

Paperless recorders and 21 CFR part 11 compliance

Videographic recorders



Introduction

Today's manufacturing environment is becoming more regulated than ever and the most well known of these regulations is the FDA's (Food & Drug Administration) 21 CFR part 11. The regulation pertains to the use of electronic records and electronic signatures in place of paper records and handwritten signatures.

This piece of legislation is particularly well known as it applies to the use of paperless recorders and, although not legislation that spans multiple industries, it has been adopted by general industry and is often specified as a necessary requirement by purchasers of paperless recording systems.

The need for security

Before the introduction of electronic recording and storage formats it was commonplace to use a pen-on-paper approach to data recording and storage.

This meant that the entire process was recorded as a continuous trend from a pen directly onto a paper chart and any chart signatures written in pen, directly onto the chart by the relevant personnel. The chart was then stored along with all the other charts for the required length of time, depending on the regulations being followed.

A pen trace is very difficult to falsify and any attempts to modify a pen trace could be detected easily on the chart, as would any changes to a persons' signature (all signatures are reported and filed with the FDA). However, when you start to look at data files where the chart is replaced by a series of electronic samples taken of the process reading that requires removal from the unit recording the data to a medium where it can be reviewed, the data could potentially be modified. Also, a hand-written unique signature then becomes a series of typed letters that are no longer truly unique to the person who wrote them.

There is a common understanding that the potential for data modification in an electronic format is far greater than that of a paper record.

As these records are used to validate manufacturing processes for items used for the treatment of humans, companies rely on these records to prove they have not had problems in the production of the product and to prove the product has been assessed using the correct production, testing and quality audits.

Purpose of this document

This document describes the requirements of the 21 CFR part 11 rule with regards to the ABB ScreenMaster paperless recorder range and provides general information for our paperless recorders in FDA compliant applications. As such, it contains ABB's interpretation of the legislation.

It is the responsibility of the end-user to ensure compliance with the rules for their production and facility. ABB accepts no responsibility for non-compliance with these rules.

21 CFR part 11 regulation

The Code of Federal Regulations (CFR) is the grouping of the general and permanent federal rules and regulations published by the executive departments and agencies of the federal government of the United States of America. Title 21 of these regulations is the section pertaining to the Food & Drug Administration (FDA) as the authoritative body is more commonly known. This particular title is divided into 3 chapters:

- chapter 1: food and drug administration
- chapter 2: drug administration
- chapter 3: national drug policy

Chapter 1 contains a number of regulations known as 'predicate rules' that dictate the procedure and requirements for manufacture of any food products, pharmaceutical products and also cosmetic products. A predicate rule is the rule which must be followed at all times when producing a product to which there is a rule that applies. These rules contain not only procedures but also requirements for storage and transportation, as well as how the data for the production should be reported and maintained and how long it should be available for in order to report to the agency.

21 CFR part 11 however is not a predicate rule. While it is very important where it applies, it is not a product-specific or manufacture-indicating rule. It was introduced in 1997 to address progress that had been made in the Instrumentation industry. That progress was the introduction of paperless recording systems and electronic record keeping. With the introduction of this technology the FDA felt that greater controls were needed to ensure the same confidence could be obtained in records and data coming from this type of system as could be found with the paper systems that had been used so successfully in the past.

The regulation itself is split into 3 separate parts:

Subpart A – general provisions

Describes where the regulation applies, meaning that it is applicable only to those records that are to be stored and submitted to the FDA in an electronic format in place of paper. It also describes general process requirements including validation.

Subpart B – electronic records

The FDA defines an electronic record in the following way:

'Electronic Record means any combination of text, graphics, data, audio, pictorial or other information representation in digital form that is created, modified, maintained, archived, retrieved or distributed by a computer system.'

Practically, this means any computer-created information submitted to the agency or kept to be maintained as per dictation given in the predicate rules that are followed in the first instance.

The following list describes the expectations / requirements:

- the ability to generate accurate and complete copies of records in both human readable format and electronic form suitable for presentation to the Agency
- protection of records to enable their accurate and ready retrieval throughout the required retention period
- limiting system access to authorized individuals
- use of secure, time-stamped audit trails to record independently any actions that could create, modify or delete electronic records
- use of authority checks to ensure that authorised personnel only can use the system
- determination that persons using the system have the necessary education, training and experience to do so
- establishment and adherence to written policies regarding electronic signing of the chart
- control over distribution of system operation and maintenance documentation
- change control procedures to maintain an audit trail of system documentation

Subpart C – electronic signatures

The FDA define an electronic signature in the following way:

'Electronic signature means a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of an individual's handwritten signature.'

This subpart is very important. In the past operators used a pen to sign their name onto a paper chart manually which makes it very hard to falsify the signature. However an electronic record cannot be signed with a pen – the chart must be signed in an electronic format.

Therefore 21 CFR part 11 lays out guidelines regarding the electronic signatures, also:

- each signature shall be unique to one individual and shall not be reused or reassigned to anyone else
- before an organization assigns or sanctions an electronic signature the organization will verify that persons identity
- persons using electronic signatures shall certify to the agency that the electronic signature they intend to use is the legally binding equivalent of their traditional handwritten signature
- each signature that is not Biometric shall employ at least 2 distinct identification components (username and password)
- when an individual executes one or more signature, each signing shall be executed using all of the electronic signature components
- each signature shall be used only by their genuine owner

Validating your system

Subpart A of the regulation mentions the requirement of system validation. This is not an extra requirement however, a validated system is required as part of the predicate rules. In fact this is just a reiteration of those predicate rules.

Validation is effectively the act of proving the system behaves as it was initially intended to behave. This is achieved by performing a series of functional tests and checks on the system in its production set-up to ensure it works as it should. These tests should be recorded in detail and that information kept on file as it will be required for reporting to the FDA as part of the predicate rules.

The FDA looks to the International Society of Pharmaceutical Engineers for guidance on the validation of computerized systems. Its GAMP (Good Automated Manufacturing Practise) guide, is a set of guidelines on how best to validate a system. It takes a full life cycle approach to the validation, which means that they look to build quality into the end product by ensuring that quality is built into the system as a whole from the beginning of its life cycle (from URS [User Requirement Specification] to retirement).

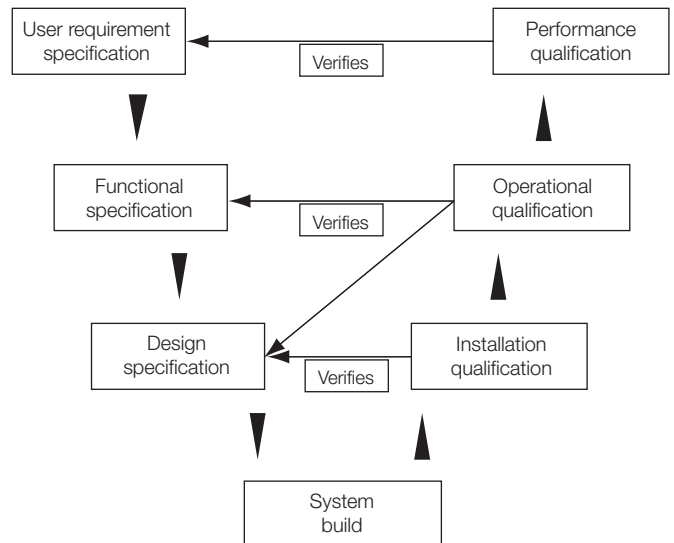


Fig. 1 System validation overview

Currently we are at GAMP 5 that includes information on how to include supplier-provided validation templates into your overall validation package by describing how they may be included as the validation template for a part, rather than the whole, system. This means that parts of a system can be validated separately and those separate templates included in the document rather than 1 large and very complicated template for the entire system. Effectively making the validation process a lot simpler.

Validation begins with the end-user creating a URS (User Requirement Specification). This is effectively the 'shopping list' used by an end-user to let potential vendors know exactly what it is they require. With larger systems this is very important as it is the documentation that the system will be designed and built to. With a paperless recorder we are able to skip a number of steps shown in the GAMP 'V' Model as we are not designing and selling a bespoke product. We can go straight from the URS stage to the Installation Qualification (IQ) stage as we are not custom designing software or custom building a product.

The IQ stage of testing is used to verify to the end user that the design specification of the project has been met. Obviously an out-of-box system such as a paperless recorder does not require a design specification like a bespoke product, but it should still match the requirements laid out at the URS stage. At the IQ stage a number of tests are performed before and during installation to ensure that the unit is what should have been received and that all I/O is correct. Once the IQ stage has been passed successfully the end-user has to move on a two-part Operational Qualification.

The Operational Qualification is defined as proving that the system can operate consistently within the predefined limits as required within the URS. This means operating correctly as is intended. The tests performed in part one of the operational qualification are functional tests. Whereas the IQ covers all parts of the instrument, it doesn't actually cover whether it works correctly within the system, just that it appears to be correct. The Operational Qualification is designed to test that functionality with live inputs and outputs to ensure the system operates correctly.

Once all those functional type tests have been performed and passed, it then moves to the second part of the operational qualification that is not related to the functionality of the system. Part II of the Operational Qualification is the standard operating procedures for the site where the system or instrument is to be used. This includes lists of those personnel who are trained and authorized to use the equipment and their permitted access levels, as well as electronic signature details.

Provision should also be made for inclusion of maintenance schedules, assigned asset information and any service agreements that are in place for that system.

What can ABB provide

ABB have a complete range of paperless recorders available, ranging from the small cost-effective SM500F, the world's first field-mounted paperless recorder, to the SM3000 multipoint paperless recorder. These recorders were designed with the 21 CFR part 11 regulation at the forefront of the design process. This means that, unlike many other manufacturers, ABB are able to offer the consumer a recorder that is compliant to 21 CFR part 11 in its most basic format. Often other manufacturers have to offer a Pharmaceutical-specific variant of the instrument that, in turn, come with a significant price-adder.

By designing these features into the ScreenMaster as standard ABB are able to offer a competitive price on a specialist product.

The features included in the ScreenMaster range as standard are:

- comprehensive Audit Log functionality
- physical security features preventing unauthorized removal of memory card and access to the recorder
- password-protected Configuration Level
- multiple users with access restrictions
- solid-state flash memory
- binary-encoded data or CSV format with encrypted digital signature
- DataManager Pro data review software
- electronic signatures

For more detailed information on exactly how the ScreenMaster Range conforms to the regulation you can download the following publications:

[INF06/119 – SM500F](#)

[INF02/70 – SM1000](#)

[INF02/70A – SM3000](#)

ABB is also able to offer an instrument that is pre-configured to the customers configuration requirements, complete with a Calibration certificate and Factory-issued Certificate of Conformity that, when used with the ABB ScreenMaster validation package, removes the need for lengthy testing at the customer side pre-installation.

Roles and responsibilities

As a manufacturer and supplier of an Electronic Data Recording system there is no legal requirement to supply an instrument that is 21 CFR part 11 compliant. However those companies that want to supply their equipment to the Pharmaceutical industry must offer compliance, otherwise there is no market for them. There is also no legal requirement to supply a validation package with those systems although many manufacturers do so in order to make their product more marketable.

The ultimate responsibility for ensuring that a system meets the requirements of the 21 CFR part 11 regulation, as well as the predicate rules that are applicable to the process / product, is that of the manufacturer and not the supplier of the equipment. However, as a supplier our responsibility is to provide a good, solid, capable product and make the end-users job of adhering to that legislation as simple and easy as possible.

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