

Making the Transition to an E-System

By Janet Gough

This is the first part of a two part article – [\(Click here for Part 2 of this article\)](#)

The impetus to go electronic may well have been FDA's mandate that as of June 2009 the agency will only accept electronic submissions. Even though the last day to file a paper submission was 31 Dec 2007, many companies managed to get waivers. So the new mandate has spurred the decision to go fully electronic for more than one firm. With that decision comes a whole spate of issues.

Electronic systems require four essentials: validation, security, audit trails, and accountability. None of these are clear cut, and companies still struggle to make sense of the very vague Part 11 regulation – which itself was slated for revision by 2006 to focus on risk, but industry has yet to see it. The current, original final rule provides little help in the actual “how to” for bringing a system on board, and more than one company has found itself mired in the transition process after having selected a suitable vendor, agreed to contractual terms, and purchased a configurable off the shelf (COTS) software program.

If the company has thought through the requirements it needs in an electronic document management system, it has done its homework and selected a system that is optimum for its business needs. Yet such a foundation does not guarantee that the company will implement the system efficiently.

The transition can be a torment, or it can be efficient, depending on several factors. The first is getting people on board and actively involved in the process. The second is being systematic in validating for “intended performance. The third is training. And the fourth is building the repository for documents and records within the system.

With an electronic system, the company has entered into a relationship with the vendor. It is important that the workforce knows this. Enthusiasm from the top down from the start of the process – ideally when the decision to purchase an e-system is made – helps bring people on board. The knowledge that the system will be easy to use, save time, and pay for itself in short order are benefits the users need to know and understand. The people who made the decision to purchase a software program are the ones who need to communicate with the workforce. That means upper management who authorized the purchase must be vocal and visible in endorsing the system. Those who participated in selecting it and understand its features should be advocates as well. Indeed, those people who participated in the process are the ideal people to form a validation team,

because they are the very ones who understand “intended performance” best and can drive the transition.

An ideal validation team has a validation lead, typically from the unit that will administrate the system, team members representing every area of the company that will use the system, and an IT representative. The team may include other members, such as consultants and part time employees. These people, however, should not serve as the validation lead, nor should IT. IT is important because a validation is not just for software, but for the entire system, software as well as hardware, and IT is vital for total system support. IT thus provides an essential service, but doesn't actually have to know the software itself. It can be disastrous if IT dictates how the system will work, when in fact, IT will not use the system on a day-to-day basis.

An important task of the validation team is to communicate with their respective departments as to the progress of the project. The responsibility of the validation team is also to drive the validation process systematically and deliver validation documents which go into a validation packet. This process verifies security, audit trails, and user accountability, and ensures that system users undergo training. The team itself needs to understand the system and be trained on it; such training is documented as part of the process. Next they need to ensure that enough users are trained so that they can test and verify that the system does what it's supposed to as they proceed through the validation activities. To produce the validation packet and the other documents and records the system needs requires a document management separate from the one undergoing validation. This system is frequently the one that will phase out over time once the validation is complete.

Another essential piece of validation is ensuring that SOPs that support the system and the validation activities are in place before the system goes live. That means they have to look at SOPs already in place and see if they need to revise them to accommodate the new system. They will also have to create new SOPs to support the new system and the perhaps the transition phase. SOPs to think about include the following:

- Facilities Security – covers access control account, account termination, visitors, loss management
- Network Security – covers network user access, passwords, and virus protection
- System backup – covers backup and data recovery and media use
- Data Archiving – covers how to make more storage space available
- System Event Recording – covers logs for recording modifications to the system that events may signal
- Computer System Change Control – covers requested changes to the system
- System Disaster Recovery – covers how the system can be brought back online following loss

- Electronic Signature policy – covers user accountability
- Training – either general training or computer system training
- Record Retention – covers how long you must keep your records
- Scanning – covers how to scan and verify replication
- Computer System Validation – covers how to validate, test, and verify
- E-Mail Policy – covers back up archiving, and retention
- Time Management – covers handling time and date stamps between multiple sites
- Software/Product Procurement – covers how to evaluate vendors in relation to user requirements
- Software Vendor Auditing – covers how to evaluate a vendor and the software development life cycle
- Systems Inventory – covers how a new system is added to inventory
- General Auditing – covers company audit practices (which will include the new system)
- Hosting a Compliance Inspection – covers how to receive an inspection and what records a company makes available
- Document/Records Management – Explains the software system functions
- Software System Use – covers the “how to” for using the system
- Transition Procedure – covers which categories of documents will move into the validated system and how it will happen

Training is the next important component. Before anyone can use the system, there must be training. The validation team must train enough users initially so that they can test and verify system function during the validation process. Often the validation process itself flags issues that new users have with a system, and there may be retraining as the validation progresses.

Once the system goes into production, training must occur in earnest. Again, maintaining a level of enthusiasm is important for a fluid transition. Users need to know that their electronic signature is the legally binding equivalent of their handwritten signature, and that whatever they enter into the system becomes part of the audit trail for the system. Training also needs to spell out privileges – which users have access to which files and which users can perform certain functions. Once trained, people can use the system, even in its fledgling state to generate new documents and records, and access other documents as the system builds.

Part 2 of this article (starting on Page 4) discusses how to build the system once it is live.

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Once an electronic system has gone through the validation process and is in production, users can access it to initiate, review, and approve documents in accord with the SOPs against which they have undergone training. The validation process will have set specifications for the system based on the user requirements, so the system will be able to accommodate all the documents the system has been built to hold and to identify users by passwords linked to the user's names.

The first step in creating a new document in a new system is to ascertain whether the document is actually needed. A brand new system is not searchable, so initial determination for a document needs to be based on the former system. If a document is necessary, reviewers confirm within the new system, and the author can begin to prepare a document. Typically, system administrators make templates available to authors so that they can generate a new document.

To make the system fully usable and searchable for the categories of documents the system will ultimately house, legacy documents must also come into the system. There are a few approaches for building the document repository in an electronic system.

How the documents come into the system must first be thought out and documented in an SOP that covers the transitioning phase – and it can be retired when the system is fully loaded. The former system must stay up and running until all documents have either been retired or transitioned to the new system. Then the old system and its SOPs can be retired.

Companies also need to have an SOP in place for handling legacy documents that may continue to be generated outside the system; such documents may be study protocols or reports prepared by contractors, for instance. Importing these documents into the system can follow the same process as for bringing pre-existing documents in.

In new systems, many companies determine to simplify conventions such as the numbering system and formatting for specific types of documents, and the transition period is a good time to undertake such an activity. If the document conventions are predetermined, they can be applied before a document enters the system.

Versioned Documents

Typically companies begin to build a document repository by addressing their procedures; they handle documents such as work instructions and forms the same way. A reasonable place to start is by determining if any documents are ready for retirement. If they are, they can be put into review in the former system and simply retired within that system. They can also be brought in as any other SOPs that are ready to go into the review cycle, but then they must follow the SOP for importing documents to the new system.

Documents that are ready for review can also undergo reformatting – but not content changing. This is possible if the original system has secure electronic files of the final approved document. A reformatted document can then be imported into the system, checked for exact replication (Quality Control check) as the approved, signed document, and put into review. It is not the best idea to scan versioned documents because the text will have to be recreated anyway for updating during the review cycle. If the numbering system has changed for the new system, the document history in the electronic system should identify the previous number and version and link it to the new number. This history links the e-file in the new system to the document from the former system.

The next procedures to address are those that require updating before their periodic review cycle. Many companies set priorities and determine which of these documents should enter the system first. Bear in mind, however, that they are still active in the older system and will continue to be until they enter the new system. These can be imported the same way as other SOPs.

Other Electronic Documents

Protocols, amendments, reports and other documents and records that must be available for reuse can be handled the same way as versioned documents, since companies need to have electronic files for updates. The key is to ensure exact replication of the original signed document. Again, if the earlier system has a feature that ensures security of the electronic file, it can be imported with a QC check for exact replication.

Manually Signed Documents

To import a document bearing a wet signature into the electronic system, FDA recommends .pdf copies. For best readability and replication, these are the recommended resolutions:

- Text 300 dpi

- Photos 600 dpi resolution

- Gels and karyotypes: 600 dpi; 8-bit grayscale depth

- Plotter graphics: 300 dpi

HPLC: 300 dpi

The Quality Control (QC) Check

Each document coming into the new system, whether an electronic file or a scan, requires a 100% quality control check to ensure that documents and records are exact replicas, in keeping with the requirements of Part 11. A 100% QC check of text is verification of the number of pages, and confirmation that the first and last word. Images, diagrams, photos, and other require a visual confirmation that the copy is identical to the original. The QC check is ideally performed by a different person from the one who has done the actual scanning, and the QC check is documented. Precise QC of documents and records make it possible for companies ultimately to do away with paper and use the electronic files as official records.

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