

## Release Notes for the EU eCTD Validation Criteria version 5.0

### Comparison of the new major version (5.0) with the current version (4.1)

Criterion Number in version 5.0	Criterion Number in version 4.1	Changes
<i>TabSheet "eCTD Validation Criteria":</i>		
3.3	3.3	Updated md5 checksum value for EU M1 DTD in 'Comments' to reflect v.2.0
3.4	3.4	In the example at 'Comments' changed reference to DTD 1.3 into 1.4 and reference to 1.4 into 2.0
3.5	3.5	In the example at 'Comments' changed reference to DTD 1.3 into 1.4 and reference to 1.4 into 2.0
4.3	4.3	Updated md5 checksum value for eu-leaf.mod in 'Comments' to reflect v.2.0
5.3	5.3	Updated md5 checksum value for eu-envelope.mod in 'Comments' to reflect v.2.0
6.3	6.3	Updated md5 checksum value for the EU M1 Stylesheet in 'Comments' to reflect v.2.0
11.9	11.9	Added in 'Comments' that this test applies to all procedures. Also indicated that "In common MRP/DCP sequences, replacing previously submitted national content can result in a fail according to this criterion in other member states. Therefore, unless a technical solution to prevent this from occurring is available in the eCTD Building tool, applicants should avoid replacing deleting or appending to content submitted in national sequences (other than the first national phase before MRP), and vice versa." (refer to CR 20110627)
-	11.10	Newly added as a response to CR 20121004, this check is added to make sure no leaf life cycle operations occur across different CTD sections (with the exception of the use of 'delete' for removing content in EU M1 sections that are no longer used due to updates of the DTD, like m1-3-4-readability which was renamed to m1-3-4-consultation)
14.1	14.1	Changed "emea" to "ema"
14.2	14.2	Changed "emea" to "ema"
14.3	14.3	Changed "emea" to "ema"
14.4	14.4	Changed "emea" to "ema"
15.1	15.1	Indicated in 'Comments' that the XML format is acceptable where a specification exists
15.12	15.12	Changed in 'Comments' the file name for the tracking table from "common-cover-tracking-var.pdf" to "common-tracking-var.pdf". Indicated that 'common' is the appropriate value for 'cc' in MRP/DCP (refer to CR 20130204).
<i>TabSheet "File-Folder Structure &amp; Names":</i>		
Row 32	Row 32	Changed "cc-cover-tracking-var.pdf" to "cc-tracking-var.pdf"
-	Row 191	Newly added the file name " <b>excipients.pdf</b> " as a response to ICH eCTD Q&A73 (options 1&2, file name entirely variable, multiple files allowed).
-	Row 242	Added optional folder for section 3.3 (for consistency with 5.4)

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-	Row 345	Added optional folder for section 4.3 (for consistency with 5.4)
-	Row 413	Added optional folder for section 5.3.6. (to align with "Files and Folders Q&A")
-	Row 419	Added optional folder for section 5.4. (to align with "Files and Folders Q&A")
<i>Tabsheet "Files and Folders Q&amp;A":</i>		
Row 10		Removed specific reference to EU M1, v1.4 and ICH v.3.2.2
Row 14		Added that for section 3.3 additional folders are optional as well (for consistency with 4.3 and 5.4)
Row 18		Clarified that for m5.2 additional folders are not allowed and that for m5.3.6 and m5.4 additional folders are optional.
<i>Tabsheet "Picklist Values":</i>		
Country		Changed "emea" to "ema" and "EMEA" to "EMA"
Country		Added "hr" and "Croatia"
Language		Added "hr" and "Croatian"