IDMP Services

EXTEDO eRegulatory Affairs

IDMP Services

Ensuring a successful transition from XEVMPD to IDMP

Is our company able to meet the latest IDMP requirements? This is the question that a lot of organizations are asking as they get ready for the transition from Extended Eudravigilance Medicinal Product Dictionary (XEVMPD) to Identification of Medicinal Products (IDMP).

Benefits

- Reduce time and resources associated with the transition from XEVMPD to IDMP
- Ensure data quality via business & technical validation
- End-to-end service that encapsulates the complexities of the entire transitioning process
- Simplify and streamline the management of IDMP data
- Ensure effective IDMP maintenance

As the partner of choice to over 35 regulatory authorities around the world, EXTEDO's services team is well-equipped with the knowledge and experience to help your organization transition painlessly from XEVMPD to IDMP.

A holistic approach to IDMP

At EXTEDO we understand the fine details of the new IDMP requirements, in fact a number of our consultants were involved in the definition of the standard itself. Our team of technical and regulatory consultants is able to provide you with an in-depth analysis of your existing processes and technologies and create an accurate assessment of the changes your organization needs to make in order to ensure IDMP compliance.

EXTEDO's IDMP transition framework includes the following phases:

- strategic planning
- regulatory business process consulting
- system implementation & integration
- data analysis, acquisition and management
- data transfer
- transition to IDMP & IDMP maintenance

Strategic planning

During the initial phase of the transition, EXTEDO's team will conduct an audit to assess your organization's IDMP readiness and current technology infrastructure. Based on this audit, we conduct a gap analysis, define the project objectives and draft an implementation plan.

Regulatory business process consulting

Following this initial preparation EXTEDO's team conducts a data quality analysis, assesses the need for integration or migration of IT systems, prioritizes any necessary XEVMPD/IDMP corrections, and ensures that all mandatory IDMP processes are implemented.

System implementation and integration

For successful implementation of the IDMP standard it is essential that your RIM platform is not isolated from other key data sources. EXTEDO offers the perfect solution for this. Through MPDmanager and RImanager we simplify the process of maintaining IDMP submissions, delivering a single source of truth for all IDMP data. By providing a repository for all registrations and enabling the electronic submission of data directly to the authorities, MPDmanager's powerful medicinal product database enables you to efficiently fulfill regulatory requirements surrounding the management of product data.

As a part of our IDMP service package, EXTEDO offers the following services to support your MPDmanager and RImanager implementation and configuration:

- implementation strategy
- installation
- administration/power user training
- system configuration
- system validation support
- user training

Data acquisition and management

EXTEDO's team is able to support your organization with various data acquisition and management tasks including the capture of data from legacy repositories, technical data migration (e.g. downloads from EVWEB), data correction, audit of previously submitted data, and any corrective actions necessary to meet IDMP guidelines.

In addition to this, we will help you to ensure that all new mandatory and conditional data elements are correctly implemented and captured.

Data transfer

Once all data has been successfully acquired, audited and updated, EXTEDO's team will ensure a smooth and quick data transfer, including data validation and archiving. Depending on your business needs data transfers can be made using either an all-in-one or phased approach. In the case of the all-in-one approach all information is converted into the IDMP format in a single pass. Using a phased approach data is migrated in blocks, e.g. all data related to "heart" products is migrated first, followed by data for products that fall within the "skin" health area.

IDMP maintenance

Once your transition to IDMP is complete, our commitment to you is that EXTEDO will continue to monitor future developments in both global and regional standards to ensure that you are kept up-to-date with any changes that may affect your business.

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For further information contact your local EXTEDO representative:

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About us

EXTEDO is a leading solutions and services provider in the field of Regulatory Information Management (RIM). We focus on optimizing our clients' eRegulatory business processes and are the only vendor that provides solutions covering the entire regulatory landscape. Today, EXTEDO enables more than 35 regulatory authorities and over 700 maintained customers across 60 countries to deliver Effortless Compliance™.

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