

ISO IDMP in the EU: What It Means for You

Helping You Navigate Compliance, Efficiency & Pharmacovigilance Improvements

Why It Matters?

The EU's implementation of **ISO IDMP (Identification of Medicinal Products)** is transforming how pharmaceutical companies manage product data. These standards streamline regulatory submissions, enhance pharmacovigilance, and significantly reduce the risk of errors and adverse event misattribution. The European Medicines Agency (EMA) has adopted a phased approach through its **SPOR data model** (Substance, Product, Organization, Referential), making now the time to prepare.



Key Implementation Priorities

- ✓ **Align internal data** to ISO IDMP standards
- ✓ **Integrate with EMA platforms** (PMS, OMS, RMS, SMS)
- ✓ **Maintain data consistency** across regulatory submissions
- ✓ **Upgrade systems** to support new data models
- ✓ **Train staff** on IDMP processes



Common Challenges

- ✓ Managing scattered data across legacy systems
- ✓ Ensuring high data quality and completeness
- ✓ Technical integration and system compatibility



Strategic Benefits of ISO IDMP

- ✓ Enhanced pharmacovigilance through more accurate signal detection
- ✓ Improved regulatory efficiency with standardized data
- ✓ Stronger product traceability and patient safety

PrimeVigilance Can Help.

As regulatory complexity increases, having the right partner is critical. PrimeVigilance offers proven expertise in:

- ✓ **ISO IDMP readiness and implementation**
- ✓ **Data mapping and regulatory integration**
- ✓ **Pharmacovigilance and safety systems support**

Ready to simplify your path to IDMP compliance?

Learn more at www.primevigilance.com or contact us directly to explore how we can support your regulatory transformation.