

Final Concept Paper
Addressing CTD-Q-Related Questions/Change Requests
Raised by eCTD
Dated 3 September 2007
Endorsed by the Steering Committee 7 September 2007

Situation

With the continuing implementation of eCTD there is an increasing number of Questions/Change Requests (QCRs) being submitted to the eCTD IWG, many of which relate to the organisation of the Quality section of the eCTD (Modules 2 & 3). This increase seems largely related to the increasing number of applicants submitting eCTDs but it is also the consequence of the occurrence of real-life situations that are now appearing during the lifecycle management of eCTDs.

These QCRs cannot be addressed by the eCTD IWG alone since they require input from content matter experts. Currently the eCTD IWG is holding 17 such QCRs. Furthermore, it is known that both PhRMA and EFPIA have groups working on elucidation of Quality/eCTD matters which over coming months will likely propose several more QCRs.

CTD-Q is no longer an active Expert Working Group of ICH and in its absence the eCTD IWG has no mechanism to address these items. At the ICH SC in Brussels, May 2007, M2 proposed that CTD-Q be reconvened to help address these outstanding QCRs. The discussion was deferred until a specially convened teleconference of the Steering Committee in July 2007. This meeting agreed that there was justification in addressing the issues raised by eCTD IWG and that a proposal should be developed by the M2 Rapporteur and the Rapporteur of the former CTD-Q EWG.

A potential constraint was proposed in that it may be significantly easier to address these as Q&As rather than as changes to the CTD-Q guidance itself. It was proposed that the items could be addressed at a half-day meeting in Yokohama, October 2007, of Quality Experts present for other Quality-related EWGs and representatives from M2.

A concept paper was requested to describe this activity.

Target

To establish a mechanism by which CTD-Q related eCTD QCRs can be addressed within the timeframe of 2007 through early-2008.

To establish a process by which future CTD-Q related eCTD QCRs can be considered on a routine basis.

Proposal

- Steering Committee to establish a group of Quality Experts who will be able to address CTD-Q related eCTD QCRs. It is anticipated that this would be

- constituted from Quality Experts who will be present in Yokohama for Quality-related EWGs. At least one representative from each party should be nominated.
- Schedule two one-hour (8-9am) meetings in Yokohama (October 2007) of Quality Experts and eCTD experts to review
 - Meeting 1 : present the background to the issues (received by end-September 2007)
 - Meeting 2 : agree a plan to address issues between Yokohama and next ICH meeting
 - The scope of the potential resolutions for these QCRs will need to be restricted to either
 - CTD-Q Q&As
 - Joint CTD-Q/eCTD Q&As
 - Minor changes to the eCTD specification, commensurate with inclusion in eCTD Specification v3.3.3
 - QCRs that would result in changes to CTD-Q and major changes to the eCTD Specification would have to be deferred, after review and documentation, to the next major release of the eCTD and any review of the CTD which may occur at that point (see separate Concept Paper to be developed by FDA).
 - In preparation for the meeting in Yokohama, the eCTD IWG should prepare and circulate an assessment of the issue behind each QCR or group of QCRs together with options for proposed solution for consideration by the Quality Experts
 - Key deliverable by the end of the Yokohama joint meeting should be
 - An understanding of the issue by the Quality Experts
 - A process and timeline by which remaining CTD-Q-related eCTD QCRs can be resolved
 - a process by which future CTD-Q-related eCTD QCRs can be considered on a routine basis
 - In order to ensure robustness of the agreed resolutions these should be made available for consultation within parties before formal adoption by SC.

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