

NAVIGATING EMA PMS IMPLEMENTATION

A Strategic Guide
for Regulatory Leaders

// MARCH 2025

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Navigating EMA PMS Requirements

A Strategic Guide for Regulatory Leaders.

Regulatory requirements in the pharmaceutical industry are becoming more stringent.

By 2026, IDMP compliance will become drastically more challenging for all pharmaceutical companies operating in the EU due to the broader adoption of the IDMP data model. The EMA Product Management Services (PMS) Requirements present a strategic opportunity, not just another regulatory burden. This whitepaper provides actionable insights for regulatory leaders to streamline compliance, enhance efficiency and drive competitive advantage.

What does it mean for Pharma?

By understanding and implementing the ISO IDMP standards and, therefore, aligning to EMA PMS requirements, pharmaceutical companies can streamline their regulatory submissions, improve data accuracy and facilitate efficient communication with regulatory authorities. This proactive approach not only ensures compliance but also enhances the accuracy of product lifecycle management, ultimately leading to faster approval times and improved market access.

Who should read this?

This whitepaper is designed for regulatory professionals and decision-makers in the pharmaceutical industry, including:

- » **Heads of Regulatory Affairs & Compliance:**
Ensuring alignment with EMA PMS requirements and IDMP standards.
- » **Regulatory Operations Teams:**
Managing data standardization and submission processes.
- » **IT & Digital Transformation Leaders:**
Implementing and integrating PMS-compliant data infrastructures and exchanges.
- » **Quality & Pharmacovigilance Professionals:**
Enhancing data accuracy and patient safety.



Improve data quality and reduce compliance risks.



Enhance operational efficiency – Accelerating regulatory processes.



Position your company for digital regulatory excellence.

Introduction

What is EMA PMS?

Centralizing Medicinal Product Data for Streamlined Compliance and Interoperability

The European Medicines Agency (EMA) Product Management Services (PMS) is a centralized platform designed to streamline the management and exchange of medicinal product information across the European Union. It establishes a single, authoritative source of truth for product data, reducing inconsistencies and improving overall data quality. By implementing ISO Identification of Medicinal Products (IDMP) standards in PMS, EMA ensures data interoperability and facilitates the consistent identification of medicinal products throughout their lifecycle.

EMA Product Management Services (PMS)

PMS is part of EMA's broader SPOR (Substance, Product, Organization, Referentials) initiative, which aims to standardize medicinal product data across Europe ensuring:

- » Standardized data exchange across regulatory bodies (e.g., NCAs)
- » Improved data accuracy and consistency
- » Integration with the IDMP framework

Key Compliance Requirements

- » **ISO IDMP Data Alignment:**
Structured product information must comply with IDMP data standards and data model.
- » **Substance, Organizations, Referentials Alignment:**
Companies must adopt the reference data standards part of EMA SPOR
- » **PMS Database Alignment:**
Companies must ensure their internal data remains aligned with the EMA PMS database.



Unified standards for regulatory exchange.



Enhances accuracy and consistency.





Seamless integration with global standards.



SPOR and 5 ISO IDMP Standards.

SPOR Data Management Services.

-  Substance Management Services (SMS)
-  Product Management Services (PMS)
-  Organisation Management Services (OMS)
-  Referentials Management Services (RMS)



Provides the open-source IDMP Ontology

- » Developed with sponsorship and collaboration of 10+ pharma, the IDMP Ontology provides the digital semantic model for the ISO IDMP standards.
- » Facilitates consistent IDMP data standardization and adoption across industry and regulators.
- » Interoperable with HL7 FHIR.

The 5 ISO IDMP Standards.

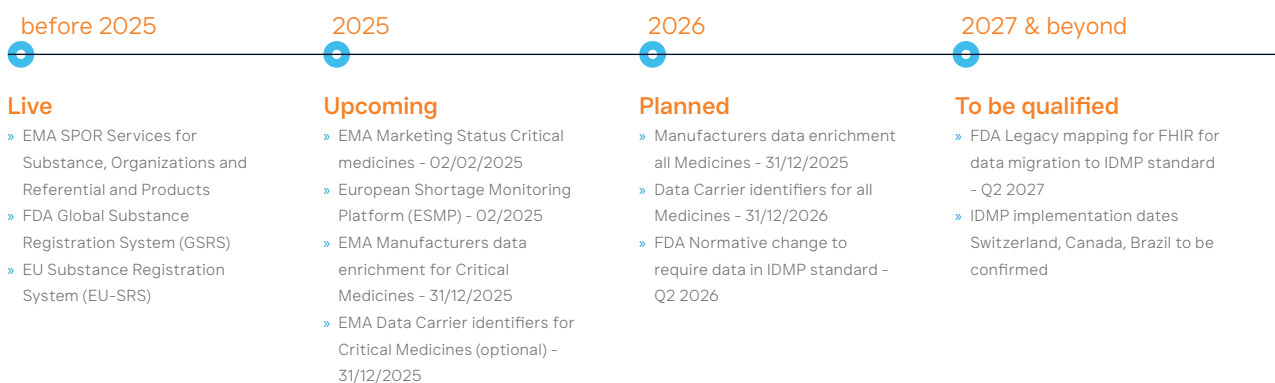
ISO IS Content of the Standard

11615	Medicinal Product Information
11616	Pharmaceutical Product Information
11238	Substances Information
11239	Forms, Presentation Units, RoA and Packaging
11240	Units of Measurement

Implementation Partner.

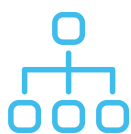


Pharma Sponsors



Features

EMA PMS Key Features



Central Hub

Centralized repository for all medicinal product data, streamlining data management and ensuring consistency across the product lifecycle. Provides a single source of truth for key product-related information.



ISO-Compliant Identifiers

Utilizes ISO-compliant identifiers (MPID, PhPID, PCID) to ensure data integrity and interoperability. These unique identifiers facilitate accurate tracking and, together with EMA's PMS ID and Package PMS ID, support identification of medicinal products throughout their lifecycle.



Lifecycle Management

Supports end-to-end lifecycle management of medicinal products, from initial registration to post-marketing surveillance. Streamlines regulatory processes and ensures compliance throughout the product's lifespan.



FHIR Integration

Seamless integration with the Fast Healthcare Interoperability Resources (FHIR) standard enables efficient data exchange between systems. This interoperability simplifies data sharing and collaboration with healthcare providers, regulatory bodies and industry.

Benefits

Key Benefits of EMA PMS Implementation

1 Enhanced Data Quality

Leveraging ISO-compliant identifiers (MPID, PhPID, PCID), EMA PMS eliminates data inconsistencies and ambiguities. The centralized data structures inherent in the system facilitate the creation and submission of high-quality, standardized data sets, improving regulatory compliance and interoperability.

2 Simplified Compliance

EMA PMS aligns seamlessly with key regulations such as ESMP and EU-FMD, ensuring European regulatory harmony and minimizing compliance complexities. The PMS system centralizes compliance requirements, reducing the burden on pharmaceutical companies and ensuring consistent adherence to the standards.

3 Operational Efficiency

By centralizing data management processes, EMA PMS reduces errors and eliminates redundant tasks, freeing up valuable resources. This streamlined approach accelerates regulatory submission management, enabling faster time-to-market for medicinal products.

4 Risk Mitigation

Implementing EMA PMS significantly minimizes the risk of non-compliance penalties and associated financial losses. Furthermore, it enhances patient safety by enabling accurate and comprehensive product tracking throughout the supply chain.

5 Future-Readiness

The flexible FHIR interface of EMA PMS ensure flexible connectivity with evolving industry IT systems, preparing companies for facilitated digital submissions. This requires a scalable architecture of IT systems to support new compliance initiatives and allows for seamless adaptation to EMA's advancements.

Business value of implementing a Product Management Services (PMS) aligned system for efficient data management and regulatory compliance.



Improved Data Consistency



Increased Operational Efficiency



Enhanced Compliance



Reduction in Data Errors



Accelerated Time to Market

References

Pistoia Alliance, "IDMP Ontology Report," 2024
Contract Pharma, "IDMP Common Core Ontology Project," 2023
PharmaLex, "EMA PMS Regulatory Compliance Report," 2023
Pharmaceutical Commerce, "IDMP & Digitalization in Pharma," 2023

Plan

Your 5-Steps Plan for EMA PMS Alignment

To achieve EMA PMS alignment, pharmaceutical companies should adopt a step-by-step approach. Here's a practical strategy:

Readiness Assessment

- » Conduct an internal audit of regulatory data and IT infrastructure
- » Identify gaps for conforming to ISO IDMP

Develop a Strategy & Roadmap

- » Define milestones and align them with EMA timelines
- » Allocate resources and assign responsibilities

Implement Data Standardization

- » Adopt ISO IDMP-compliant data model
- » Establish automated quality control processes

System Integration & Automation

- » Connect internal systems with EMA PMS (FHIR-based Integration)
- » Implement validation mechanism for regulatory submissions

Train Regulatory Teams

- » Educate regulatory teams on ISO IDMP standards and PMS requirements
- » Establish ongoing compliance monitoring and governance

3 Success factors for fast PMS data alignment

Start Early

The earlier you prepare, the lower the compliance costs. Proactive planning prevent last minute risks.

Leverage automation

Automated updates through interface with Accurids software accelerates alerts on delta changes

Engage with EMA & Industry Experts

Participating in our EMA PMS data alignment pilots provides crucial regulatory insights and competitive advantages.

Regulatory Digitalization

The Future of Regulatory Digitalization

Regulatory digitalization is reshaping the pharmaceutical industry, driven by ISO IDMP standards, automation, the need for shared data language and greater data transparency.

To stay competitive and ensure long-term success, companies must proactively adapt to evolving regulatory requirements and digital transformation.

Key Trends Shaping the Future

Full IDMP Adoption

- » EMA broadens the adoption of the IDMP data model in the next years
- » Standardized product data required
- » Investment in data & tech needed
- » Boosts efficiency, cuts risks

Increased Automation

- » Automation streamlines compliance
- » Leverage data validation & submissions
- » Enhances adverse event detection
- » Reduces errors, speeds up processes
- » Standardized data

Greater Data Transparency

- » Regulators require real-time data
- » Ensures continuous drug monitoring
- » Needs strong data management
- » Secure communication for accuracy

Future-Proof Your Business

Regulatory digitalization is no longer optional - it's essential. Companies that embrace IDMP, automation and data transparency will stay ahead in an evolving regulatory landscape. Early adoption is key to achieving operational excellence and compliance.

Contact

Get Your Compliance Roadmap Today!

The EMA Product Management Services (PMS) Requirements are not merely regulatory hurdles: They offer a strategic opportunity to enhance efficiency, streamline compliance, and gain a competitive edge. Let's turn Compliance into Opportunity!

Your next steps: Successfully align with EMA PMS!

Boost Efficiency:

Streamlined processes, optimized data management, and reduced manual intervention translate to significant cost savings and improved productivity.

Reduced Risks:

Proactive compliance minimizes the likelihood of regulatory penalties, product recalls, and reputational damage, safeguarding business continuity and stakeholder trust.

Market Leadership:

Early adoption demonstrates a commitment to industry best practices, enhancing brand reputation and attracting top talent, consolidating a company's position as a market leader.

Take action today!

**Schedule a free consultation
with our experts!**

Contact us:



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For more insights, visit us:



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