AMPLEXOR
AN ACOLAD COMPANY

LIFE SCIENCES SUITE

Let us help you to get IDMP ready

At Amplexor, we recognize that compliance with IDMP requirements is a huge challenge for Life Sciences companies, increasing the workload for regulatory resources that are already thinly stretched. However, IDMP also presents a unique opportunity for substantial long-term improvement of regulatory operations.

IDMP standards specify the use of standardized definitions for the identification and description of medicinal products for human use, facilitating the reliable exchange of medicinal product information in a robust and consistent manner. This enables wide interoperability across global regulatory and healthcare communities, which is critical in ensuring accurate analysis and clear communication across jurisdictions.

Why IDMP?

The benefits of IDMP reach beyond pure compliance: the target operating model (TOM) defined in Europe will fundamentally change regulatory operations, enabling better quality and shortening time to market for the benefit of the patients, while the standardization of data and processes will significantly contribute to improving operations along the entire value chain.

Your path to IDMP success

We provide IDMP software solutions that enable our customers to achieve IDMP compliance. And we've created a 4-step process to guide you on the journey to IDMP compliance and beyond. Step by step, we will help you identify where you are in relation to IDMP readiness, as we chart and manage your journey for you. Our approach draws on the industry experience, insight and learnings, distilled through our IDMP Customer Circle into emerging IDMP common practices.

Kickstart your IDMP Acceleration Program

Our consultative IDMP health check is the ideal way to get started. Together we look at some key questions about your IDMP journey to ascertain where you are and what support you need.

Following your IDMP health check results, we'll onboard you at the step that best reflects where you are on your IDMP journey:

- **Awareness**: IDMP resources, events and induction training
- **Preparation**: Impact assessments; IDMP data preparation; Project preparation; PoC -> proof of concept
- **Implementation**: IDMP solution implementation; Legacy data transformation; Initial data load
- **Production**: In-process IDMP data enrichment; Data validation; Data submission; Data maintenance; Regular solution updates; Continuous process optimization

Within implementation, there are three broad scenarios that map to varying levels of IDMP maturity:

Scenario 1

Without a RIM system currently in place

- Companies that are still managing the bulk of their regulated product information using spreadsheets must look for a solution which provides a clear path to IDMP compliance aligned with other regulatory needs.

Scenario 2

Existing RIM platform

- Companies which have already deployed a RIM system need to assess how IDMP features in their software vendor's plans.
- Upgrading to next-generation product releases will minimize disruption and maximize the return on existing investments.

Scenario 3

Best-of-breed solution landscape

- The life sciences software industry has advocated developing a 'single source of truth' for regulated product information.
- Nevertheless, open-standards based infrastructure supports connectivity and data exchange with function-specific applications, via APIs.
- Therefore, companies can still choose best-of-breed suppliers respectively for document management, eCTD, IDMP, and so on.

Our Credentials

Deep expertise

- Internal consulting team with senior industry background
- Deep knowledge of regulatory guidelines and direct involvement in the design and development process
- Strong partner ecosystem for extensive consulting engagements

Rich experience

- Industry leadership on XEVMPD - first solution on the market with largest share of gateway submitted records
- Engagement in IDMP since ISO IDMP standards publication
- Proven track record on complex data migrations and integrations

Customer relations

- Customer circle community of industry experts promoting constructive exchange of IDMP information
- Customer-driven design through direct input and feedback that shapes the IDMP functionality

Amplexor Life Sciences Suite and IDMP

Amplexor's holistic RIM platform offers a streamlined approach that enables Life Sciences companies to achieve long term business benefits beyond compliance, and drive, manage and control the processes of releasing new products or maintaining existing products on the market. The platform helps you to:

- Manage product data and content in line with the IDMP TOM
- Manage information throughout the products lifecycle
- Plan and track regulatory activities
- Manage interactions with health authorities and other regulatory bodies
- Oversee the authoring, reviewing and approval of submission documents
- Support global label management processes
- Plan, compile, review, publish, and manage submissions

IDMP compliance is a cornerstone of Amplexor Life Sciences Suite featuring:

Ease of compliance

- Our IDMP solution, ProductExpert™, is a seamless part of the end-to-end RIM user experience in a familiar user interface

Data-centric processes

- IDMP-compliant data management is driven by a common master and reference data model shared across the complete Life Sciences Suite
- Interconnected data model enables transparent and efficient data-driven change management process
- Improved granularity of structured data brings new potential for automated content creation and other business benefits

Data connectivity

- Flexible connectors allow configurable connectivity to external data sources
- Integrated support for AI-based IDMP data extraction
- SPOR interoperability drives external alignment on reference sources
- Can serve as a central regulatory data hub for your wider company needs
- Built-in B2B gateway enables direct submission of FHIR messages

Process connectivity

- IDMP target operating model is a natural part of the end-to-end regulatory information management where IDMP message is submitted together with eCTD sequence
- Regulatory activity planning & tracking drives both data and content components of the regulatory submissions
- Direct connection to the submission management capabilities enables automated inclusion of FHIR messages in eCTD sequences

Ease of implementation

- Upgrade path from existing RIM and XEVMPD implementations, leveraging and transforming existing data
- Plug&Play solution for new customers on premise or in the cloud with full support for data migration

Future-proof design

- Configurable data, content and process model allows for simple adjustment to emerging requirements, evolving processes and emerging common practices
- Regular product releases bring new or enhanced solution capabilities in a frequent pace

Please get in touch to find out more or visit us online.

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ABOUT AMPLEXOR LIFE SCIENCES

Amplexor Life Sciences is a global provider of regulatory, quality and safety software solutions, serving and trusted by pharmaceutical, biotechnology and medical device companies for over 25 years. Its holistic Life Sciences Suite solution helps life sciences organizations to be efficient with launching products and breaking into new markets quickly while ensuring quality, efficiacy and safety through end-to-end support to product lifecycle processes, data and content management.

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