
PTI
REGULATORY INFORMATION MANAGEMENT & IDMP TRAINING
LIVE Online Academy
30 September - 9 October 2020

PTI

Learn the key aspects of RIM and the IDMP standard so you can build an effective strategy and meet IDMP deadlines

COURSE OVERVIEW

Regulatory Information Management (RIM) software is vital in an industry where vast amounts of regulatory information must be gathered from multiple departments, then submitted to the regulatory agency for approval. When an organisation has many products RIM becomes even more crucial to regulatory operations and requires strategic planning. Identification of Medicinal Products (IDMP) was designed in response to the demand for harmonised specifications for medicinal products. Currently, the identification of medicinal products is dependent on the country and company but changes to this under the new IDMP standards are imminent.

You will learn the key aspects of RIM and the new IDMP standards such as training and user compliance, outsourcing, and data/content management. Once completed you will have the necessary skills to plan, prepare, and implement a strategy ready to meet IDMP deadlines. With a dedicated day to each topic and practical elements on both days, this course will help you get to grips with the key aspects of electronic submissions.

MEET THE TRAINERS

Christine Hirt

Christine Hirt is a Managing Consultant and is responsible for regulatory business consulting at EXTEDO's Regulatory Competence Center. She has more than 10 years of experience in the field of Regulatory Affairs and worked for several pharmaceutical companies, most recently as Head of Regulatory Affairs, before she joined EXTEDO.

Karl-Heinz Loebel

Karl-Heinz Loebel is Head of Regulatory Operations at PharmaLex. Having finished his studies in Chemistry at Heidelberg University, Germany, he joined a Biotech startup company as a Scientific Advisor and a Management Executive for several years. In early 2005 he joined PharmaLex International and was recently promoted to Head of Regulatory Operations.

SESSION ONE 09:00 BST SETPTEMBER 30

Introduction to ISO IDMP

- Overview of ISO IDMP – where are we currently and where are we going?
- IDMP comparison between different regulatory agencies: FDA, EMA, Japan
- Overview of the new ISO IDMP standard – what does it mean for the industry?
- Examining the timelines involved
- How the new IDMP standard will impact the industry and your organisation

Strategically Preparing for IDMP

- Cleaning of RIM data ready for IDMP
- A strategic approach to data preparation
- Step by step approach – How to plan now and implement successfully
- Best practices for SME’s to prepare for IDMP

SESSION TWO 09:00 BST OCTOBER 1

Implementing IDMP (CHI)

- How to organise your data ready for IDMP compliance
- Generally rolling out and designing systems that are ISO IDMP compliant

IDMP and Outsourcing (KHL)

- Who are the vendors on the market and what are they offering?
- Examining the advantages and disadvantages of different IDMP systems
- Assessing the options for SME’s

SESSION TWO 09:00 BST OCTOBER 1

IDMP – Data Collection exercise (KHL)

- Data pilot with an excel spread sheet
- Group exercise

Group Discussion

Practical guidance for IDMP compliance. Delegates and trainers will construct a take-home plan outlining the steps they must undertake over the coming months in preparation for the new IDMP standard.

SESSION THREE 09:00 BST OCTOBER 8

Introduction to RIM (KHL)

- How do different organisations define RIM?
- Examining the various RIM systems on the market
- Addressing the advantages and disadvantages of different RIM systems
- What RIM systems are available for SME's?

RIM and Regulatory Agency Correspondence (CHI)

- Capturing communications between regulatory affairs and health agencies
- Strategically ensure regulatory intelligence and operations are working effectively together

SESSION THREE 09:00 BST OCTOBER 8

Content Management (CHI)

- Strategic guidance for managing RIM
- What tools are available to pull metadata from the content
- Cross mapping metadata
- Managing the master source of data

SESSION FOUR 09:00 BST OCTOBER 9

RIM Integration (KHL/CHI)

- Integrating systems from different departments
- Master data management (MDM) integration
- Change management system integration
- Integrating Electronic Data Management systems (live demo in a tool)
- Business intelligence integration
- Integrating RIM with product lifecycle management

SESSION FOUR 09:00 BST OCTOBER 9

Training and User Compliance (CHI)

- Understanding that content of data is critical for compliance
- Implementing a training strategy to ensure user competency and compliance
  - Data entry training
  - Data recording
- Methods for ensuring user compliance such as e-learning for remote areas

Case Study (KHL)

Attendees will examine various case studies that illustrate how a successful RIM system functions. Examples will be discussed showing how key departments such as CMC, PV, and labelling are linked together through RIM. Specific examples will be discussed where RIM systems are used to help manage products marketed in various countries where the regulations differ significantly.

WHO IS THIS COURSE FOR?

This course is relevant for anyone working with RIM or IDMP either directly or indirectly and may include people working in the following areas:

- Regulatory Affairs
- Dossier & Document Management
- Data Management
- Electronic Submissions

For information contact our training consultants

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