

P I M

A joint EMEA – EFPIA project for electronic

Product Information Management

September 22, 2000, 10:00 – 17:00 hour
EMEA, Canary Wharf, London

The PIM project will design, build, install and validate the first simple production system supporting the electronic submission and management of Product Information (Summary of Product Characteristics, label and Package Leaflet) in the European Regulatory procedures. The implementation of this technology will support the establishment of improved business processes, which will improve information quality and reduce duplication and rework in industry and Agencies, creating more efficient and faster work processes.

The meeting will provide an opportunity for Regulatory Authorities, Industry and Vendors to learn about technical and business aspects of the new way of managing Product Information.

10:00	Welcome		Karel de Neef
	Introduction to PIM:		Andrew Marr
	The idea – the data exchange standard		
	What PIM is and aims to achieve		
10:20	Demonstration of the Document Generator v 2.0		Hanne Thisen Alec Spence
10:50	Architecture and Technical design / development		Tomas Carrasco Sigrid Woschinski
11:10	Business benefits	Regulatory Perspective Industry Perspective	Adriaan Fruijtier Steve Hasler
11:30	Coffee		
11:45	PIM future perspectives		Joachim Schmidt
12:15	Q & A session		Gabi Disselhoff
12:45 – 14:00	Lunch		
14:00	Break out sessions		
	a. User focus		Andrew Marr
	<i>This session will discuss in detail practical user aspects of the proposed approach including detailed demonstration, presentation of the information pack, impact on work practices, working with structured text – XML editors, electronic transfer between Regulator and Applicant and how to get involved.</i>		
	b. Technical focus		Richard Eddershaw
	<i>This session will discuss the concept, design and architecture of the data exchange standard, Xdossier, and the document generator in detail, provide technical specifications, review plans for the PIM phase 2 data base project and how to get involved.</i>		

15:00 Tea

15:30 Summary of breakout sessions

Co-ordinators of breakout
sessions

16:00 Q & A session

Karel de Neef

17:00 Close of meeting

For registration please send email with subject 'PIM open day' providing exact name, affiliation, telephone number and email to Stephane Callewaert at EFPIA email: Stephane_Callewaert@EFPIA.ORG

Seating capacity is limited; acceptance will be on first come, first serve basis.