



Controlling Electronic Records

Software contributes to FDA 21 CFR Part 11 compliance.

by Brenda Boughton

Electronic records—their creation, modification, maintenance, retrieval, and archiving—can create ongoing challenges for all organizations. For industries regulated by the U.S. Food and Drug Administration (FDA), such as pharmaceutical companies, medical device manufacturers, food processing plants, and biotech companies, the FDA’s Code of Federal Regulations Title 21 Part 11 applies to the specifications, use, and control of electronic records and electronic signatures.

The requirements of FDA 21 CFR Part 11 for electronic records are based on good practices, organization, and, most of all, common sense to ensure the efficient and secure handling of these records. In general, these requirements state that:

- All information is complete, and all records can be tracked to their originator and corresponding records.
- Appropriate securities are in place to ensure that tampering that would alter the record from its original intent does not take place.
- Only the appropriate parties can access the records, and only those so identified can create, modify, or review those records.

- Authorizing parties are identified, and dates of those authorizations are recorded.

- Information can be viewed in a timely fashion either electronically or in a paper format.

- Records are maintained by personnel who are experienced and/or trained in the workings of the electronic systems in use.

For most small to mid-size companies, creating a custom quality solution to

Know & Go

- The Food and Drug Administration’s Code of Federal Regulations Title 21 Part 11 covers electronic record-keeping.
- The requirements of FDA 21 CFR Part 11 are based on good practices, organization, and common sense.
- A case study involving Vistek Precision Machine Co. demonstrates how software can help a medical device manufacturer organize its systems in pursuit of ISO 13485 registration, maintain visibility over audits and cost tracking, and achieve compliance to FDA 21 CFR Part 11.
- The Vistek experience demonstrates that software integration and simplification streamlines the management of documents.

manage these requirements is not feasible. They instead look for software to automate and simplify the process.

Case in point

Vistek Precision Machine Co. of Ivyland, Pennsylvania, is a medical device manufacturer producing precision, CNC-machined components such as bone screws; implants for the spine, neck, hip, and knee; and high-performance surgical tools such as laparoscopic devices.

Early in 2008, Vistek was looking to purchase software to accomplish three primary objectives: first, to organize their quality system in pursuit of ISO 13485 registration; second, to maintain visibility over audits and cost tracking of the quality system that would enable them to be cost-competitive; and third, to enable them to be compliant under FDA 21 CFR Part 11.

“We had seen peers within our industry struggle to maintain their quality system at a high cost, just to hold their registration,” says Vince Visco, the company’s founder and president. “We didn’t want to travel down that road, so we weighed different options to prevent us from running into those same challenges.”

Vistek needed to electronically control about 700 documents. They also wanted to evolve toward a paperless quality system. Their senior management team compiled a wish list of what they wanted from a quality system. This is what they envisioned:

- The quality system would capture various production costs, costs of quality, and the costs of poor quality, and provide a series of metrics for trend analysis.
- The system would help Vistek comply with ISO 13485 and several articles under FDA 21 CFR Part 11.
- The quality system would enhance their long-term strategic plan.

These goals made good sense. The catch? Vistek management had to accomplish them with no additional staff.

“The solution to the challenges set before us was to find tools that would offer metrics, maintain security, provide work flow, and capture the elements we defined in our quality system,” says Visco.

The challenge of document security

Vistek’s first challenge in meeting the requirements of FDA 21 CFR Part 11 was dealing with security and access to their systems and documentation. They needed the flexibility to alter security and access on both closed- and open-loop documentation.

Using software from uni-Point Software Inc., of Winnipeg, Manitoba, Vistek was able to capture digital signatures from authors, collaborators, reviewers, and approvers with their corresponding date and time stamps that harmonized document flow and met FDA 21 CFR Part 11 requirements. The security features guard against tampering by requiring encrypted passwords—thereby ensuring that someone’s unattended computer could not be the source of a false sign-off.

The system also ensures that document sign-offs cannot be revoked. Document check-ins and check-outs similar to a paper system prevent staff from mistakenly using procedures or documents under development or review. All of this is done electronically, and the document revisions are complete in less than half the time it takes using the company’s paper-based method.

“The software gives us a huge advantage for organizing the storage of our documentation in a safe and secure part of the server, which we know is backed up on a regular basis,” says Visco. “We use the software as a gatekeeper, giving us a

new level of security that we have complete control of.”

The challenge of document tracking

Vistek also needed to ensure that all documents and records were organized in a manner that would save time and effort and be compliant to both ISO 13485 and FDA 21 CFR Part 11.

Vistek now categorizes its documents and records into a library and then efficiently maintains, sorts, modifies, retrieves, and archives them. All of the parameters of a document are captured, including the document number, name, type, the creation, revision, and release dates, and the department and manager owning the document. With these fields defined, users can search for a document by any parameter and organize thousands of documents in any number of ways. Managers can track a document through all stages of the process and view its status (active, pending, or

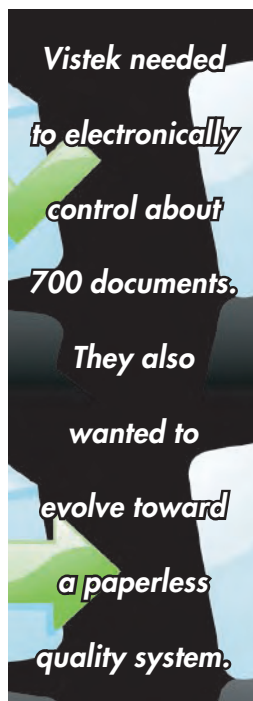
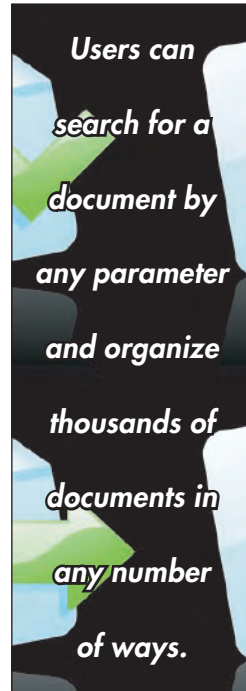
obsolete). In addition, review schedules are set up to ensure that the document is verified at a later date. Cumbersome log files are things of the past.

Document templates now automate the creation of new document records. Unlimited templates, with predefined sign-off and distribution routings and specific document securities, can be employed to quickly create new document records in the database. Documents of any file format are managed, and can be viewed either in their original format or using a document viewer.

Another function—key indicator panels—has helped managers to maintain the timely flow of documents. The user-definable panels resemble a common executive dashboard and allow managers to easily track any outstanding sign-offs, documents that are overdue for review, and new documents entering the system. This has allayed fears of document-user task assignments entering the system and getting lost.

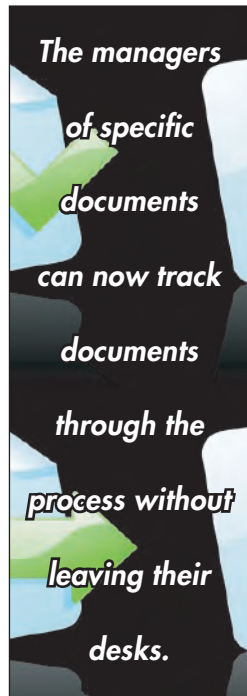
The challenge of document sign-offs

As part of the sign-off process, Vistek is now able to define the signing authori-



ties associated with the document and the order of the approval process. The software allows them to notify the appropriate personnel via e-mail that sign-off is pending their review, and it also places a task in the user's "To-do" list to help reviews progress in a timely manner. In the past this was accomplished by sending the paper copy with a cover sign-off sheet to all the people on the approval list.

"This was formerly a long and tiresome process which at times yielded no results, due to lost documents and edits, which meant we had to start the entire process again from the beginning," says Visco. "The simultaneous sign-offs in the software allow all signing authorities to view, accept, reject, and comment on the document at the same time, which is very efficient."



The managers of specific documents

track documents through the process without leaving their desks, and verify their digital signatures on document-control reports.

The challenge of document linking

With security, tracking, and sign-offs now under control, the company embarked on training the appropriate people to use the software. An education and training module enabled Vistek to manage these functions. Training records, company occupations, and employee master files have been set up, cross-referenced, and attached to the appropriate documents inside Vistek's document library. The attachment feature allows documents to be linked to any quality event in the system.

It also ensures that changes made to the document's revision level will automati-

cally inform, by e-mail, all employees who require that document for training.

"The challenge is ensuring that people continue to be trained with the latest reference materials as documents, procedures, and policies change," says Visco. "The software can associate a document to a training record and notify staff automatically, so we remain compliant."

"This module helps us manage all aspects of our training requirements, and it captures the costs associated with training and the lack thereof. The days of the old paper training matrix have come to an end, further reducing our costs and satisfying the Part 11 requirement regarding trained and experienced personnel."

The challenge of document distribution

Vistek, like most companies, has a variety of hard-copy documents on the floor, such as policies, procedures, forms, and work instructions that all need to be controlled. Each controlled document now has a complete routing destination showing where the document has been distributed, who is



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managing it, and who has copies of it. The software also requires each recipient of the document to acknowledge receipt and understanding—bringing an added element of control to a closed-loop environment.

The challenge of a document audit trail

Vistek was pleasantly surprised that the software was also able to track the

history of each document or record. The history function shows who has accessed the document, what they did with it, and exactly when they did it. “At first we used this function to track important projects on the go here at Vistek, but we have also come to use this tool to track who is accessing procedures and work instructions,” says Visco. “We feel that there is value in allowing people to access, review,

and link these documents in their day-to-day activities.”

Conclusion

It took just 60 days for Vistek to incorporate uniPoint software into their process and meet the requirements of FDA 21 CFR Part 11. In doing so, they increased efficiencies across the board, saving time and effort with the added benefit of going paperless.

They have dramatically simplified the document management process required for compliance, and reduced errors by using predefined document templates. Organizationally, they have encouraged compliant document-management practices by deploying the user-specific programs with to-do lists, e-mail reminders, and metrics—without increasing staff levels. They have reduced compliance and infrastructure costs by quickly leveraging their existing documents into a comprehensive and secure library, without disrupting the organization.

“When everything is integrated, it makes sense that the whole process becomes more streamlined from start to finish,” says Visco. “We are able to capture routine functions and also track the costs relating to those activities, something we could not do easily in the past. We can set quality goals and benchmarks, monitor them, and review corporate trends. Staff can work independently and collaboratively, leveraging the collective wisdom of the company.

“By meeting the standard we are now more efficient, while maintaining versatility.”

About the author

Brenda Boughton is a writer living in Winnipeg, Manitoba. Over the past 20 years she has created communications for private industry, government, and non-profit organizations on a wide variety of topics, including science and technology, education, sport, culture, and economic development. She is currently a communications manager with one of Canada’s largest financial service firms, where she oversees the information architecture and content of a sizable intranet. **QD**

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