

Workshop:

Basics on XEVMPD

Structure and technical data capturing

Setting up the company-internal project

Topics:

- Introduction to the XEVMPD
- How to technically capture data for the XEVPRM
- Analysis of workflows to capture data, philosophy and quality of data within your company
- Identification of your data-sources
- Creating the basis to set up your company internal project

Objectives of the Workshop:

The EMA has defined and specified the required data on more than 600 pages requesting delivery from the marketing authorization holders. Until July 2nd 2012 the requested data of all registered and approved products within the EU need to be included in EMA's database EVMPD. How to manage? And which data are really required?

- Within the first part of the workshop the data and their relationship will be explained in detail. We will thereby explicitly focus on those data which are required for your individual portfolio.
- The second part of the workshop will mainly be designed by your wishes and needs. We will discuss possibilities and scenarios on how to detect, capture and deliver data in due time.
- Important topics are:
 - Estimate amount of data sets
 - Assess quality and usability of available data
 - Identify data sources (e.g. available IT-systems) and data owners
 - Identify interfaces (e.g. IT-Systems and departments)
 - Discuss possibilities for data migration (technical vs. manual)
 - Reflect flow of data with regard to life-cycle-management
 - Design a company internal project
- Based on your product portfolio and the organizational structure of your company we will develop scenarios for frictionless workflows and data management, give hints on how to coordinate the flow of data

companywide and enable you to start your project.

These and many additional topics can be addressed and discussed in an open and confidential atmosphere within your company - the external neutral view helping to examine the complex situation and to get started!

Consultants:

Mr Holger Spalt the IT-specialist - looks back on more than 15 years' experience in pharmaceutical document management being in command of profound technical knowledge on the XEVPRM.

Dr. Mónica Unger-Bady looks back on 19 years' experience in a big pharmaceutical multinational company, where she developed and established the workflows for regulatory data (e.g. creation of "master data"). Since 2007 she provides her practical experience as an independent consultant.

Program:

Use this workshop as a kick-off for a new interface-project, as advanced training or as a round-table discussion. We would like to work with you to develop a focused program that is tailored to the precise needs of your organization.

■ How to contact us:

Telephone: +49 (30) 202 757 70
Fax: +49 (1803) 663 388 037 25
E-Mail: consulting@unger-bady.de
Internet: <http://www.unger-bady.de>

■ Duration:

This workshop is designed for 8 hours and will be carried out in-house based on individual and detailed consultation.