

21CFR PART11 - WHAT'S LEFT (FOR XRPD)?

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Compliance with cGxP and 21CFR Part11 ("Part11") regulations is of the highest priority for regulated industries such as the bio-pharmaceutical industry as well as its suppliers. The scope of cGxP and Part11 requirements is wide reaching, including but not limited to hard- and software validation and the use of electronic records and signatures in lieu of paper records.

With the withdrawal of all Part11 draft guidances for industry and the release of the new draft guidance on "Scope and applications for Part11" in February 2003 the FDA started to promote a new and more narrow approach. Unfortunately this unusual move lead to widespread uncertainties about the future of Part11, though >70% of all requirements were not affected by the new guidance. The release of the final guidance in September 2003 made this more narrow approach official and originated new planning reliability.

Until recently most companies have focused their Part11 compliance efforts on manufacturing, on clinical trials, and on development. However, benefits of being compliant are manifold also for areas, where the FDA is currently not asking for records, or even never will (see e.g. [1]):

- The FDA may decide in the future to extend Part11 requirements also for drug discovery records
- Dividing lines between the discovery and development stages are not clear cut, and drug candidates often cycle between the two stages
- It is easier and cheaper to buy new equipment with Part11 in mind now, than to deal with unnecessary risk assessments and future Part11 remediation
- Exact records support any patent filing or later patent disputes
- Electronic records have less space requirements and can be easier retrieved
- There may be a time when the FDA will not accept paper records any longer

Obviously, Part11 compliance from the very beginning can save a lot of efforts and money - even in non-regulated areas!

Recently several products and services have been introduced helping to meet the requirements of Part11 for XRPD applications as well. This presentation will discuss a full approach to achieve compliance.

[1]: P. Coffey, <http://coffeyanalysis.com/>