

# Proactive quality assurance

## Full control of quality assurance?

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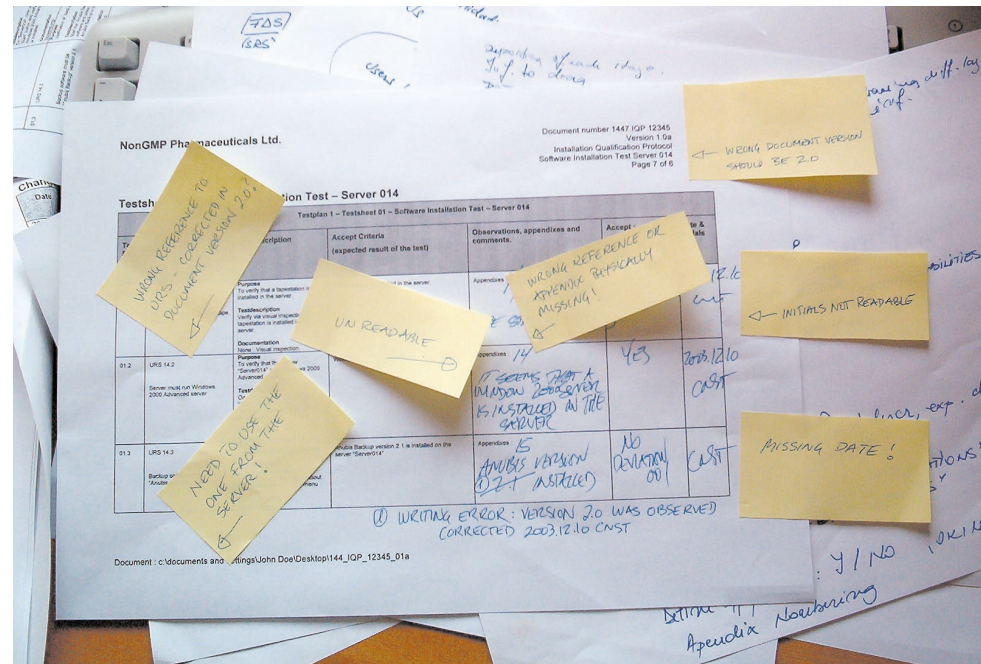
The FDA (U.S. Food and Drug Administration) has announced that they wish to carry out an inspection - the next couple of months will be busy. All documents are to be analysed, checked, updated, amended and not least produced.

Where to start, how extensive is the job, what is most important and who is going to be involved? The questions are many and the task even larger.

Imagine a situation in which all documentation was electronically stored and indexed so that it could be retrieved and that it was possible to see a status list of all ongoing and finalised validation projects with an audit trail that can be fully validated. QAssure can be used for this purpose, so that instead of a defensive angle the FDA can be met proactively.

### Unique programme suite

QAssure forms part of a unique programme suite ensuring the various QA aspects of GxP while at the same time complying with both the FDA's 21 CFR Part 11 and the European equivalent called Annex 11. In addition to preparing and/or storing all documentation electronically, QAssure also has a built-in workflow manager for controlling all the enterprise's development docu-



ments and GxP workflows in connection with the development process. With QAssure immediate accessibility is obtained, and also the possibility of giving the authorities electronic access to the documentation, full compliance with the GxP process being verifiable. QAssure's use of templates and reuse of knowledge from previous projects not only enhances an enterprise's in-house knowledge database and the access thereto considerably, but it also

entails large saving of time in relation to preparing documentation. QAtor claims that between 30 and 40% of the working hours of a manual development and validation process can be saved by doing the work fully electronically with QAssure. Over time the reuse of user requirements (URS) with related test scenarios (IQ/OQ/PQ) will further increase this saving. The entire workflow in connection with the preparation of a QA document is electronically con-

trolled, which facilitates the process immensely as for instance you can send or receive documents for review, approval, etc., without having to leave your working place. QAssure is web-based and fully supports digital signatures over the Internet. Controlled access is given via user profiles and groups. Any profile will either have an electronic or digital signature, depending on the requirements of the enterprise, so that all actions can be registered pursuant to the full Part 11 compliant audit trail. QAssure provides any pharmaceutical company with a fully compliant GxP process without the usual amount of paper involved.

### QAtor

The enterprise QAtor was set up in 2003 by a number of companies with thorough experience from many years of experience in the pharmaceutical industry. Despite its short existence so far, QAtor has long experience and concrete knowledge making it an important player when it comes to structured quality assurance.



More information on QAtor's products can be found on [www.qator.com](http://www.qator.com)