DIA Interactive Training Workshop on IDMP: "Start Early, Finish Strong"

29-30 October 2015 | ID#15110
Pullman Paris Roissy CDG Airport, Paris, France

OVERVIEW

This 2-day interactive training workshop on IDMP (Identification of Medicinal Products) is aimed at professionals in the pharmaceutical field who appreciate the importance in preparing for IDMP and want to make optimal use of the time left for implementation. Although the EU will likely apply a staged approach for IDMP implementation, this should not be interpreted as postponed activity but rather as an extension of the implementation time required.

Irrespective of the finalisation of the implementation guidelines, IDMP requires awareness, ownership and need for change of business processes as well as software tools. The ISO IDMP standards themselves clearly indicate the magnitude of change required within pharmaceutical companies as well as health authorities. Health authorities have already published their needs which in turn will have impact within industry[1, 2, 3] . The pharmaceuticals industry must consider mirroring these needs to minimise future complications following regulatory updates.

Therefore, the lack of final IDMP implementation guidelines should not to be used as an excuse for delaying your strategy for handling the IDMP implementation processes. Due to the complexity and broad scope of the topic it is recommended to start developing frameworks for IDMP projects sooner rather than later. The effort will be significant; as will the gain in efficiency, transparency and ability to identify corrective and preventive actions (CAPAs).

The workshop will cover the practical aspects of IDMP implementation and the impact on the business processes and software tools. It is designed to be an educational environment where content focuses on actively engaging the topics presented. Instructors will lead break-out sessions and group collaboration to develop creative solutions that will allow participants to contend with the demanding work ahead.

Solution providers will present different practical software solutions and offer their knowledge to the participants.

The interactive training workshop will be most useful to those professionals with basic knowledge about IDMP who want to gain a more in-depth understanding preparation for and efficient approaches to IDMP implementation.

LEARNING OBJECTIVES

At the end of this workshop participants will get insight into the following key topics:

- Various ways to approach IDMP implementation
- Semantic challenges and managing common terminology
- Generation and ownership of IDMP data on Medicinal Product
- Generation and ownership of IDMP data on substances
- IDMP as an opportunity for Business Excellence
- Difference and resemblance concerning IDMP and Master Data
- Must haves and nice to haves for a data quality framework
- Project charter for IDMP implementation
- Relevant tools and vendor knowledge bases

WHO WILL ATTEND

Professionals who already have basic knowledge about IDMP, in the roles of:

- Professionals of Pharmaceuticals industry:
  - Regulatory affairs/operations representatives
  - Regulatory compliance specialists
  - IT and support personnel
  - Document and records managers
  - Standards implementation specialists and associates
  - Quality assurance and compliance professionals
  - Validation and migration professionals
  - Knowledge/IP professionals
  - Labelling specialists
  - Pharmacovigilance professionals
- CROs, CMOs and service providers
- Agency representatives (e.g. inspectors and reviewers)

[1] European Medicines Agency (EMA) Master Data Management Roadmap (EMA/730453/2014)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500186290.pdf

[2] Annex to the European Medicines Agency (EMA) Master Data Management Roadmap (EMA/187520/2015)
http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/04/WC500186289.pdf

[3] FDA Data Standards Strategy 2015-2017
http://www.fda.gov/downloads/drugs/developmentapprovalprocess/formssubmissionrequirements/electronicsubmissions/ucm455270.pdf

DIA DEVELOP INNOVATE ADVANCE

29 OCTOBER 2015

DAY 1 – Technical Aspects of IDMP

08:30 **REGISTRATION & WELCOME COFFEE**

09:00 **ISO IDMP: A REFRESHER UPDATE ON CURRENT**

Gordon Topping (UCB)

- The implementation plans in EU, US, Japan and other countries
- Expectations of the Health Authorities
- The basics of the five ISO IDMP standards
- The role of the ISO and regional implementation guides
- Initial and future usage of IDMP; the broader perspective
- July 2016 – the implementation deadline in Europe: It's a start, not the end!

10:15 **WAYS TO APPROACH IDMP**

Hans van Bruggen (eCTDconsultancy BV)

- Reasons for potential differences in company approach
- Potential challenges for mergers and acquisitions
- Connecting the puzzle: people, processes, data and systems
- The "manual approach"
- The "fully integrated approach"
- Mixed approaches towards IDMP
- How to deal with unstructured data

11:00 Refreshment Break & Exhibition Opening

11:30 **ESTABLISHING A COMMON TERMINOLOGY**

Michiel Stam (eCTDconsultancy BV) / Timm Pauli (PharmaLex GmbH)

- Introduction to IDMP terminology, referencing existing standards and implementation guides
- Semantic challenges
- Importance of structured data
- Codification of terms/natural language by (IDMP) identifiers

12:30 Lunch Break in the Exhibition Area

13:30 **WHERE TO FIND IDMP DATA ON MEDICINAL PRODUCTS?**
INCLUDING BREAK OUT SESSION

Michiel Stam (eCTDconsultancy BV) / Timm Pauli (PharmaLex GmbH)

- Various perspectives on the Medicinal Product definition
- Collecting MP names
- Collecting authorization details
- Collecting Clinical Particulars
- Collecting Pharmaceutical Product details
- Collecting Packaging details
- Collecting Organizational details
- Ability to leverage from XEVMP

15:30 Refreshment Break in the Exhibition Area

16:00 **WHERE TO FIND IDMP DATA ON SUBSTANCES?**
INCLUDING BREAK OUT SESSION

Stan van Belkum, (CBG-MEB)

- Various perspectives on the Medicinal Product definition
- Global Substance Registration System (GSRS)
- Impact for MA holders, ASMF holders and CMOs
- Collecting high level substance information
- Collecting detailed substance information

17:30 Networking Reception in the Exhibition Area

18:30 **END OF DAY 1**

30 OCTOBER 2015

DAY2 – Procedural Impact of IDMP

08:30 **SOFTWARE VENDOR SHOWCASES**

Maximum of 7 vendors

- Real practical tool demonstrations
- Potential topics
  - Show the various views on the IDMP data
  - Potential workflow
  - Search & reporting functionalities
  - Submission and exchange with health authorities
  - Integration with other systems

10:30 Refreshment Break in the Exhibition Area)

11:00 **SOFTWARE VENDOR SHOWCASES - CONTINUED**

- Real practical tool demonstrations
- Potential topics
  - Show the various views on the IDMP data
  - Potential workflow
  - Search & reporting functionalities
  - Submission and exchange with health authorities
  - Integration with other systems

12:30 Lunch Break in the Exhibition Area

13:30 **IDMP AS AN OPPORTUNITY FOR REGULATORY OPERATIONAL EXCELLENCE**

Dr V. Balasubramanian (Cabeus)

- What does IDMP mean for your business processes: going beyond the technical challenges
- Different ways to approach IDMP: "Work hard or work smart"?
- Understanding information flow, stakeholders and key systems: IDMP as a company-wide project
- Building a business case for IDMP implementation to be compliant and improve your processes

14:30 **REGULATORY MASTER DATA MANAGEMENT**

Dr V. Balasubramanian (Cabeus)

- Importance of MDM
- How to overcome data of the same type scattered across multiple systems?
- How to overcome data quality challenges?
- Interfaces for an enterprise Master Data Management
- How to keep systems in synch in an ever changing business environment

15:30 Refreshment Break in the Exhibition Area

16:00 **DATA QUALITY FRAMEWORK**

Kirsten Langendorf (SAS)

- IDMP as the trigger for systematic change management
- Right first time: How to avoid repeated clean-up projects
- Data integrity

16:30 **TURNING THEORY INTO PRACTICE**

Karl-Heinz Loebel (PharmaLex GmbH)

- Summary of the most important conclusions (people, processes, data and systems)
- Team and governance setup
- Vision
- Work streams
- Timing

17:00 **END OF TRAINING WORKSHOP**

Training Workshop Venue

The training workshop will take place at the:
Pullman Paris Roissy CDG Airport Hotel
3 Bis Rue De La Haye - Roissypole / Cs 10008
95935 Roissy, France

DIA has blocked a limited number of rooms at the special rate of € 149.60 including breakfast, VAT and service. To book your room, please **click here** to download the booking form and send it no later than 30 September 2015.

Directions
In the heart of Roissy CDG Airport, its 3 Terminals, and next to the RER B-CDG1 station. From Terminals 1 and 2 and the TGV station: take the CDG Val shuttle for 2 stops to Roissypole stop. (7 days a week from 4 AM to 1 AM, every 4 minutes - free). From the bus station and Terminal 3: 4-minute walk following signs to hotel. From A1 Highway: Head toward Roissypole and Terminal 1-2-3 - then toward Roissypole Est and Terminal 3/hotel parking.

ABOUT DIA

DIA is the global connector in the life sciences product development process. Our association of more than 18,000 members builds productive relationships by bringing together regulators, innovators, and influencers to exchange knowledge and collaborate in an impartial setting. DIA's network creates unparalleled opportunities for exchange of knowledge and has the inter-disciplinary experience to prepare for future developments.

The dedicated efforts of DIA staff, members and speakers enable DIA to provide a comprehensive catalogue of conferences, workshops, training courses, scientific publications and educational materials. DIA is a global community representing thousands of stakeholders working together to bring safe and effective products to patients.

DIA is a neutral, nonprofit organisation with its global center located in Washington, DC, US and with regional offices covering North and South America (Horsham, Pennsylvania, US); China (Beijing); Europe, Middle East & Africa (Basel, Switzerland); India (Mumbai); and Japan (Tokyo).

Discover more opportunities at www.DIAglobal.org

CALL FOR ABSTRACTS

> Call for Abstracts on Vendor IDMP Showcases

Deadline for submission: 9 October 2015

Adopting IDMP will have a significant impact on the business processes within pharmaceutical companies. Successful implementation relies on smart and inventive software solutions. Industry must stay informed about the latest trends and developments of software solutions supporting IDMP. Sufficient time of the workshop is therefore allocated for non-promotional showcases by software vendors. Showcases should include:

- The various views on the IDMP data
- Potential workflows within and across systems
- Search & reporting functionalities
- Integration with other systems
- Submission and exchange with health authorities

The showcases must be educational and not promotional. Participation in this event offers software vendors an opportunity to demonstrate their knowledge and subject matter expertise on IDMP though hands on engagement with participants. The intent of the showcase is to highlight software in development by the various software vendors, preferably by live demonstrations which reflect the interactive educational points of the training conducted.

A maximum of 7 showcase slots are available and limited to software vendors only.

The selection of showcases is up to the discretion of the organising committee and DIA.

The deadline for submitting abstracts is Friday, 9 October 2015, please send your abstract in word format to: Thomas.Denman@DIAglobal.org

EXHIBITING OPPORTUNITIES AVAILABLE

Don't miss the opportunity to showcase your product or service to an international audience of qualified professionals, from entry level to expert, in the pharmaceutical, biotechnology, devices and related healthcare industries, government, academia and healthcare delivery.

The exhibition fee is € 3,500.00 including a 3m x 2m exhibit space, one (1) complimentary full meeting registration and one (1) exhibit booth personnel registration. Any staff required above those allotted per 3m x 2m must register as a full attendee incurring full registration fees. Each booth space includes one (1) table, two (2) chairs and one (1) electrical connection.

Please note that there will be NO pre-fitted shell scheme provided. Any additional expenses associated with the exhibit, including pop up stand, lights, phone or carpeting, additional electrical connections, etc., will be the responsibility of the exhibitor.

For more information on exhibiting space and facilities, please contact the DIA EMEA Exhibits Department on +41 61 225 51 51 or email: EMEA.exhibition@DIAglobal.org

REGISTRATION FORM

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Early-bird discount available for members: Register by 23 September 2015

Join DIA now to qualify for the Early-bird member fee! The Early-bird registration form and accompanying payment must be received by the date above.

Early-bird fee applies to industry members only. Click **here** to become a member now. **€ 1'200.00** ❑

CATEGORY	Member (after 23 September 2015)*	Non-Member*
Industry	€ 1'400.00 ❑	€ 1'585.00 ❑
Government/Charitable/Non-profit/Academia (Full-Time)	€ 700.00 ❑	€ 885.00 ❑

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee . Group discount/SME rates available. Please contact DIA EMEA for more information. Registration fee includes: refreshments, lunches, reception and meeting materials.

*All fees are subject to 20% French VAT. Payment due 30 days after registration and must be paid in full by commencement of the event.

TOTAL AMOUNT DUE: € _____

ATTENDEE DETAILS

PLEASE COMPLETE IN BLOCK CAPITAL LETTERS OR MAKE REGISTRATION EVEN SIMPLER BY ATTACHING THE ATTENDEE'S BUSINESS CARD HERE

❑ Prof ❑ Dr ❑ Ms ❑ Mr

Last Name

First Name

Company

Job Title

Address

Postal Code City

Country

Telephone

Fax

Email

Please provide your European VAT number

PAYMENT METHODS

Credit cards: Payments by VISA, Mastercard or AMEX can be made by completing the details below. Please note that other types of credit card cannot be accepted.

❑ **Please charge my** ❑ VISA ❑ MC ❑ AMEX

Card N°

Exp. Date /

Cardholder's Name

❑ **Bank transfers:** When DIA completes your registration, an email will be sent to the address on the registration form with instructions on how to complete the bank transfer. Payments in EURO should be addressed to "Account Holder: DIA." Please include your name, company, Course ID#15110 as well as the invoice number to ensure correct allocation of your payment.

Payments must be net of all charges and bank charges must be borne by the payer. **If you have not received your confirmation within five working days, please contact DIA Europe, Middle East and Africa.**

By signing below, I confirm that I agree with DIA's Terms and Conditions of booking. These are available from the office or online by clicking **here**.

Date	Signature

DIA MEMBERSHIP

Join DIA now to qualify to save on future events and to receive all the benefits of membership. Visit www.diaglobal.org and click on Membership for more details.

DIA offers one year complimentary membership against event registration at non-member rate

❑ **I do not want complimentary membership**

TERMS AND CONDITIONS

Cancellations

All cancellations must be in writing and received at the DIA EMEA office by 17:00 CET on 29 September 2015 and will be subject to an administrative fee:

Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00
Academia/Charitable/Government /Non-profit (Member/Non-member) = € 100.00
Tutorial cancellation: € 50.00

For cancellations after this date, or if the delegate fails to attend the meeting, no refund of fees will be given and be responsible for the full registration fee. DIA EMEA reserves the right to alter the venue and dates if necessary. If an event is cancelled, DIA EMEA is not responsible for airfare, hotel or other costs incurred by registered attendees. Registered attendees are responsible for cancelling their own hotel and travel reservations.

Transfer Policy

You may transfer your registration to a colleague prior to the start of the event but membership is not transferable. Substitute attendees will be responsible for the non-member fee, if applicable. Please notify the DIA EMEA office of any such substitutions as soon as possible.

Photography Policy

By attending the event, you give permission for images of you, captured during the conference through video, photo, and/or digital camera, to be used by DIA in promotional materials, publications, and website and waive any and all rights including but not limited to compensation or ownership.

The DIA Europe, Middle East & Africa Contact Center will be pleased to assist you with your registration from Monday to Friday between 08:00 and 17:00 CET.

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