An Introduction to Product Information Management (PIM)

Course #10539
October 28-29, 2010
Novotel, Geneva, Switzerland

Course Instructors

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This course has limited capacity. Register early.

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

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THURSDAY | OCTOBER 28, 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**

FRIDAY | OCTOBER 29, 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 AUTHORING 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**

Hotel Information

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

Novotel Genève Centre
Rue de Zurich 19
1201 Geneva
Switzerland

Tel.: +41 22 90 99 000
Fax: +41 22 90 99 001
Website: http://www.novotel.com/gb/hotel-3133-novotel-geneve-centre/index.shtml
E-mail: H3133@accor.com

at the special rate of CHF 245.00 for a single room including breakfast, service and VAT but excluding CHF 3.60 city tax.

To reserve a room please call the hotel mentioning the DIA training course on "PIM" at +41 22 909 93 03 or fax + 41 22 909 94 62 or email h3133-sb1@accor.co the hotel booking form you find on the DIA website.

IMPORTANT: To be assured of accommodation at the Novotel Genève Centre, registrants are recommended to complete their reservation by October 12, 2010 at the latest.

DIA Upcoming Training Courses in 2010

Clinical Research

Advanced GCP Study Monitoring
4 June 2010 | Prague, Czech Republic | ID 10560
19 November 2010 | Paris, France | ID 10561

Clinical Project Management in Europe – Part I
22-24 September 2010 | Basel, Switzerland | ID 10544

Clinical Statistics for Non-Statisticians
13-14 September 2010 | Paris, France | ID 10542

Essentials of Clinical Study Management
5-7 May 2010 | Vienna, Austria | ID 10527
10-12 November 2010 | Lisbon, Portugal | ID 10528

Practical GCP Compliance Auditing of Trials & Systems
6-8 October 2010 | London, United Kingdom | ID 10546

Regulatory Affairs

An Introduction to Product Information Management (PIM)
26-27 April 2010 | Vienna, Austria | ID 10541
28-29 October 2010 | Geneva, Switzerland | ID 10539

Building the eCTD
23-24 September 2010 | Basel, Switzerland | ID 10545

Comprehensive Training on European Regulatory Affairs including Different Registration Procedures and Variations: Expert Overview
4-6 October 2010 | Location to be confirmed

CTD Dossier Requirements: Focus on EU Module 1 and Quality Module 3
26-28 April 2010 | Vienna, Austria | ID 10529
5-7 December 2010 | United Arab Emirates | ID 10530

European Regulatory Affairs: Review of Current Registration Procedures in the EU
3-4 June 2010 | Prague, Czech Republic | ID 10538
18-19 November 2010 | Paris, France | ID 10540

Good Management of Medical Devices
26-28 April 2010 | Paris, France | ID 10543
27-29 October 2010 | Geneva, Switzerland | ID 10547

US Regulatory Affairs
18-21 October 2010 | Prague, Czech Republic | ID 10552

Quality by Design
Training Course is currently under development by the expert faculty: Dr. Fritz Erni and Professor Johannes Khinast

Safety and Pharmacovigilance

Excellence in Pharmacovigilance: Clinical Trials and Post Marketing
25-29 October 2010 | Vienna, Austria | ID 10533

Introduction to Signal Detection and Data Mining in Pharmacovigilance
26 April 2010 | Paris, France | ID 10550
7 October 2010 | London, United Kingdom | ID 10558

How to Prepare for Pharmacovigilance Audits and Inspections
27 April 2010 | Paris, France | ID 10551
8 October 2010 | London, United Kingdom | ID 10559

Medical Approach in Diagnosis and Management of ADRs
13-14 September 2010 | Paris, France | ID 10531

Practical Guide for Pharmacovigilance: Clinical Trials and Post Marketing
2-4 June 2010 | Prague, Czech Republic | ID 10525
1-3 December 2010 | Paris, France | ID 10526

EudraVigilance Information Day at the European Medicines Agency
22 June 2010 | London, United Kingdom | ID 10534
19 October 2010 | London , United Kingdom | ID 10535

EudraVigilance (EV) and EudraVigilance Medicinal Product Dictionary (EVMPD) at the European Medicines Agency
Courses throughout the year | European Medicines Agency, London, UK
For course details on EV, please visit www.diahome.org > Educational Offerings > EudraVigilance > Click on Related Courses

Non-Clinical Sciences

Non-Clinical Safety Sciences and Their Regulatory Aspects
22-26 November 2010 | Lisbon, Portugal | ID 10562

All Curricular Areas

Crisis Management
3-4 June 2010 I Basel, Switzerland I ID 10563
14-15 October 2010 I Paris, France I ID 10564

REGISTRATION FORM

An Introduction to Product Information Management (PIM)

October 28-29, 2010 - Novotel, Geneva, Switzerland

ID# 10539

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.

CATEGORY	MEMBER			NON-MEMBER (with optional membership)				NON-MEMBER (without optional membership)		
	FEE	VAT 7.6%	TOTAL	FEE	VAT 7.6%	Membership	TOTAL	FEE	VAT 7.6%	TOTAL
Industry	€ 1'365.00	€ 103.74	€ **1'468.74** ❑	€ 1'365.00	€ 103.74	€ 115.00	€ **1'583.74** ❑	€ 1'480.00	€ 112.48	€ **1'592.48** ❑
Government/Academia (Full-Time)	€ 683.00	€ 51.91	€ **734.91** ❑	€ 683.00	€ 51.91	€ 115.00	€ **849.91** ❑	€ 798.00	€ 60.65	€ **858.65** ❑

TOTAL AMOUNT DUE: € _____ **NOTE:** Payment due 30 days after registration and must be paid in full by commencement of the course

Please indicate your areas of professional interest:

10539DIAWEB

- ❑ 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
- ❑ IMP - 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 - Pharmaceutics
- ❑ 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

REGISTRANT

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

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Last Name

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Please indicate your professional category: ❑ **Academia** ❑ **Government** ❑ **Industry** ❑ **Contract Service Organisation**

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

Date Cardholder's Signature

❑ **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# 10539 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 made 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.

Online	**Fax**	**Email**	**Mail**
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