INTRODUCTION

Electronic records keeping is generally understood to be an activity, which if undertaken, can significantly reduce the burden associated with traditional paper records. In response to Industry demands for guidelines for the generation of approved electronic records, the FDA has issued a set of regulations: 21 CFR Part 11 Electronic Signatures, Final Rule. The implication of 21 CFR Part 11 is that all electronic data acquisition and processing systems is that the software used to operate these systems must be capable of generating electronic files which conform to the regulation. In order to comply to the regulation, software must provide a means of controlling access to, authenticating, and assigning (by means of an authorized signature) any records whose submission or inspection is required by the FDA. All of the normal procedures for managing FDA required paper records apply to electronic records, as specified in the Final Rule.

Analyst 1.2 software, provided by Applied Biosystems/MDS Sciex, for the operation of the API line of triple quadrupole mass spectrometers, was designed to provide a complete set of tools for the implementation of 21CFR Part 11 compliant record-keeping. This paper is a review of customer comments and experiences with the Analyst 1.2 software, which has been in use in the market for about 6 months. The feedback received through support activities and customer audio is used to highlight the strengths of Analyst 1.2, the requests for improvements with respect to the system design, and to clarify the roles of facility management, IT departments, lab administration and the manufacturer.

The generic requirements of a 21 CFR Part 11 compliant system may be distilled to the following basic elements:

- Least-modified security linked to network security
- Access control to system functions, data and records
- Audit trails for access, maintenance, data acquisition, data review, and report generation
- Electronic signatures utilizing user ID and password

Within 21 CFR Part 11, there are requirements for the control of electronic records, created within Analyst, which extends beyond the domain of the acquisition and processing software, such as distribution and control of records in a closed and open system. As a result for producing electronic records, the instrument software must form a part of an overall strategy of compliance, and provides tools to ensure that records created conform to the 21 CFR Part 11 standards for electronic records in a secure GUP environment.

MATERIALS AND METHODS

The properties presented in this paper were developed based on experiences with Analyst 1.2 software, operating in the Windows NT and Windows 2000 network environment. Specific, customer provided comments regarding the functionality of the 21 CFR Part 11 final rule are included. The document 59909V 25, obtained from the Federal Register Online via GPO Access (www.access.gpo.gov), was consulted. A review of comments and such results indicates that Analyst provides the following features:

- To satisfy the requirements of the 21 CFR Part 11 Electronic Signatures, a separate login using both username and password is provided. Analyst provides standard security, allowing individual users or groups to be assigned desired access. Analyst (in a familiar Windows format), thereby controlling who has access to what functionality within the data acquisition or processing systems.
- The file information is complete, stored as part of the data file, and provides a complete record of the acquisition parameters, operator and work procedures. In addition, the file may be divided into a header included, to allow automatic validation of the file integrity during processing or review.
- The Audit Trail Manager provides access to Audit trail records. Records include; login, instrument service, method creation/modification, data collection, and straver modification of results files. Audit records may be archived with project information and be searchable through the Audit Trail manager. Audit trail settings are configurable globally, or on a project-by-project basis.
- E-Signatures are recorded in the Audit Trail for predefined events.
- Any changes made to methods or results are tracked for a signature. A valid reason must be specified, along with the currently logged on user password.

If there is a single recurring theme in the experiences reported by customers attempting to implement electronic records systems, it is that the process is a collaborative effort between the customer, different departments, but also between different pieces of software. The MS Instrument software is limited in its role within the system. Any information which passes the boundary from the MS software forms is record and must be audited and reviewed where necessary. The movement of data, records, audit trails, etc. may be accomplished by third party or custom software, but must maintain the integrity of the audit trails and the ability to further alter those records and maintain the audit trail and e-sign integrity.

DISCUSSION

With traditional Paper record-keeping, many of the facilities of the paper system are removed. The Administrator is still responsible for the creation, maintenance, distribution and enforcement of SOPs, however the system is used to monitor and ensure adherence. Privately designed systems will generate nothing but records which conform to the FDA requirements. The access to the system is controlled by login and password, and E-Signatures are executed as a combination of username and password. Comprehensive Audit Event Logs are generated at all levels, tracking instrument service, tuning, data generation, report generation, modification of results, and approval of analytical electronic records is achieved through the use of automation andTypically the 21 CFR Part 11 final rule is not designed to log security events, such as system logins and attempted logins. Since access to data files must be controlled by the acquisition system itself. The system must be integrated with the network to provide access control to all records.

Implementation of a 21 CFR Part 11 compliant LC/MS/MS system

Poster MPK343

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CONCLUSIONS

- The requirements of 21 CFR Part 11 Electronic Records, Electronic Signatures for the generation of electronic records may be met by the application of Analyst 1.2. Several customers report that they have compliance with the rule, based on the current feature set.
- The implementation of an electronic records system requires much more than software from a single vendor. It is a collaborative effort between facilities, IT and laboratory management.
- Changes to the Analyst software are based on the experiences of those attempting to build the first electronic records systems.