An Introduction to Product Information Management (PIM)

Course Overview
PIM is a new method of submitting product information in the Centralised Procedure (CP). With more than 20 different languages in the EU leading to 1000 or more documents for a single trade name, there is an increased burden on applicants and authorities to handle information for packaging leaflets and product characteristics, especially during the time critical translation process. PIM has been introduced by the EMEA to increase efficiency during exchange of product information and improve the quality and constancy of product information.

This training course is designed to give the participants a good understanding about Product Information Management, the PIM submission process and variations, the translation process and comment handling as well as the exchange standard and templates used.

Key Topics
- PIM Essentials
- Initial Submissions
- Comment Handling
- Translation Process
- PIM Variations
- LAT – The Light Authoring Tool

Who Will Attend
Professionals in:
- Document Management
- Information Technology / e-Business
- Marketing / Advertising
- Medical Communications / Information
- Manufacturing: Drug Substance, Drug Product, Packaging
- Quality Control / Quality Assurance
- Regulatory Affairs / Policy / Drug or Device Approval / GRP

Learning Objectives
At the conclusion of this course, participants should be able to:
- Explain the procedures for Product Information Management
- Discuss the Product Information Management submission process and variations
- Describe the translation process and comment handling
- Recognise the exchange standard and templates
MONDAY | APRIL 26, 2010

08:00 Registration
09:00 Introduction, logistics, and overview of learning objectives of day 1
09:15 Session 1

PIM ESSENTIALS

The purpose of this session is to give the participants an overview about Product Information Management (PIM), the terminology used and the PIM process. It also presents the basic PIM exchange format with the authorities and the challenges faced.

• Basic PIM terminology
• The PIM process and advantages
• Exchanging information with authorities
• Structures labelling content, meta data, and style sheets
• Structured Product Labelling (SPL)

10:45 Coffee Break
11:15 Session 2

THE AGENCY VIEW

The purpose of this session is to give the participants an overview of the current status of PIM submissions at the EMEA.

• Current status of the PIM project
• The PIM Review System PRS
• The PIM submission process and agency requirements
• Current time lines, restrictions, and constraints
• Advantages of moving to PIM
• The PIM review process from the agency perspective

12:45 Lunch
14:00 Session 3

INITIAL SUBMISSIONS

The purpose of this session is to give the participants an overview of the initial PIM submission, the processes triggered, and the procedures required.

• Authoring and validation of content
• Publishing structured labelling content to different formats
• Integration with Submission Management Systems
• Translation to multiple languages
• PIM data exchange with the authorities

15:30 Coffee Break
16:00 Session 4

PRACTICAL EXERCISE: THE INITIAL SUBMISSION PROCESS

The objective of this session is to let participants gain first hand experience in undertaking the initial submission process and learn about its complexity.

• Processes and procedures required
• Building a product hierarchy
• Working with QRD templates
• Authoring of source documents
• The validation process

17:30 End of Day One
17:30 Reception

TUESDAY | APRIL 27, 2010

09:00 Introduction, logistics, and overview of learning objectives of day 2
09:15 Session 5

TRANSLATION PROCESS

The purpose of this session is to share information about possible translation automation and manual processes in the tight time lines given by authorities.

• Product translation information
• Introduction to translation technology
• Impact assessment
• Internal/external translations
• Machine and computer assisted translations
• Translation memories

10:45 Coffee Break
11:15 Session 6

PIM CASE STUDY

The objective of this session is to present a real case study, giving the participants first hand knowledge about the PIM submission process and complexity.

• How to plan and prepare your company for PIM submissions
• Interaction and communication with the agency
• The transition process
• Experience gained

12:45 Lunch
14:00 Session 7

PIM POST AUTHORISATION

The Post Authorisation process and its complexity.

• Preparing for PAP
• Business requirements and modelling
• Parallel post authorisation procedure
• Practical exercise: PAP adaptation on business model

15:30 Coffee Break
16:00 Session 8

LAT – THE LIGHT AUTHORIZING TOOL

Authorities supply the free LAT (Light Authoring Tool) to allow applicants to submit in PIM format. This session looks at the advantages and disadvantages of going down this route.

• Functionality LAT
• Working practice LAT
• Considerations, advantages and disadvantages

17:30 End of Training Course

Unless otherwise disclosed, DIA acknowledges that the statements made by speakers are their own opinion and not necessarily that of the organisation they represent, or that of the Drug Information Association.
Hotel Information

The DIA has blocked a limited number of rooms at the:

Austria Trend Hotel Savoyen
Rennweg 16
1030 Vienna
Austria

Tel.: +43 (1) 206 33 0
Fax: +43 (1) 206 33 9110
Website: www.austria-trend.at/sav
E-mail: reservierung.savoyen@austria-trend.at

at the special rate of EUR 150.00 for a single and EUR 160.00 for a double room including breakfast, service and VAT.

To reserve a room, please send an email to the hotel or use the booking form that you find on the DIA website.

IMPORTANT: To be assured of accommodation at the Austria Trend Hotel Savoyen, registrants are recommended to complete their reservation by January 26, 2010 at the latest.

DIA Upcoming Training Courses in 2010

Clinical Research

Essentials of Clinical Study Management
May 5-7, 2010 / Vienna, Austria
November 10-12, 2010 / Lisbon, Portugal

Clinical Project Management in Europe – Part I
February 9-12, 2010 / Paris, France

Practical GCP Compliance Auditing of Trials & Systems
October 6-8, 2010 / London, United Kingdom

Clinical Statistics for Non-Statisticians
September 13-14, 2010 / Paris, France

Regulatory Affairs

Comprehensive Training on European Regulatory Affairs:
Expert Overview
January 24-26, 2010 / Dubai, United Arab Emirates

CTD Dossier Requirements:
Focus on EU Module 1 and Quality Module 3
April 26-28, 2010 / Vienna, Austria
December 5-7, 2010 / Dubai, United Arab Emirates

European Regulatory Affairs:
Review of Current Registration Procedures in the EU
February 15-16, 2010 / Lisbon, Portugal
June 3-4, 2010 / Prague, Czech Republic
November 18-19, 2010 / Paris, France

US Regulatory Affairs
November 9-12, 2010 / Lisbon, Portugal

Good Management of Medical Devices
April 26-28, 2010 / Paris, France

Building the eCTD
February 11-12, 2010 / Paris, France

An Introduction to Product Information Management (PIM)
April 26-27, 2010 / Vienna, Austria
October 28-29, 2010 / Geneva, Switzerland

Safety and Pharmacovigilance

Excellence in Pharmacovigilance:
Clinical Trials and Post Marketing
February 8-12, 2010 / Paris, France
October 25-29, 2010 / Vienna, Austria

Practical Guide for Pharmacovigilance:
Clinical Trials and Post Marketing
June 2-4, 2010 / Prague, Czech Republic
December 1-3, 2010 / Paris, France

Medical Approach in Diagnosis and Management of ADRs
September 13-14, 2010 / Paris, France

EudraVigilance Information Day
June 22, 2010 / EMEA, London, United Kingdom
October 19, 2010 / EMEA, London, United Kingdom
REGISTRATION FORM
An Introduction to Product Information Management (PIM)
April 26-27, 2010 - Austria Trend Hotel Savoyen, Vienna, Austria

If DIA cannot verify your membership upon receipt of registration form, you will be charged the non-member fee. Registration fee includes course material. The fee is inclusive of lunch and coffee breaks of EUR 125.00 per day.

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TOTAL AMOUNT DUE: €

Please indicate your areas of professional interest:

- AH - Academic Health Centres
- AM - Alternative / Herbal Medicine
- BT - Biotechnology
- CD - Clinical Data Management
- CH - Chemistry / Drug Design
- CL - Clinical Laboratory Data
- CM - CMC
- CP - Clinical Safety/Pharmacovigilance
- CR - Clinical Research & Development
- CS - Clinical Supplies
- DC - Dictionaries / Data Standards
- DE - Devices
- DM - Document Management
- FI - Finance
- EC - e-Clinical
- GC - GCP
- GE - Generic Manufacturing
- GL - GLP
- GM - GMP
- IM - Information Management
- MP - Impact
- IS - Investigator Site
- IT - Information Technology / e-Business
- LA - Legal Affairs
- MA - Marketing / Advertising
- MC - Medical Communications / Information
- MH - Managed Healthcare
- MN - Manufacturing: Drug Substance, Drug Product, Packaging
- MW - Medical / Scientific Writing
- NC - Non-clinical Safety & Efficacy / Toxicology
- NH - Natural Health Products
- OS - Outsourcing / Virtual Development
- OT - Over the Counter
- PC - Pharmaceuticals
- PD - Professional Development
- PE - Pharmacoepidemiology / Quality of Life / Health Economics / Outcomes Research / Managed Healthcare
- PH - Pharmacology
- PK - Pharmacokinetics / Metabolism / Pharmacodynamics
- PM - Project Management
- PP - Public Policy / Law
- QC - Quality Control / Quality Assurance
- RA - Regulatory Affairs / Policy / Drug or Device Approval / GRP
- RD - Research & Development / Strategic Issues
- ST - Statistics / Biostatistics / Mathematical Modelling
- TR - Training
- VA - Validation

PAYMENT METHODS

- Please charge my credit card - credit card payments by VISA, Mastercard or AMEX can be made by completing the relevant details below. Please note that other types of credit card cannot be accepted.
  - VISA
  - MC
  - AMEX

Card Number
Exp Date
Cardholder's Name
Cheques should be made payable to: D.I.A. and mailed together with a copy of the registration form to facilitate identification to:
D.I.A., Elisabethenanlage 25, Postfach, 4002 Basel, Switzerland

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,” including your name, company, Meeting ID# 10541 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.

Persons under 18 are not allowed to attend DIA meetings.

CANCELLATION POLICY

Cancellations must be in writing and be received at the DIA Europe office five working days prior to the course start date.

Cancellations are subject to an administrative fee: Full Meeting Cancellation: Industry (Member/Non-member) = € 200.00 - Government/Academia/Non-profit (Member/Non-member) = € 100.00.
Registrants who do not cancel five working days prior to the course start date and do not attend, will be responsible for the full registration fee. DIA Europe reserves the right to alter the venue and dates if necessary. If an event is cancelled DIA Europe is not responsible for airfare, hotel or other costs incurred by registrants. Registrants 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 registrants will be responsible for the non-member fee, if applicable. Please notify the DIA Europe office of any such substitutions as soon as possible.

IMPORTANT:
Hotel and travel reservations should be made ONLY after receipt of written registration confirmation from DIA.
If you have not received your confirmation within five working days, please contact DIA.

HOW TO REGISTER

The DIA Customer Services Team will be pleased to assist you with your registration.
Please call us on +41 61 225 51 51 from Monday to Friday between 08:00 and 17:00 CET.

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