ICH

INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

Change Control Process for the eCTD

Version 1.8

June 10, 2004

Document Change History

Version Number	Date	Description
Version 1.0		Initial Baseline
Version 1.1	December 2002	Teleconference review of required section
Version 1.2	January 2003	Revised by subsection of M2 EWG
Version 1.3	January 2003	Comments from subset of M2 members
Version 1.4	February 2003	ICH Tokyo M2 Meeting
Version 1.5	July 15, 2003	ICH Brussels M2 Meeting
Version 1.6	July 17, 2003	ICH Brussels M2 Meeting
Version 1.7	July 18, 2003	ICH Brussels M2 Meeting – FDA Lawyer Comments
Version 1.8	June 10, 2004	ICH Tyson's Corner Meeting – Add release schedules

Contents

Introduction

At the September 2002 ICH Steering Committee meeting, the ICH M2 Expert Working Group (EWG) presented the signed Step 3 eCTD Specification for Step 4 consideration by the ICH Steering Committee. The Steering Committee signed the specification to Step 4 and tasked the M2 EWG to also be the Implementation Working Group (IWG) for the eCTD Specification. To implement the eCTD across all three regions, change control should be in place to effectively communicate and execute changes to the eCTD Specification.

Scope

This document establishes the change control process for the eCTD Specification. Change control for regional eCTD Module 1 specifications is the regional authority's responsibility.

Purpose

The eCTD IWG is authorised by the ICH Steering Committee to administer changes to the eCTD Specification. Change control is established to serve the following purposes:
- Evaluate and approve or disapprove proposed changes to the eCTD Specification
- Ensure implementation of approved changes
- Represent the interests of all groups who might be affected by changes

Members

The eCTD IWG consists of a Topic Leader, Deputy Topic Leader, and Experts from each of the six ICH parties, and ICH observers. The Steering Committee can also nominate, or the eCTD IWG can request, additional members to work with the eCTD IWG to support eCTD change control.

These members of the eCTD IWG are responsible for performing functions related to eCTD change control.

Rapporteur
The eCTD IWG Rapporteur will be responsible for:
- Organising and presenting change requests to eCTD IWG in RTF format
- Presenting results of eCTD change control meetings to ICH Steering Committee
- Ensuring results of change control meetings are posted on the ICH Web site (www.ich.org)
- Identifying change requests in the eCTD Q&A document

Topic Leaders/Deputy Topic Leaders
The Topic Leaders for ICH parties will be responsible for:
- Submitting their party's vote on eCTD change control
- Assigning regional members to present change requests originating in their region as needed

Experts

Experts from each region will be responsible for:
- Defining issues related to change requests
- Providing practical solutions

Secretary

The eCTD IWG Secretary will be responsible for:
- Recording approved change requests
- Recording change control meeting minutes

Change Control Process

Change Requests

Change requests can originate in ICH CTD change control or through eCTD implementation, as follows:

1. During CTD change control process, CTD IWGs should consult with the eCTD IWG. All change requests from a CTD IWG should be documented, showing concurrence of all ICH parties, including the eCTD IWG, and should receive Steering Committee approval prior to being submitted to the eCTD IWG as a change request. The eCTD IWG Rapporteur should make CTD changes a high priority on the eCTD change control list.

2. For change requests originating in an ICH region, the change request could be submitted by any interested party to an eCTD IWG member from their region. Change requests from non-ICH regions can be forwarded to the eCTD IWG Rapporteur or the ICH Secretariat. Prior to being submitted to the eCTD IWG, the proposed change should undergo any necessary testing by the eCTD IWG parties in the region sponsoring the request. Change requests should then be forwarded to the eCTD IWG Rapporteur for tracking, submission, and resolution.

A change request form is provided in Appendix A. The form is for change requests originating outside of ICH.

Each change request should contain at least the following information:
* Contact information
* Summary of the problem, including rationale
* Reference to the area of the specification to be changed
* Version number and date of the eCTD specification
* Detailed description, including results of any testing
* Recommended solution, if any

eCTD Change Control Meetings

One day will be set aside at each M2 EWG meeting for eCTD change control. Meetings can take place at regularly scheduled ICH Steering Committee meetings or via meetings, teleconferences, or videoconferences approved by the Steering Committee.

Emergency Meetings

Any member of the eCTD IWG can request that the Rapporteur schedule an emergency eCTD change control meeting.

Preparing for the Meeting

A list of change requests will be organised and presented by the Rapporteur to the eCTD IWG prior to each change control meeting.

Change Control Review

Change requests would be categorised by the Rapporteur prior to the eCTD change control meeting.

* Any change requests requiring testing will be assigned to a sub group of the eCTD IWG
* Change requests not requiring additional testing will be sent to the eCTD IWG prior to the next change control meeting

* A discussion of the disposition of a change request with input from each ICH party will occur at the change control meetings. Any requests that required testing will be presented by the sub group assigned to the testing. This discussion can involve CTD review if additional information on the initial change request and/or proposed solution is warranted.

After the discussion, the change request would take one of the following paths:

1. Defined as out the of scope of eCTD IWG include:

* Is not relevant
* Involves a significant new concept
* Involves the M2 EWG or other ICH groups and the ICH step process to make the necessary eCTD change

2. Defined as in the scope of the eCTD IWG: can be processed by the eCTD IWG and would take one of the following paths:
- Approved by a unanimous vote from all six ICH parties
    – Specification change
    – Q&A document
- Deferred to
    – Next change control meeting
- Assigned to a subgroup for testing
- Rejected

Additional testing may be called for before a change request can be fully evaluated. When a change request is assigned for testing, a particular ICH party, or members from each party, can be assigned to test the change request. The change request would stay on the eCTD change control agenda and be presented at the next change control meeting for additional review.

Approved Change Requests

Change requests approved by the eCTD IWG would either be addressed in Q&A or implemented into the eCTD specification by the Rapporteur and presented to the ICH Steering Committee for approval.

The recommendation on which versions of the eCTD specification will be supported by regulators will be provided with each new eCTD version.

Documentation
 Once approved by the Steering Committee, the following documentation would be posted on the ICH Web site:
- New Version of the eCTD Specification
- Updated change request tracking document that includes the status of approved, rejected, and deferred requests

Appendix B displays the process flow of an eCTD change request.

eCTD Release Strategy

Stability of the ICH eCTD Specification is important to ensure that industry and regulators can develop or procure efficient tools.   In order to provide this stability, the ICH eCTD Specification will follow a specific release strategy that allows software application developers and managers to plan for the future.

Major Releases

Major new releases of the eCTD Specification will be announced at least two years before Step 4. Major releases include changes that significantly impact the DTD, completely modify the eCTD architecture, or significantly impact the software applications being used in the three regions. These major releases will be addressed by the M2 Expert Working Group (EWG) and follow the ICH step process. Following this process allows comments from parties external to ICH.

Major releases will be identified by a new numbering sequence (e.g., 4.0).

Minor Releases

In between major releases of the ICH eCTD Specification, the eCTD Implementation Working Group (IWG) could also release new, minor releases of the ICH eCTD Specification. The scope of these minor releases will be to correct minor issues with the specification that hinder eCTD implementation or software application development. Since these are minor modifications to the eCTD Specification, notification will occur when the minor release is published on the ICH Web site.

Minor releases will continue the numbering sequence of the last major release (e.g., 4.1).

Version Compatibility

Backwards compatibility will be considered for each eCTD Specification release. Descriptions of the scope of each change will be provided with each new release.

APPENDIX A: ECTD Q&A OR CHANGE REQUEST

This form should be used to request a change to the ICH eCTD Specification. The change can be to fix a perceived "bug", meet a new requirement or to enhance existing functionality. Please provide the following information.

Contact Information

Organisation Name:	
Organisation Address:	
Contact Name:	
Address:	
Telephone Number:	
E-mail Address:	

Question or Change Request

Summary	*This should be a short summary of the problem submitted including rationale.*
Submit Date	*Date you submit the change request (YYYY-MM-DD)*
Item to be Changed/ Question	*Reference to the area of the specification to be changed (e.g., the eCTD DTD, the written specification, the M2 eCTD style sheet)*
Version Number and Date	*Indicate the specific version and date of the eCTD Specification for which the change is proposed.*
Description	*Provide a detailed explanation of the problem, any known solutions, and steps on how to recreate the error, if applicable. If this is a new requirement or enhancement, please provide the reason for the requirement or enhancement and any known solutions. If you have any sample output, sample code or other examples to help clarify the description, attach the samples to this form. You should also provide a detailed description of any testing or research that was done to support the solution(s) being proposed and any advice on backward compatibility issues.*

Submit a completed copy of this form to an eCTD IWG member in your region in RTF format. Those not residing in an ICH region can forward this request to the eCTD IWG Rapporteur or to the ICH Secretariat at the following address. An electronic copy is preferred with the subject field "eCTD Change Request".

ICH Secretariat
c/o IFPMA,
30 rue de St-Jean
P.O. Box 758
1211 Geneva 13, Switzerland
Tel: +41 (22) 338 32 06, Telefax: +41 (22) 338 32 30
E-mail : ich@ifpma.org

APPENDIX B: ECTD CHANGE CONTROL PROCESS

Process Flow Key

- Stop/Start
- Action
- Decision

Change Request from ICH Region, other Regions or Secretariat

Change Request from CTD IWG

Change Request Submitted to eCTD IWG Rapporteur

Change Request Added to eCTD IWG Tracking Document

Change Request Forwarded/Tested

Change Discussed at eCTD Change Control Meeting

Evaluation to or Discussion with CTD

Added to Q&A and Tracking Document

In IWG Scope — No → M2 EWG and Tracking Document

In IWG Scope — Yes → Approved

Approved — Yes → eCTD Change

eCTD Change — No → Added to Q&A and Tracking Document

eCTD Change — Yes → New Specification and Tracking Document

Approved — No → Rejected

Rejected — Yes → Rejected and Tracking Document

Rejected — No → Require Testing

Require Testing — Yes → IWG Review, Test, and Pilot and Provides Summary

Require Testing — No → Deferred and Tracking Document Posted