

DRIVING REGULATORY TRANSFORMATION

Building a Future-Ready Global RIM Ecosystem



CHALLENGE

A big Pharmaceutical company managed regulatory data in **separate databases** for:

- Pharma and Non-Pharma products
- Europe
- Portugal
- ROW + Partner/Client markets

This caused **operational challenges** and compliance issues with **ISO IDMP**.

PMS, as a structured data source, now **requires integration** with platforms like ESMP, eAF, ePI, and others.

Regulatory data is now **dynamic** and **interconnected**, requiring deep regulatory interpretation and **strategic planning**.



SOLUTION

Transforming regulatory processes focused on **current and future needs**. Key contributions included:

- IDMP gap analysis
- EMA PMS alignment
- Redesign of the data model
- Migration governance
- Data migration leadership
- Process harmonization
- Post-go-live support

Asphalion ensured the **RIM platform** functioned as a regulatory intelligence one. The project involved:

- Full data migration
- System consolidation
- Market integration
- Elimination of free-text fields
- ISO IDMP enrichment
- Establishment of a global source of truth



OUTCOME



Unified Global Regulatory Platform

One harmonized system across all products and markets.



IDMP & PMS Readiness

Structured data aligned with EMA's evolving digital ecosystem.



Strengthened Inspection Preparedness

Improved traceability, transparency, and compliance robustness.



Operational Efficiency & Process Harmonization

Standardized workflows and reduced complexity.



Future-Proof Regulatory Governance

A scalable model capable of adapting to new regulatory platforms and data requirements.