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The Road to Performance Excellence

COMMENTARY

Selecting a Training Documentation/Recordkeeping System in a Pharmaceutical Manufacturing Environment

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Introduction

Few things are more talked about in pharmaceutical manufacturing training than documentation and recordkeeping. Debates abound. Some issues training managers are grappling with include the following:

- What are the documentation/recordkeeping requirements?
- Does the organization need an electronic documentation/recordkeeping system?
- How does one select an electronic documentation/recordkeeping system?
- Is validation of the electronic documentation/recordkeeping system required?
- If validation is required, how is it done?
- How does Part 11 affect training recordkeeping?

The long and short of it is that training or training management personnel in the pharmaceutical manufacturing industry are faced with a myriad of questions about training documentation and recordkeeping. Like many training people, they may feel that answers are in short supply. This paper looks at these questions and suggests some strategies for addressing training documentation and recordkeeping within the pharmaceutical manufacturing industry.

FDA Requirements

Section 21 of the Code of Federal Regulations (CFR) Parts 210 and 211 (1,2) offers training direction for the pharmaceutical manufacturing industry. Although no specific requirement exists for training documentation or recordkeeping in 21 CFR 210 and 211, the regulations state that:

> *There shall be adequate numbers of qualified personnel to perform and supervise the manufacture, processing, and packing of each drug product (3).*

The key words in this paragraph for pharmaceutical manufacturing training are *"adequate numbers of qualified personnel."* And some type of documentation/recordkeeping system is required if pharmaceutical manufacturers are to know whether an adequate number of qualified personnel exist for performing and supervising the manufacture, processing, and packaging of each drug product.

Although the FDA has not issued formal guidelines on training documentation or recordkeeping, recent 483s and consent decrees have stipulated the need for training documentation requirements. The following is taken from a consent decree issued in 1998:

> Within 120 days after entry of this Decree, defendants, working with the expert consultant, shall design and implement a formal training program for all employees involved in the manufacture, storage, or distribution of drugs and biologic products. The formal training program shall apply to all employees, whether part-time or full-time and, at a minimum, provide for the following:
>
> Procedures to ensure that all training is documented; that training files, including copies of all of training materials and employee training records, are retained for a period of no less than five (5) years from the date of training;
>
> Controls to ensure documented annual competency reviews of each employee's job performance including actual performance of testing and data entry in controlled situations; additional training or re-training of personnel who, based on competency reviews, audits, or other information, do not demonstrate the requisite knowledge

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to perform their jobs satisfactorily or have not performed their jobs satisfactorily; and controls to ensure that such employees do not resume independent performance of their jobs before the additional training has been given and has been determined and documented to be effective;

Procedures to ensure that each employee's training file includes a current list of each procedure for which the employee is responsible;

Statements signed by the employee attesting that the employee has read and understands all SOPs that relate to his or her job, and that the employee has received and understands the training received; and a statement by the employee's supervisor that as a result of the foregoing, the employee is qualified, competent, and skilled to perform each such procedure. When appropriate, the file shall also include signed updated statements from the employee and from his or her supervisor that the employee has received and understands any additional or corrective training received (4).

FDA did not specify training documentation/recordkeeping requirements in the CFR, but it has made them an industry requirement by virtue of precedent-setting industry demands.

Discussions with training managers at pharmaceutical manufacturing companies audited by FDA suggest that it is through documentation/recordkeeping that FDA "backs into" an audit of a company's training. This typically happens in one of three ways:

1. Auditors ask to see a Standard Operating Procedure (SOP) and observe an employee perform the procedure. Depending on the employee's performance, the auditors may ask to review the documents or records of the observed employee's training.

2. Through investigation of production records, auditors spot deviations or out-of-specification issues. This in turn may lead to an examination of an operator's work and qualifications for the job. The auditors may ask how or what additional training was conducted and request the records that prove training was provided.

3. Auditors identify processes or work practices that appear to be performed incorrectly during a routine tour of a manufacturing facility. The auditors may ask to see the training materials or training records associated with individuals working in the area.

Further, training managers note that if the training department can produce training documentation quickly and in an organized fashion, auditors are more likely to view the overall training effort as effective. At the same time, when solid training documentation cannot be produced quickly, a more in-depth review of the training system may occur.

In addition to CFR 21, 210 and 211, Part 11 will also affect training documentation. This is discussed later.

Types of Documentation/Recordkeeping Systems

Any documentation system may meet the requirements of "produce. . . quickly and present in an organized fashion."

Three types of methods are commonly used for training documentation/recordkeeping in the pharmaceutical manufacturing industry: paper systems, electronic systems with paper backup, and stand-alone electronic systems.

Some pharmaceutical companies use a paper-based documentation system. But data gathered from pharmaceutical training personnel presented at the 2001 GMP-TEA conference (5), along with surveys conducted through a show-of-hands at PDA and GMP-TEA training conferences, suggest that most companies use some type of electronic system, with or without paper backup. These electronic systems, also known as Learning Management Systems or LMSs, range from elaborate programs such as IsoTrain, SAP, Plateau, and Registrar, to departmental databases created in Microsoft Access. Paper backup typically includes at least sign-in sheets and sometimes evaluation instruments.

An LMS is essentially a database made up of multiple tables to store discrete units of information. These might include employee information, course information, evaluation data, and training programs or materials. These tables can be merged and queried to produce specific reports. Report capabilities allow users to compare, analyze, question, and project needs.

According to a paper presented at the 2001 GMP-TEA Training Conference (6), most companies that had not implemented a comprehensive electronic documentation/recordkeeping system were planning to do so in the next 12 to 36 months. The major task for them is to understand how to select and implement the system that will best support corporate objectives. The remainder of this paper will focus on the selection and use of an electronic documentation/recordkeeping system.

Steps to Selecting and Implementing an Electronic Documentation/Recordkeeping System

Dust (7), Stromp (8), and VanderWall (9) suggest that taking the following steps can ensure the successful selection and implementation of an electronic documentation/recordkeeping system.

1. Establish a review team
2. Determine responsibilities
3. Determine documentation/recordkeeping requirements
4. Identify electronic documentation/recordkeeping systems
5. Select electronic documentation/recordkeeping systems to review
6. Review electronic documentation/recordkeeping systems
7. Check references
8. Select and install electronic documentation/recordkeeping system
9. Train appropriate personnel on the electronic documentation/recordkeeping system

These steps are explained below.

1. Establish a review team

The first step in selecting an electronic documentation/recordkeeping system is to establish a team to review and select a system. As with any team, the fewer the number of players, the easier it will be to reach consensus on key issues. At the same time though, certain functional areas should be represented. People or departments that should be considered as part of the review team including a training manager, trainers and representatives from various departments from Human Resources, Information Systems, Quality Assurance, Manufacturing, R & D, Packaging, Warehousing, and other functional departments.

2. Determine responsibilities

Key questions related to the administration and management responsibilities of the system must be answered (e.g., Who will enter, verify and maintain the data?).

Data entry is a key component of any electronic documentation/recordkeeping system. In fact, the system will only be as good as the data entered. It is also important to note that data entry offers an opportunity for system corruption if not handled expertly.

Methods of data entry vary from company to company and sometimes even from facility to facility within companies. Some organizations use paper copies of sign-in sheets and test results are provided to a dedicated data entry person whose sole job is to enter information into the documentation/recordkeeping system. In other companies, the person who presented the training is responsible for entering the data. Then there are companies whose supervisors or managers enter information into the documentation/recordkeeping system.

The data entry task is often relegated to someone other than a full-time company employee. This frees up training professionals from data entry tasks but presents another set of problems. For instance, entry-level clerks, contractors, or temporary employees may not have the experience to evaluate the accuracy or plausibility of the data they enter. And a part-time person may not be able to keep up with the amount of data to be entered.

A good argument exists for using experienced employees for data entry. For instance, an experienced employee may question a record that shows an employee was trained on 30 SOPs in one 2-hour time period. This kind of checking helps ensure the accuracy of the data, a critical element in electronic recordkeeping.

Another important question is: Who will have access to the data? Access—and therefore security—typically falls into three levels: system administration, data entry, and system users. System administration usually means the Training Manager and a person from the Information Systems Department are dedicated to the training documentation/recordkeeping system. System administration has complete access to the system and can view data design or generate queries and replace, add data, and revise system capabilities, if necessary.

Data entry includes people who can enter information into the system. Security for data entry personnel allows them to view the system and add data to it. Beyond that point, they are locked out and cannot change or modify the system.

System users may include all facility employees. This level allows employees to be responsible for their own training. They can generate reports to determine which programs they have completed and which programs they must take to remain competent in their jobs or satisfy state or federal training requirements. Likewise, supervisors and managers have the ability to query the system to determine which employees are qualified to perform job functions and who is up-to-date on required training. Typically, security for system users allows them only to read data and print reports.

Who will store the various forms of training documentation and for how long? Many training departments continue to store sign-in sheets, paper tests or other forms of raw data even though they have an electronic system because of confusion about what the FDA expects. Paul Motise of the FDA says that grades should be recorded but the raw data (actual test) need not be saved (10). If the course content, method of evaluation, and trainees' scores have been recorded, there is a complete picture of employee training and workforce capabilities to perform a certain task. Of course, employment law or internal HR policy may require documentation of actual test failure to demonstrate poor performance.

How will this information interface with existing HR systems and databases? Often companies require that only one database on employee information be maintained. Creating a separate database for training administration is a redundant activity. Will this documentation/recordkeeping system interface (read from and feed into) an existing HR system? What system is that? Is this documentation/recordkeeping system capable of interfacing with this system?

3. Determine documentation/recordkeeping system requirements

Perhaps the most important part of selecting an electronic system is determining system requirements. This involves mapping the current process and testing it to make the system as efficient as possible. This process helps avoid the "garbage in, garbage out" problems. It includes evaluating the quality, organization, and content of the records being maintained. Every document should be identified along with its link(s) to other documents such as SOPs, batch records, guidelines, or other information that may be used in training but might not be labeled as training documents.

The method for determining the system requirements stems from the workflow and the desired system outcomes. A number of questions require resolution including: What reports will be required?/What queries will be required?/What level of security is required?/What other databases or electronic systems will training documentation have to interact with?/Is the system compliant with 21 CFR Part 11?

The objective of the training documentation can be used as a guide in determining what data needs to be recorded. Most people agree that at least the following should be included in a "bare bones" training documentation/recordkeeping system: Who received the training? Who provided the training? The date training was provided and the location of the training; the training program content with course objectives, outlines or lesson plans; evaluations or tests; and tests and evaluation results.

After these minimum requirements have been fulfilled, additional data may need to be added such as, job information, including job description and job tasks, prerequisite knowledge and skills, training requirements, SOP requirements, and training effectiveness indicators for both knowledge and skill.

John Stromp, writing in the *Journal of cGMP Compliance* (8), sums up the process this way: evaluate your paper documentation/recordkeeping system. If your paper system is flawed, it must be redesigned.

Start with identifying all documents included in the paper system. Not all documents in the paper system need to be electronic, and not all systems can manage all types of documents. Will some documents have attachments such as drawings or graphics? Will all documents be subject to GMP requirements?

4. Identify electronic documentation/recordkeeping systems

Electronic documentation/recordkeeping systems fall into two classifications: proprietary systems usually created using Microsoft Access and commercially prepared, off-the-shelf systems. In a show-of-hands by training personnel attending a general session of the GMP-TEA 2001 conference, two points appear consistently. First,

proprietary programs account for 50% of the market; and second, no commercially prepared system has a definitive market share.

More than 30 commercially prepared, off-the-shelf training documentation/recordkeeping systems are on the market today. The greatest challenge for many companies today is selecting the right commercially available electronic documentation/recordkeeping system.

5. Select electronic documentation/recordkeeping systems to review

With so many systems out there, how does one choose those to review? First, an internal team should determine requirements and put them on paper, considering these additional selection points: How many records (employees) are needed in the system? How many facilities will be using the system? How many people will have access to the system? What level of access will they have?

There are many questions for the program developer/supplier: What is the cost for the demonstration program? Will he/she provide an on-site demonstration of the system? How many records will the system hold? What type of end user training does he/she provide? Is end user documentation provided? What is the policy on technical support and is this part of the overall cost, or is it extra? What does the program cost and how is that cost determined? Will he/she help to install and set up the program? Will he/she enter initial data, and, if so, at what cost? How will archive data be handled and how much customization of the system is required? How will updates to the software be handled, and how will this affect any customization that has taken place? How will updates to supporting software affect the documentation/recordkeeping system (changes to the system operating system, changes to the HR system, etc.)? Is it easy to create standardized reports? If not, can the organization contract with the developer to create them, and what is the cost for this?

Additional questions may include: What is the company's experience in the documentation management business? Does the firm have extensive knowledge in this area or is this a new venture? How large is the company? Is third party support offered? If so, from whom and for how long? Who else is currently using this company's software? Does the company understand the word validation? Can and will the firm validate its software according to GMP requirements? (8).

Once this information is together, a Request for Proposal (RFP) for selected vendors can be developed.

6. Review selected electronic documentation/recordkeeping systems

Perhaps at this point the selection process is narrowed down to two or three vendors. A two-step review process is helpful. First, a demonstration disk is requested, with everyone in the organization who is going to use the software giving it a thorough review. Reviewers should write down their questions and what they like and dislike about the system.

The second step is for selected vendors to demonstrate their system to a review team. Someone familiar with internal technical requirements should be present to ask and answer technical questions. Vendors should be reminded that this is a one-time demonstration and questions that cannot be answered on the spot may place the product in a negative light.

During the review, Stromp (8) suggests determining answers to these questions: Is the system user-friendly? Does the system manage the old paper system? Does the system handle all of the different types of documents in the old system? What is the scope of the databases that the system can manage? Does the management of workflow match the organization's needs? What is the true cost of the system? Customization options? What reports come as standard reports within the documentation/recordkeeping system? How easy is it to create ad hoc reports and add them to the list of standard reports?

7. Check references

Once selected systems are reviewed, references are checked. References should identify experiences vendors have had with the system and whether they know others in the industry who have had similar or different experiences.

It is best to identify and talk with reference accounts that most resemble the specified environment and business. Before interfacing a documentation/recordkeeping system with another, such as an HR system, speaking with a reference who is doing the same thing with the same system is suggested. The more information attained on the front end about the problems that may occur will make the back end installation process go much more smoothly.

8. Select and install electronic documentation/ recordkeeping system

Systems review and reference checks will help in selecting and purchasing the system that best meets the overall requirements. Once the system has been purchased, it must be installed. This is usually a cooperative venture between the vendor, the department responsible for the system within the facility, and the Information Technology department.

During the installation process, Installation Qualification (IQ), Operations Qualification (OQ), and Performance Qualification (PQ) should be run.

Next, the length of the "crossover" period should be determined. It will be during this time that both the current tracking system and the new documentation/ recordkeeping system will be maintained. This will ensure that the data collected and recorded electronically is accurate and that it is time to completely move to the new system.

9. Train personnel on the electronic document/ recordkeeping system

Once the system has been selected, purchased and installed, all those with a relationship to the system must be trained. This training should focus on how the end user will use the system. Reference materials and job aids can reduce the amount of formal training required. Each end user should be challenged during training with exercises that mirror actual workplace requirements.

The Validation Issue

Pharmaceutical manufacturing training managers will debate about whether electronic training documentation/ recordkeeping systems need to be validated. Once again, consider the objective of training documentation/ recordkeeping in maintaining a quality system. To date, FDA has not consistently required validation of electronic training documentation/recordkeeping systems, but these systems should be validated to ensure the reliability of their performance.

Validation is the process of establishing documented evidence with a high degree of assurance that a computer system will consistently perform according to pre-set specifications and quality attributes. It ensures that the system operates as it was intended and produces reliable work outcomes. Any computer system used to manufacture, process, package, hold, distribute, or test a drug product must be validated. So must computer systems that could adversely impact the identity, strength, quality, or purity of a drug product. Electronic training documentation/recordkeeping systems fall under this category if the system will determine training/retraining requirements.

Protocols should include repetitive testing to achieve a high degree of confidence that the results will be replicable. Organizations must retain records of all test results. Individuals must sign and date that tests were performed and data results were checked.

Systems should be validated under normal conditions as well as anticipated upset conditions. Response time must be known when the system is loaded. Too often reports are made of systems that met all of validation criteria, but when the system was fully operational and loaded, the response time was not acceptable to the users. Finally, backup and recovery procedures must be developed and validated.

Once a system is validated and put into use, change control is necessary to maintain the validated state. All changes must be reviewed and approved prior to implementation. It is also a good idea to perform periodic reviews of the computer system. This involves a review of all changes over time as well as any problems that have occurred with the system.

The Part 11 Issue

In the Federal Register (11), FDA issued a notice of final rulemaking for 21 CFR, Part 11 Electronic Records; Electronic Signatures. The rule went into effect on August 20, 1997. Part 11 is intended to create criteria for acceptance and promotion of electronic recordkeeping technologies while preserving the agency's ability to protect and promote public health—that is, by facilitating timely review and approval of safe and effective new medical products, conducting efficient audits of required records, and when necessary, pursuing regulatory actions. Part 11 applies to all FDA program areas but does not mandate electronic recordkeeping. It describes the technical and procedural requirements that must be met if a person chooses to maintain records electronically and use electronic signatures. It consists of two subparts, Subpart B: Electronic Documentation, and Subpart C: Electronic Signatures.

Subpart B requires an electronic audit trail for all electronic records. This means that from the initial creation of a record an audit trail of all changes made, the date and time of change, and the individual who made the change must be captured electronically.

Subpart C is often the main issue, but from a cost perspective Subpart B can also be a major concern. If electronic signatures are to be used, some requirements must be satisfied. Electronic signatures must be the equivalent of hand-written signatures and include the printed name of signer, date and time of signing, and meaning of the signature (author, approver, etc.). They must be linked to record on which it is applied and should appear whenever the record is viewed or printed.

Part 11 only requires compliance with the portion of the regulation that applies to a company's system. If the training system is used to store electronic training records, but does not use electronic signatures, then compliance is only required with Subpart B.

The Training Documentation/Recordkeeping SOP

SOPs should be written for the entire documentation/recordkeeping system. An "umbrella" SOP should be created that describes the entire workflow at a high level. The workflow created in Step 3 can serve as the foundation for this SOP.

From that workflow, it must decided which steps and forms in the flow are involved enough to require their own SOPs. Additional SOP titles could include: Training Program Attendance Recording/On-the-Job Training/Training Program Outlines/Qualifying Trainers/Assessing for Independent Performance/Training Curricula/New Employee Orientation/Contractor Training/Human Resource Upload/Database Interface/Data Integrity Verification/Training Data Entry/Course Coding/Entering & Revising Curriculum/Catastrophic Recovery/Data Entry Training Requirements/System Security.

Fully compliant, electronic training documentation and recordkeeping systems have not been widely implemented in the industry, but this is changing. As this trend gathers momentum, more information about the challenges, pitfalls, and solutions will become available.

References

1. "Current Good Manufacturing Practice in Manufacturing, Processing, Packing, or Holding of Drugs; General," *21 C.F.R.* 210 (2002).

2. "Current Good Manufacturing Practice for Finished Pharmaceuticals," *21 C.F.R.* 211 (2002).

3. "Current Good Manufacturing Practice for Finished Pharmaceuticals," *21 C.F.R.* 211.25 (2002).

4. "United States v. Alpha Therapeutic Corporation," Consent Decree of Permanent Injunction, United States District Court for the Central District of California (1998).

5. Gallup, D., General Session, 2001 GMP-TEA Conference, Montreal Canada, (September 2001).

6. Gallup, D., "PDA Benchmarking Survey Report," paper presented at 2001 GMP-TEA Conference, Montreal Canada, (September 2001).

7. Dust, B., "Keeping Good Records," *Training and Development Journal*, p. 50, (December 1996).

8. Stromp, J., "Selecting an Electronic Documentation Management System," *Journal of CGMP Compliance*, **2**, (1), Institute of Validation Technology, Royal Palm Beach, FL, p. 6-8, (October 1997).

9. VanDer Wall, S., "Software Bits," *HRMagazine*, p. 130-131, (November 1999).

10. Motise, P., "GMP Notes," Drug Guidance Documents, (September 1999).

11. "Electronic Records; Electronic Signatures," *Federal Register*, Volume 62, 13429 (1997).