data across the Drug Development Value Chain
- Improve Operational Efficiencies

Fresh Gravity's *Molecule to Market* solution is an end-to-end data model that focuses on mastering data with "Medicinal Product" as an anchor entity. This data model spans across multiple processes and functions from R&D to clinical to commercialization and safety. The solution inherits an additional Data Governance and stewardship layer that helps better manage data quality on an ongoing basis.

The approach is broken down into three phases:

Planning » Implementation » Business As Usual (BAU)

As a first step in the Planning phase, a gap analysis needs to be conducted to assess IDMP requirements vis-à-vis the data available within the organization. Another outcome of this stage is to unearth organizational readiness with respect to the availability of people with specific roles, specific data sets and process for data management. The gap analysis also reveals opportunities for data standardization and data enrichment using external sources.

After a complete assessment, Fresh Gravity works in collaboration with the clients to create a strategy for IDMP compliance along with high level timelines, pricing, resources, and a complete execution plan.

The second Implementation phase consists of the following core components:

- Data Discovery and Extraction
- Enrichment & Standardization
- Comprehensive data model designed to support all entities, attributes and relationships mandated by ISO for IDMP compliance
- Master Data Management for Medicinal Products
- Reference Data Management to manage and map SPOR RMS data
- Data Stewardship and Governance Workflows
- Downstream to reporting/Submission

Fresh Gravity Solution Value Add:

- A comprehensive data model that ensures IDMP compliance for pharma companies
- Integration with EMA's SPOR RMS service
- Submission ready messages to downstream applications
- Master Data Management implementation expertise
- Robust tracking of important IDs such as PMS, MPID, PCID, PhPID throughout the drug lifecycle

DATA EXTRACTION *(Master Data)*	**ENRICHMENT AND STANDARDIZATION DATA**	**MASTER DATA MANAGEMENT**	**DOWNSTREAM TO REPORTING/ SUBMISSION**
RIM | CTMS	Citeline	Medicinal Product	
Labelling Management Systems		Pharmaceutical Product	
Adverse Event Reporting Systems	G-SRS	Organization	Data Warehouse
Safety Monitoring System		Indications	Reporting/ Submission Systems
Product and Substance Data	DrugDev	Substance	
DATA EXTRACTION *(Reference Data)*		Packaging	Other downstream Systems
MedDRA	CT.GOV	Devices	
ICD10		Reference Data	
SNOMED	Others		
RMS(SPOR)			

About Fresh Gravity

Founded in 2015, Fresh Gravity helps Life Sciences companies adopt digital transformation through innovation driven by modern technologies. This Molecule to Market solution is a result of our steadfast commitment to finding solutions to the most pressing problems in the industry. To know more about us and our offerings, contact us at ***info@freshgravity.com***

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