

benefit to the company or to the regulators. An example of a high risk system would be the use of computer systems to program EEPROMs for heart pacemakers. Where the code controlled in those computer systems could be changed by the design group, appropriate signature and change controls according to Part 11 would be very appropriate.

The use of the Risk Management process according to the standards currently existing (ISO 14971, EN 1441) is a cornerstone of current cGMP regulatory strategy and could be very effectively implemented here.

The revised guidance takes this comment into consideration.

- b) The second category is documents that are developed in word processing systems where the word processing system is simply a convenience and the electronic format does not add benefit to the content of the document. These documents are subject to review and approval in accordance with document controls established in quality system regulations (21 CFR part 820, 21 CFR part 210/211, etc.). A revision history is required for these documents but not an audit trail for all changes made by any personnel throughout the life of the document such as for drafts and preliminary document versions. These documents have been formally reviewed prior to release. As such, these documents, when used as an electronic record, should include read only access to the documents on-line and manual controls to ensure that the versions provided on-line are accurate.

The revised guidance takes this comment into consideration.

4. Data collected for assessment of machine performance and other quality system data not explicitly required by regulation, need not be controlled as electronic records if the data is only used to define potential corrective and/or preventive actions that are later subject to validation.

The revised guidance takes this comment into consideration.

5. Monitoring systems that are used as the basis for real-time process adjustments must be validated and controlled.

The revised guidance takes this comment into consideration.

6. Where automated systems have been validated and the results are controlled, incoming machine data and results of intermediate processing from the automated system need not be controlled as an electronic record.

The revised guidance takes this comment into consideration.

7. Paper based output of a computer system is acceptable given validation has been conducted. If the process definition requires only summary data from the process, then only this data need be transferred (electronically or hard copy) to the target quality record.

The revised guidance takes this comment into consideration.

Use of Risk Management Techniques

The application and implementation of Part 11 requirements to a quality system should be considered and structured by the manufacturer using available risk management systems and techniques. Where a system can be defined as low-risk the application of controls would be less. An example would be application of electronic bill-of-materials systems for production of Class 1 products. Since the risk of those products is very low by definition the use of extreme part 11 controls and the associated cost would have little

Introduction

ASQ is presenting the following positions on the new 21 CFR Part 11 guidance document. These positions represent the views of the Biomedical Division. In general we are pleased to see that the new guidance document takes a position similar to our previous recommendations.

Electronic Records and Part 11 Applicability

The definition of an electronic record includes any electronic data, however, when that data is subject to compliance with electronic record requirements, this definition can be interpreted in several ways. These different interpretations can be significant with respect to defining when audit trails and additional Part 11 controls are required.

The division believes that the new guidance document takes into consideration and accurately represents its position previously stated on Part 11 applicability.

Electronic Record Definition

ASQ previously stated the following positions on interpretation. The following comments apply.

1. Manufacturers can define how electronic equipment is used to support the predicate regulations and therefore whether the data must be retained as an electronic record in support of the quality system or paper based record. All electronic equipment used in manufacturing need not be controlled in accordance with Part 11.

The revised guidance takes this comment into consideration.

2. “Raw data” from an instrument that cannot be modified based on security and procedural controls need not have “secure, computer-generated time-stamped audit trail” (11.10(e)) functions implemented. Audit trails for these instruments can be established based on demonstrating the effectiveness of the security and procedural controls that prevent access to modification of run data. Audit trails for these systems can be established by demonstrating that each run generates a unique record that is archived as read-only data.

The revised guidance takes this comment into consideration.

3. Even when a manufacturer is using electronic records, the applicability of audit trails requires clarification. Audit trails should be defined in two different categories:
 - a) The first category is “raw data” that is captured by equipment or manually entered based on observed information and can be changed on-line requires all changes to the data to be tracked as “secure, computer-generated time-stamped audit trails” (11.10(e)).