

Federal agency for medicines and health
products

Part 2

**How to use tools and templates to create
a dossier**

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Agenda

- Introduction
- Tools and templates
- VNeS Checker and demo
- New guidance
- Common errors



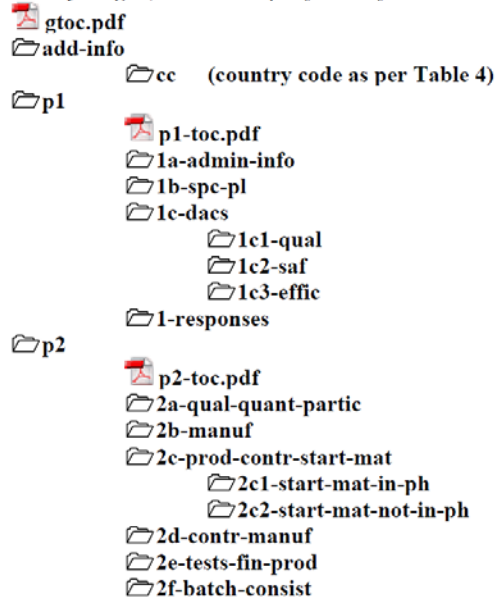
Tools and templates

- Aligned documents : (i) Guideline, (ii) technical validation criteria (iii) Q&A, (iv) practical guidance on TOCs

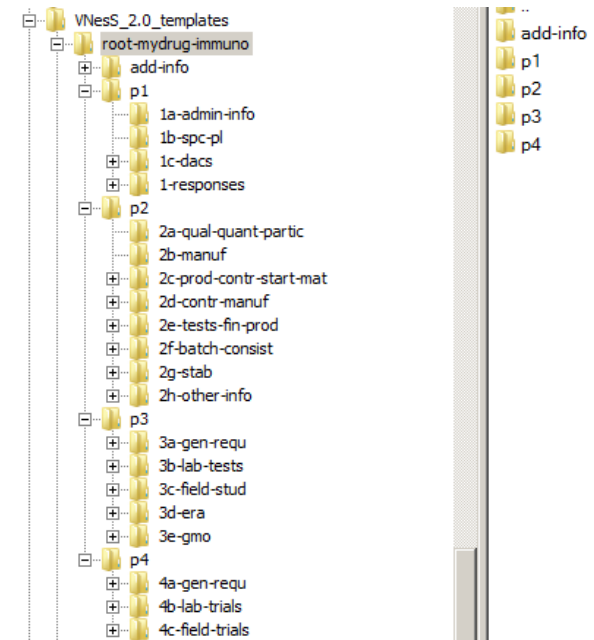
<http://esubmission.emea.europa.eu/tiges/vetesub.htm>.

- Focus on folder structure: There are three folder structures in Guideline: immunological, pharmaceutical, MRL
- Start with empty templates from Agencia Española de Medicamentos y Productos Sanitarios - a real timesaver !

root-<mydrug> (submission-specific root folder - see section 8.(a) for naming conventions)



From Guideline to Template



VNees Checker (1/4)

- Automates the verification of the technical validation criteria
- Two types of installation are available: (i) installer which needs admin rights and (ii) a portable apps.
- Tested by Tiges vet members

Specifications of checker:

- Verifies nested folder structures for the three different templates (manual selection of dossier type, which is in the beginning a common error)
- Dossier and file naming convention (extensions)
- Maximum size for MA dossier files
- File version of the PDF format
- Functional and relative links in the tocs and unreferenced files
- Check to open the PDF's, password detection on the PDF's.



VNeS Checker (2/4)

Specifications of checker (continued):













- Volumes 5 and 6 for immunological dossiers are taken into account (including verification of associated TOCs working hyperlinks, unreferenced files detection)
- TOCs with hyperlinks built in the bookmarks pane are also detected and checked. Absolute hyperlinks are detected.
- Possibility to indicate the location of the report on any writable folder or device (so you could run the VNeS Checker on a network driver, removable device, including when the dossier is stored on a CD/DVD)
- Checks the presence of external hyperlinks in the TOCs (e.g. websites) and produces an error



VNeerS Checker (3/4)

Checker produces a coloured detailed html report.

Legend:

-  File or Folder completely OK
-  Name not conform VNeerS guideline
-  GTOC file missing
-  TOC file missing (warning only)
-  Name contains illegal characters (only alphanumerics and '-' allowed)
-  File has an extension that is not allowed (see VNeerS guideline for more details)
-  Total path length is too large (number of characters greater than 180)
-  PDF file version is incorrect (see VNeerS guideline for more details)
-  File size is too large (must be < 100MB)
-  PDF File can not be opened
-  PDF File is protected by a password
-  File is not referenced in TOCs

Use the checker to know the compliance of your submission concerning the technical validation criteria

Use the tool tips in the report for more information



VNeeS Checker (4/4)

Example output: multiple errors in one file are found

The screenshot shows the output of the VNeeS Checker. It lists several files and folders with their status and size. The files are: mock-up.pdf (4KB), 1a-admin-info, mock-up.pdf (4KB), mockup.doc (4KB), this-is-a-wordfile-renamed-to.pdf.pdf (7.2KB), 1b-spc-pl, mock-up.pdf (4KB), 1e-dacs, and 1c1-equal. The status is indicated by colored squares: green for OK, pink for name issues, cyan for missing GTOC, light blue for missing TOC, purple for illegal characters, dark purple for disallowed extensions, grey for long paths, blue for incorrect PDF versions, yellow for large file sizes, red for unopenable PDFs, brown for password-protected PDFs, and orange for files not referenced in TOCs. Arrows point from the legend to the corresponding error markers in the output.

- File or Folder completely OK
- Name not conform VNeeS guideline
- GTOC file missing
- TOC file missing (warning only)
- Name contains illegal characters (only alphanumerics and '-' allowed)
- File has an extension that is not allowed (see VNeeS guideline for more details)
- Total path length is too large (number of characters greater than 180)
- PDF file version is incorrect (see VNeeS guideline for more details)
- File size is too large (must be < 100MB)
- PDF File can not be opened
- PDF File is protected by a password
- File is not referenced in TOCs

-> Use tool tips in the web browser



New Guidance

- As from the alignment between Guidance, validation criteria and tools - concerted action.
- From 1.7.2013: Guideline 2.2 is valid, with tools. Main differences for dossiers: PDF versions are widened (1.4-1.7) and the slashes in the paths for the hyperlinks need to be forward slashes. Use Checker v2.2
- From now till 1.7.2013: use guideline v2.1 and checker v2.1b. But if wanted, applicants can **easily** make a dossier which passes both v2.1 and v2.2: use PDF 1.4-1.7, and a toc builder v2.2. Always validate with checker v2.1b.



Thank you !
Any questions ?

