URSULA TSCHORN

THE COMPANY

DACON Datenbank Consulting GmbH

DACON has dealt with international drug information since 1989.Along with its website [pharmazie.com] it offers access to 35 fact databases which network medicinal products authorised in around 50 countries.

Services offered in terms of controlled vocabularies

- Expert advice to Steering Committees and Project Teams handling Extended EudraVigilance Medicinal Product Dictionary (XEVMPD) or IDMP projects
- Review excisting database structure
- Provide a data overview, gap analysis and platform for future decision-making
- Mapping pharmaceutical customers' data sources against the required controlled vocabularies
- Advice on coding Medical Dictionary for Regulatory Activities (MedDRA)

DACON DATENBANK CONSULTING GMBH

Bergstraße 81
61118 Bad Vilbel
Germany
Phone: +49 6101 128201
Fax: +49 6101 582919
ursula.tschorn@pharmazie.com
www.pharmazie.com

[pharmazie.com]

Pharmacist
Project Manager (IPMA)
IT and Data Manager Expert
Coding ISO IDMP, MedDRA

Managing Director
DACON Datenbank Consulting GmbH

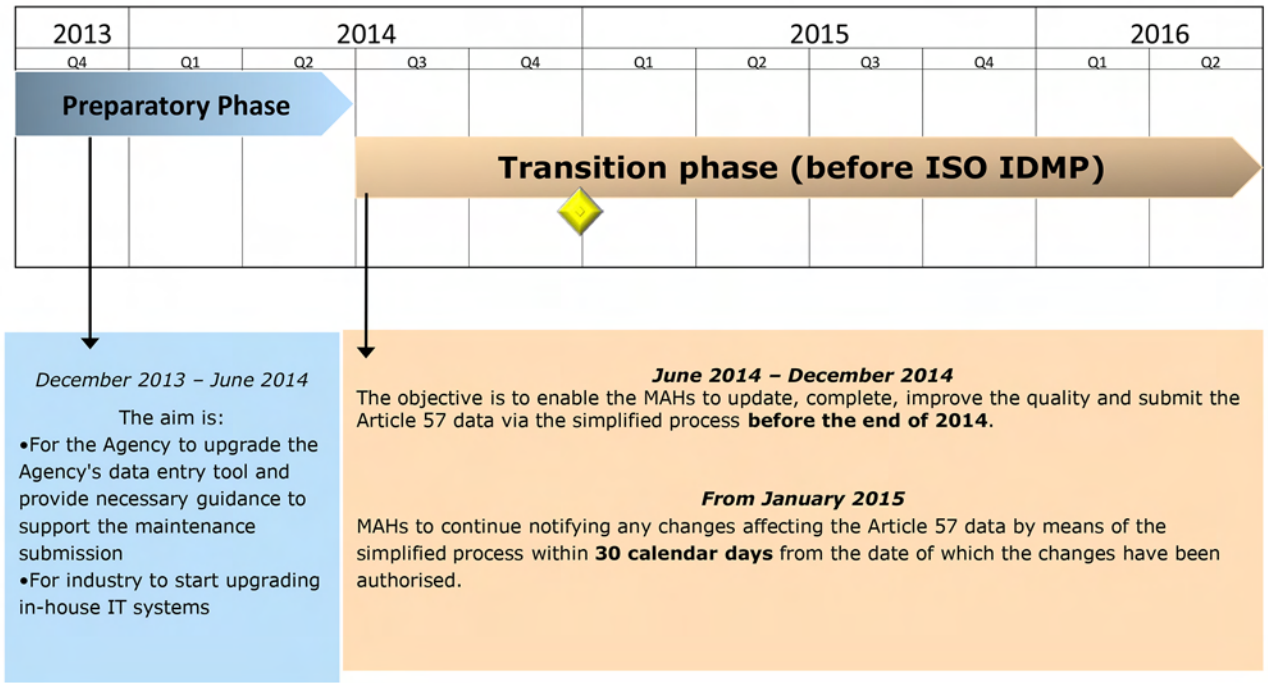
I help you make your IT projects a success

XING, LinkedIn: Ursula Tschorn

Regulatory Process

Overview

Current regulations in the US and Europe require substantially different technologies, terminologies and vocabularies for the registration of medicinal products. In the US, the FDA requires a "Structured Product Labeling" (SPL). In Europe, the European Medicines Agency (EMA) initiated a new standard called IDentification of Medicinal Products (IDMP). It is most likely that FDA will takeover these standards in the near future. IDMP raised the bar significantly by requiring information be sent in specific form for each country and language and coded with an ISO Code. IDMP integration is mandatory by 1st July 2016 at the latest.



Implications for Marketing Authorisation Holders (MAHs)

To be able to submit the data, all branches of a company should share a common language, from pharmacovigilance to product supply in order to comply with the controlled vocabulary specified.

The terminology needs to be aligned throughout the company.

Controlled Vocabularies Submission Plan 2014-2016 *

EMA significantly cleaned up the substance standard vocabulary, which will have an impact on the codes which are to be used for valid authorisation data.

The integration of structured substance information, and controlled vocabularies for pharmaceutical dose forms, units of presentation, routes of administration, and packaging in MAH's own system will be challenging.

Where DACON is expert in:

- networking international medicinal products
- cleaning up databases
- mapping clinical terminologies
- developing data management concepts

* As of article 40 of the pharmacovigilance impelmenting Measures