How to bring Thermal Analysis Software in line with 21 CFR, Part 11

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In the pharmaceutical industry, Thermal Analysis is nowadays well established in research, development and quality control. Almost all thermoanalytical data are created, modified, maintained, archived, retrieved or transmitted electronically. Therefore, such electronic records must be trustworthy, have integrity and be authentic. This is one of the primary purposes of 21 CFR Part 11, the Code of Federal Regulations, Title 21 (Food and Drugs), Part 11. The second purpose is a safeguard for electronic signatures in lieu of handwritten ones.

The intention of the regulation, published in 1997 by the U.S. Federal Food and Drug Administration (FDA), was to reduce the vast quantity of documents stored in paper form. However, the regulation applies not only to materials characterization, but also to all aspects of research, clinical study, maintenance, manufacturing and distribution of pharmaceutical products in general. Thus, there is no recipe for how to implement the requirements into an analytical software. However, there are some universal and comprehensive key features, like access control, user management or audit trail.

Besides this technical control, several organizational measures should be taken by the software supplier, for example the validation of the software in order to ensure the quality of the development process.

In the current contribution, it will be shown what the key features of 21 CFR Part 11 are in detail, what kind of concept might be optimal to realize compliance, and what this means for the supplier.

Reference

21 CFR Part 11 – Electronic Records; Electronic Signatures, Final Rule - March 20, 1997;
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