21 CFR Part 11

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Med-ic ECM: Incorporating the Technical Controls for 21 CFR Part 11 Compliance

Electronic record keeping has to control for the possibility of data tampering. FDA 21 CFR Part 11 was established in 1997 to govern the use of electronic records and electronic signatures. This regulation outlines the criteria whereby electronic records and signatures will be considered equivalent to paper records and handwritten signatures. The regulation covers electronic records throughout their lifecycle from creation through modification, storage, and final submission, to audit.

21 CFR Part 11 is designed to ensure that the data stored and modified on electronic media are trustworthy and transparent. Source data containing critical information relating to compliance must be reliable and authentic. Data integrity has to be guarded and monitored to prevent unauthorized modifications. A detailed audit trail of all user activities must be kept and made available for auditing purposes.

A vendor cannot claim that its software products are certified 21 CFR Part 11 compliant. It can only claim that the product contains all of the technical controls for 21 CFR Part 11 compliance. The ultimate responsibility for 21 CFR Part 11 compliance lies with the system owner and system integrator.

An Electronic Compliance Monitoring (ECM) system can assist in compliance with this regulation. The Med-ic ECM incorporates several 21 CFR Part 11 compliance controls. CertiScan *.tdf (trial data file) files are in binary and checksummed format proprietary to IMC to guard against tampering.

Complete and accurate copies can be viewed on screen using CertiScan Software. Complete and accurate electronic copies are available by exporting the raw data files to .csv (comma separated value) files for viewing and printing in spreadsheets like MS-Excel. Med-ic obtains patient compliance data directly from the source and bypasses the requirement for much of the protocol for recording information, offering significant cost savings in the capture of patient compliance data.