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FDA Paper Review on 21CFR Part 11

In February 2003 The Food and Drug Administration (FDA) released a 'Guidance for Industry' note regarding 21CFR11. I have reviewed this document and in particular looked at how it impacts Particle Measuring Systems' products.

Summary

The guidance note when finalized will represent the FDA's current thinking on this topic, as they are currently re-examining Part 11 and how it applies to all regulated products. They state they intend to exercise discretion with respect to certain part 11 requirements.

Retained requirements

- Limiting system to authorized individuals (user name & password)
- Operational checks (sequential operations in application)
- Authority checks (Security access levels)
- Device checks (source of data)
- User and developer training
- Written procedures for system use

Discretionary requirements

- System validation
- Audit trail
- Record retention
- Record copying

They say that some statements by the FDA may have been misunderstood and as a result the system has caused manufacturers to restrict the use of electronic technologies and that it significantly increases the cost of compliance. The overall approach will mean that fewer records will be considered subject to Part11 and for those records that are subject they intend to exercise discretion to those parts they consider to be negotiable.

They still recommend validating the system, to ensure the accuracy and reliability of the Part11 records contained in the system, and that guidance from the GAMP® 4 industry guide should be sought in how to perform system validation.

Impact to Particle Measuring Systems

The release of this guidance is obviously welcomed in the industry as it was reducing the number of applications for new products, and with this element removed we may see more new products trying to be released and therefore an overall increase in pharmaceutical manufacturing.



Pharmaceutical Net

This software met the original interpretation of the Part11 ruling, so with a relaxing of the rule we loose headway on some of our competition, which could not achieve the standard PMS had set. It is still worth pressing to the pharmaceutical industry our original stance and that should the ruling be re-enforced PMS are in an ideal situation. It may push some of the focus onto those remaining elements of the system.

APSS-View 21CFR

This software, which originally met the ruling, and due to lack of complete audit trail lost some ground on interpretation is now back in line with eth ruling.

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