IDMP Pre-Collection Service Package

Preparing your organization ready for the move to IDMP

The transition from XEVMPD to IDMP is significant. IDMP requires the collection of a much broader set of data than XEVMPD or other similar standards. It includes things such as medicinal products, pharmaceutical products, clinical particulars, substance information, packaging, manufacturing and marketing authorizations. This information comes from various systems and groups within your organization including: product development, regulatory affairs, manufacturing, and drug safety.

With so many things to consider, the question is where to start?

Benefits
⟩ Learn about the IDMP migration process
⟩ Reduce time and resources associated with the transition to IDMP
⟩ Understand the efforts involved in migrating your data to IDMP
⟩ Ensure effective IDMP data planning
⟩ Start IDMP data collection now in a lean and efficient way
⟩ Ensure effortless product data governance

Preparing your existing data for IDMP

At EXTEDO we understand the finer details of the new IDMP requirements, in fact several of our lead consultants were involved in the definition of the standard itself. Our team of technical and regulatory consultants can 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 to ensure IDMP compliance.

An important service EXTEDO offers in this process is our IDMP Pre-Collection Service Package. It is designed to help organizations of all types to understand the data required by the IDMP standard.

The IDMP Pre-Collection Service Package covers the entire IDMP standard and is adapted to the needs of each customer. It is a bundle of services, including training and consulting, to guide your organization through the early stages of IDMP preparation and planning. After utilizing the IDMP Pre-Collection services the user will be ready and prepared to collect all required IDMP data.

Supporting you through your first steps

Presented by one of EXTEDO's leading IDMP experts, an initial workshop and day of training will ensure that your staff understands the IDMP standard and its implications on your business. We will also review your requirements, including details of the data that needs to be captured and stored.

Having gained a full understanding of your requirements, we will work with your team on the configuration and completion of your IDMP pre-collection process. After final creation of your pre-collected data we will provide detailed IDMP training for your staff, enabling your team to collect and manage all necessary data to remain Art. 57 compliant for now and for the future and to be ready for any IDMP adventures that will come along our path.

IDMP Data Pilot

Our team of IDMP experts will help you to identify where data currently exists and where there are gaps in your product data creation and maintenance processes. With your knowledge of your business and our knowledge of the standard, we will ensure that no stone goes unturned. Using our internal tools, EXTEDO is able to extract a large part of the mandatory IDMP data from your existing XEVMPD data directly from EVWEB as well as extract data directly from SmPCs. This saves you the time associated with having to fill in mandatory IDMP data manually.

Looking forward, our goal is to enable you to extract all the data you have collected in SPL or any other XML format and directly import it to your chosen IDMP management solution, such as EXTEDO's MPDmanager. With all the necessary IDMP data in MPDmanager, the tool allows you submit it directly to the authorities. With EXTEDO by your side, you no longer have to worry about the upcoming IDMP changes anymore.

Get ready for IDMP now

Even though the EMA have recently announced that they will be delaying the roll-out of the new ISO IDMP standard after the completion of the Brexit, we believe in IDMP and you should too.

Our recommendation is to stay on your pathway to IDMP but to shift your focus from "How do we become IDMP compliant" to "How can we become more efficient how can we achieve effortless compliance and how can we achieve IDMP compliance while not needing to worry about IDMP compliance."

The choice is yours, but with so much to be gained we have prepared our top five reasons for continuing at pace with your IDMP roll-out.

Additionally, with SPOR being live from October 2017 and the industry will have access to O&R data. Industry stakeholders can start registering their super users and start using RMS and OMS.

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.

If you would like to start a discussion and learn more about our solutions for accelerating IDMP compliance within your company, visit our website (www.extedo.com) or contact one of our specialists at info@extedo.com.

EXTEDO
eRegulatory Affairs

EXTEDO Germany

Phone +49 (89) 189454-0
Email   info@extedo.com
Web   www.extedo.com

EXTEDO US

Phone +1 (855) 328 3500
Email   info@extedo.com
Web   www.extedo.com

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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