Seminar title: e-Submission the quality review

Venue: Hyatt Regency Sharm El Sheikh

Time: 6-8 October 2012

Themes: This is multi event seminar. We have designed the events to run parallel whenever is possible to allow speakers enough time to explain fully the theme subjects and to allow maximum interaction between attendants and speakers. The seminar themes are the following:

Authority transferal to e-Submission (2days event)
This theme is intended mainly for governmental authorities planning to transfer their paper based submission & review procedure to electronic submission & review of dossiers. Expert speakers from European authorities but mainly from MHRA will review their country experience in detail for such operation pointing the required planning, resource requirement and review process re-engineering. Smooth system usage through gentle system utilization by the applicants is explained together with difficulties experienced in such projects. EiY will be used to demonstrate to authorities' life the review process in addition the full technology aspects of EiY will be revealed.

Quality Review (2days event)
In this theme Speakers from AGES, ICH & German MOH will demonstrate how to review quality aspects of a submission whether in CTD, NeeS or eCTD format. In this theme authority attendants will be trained to review quality issues in module 3 according to European standards especially those related to quality risk assessment as stated in Q8, Q9 & Q10 by ICH. This will include API impurities and stability reviews. Good review practices will be demonstrated to attendants and allowed to have hand on experience on such GRP.

eCTD full cycle management (1 day practical event)
In this theme we will explain the full work required by an applicant to produce NeeS as well as eCTD dossiers. The production & regulatory life cycle management of the dossier will be demonstrated. This theme is conducted as hand on experience for attendants from industry. Therefore, attendants wishing to gain practical experience must bring their own laptop computers to install eCTDmanager software for them.

How the events are arranged

Over 3 days period two halls **A** and **B** will be used in this seminar and presentations for day (1) and day (2) will run parallel as follows:

Authority transferal to e-Submission (2days event)

Time	Subject	Speaker
DAY (1) hall (A)		
08:00-09:00	**Registration**	
09:00-09:30	**Opening**	
09:30-10:30	Authorities presentation: current plans & expectations	JO, GCC, UAE, KWT, OM & EG
10:30-11:30	SFDA pioneering case	SFDA
11:30-12:00	**Coffee Break**	
12:00-16:00 Including 15 min. break	Initial overview of what has been done at MHRA: ○ Brief history of what has been done prior to eCTD ○ The eCTD project which is just completed and how this implementation is tied into European Changes ○ Live demo of how the implementations are integrated ○ Next Steps in the project	Mr. Gary Mckelvey
	An Assessors perspective on the use of eCTD in their review processes	Dr. Ryan Tomlinson & Dr. Michael Craig
16:00	**Lunch**	
DAY (2) hall (A)		
09:00-13:00 Including 30 min. break	Case Review for eCTD implementation authority model: ○ current processes ○ re-engineered processes for eCTD ○ analysis of how eCTD streamline processes	Gary Mckelvey, Dr. Ryan Tomlinson, Dr. Michael Craig & Extedo
13:00-15:00 Including 15 min. break	Technology and process overview	Extedo
	What documentation is needed for a successful implementation	Extedo
	Implementation process of e-submission using EiY	Extedo
16:00	**Lunch**	

Quality Review- CTD dossier (2days event)

Time	Subject	Speaker
	DAY (1) hall (B)	
15:00-16:00	**Lunch**	
16.00 - 16.40	Introduction - CTD & Module 3 (product & substance)	Dr. Christa Wirthumer-Hoche/Dr. Cornelia Nopitsch-Mai
16.40 - 17.00	GRP regarding (CTD, Module 3.2.S) leading to product quality	Dr. Cornelia Nopitsch-Mai
17.00 - 18.15	New opportunities for the implementation of ICH Q8, Q9, Q10 & Q11 in dossier review process - authorities point of view - industry point of view	 Dr. Christa Wirthumer-Hoche Dr. Fritz Erni
18.15 - 18.45	**Coffee Break**	
18.45 - 20.30	Possibilities of Risk Based Review. Quality Risk Management case study for regulators (incl. classwork in small groups and final presentation in plenary)	Dr. Christa Wirthumer-Hoche/Dr. Fritz Erni
	DAY (2) hall (B)	
15:00-16:00	**Lunch**	
16.00 - 17.00	Good review practices (GRP) - assessment/list of questions/clock stop/assessment of responses	Dr. Cornelia Nopitsch-Mai
17.00 - 17.15	Plan a meeting between Authorities and Industry	Dr. Christa Wirthumer-Hoche/Dr. Fritz Erni
17.15 - 18.15	Impurity and Stability requirements for product quality	Dr. Fritz Erni
18.15 - 18.45	**Coffee Break**	
18.45 - 20.30	Case study: Review of Stability and Impurity Data (incl. classwork in small groups and final presentation in plenary)	Christa Wirthumer-Hoche/Fritz Erni/ Cornelia Nopitsch-Mai

eCTD full cycle management (1 day practical event)

Time	Subject	Speaker
DAY (3) hall (A)		
09:00-09:30	eCTD BUSINESS PROCESSES An overview about the eCTD principles and key guidance documents provides insight to the eCTD benefits, structure, document granularity, technical specification and implementation status. We will examine the business case for moving to eCTD and making a smooth transition from paper to electronic.	Extedo group EMRO group
09:30-10:15	COMPILATION OF eCTD MODULES 2 & 3 Participants will compile Modules 2 and 3 in their submissions. Participants will also be made aware of submission metadata and their use in these modules as well as the relationship between the two modules.	
10:15-10:30	**Coffee break**	
10:30-11:15	SUBMISSION PROCESSING, PUBLISHING, AND VALIDATION Participants will create, compile, publish and validate their submission.	
11:15-12:00	eCTD LIFECYCLE MANAGEMENT Participants will be introduced to eCTD lifecycle including the technical background, typical lifecycle submission scenarios and potential challenges	
12:00-12:15	**Coffee break**	
12:15-13:00	COORDINATING GLOBAL eCTD SUBMISSION An interactive presentation on coordinating the simultaneous submission of eCTD globally	
13:00-13:45	eCTD LIFECYCLE MANAGEMENT Participants will create a new sequence of their submission using globally defined Life Cycle Operations. They will then review and publish their 0001 submission.	
13:45-14:30	RE-USING YOUR EU SUBMISSION FOR OTHER REGIONS Participants will have an opportunity to make the most of the re-usability of the eCTD and re-purpose their submissions for other regions.	
14:30-16:00	Group meeting	
16:00	**Lunch**	

Events Planner

DAY (1)		DAY (2)		DAY (3)
Hall A	Hall B	Hall A	Hall B	Hall A
Authority transferal to e-Submission 9:00 am to 4:00 pm	Quality Review	Authority transferal to e-Submission 9:00 am to 4:00 pm	Quality Review	eCTD full cycle management 8:00 am to 6:00pm