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Europharm Best Practice Academy

eCTD Workshop 29th Jan. 2010

Dear Madam,
Dear Sir,

During its last meeting in October 2009, the Board of Europharm SMC decided to start a workshop programme named "**Europharm Best Practice Academy**".

These workshops will be focused on very practical topics but at the same time important topics for SMEs (regulatory & legal affairs, in-/out-licensing, business skills, etc.).

Regulatory practice is on change. The point is that if you stay in your seat and just watch, your survival is not guaranteed and, certainly, you will not evolve. The unique gateway to survival AND to evolution is taking part the challenge.

We therefore are very pleased to invite you to our first workshop:

"SMEs & eCTD in Europe – Moving from Theory to Practice" 29th January 2010 Brussels Airport

Why eCTD? Because it is hot and you will need to have at least a good understanding of the philosophy and processes behind it. Indeed, electronic submission of marketing authorization applications and variations in eCTD format will become mandatory for the "Centralized Procedure" in January 2010. The same deadline does not yet apply for MRP and DCP, however it is expected soon for those registration procedures, too. In fact the target is that all NCAs (National Competent Authorities) can accept eCTD-only submissions by January 2010.

Distinguished experts will give speeches in this workshop. In the afternoon workshops you will have the opportunity to address questions and concerns with the speakers. We will conclude with learning points sharing to make it a real learning experience for all participants.

You'll find enclosed the detailed programme of this workshop as well as all practical informations. All documents are also available for download on our website www.europharmsmc.org (click [Upcoming events](#)).

Please note that the number of participants to this workshop is limited to 50 people, so please register in time as it will be taken care of on a first come first served basis !

We look forward to welcoming you to this eCTD Workshop and remains,

Yours faithfully,

Alain Verrijdt
Managing Director

Alexander Burstein
Président

Thank you to the sponsor of this workshop