WORKSHOP

FORUM
40 YEARS

IDMP 2020 - the first iteration!

With practical examples of how to describe your products in IDMP

TOPICS

- Status of implementation
- Details of the IDMP EU Implementation Guide
- Collection, cleaning and structuring of data - your urgent to-dos
- Structured electronic product information (ePI)
- The link between ePI, IDMP and SPOR

YOUR SPEAKERS

Remco Munnik
IPERION, Vlijmen,
THE NETHERLANDS

Associate Director

Georg Neuwirther
AGES Austrian Medicines and Medical Devices Agency, Vienna, AUSTRIA

Head of IT

12 DECEMBER 2019 IN FRANKFURT

IDMP 2020 - the first iteration!

Aims and objectives

The first iteration of IDMP is approaching - high time to implement IDMP. This workshop helps you collect, clean and structure all necessary data, as well as showing you how to build efficient project teams for the implementation.

Related topics, such as SPOR and structured electronic product information, will also be addressed in detail.

Be ready for IDMP iteration 2!

Who should attend?

This meeting is for everyone working with regulatory databases, dealing with XEVMPD, IDMP or SPOR.

It will also be useful for those who prepare data for these databases or who are involved in regulatory digitalisation projects.

Limited number of attendees

This workshop is limited to 15 participants. This limitation, a feature of all FORUM seminars, enables participants to thoroughly discuss the complex issues covered by the programme.

Your speakers

Remco Munnik
IPERION, Vlijmen,
THE NETHERLANDS

Associate Director

Georg Neuwirther
AGES Austrian Medicines and Medical Devices Agency, Vienna, AUSTRIA

Head of IT

Your benefits

This is why you should attend:

- Two IDMP/SPOR experts
- Authority and industry know-how combined
- IDMP description using your products as practical examples

Blended Learning

Do you need CTD content know-how? Then our 'Common Technical Document and eCTD' elearning course is the fast track to becoming knowledgeable in this field and also the ideal preparation for the seminar. No prior dossier experience is required. It can be also used as a refresher course.

Booking options

You have the option to organise your training according to your level of expertise and requirements. If you book the 'Common Technical Document and eCTD' e-learning course in addition to the seminar, you will receive a €100 discount.

With practical examples - bring your products!

Your programme 09:00 - 17:00

IDMP introduction, motivation and status of implementation

Georg Neuwirther

- ISO IDMP: motivation and status of implementation
- ISO IDMP essential theory: The data structure and ID's: Pharmaceutical Product Identifier (PhPID), Medicinal Product Identifier (MPID), Packaging ID (PCID)
- ISO IDMP and the potential use in telematics projects (eAF, CESP, TOM)

IDMP EU Implementation Guide - version 1: the details

Remco Munnik

- Data-elements as requested for Iteration 1 - Review of the mandatory data-elements, including an evaluation of the source and data-management of these fields.
- Which medical product information shall be submitted in the new format
  - Pharmaceutical & medicinal product
  - Marketing authorisation information
  - Therapeutic (product) indication
  - Ingredient
  - Packaged Medicinal Product Identifier (PCID)
- Technical specifications on structure and format
- Migration from XEVMPD to PMS, status

Bring your products

Remco Munnik, Georg Neuwirther

- Describing medicinal products in IDMP, based on examples submitted by participants in advance

Collection, cleaning and structuring of data in the companies - your most urgent to-dos

Remco Munnik

- Regulatory data
- PV data
- Production data

Building project teams to process IDMP implementation

Remco Munnik

- Responsibilities, duties and project leadership

IDMP and SPOR - how are they related?

Georg Neuwirther

- SPOR necessities

ePI: structured electronic product information - a digitalisation project potentially utilizing IDMP and SPOR

Georg Neuwirther

Regulatory Information Management - the essentials

Remco Munnik

- Do I need master data management?
- Do I need a content management system?

The next steps

Remco Munnik, Georg Neuwirther

- PMS and data-feeding processes (Art 57 data-feeding processes), TOM (target-operating model)
- IDMP EU Implementation Guide: version 2 forecast for mid-2020

IDMP 2020 - the first iteration!

REGISTRATION UNDER

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REGISTRATION FORM

Yes, I will attend

☐ IDMP 2020 - the first iteration! (1912234)

☐ e-learning (1912222)

☐ Yes, I agree that FORUM Institut may inform me about events by:
☐ email; and/or ☐ telephone.
I may withdraw my consent at any time.

Name

Position, department

Company

Street

Post code, city, country

Tel. no./Fax no.

E-mail

Contact person at office

Date, signature

Date and venue
Thursday, 12 December 2019 in Frankfurt
08:30 registration; 09:00 - 17:00 seminar
Mercure Hotel Kaiserhof Frankfurt City Center
Kaiserstraße 62-64 · 60329 Frankfurt
Tel. 069 2561790 · Fax

Fee
€ 1,090.00 (+ German VAT)
The fee includes course documentation (including free download) as well as refreshments, lunch and a certificate. You will receive an invoice as well as confirmation.

Fee e-learning
€ 490.00 (+ German VAT)
e-learning "Common Technical Document & eCTD" (1912222). This price is only valid in combination with the above mentioned seminar.

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CANCELLATION POLICY

Our general terms and conditions (as of1 January 2016) apply and are available upon request.We can send them to you at any time. Alternatively, you can access them online at www.forum-institut.com/t&c

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