

<The tool for analytic processing of documents>



SOCAnalytic
UNIQUE ANALYTIC PROCESSING

D O C U M E N T R E V I E W

The SOCAnalytic tool is the lazy way of reviewing GxP documents for the most obvious errors.

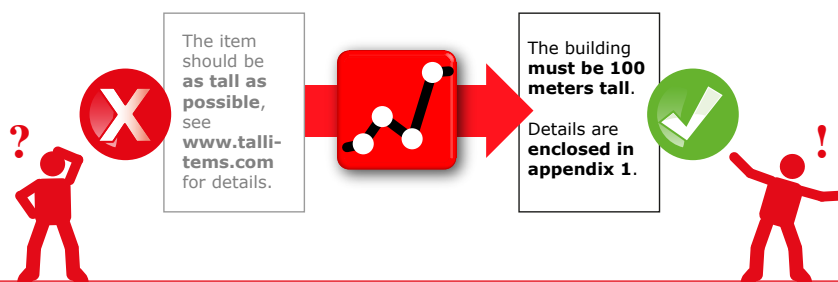
Imagine the situation that a good requirement has been designed, but the wording is not as good as the intentions of the requirement:

“ The item should be as tall as possible, see www.tallitems.com for details.

One of the issues with bad requirements is that they are unprecise, and may even refer to things which do not exist. In addition, the document may have loads of other challenges, which could be caught automatically – rather than by a person.

System feedback from a test of a document containing the requirement above:

- Use of the word “item” is not specific – use a specific word instead.
- Use of the word “should” is not specific – use a specific word instead.
- Use of the word “possible” is not precise, and quantifiable – use a specific quantity instead.
- The requirement contains a WEB address. Contents may alter without notice. Access to the server carrying the WEB contents may be unreachable from where the document is used.
- The link “www.tallitems.com”, returns an error 404 which is common for a web address which is not reachable (or doesn’t exist). Consider to enclose contents of intended address.



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Instead of having QA discuss specific (or unspecific) wording with the technician, the technician can run it through the SOCAnalytic tool:

- The tool will then suggest rethinking the use of "as possible", (because it is undefined), and warn against the usage of links (as they might not point to content, or that contents may not be possible to access from the point of usage).
- It will also test the link and verify that it actually answers.

SOCAnalytic will further review the input document for compliance to the PDF/A standard, and identify contents which does not comply to this standard (active contents such as film clips, executable code and links, fonts and so forth), and warn if a valid PDF/A cannot be created.

Users can add their own language file, which can be updated when new words are identified as inappropriate for GxP purposes. In that way, company specific wording or languages can be added to the system.

The system is either cloud based (but does not store any of the input data) or can be placed on users own server. It will be able to analyze contents of requirement documents (.docx or .xlsx), or any other document written in these formats.

The system can also be applied for submission documentation

**“ The building must be 100 meters tall.
Details are enclosed in appendix 1.**

Users spend way too much time validating contents manually, where our tool will do it in milliseconds and according to user set standards.

Disclaimer

The SOCAnalytic tool is invented and developed by Stage One Computing A/S. Stage One Computing A/S have all the copyrights of the tool and the related documentation. Stage One Computing A/S owns all the intellectual properties in the entire life time of the tool, without limitation.

Stage One Computing A/S has provided this program intended for automatic analysis of documents. The program is intended for use within a GxP regulated area, but is provided as a "qualify yourself" application/tool.

Stage One Computing vouches for the functionality, and has tested the application under IT laboratory conditions. It is however the responsibility of the end-user of the application/tool to validate the tool/installation in the end-users IT set-up/IT- architecture "for intended use".

