



## 21 CFR Part 11

21 CFR Part 11, the FDA guidelines for trustworthy electronic records, requires companies to employ procedures and controls designed to ensure the authenticity, integrity and when appropriate the confidentiality of electronic records.

To validate a system, organisations must have documentation on the way their systems have been installed and configured to prove that the IQ, OQ, and PQ processes were completed. Many companies have learned the hard way that, as far as an auditor is concerned, if it's not documented, it never happened.

### Ecora's Approach to System Validation

You need to provide an audit trail, showing that you have control over your infrastructure. You also need to establish documented evidence that provides a high degree of assurance that a specific computer-related system is configured to operate in accordance with predetermined requirements and specifications.

Ecora Enterprise Auditor helps '**automate**' the system validation process by collecting thousands of configuration settings into natural language **audit-ready reports**. Our solution provides you with the documented **evidence** that your systems are configured the way you say they are.

Enterprise Auditor can help answer the following questions:

- Who has access to systems holding financial records?
- Which servers house which data?
- Who has access to Share information?
- Where are there internal security vulnerabilities?
- What patch levels are we at?
- Are configuration changes being tracked and documented?
- What policies are changing within Active Directory?
- Can we show an audit trail?
- And hundreds of other out-of-the-box reports...

Ecora has documented '**An IT Professionals Guide for Automating System Validation**', which can help you with system validation today!

Download the guide here:

<http://www.pillar-solutions.com/part11/>

For more information on Ecora Enterprise Auditor please call us on 01732 363670.

