

eCTD tracking system

10. 6.2001 vytvorené:
37 validovaných žiadostí
27 importovaných žiadostí
3 plne vyhoveli validačným kritériám
new eCTD validation criteria v 3.1

Validation Criterion	Errors
2. ICH stylesheet	
3. A currently acceptable version of the stylesheet is used	█
4. The valid version of the stylesheet is used (checksum matches the published value)	█
3. EU M1 DTD	
3. A currently acceptable version of the DTD is used	█
4. The valid version of the DTD is used (checksum matches the published value)	█
4. EU M1 leaf MOD file	
3. A currently acceptable version of the eu-leaf.mod file is used	█
4. EU M1 leaf MOD file	█
5. EU M1 envelope MOD file	
3. A currently acceptable version of the eu-envelope.mod file is used	█
4. The valid version of the eu-envelope.mod file is used (checksum matches the published value)	█
6. EU M1 stylesheet	
3. A currently acceptable version of the stylesheet is used	█
4. The valid version of the stylesheet is used (checksum matches the published value)	█
7. Index XML	
3. The file is well formed	
9. EU regional XML	
3. The file is well formed	
4. The file is valid	█
10. Submission Structure	
1. All the lowest level heading elements in the XML (including node-extensions) included in the submission contain at least one leaf	
11. leaf attributes	
1. The leaf attribute "checksum-type" has a value of md5 or MD5	
2. The regenerated checksum for each file matches the value in the leaf attribute "checksum"	█
3. For every leaf the "title" attribute is not empty	
4. All leaves with an operation attribute value of new, replace or append must have a value for xlink:href	
5. All leaves with an operation attribute value of delete must have no value for xlink:href	
6. The file referenced by the xlink:href must exist in the same or a previously submitted sequence within the same eCTD application	
7. All leaves with an operation attribute value of replace, delete or append must have a value for modified-file	
8. All leaves with an operation attribute value of new must have no value for modified-file	
12. Node extensions	
1. For every node-extension the "title" attribute is not empty	
13. Sequence number	
2. The sequence number has not already been used	█
3. The sequence folder name matches the sequence number in the envelope in eu-regional.xml	█
14. Envelope Attributes	
1. There is a single envelope with the country attribute value of emea if the procedure type = centralised	
15. Files/Folders	
1. The files provided in the folders for Module 1 are in acceptable formats	█
3. Total file folder path length must not exceed 180 characters	
8. There are no unreferenced files in M1, M2, M3, M4 and M5 folders	█
11. (If the procedure type in the envelope is "decentralised" or "mutual-recognition") The tracking table file is present in the correct location	█
12. (If the procedure type in the envelope is "decentralised" or "mutual-recognition") The tracking table file is correctly named	█
16. PDF Files	
1. No PDF has been created and saved as version 1.3 or earlier	█
2. There is no security setting to open any individual file	█
3. There are no further security settings applied to any individual file (except for files in Modules 3.3, 4.3 and 5.4)	█