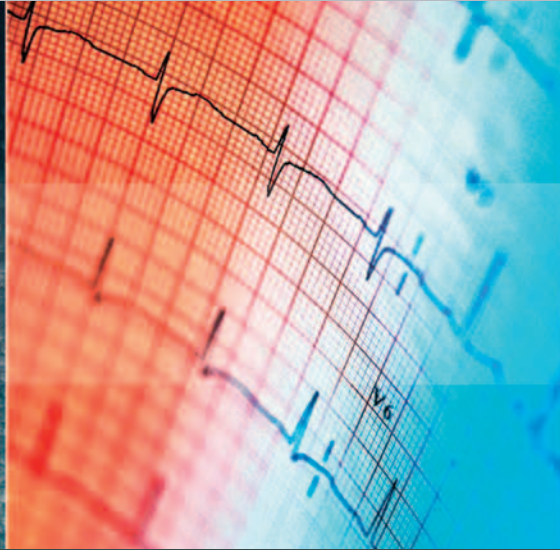
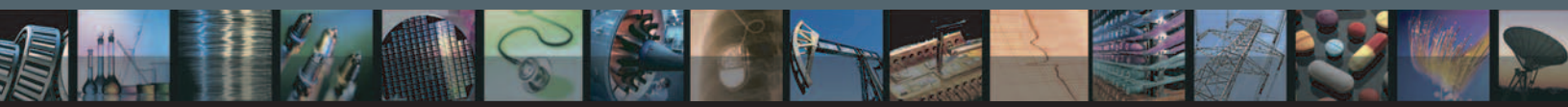


GUIDANT



CUSTOMER CASE STUDY

THE PERILS OF PAPER IN AN FDA-REGULATED ENVIRONMENT



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According to Ken Miles of the FDA, “One of the biggest challenges facing companies today is migrating from paper intensive systems to paperless electronic systems. The more involved companies get with their paper systems, the more they open themselves up to mistakes.”

In March of 1997, the FDA published its final rule on electronic records, electronic signatures and audit trails. This rule – known as 21 CFR Part 11—establishes the criteria under which the FDA recognizes electronic records and electronic signatures as the equivalent of paper records and traditional handwritten signatures.

Electronic records are essentially all of the quality records that you maintain as well as other records you are required by regulation to submit to the FDA. An electronic signature is defined as “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 the individual’s handwritten signature.” Electronic signatures must include the signer’s printed name, date and time stamp of signing, as well as the meaning of the signature – e.g., review, approval, acknowledgement, etc. Companies need to make sure to inform their employees that they understand the implications of electronic signatures and that any false activity on company records could result in criminal penalties.

When electronic records are in use, 21 CFR Part 11 requires that an audit trail be maintained automatically by the system. An audit trail provides a view-only, non-editable archive of all changes to the records. Users must not be allowed to circumvent it under any circumstances.

Simply entering data or information into Microsoft Word or Excel files does not constitute an acceptable “electronic record” according to the FDA’s definition. Systems must comply with all of the provisions set forth in the 21 CFR Part 11 regulations, which mandates authenticity as well as security of the data. Systems must be validated to establish that they are suitable for their intended use.

Medical device companies are finding that it is not an easy task to convert from paper-based record keeping to electronic records, nor do they fully understand the final Part 11 rules issued by the FDA. In a survey conducted by NuGenesis Technologies Corp. during 2001, “thirty-eight percent of the respondents admitted they did not fully understand the implications of Part 11 as it affected their companies. And while 75% of respondents claimed they had begun putting Part 11 measures in place, only 11% said they were fully Part 11 compliant in at least some areas.”

The regulations are not only subject to interpretation, but FDA inspectors have been inconsistent with the enforcement of these regulations. They tend to enforce Part 11 when other problems are found during a broader inspection, rather than look for Part 11 violations directly. However, as FDA inspectors become more experienced with Part 11 requirements, they are spotting deficiencies in systems on a much more regular basis. That trend is likely to continue.

Mr. Miles points out that the FDA is facing the same challenges as the organizations it regulates. “We are implementing electronic quality systems for our field people, managers, and laboratories. We are performing audits, collaborating between different groups, validating our systems – basically adhering to the same standards that we place on regulated industry.”

When asked how soon organizations should convert to paperless systems, Ken Miles said, “it would be best for organizations to move to electronic systems sooner rather than later. Efficiency will be improved and the error-rate will be reduced tremendously. It’s a form of quality assurance, and has long range effects on better product, higher profits, fewer mistakes and

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– Ken Miles, FDA

fewer product recalls. When you have better control of your records, and can distribute and share your information in a timely manner, it can only have positive impacts on quality.”

In 2001, Guidant Corporation took the same view. They were operating on a hybrid system comprised of paper and electronic records, with some of the facilities operating on paper-based systems only. The decision to combine all of these processes into a single, centralized system was initiated by Myrna Santos, Regulatory and Compliance Auditor for Guidant Puerto Rico. Santos was looking for a 21 CFR Part 11 compliant Corrective and Preventive Action (CAPA) system that could provide the flexibility Guidant required. As a world leader in the design, development and manufacture of cardiovascular medical products, Guidant required accessibility for all of its locations around the globe.

Incorporated in 1994, Guidant Corporation has grown to revenues of \$3.2 billion and employs more than 10,000 people worldwide. Corporate headquarters are in Indianapolis, IN, with major operations in California, Minnesota, Texas, Washington, Puerto Rico and Ireland. Other locations include Canada, Europe, Japan, Latin America, as well as several locations throughout the United States.

Guidant Corporation is comprised of four business units:

- **CARDIAC RHYTHM MANAGEMENT**, produces some of the smallest, most advanced pacemakers in the industry.
- **CARDIAC SURGERY**, focuses on less-invasive procedures for patients requiring bypass surgery. The CS division’s products enable surgeons to perform bypass surgery without stopping the heart or making a large incision in the patient’s leg to harvest the vein typically used in bypass surgery.
- **ENDOVASCULAR SOLUTIONS**, develops solutions for treating a variety of vascular diseases including aortic aneurysms, neurological, carotid, and peripheral diseases.

- **VASCULAR INTERVENTION**, creates advanced treatments for coronary artery disease. The VI division offers one of the broadest product lines of stent and stent delivery systems.

After looking at numerous CAPA systems on the market, Guidant selected CATSWeb® from AssurX, Inc. The primary decision factor was the degree of compliance with 21 CFR Part 11, followed by cost and ease of use. CATSWeb is a highly flexible, truly web-based enterprise quality tracking system that is extremely configurable and customizable. Guidant’s initial proof-of-concept program began with three facilities – Puerto Rico, Ireland and California. The project began in April 2002, and went “live” by the third week in July 2002. This included designing the workflow, performing the process and software validation, as well as training the users. AssurX provided the procedural templates that helped to expedite the software validation process, as well as onsite training for the administrators and users.

According to Ken Miles, “Validation of the software is very important. FDA inspectors will often write-up companies who fail to provide process validation and SOPs. Failure to maintain proper corrective and preventive action procedures are cited in a high rate of 483s (Notices of Inspectional Observations) issued to medical device companies. The last thing the organization wants is to be fined or forced to recall their product.”

Pat McCrumb, Manager, Quality Operations at Guidant’s Santa Clara Cardiac Surgery Unit said, “Planning and training were key to our success. We took the time to carefully map out our workflow in advance. The system has significantly increased visibility, as well as productivity. And since the system is so flexible, you’re only limited by your imagination in what you can do with it.” McCrumb plans to use CATSWeb for final product releases, as well as external corrective actions with suppliers in the future.

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The users were impressed with the short learning curve and ease of entering information electronically. They are now able to record all information into a single electronic system that eliminates the potential for mistakes, and allows management to view real time data to make better, faster decisions.

McCrum uses CATSWeb primarily for entering non-conforming material issues. These records are frequently accompanied by digital images, which are stored securely within the database, thereby benefiting from the same audit trail and controls. The system has proven to be so efficient that closure rates have been significantly reduced. For example, 70% of non-conformances are closed within five days, and 60% are closed within 48 hours. "In addition to reduced closure rates, it used to take me two to three weeks to prepare quarterly non-conformance reports. Now it only takes me two days. I also publish weekly open activity reports that take me less than 30 minutes to prepare. The query functionality is key. Before, I used to have to do all of this by hand – on paper!" said McCrum.

The integrated query and analysis functionality enables McCrum to effectively identify trends in quality data and proactively react to the trends in real time. CATSWeb is used at every level of the organization including design/engineering, incoming inspection, quality control, manufacturing, distribution, and management – essentially throughout the product life cycle.

Santos states that CATSWeb has helped her tremendously in assuring that manufacturing-related complaints are addressed in a timely fashion. The quality assurance and compliance group enter incoming complaints and issues, and assign actions to appropriate personnel. Assigned tasks are typically due in one week. Santos established notification rules that automatically remind assignees of pending tasks two days prior to the due date, then again the following day. All of the notifications are sent via Guidant's e-mail system. Escalation rules automatically reassign the tasks to management if they are not addressed within a predetermined period of time.

During weekly cross-functional meetings, data from the system is reviewed, and more effective preventive actions are put into place. Management can then query the information at any time to make more informed productivity decisions, generate progress reports, view quality indicators and set future goals. According to Santos, "We have cut the time required for quality indicator chart generation by more than 50%."

Since July 2002, Guidant users have entered over 2,000 issues into the system. 365 people currently use the system, and that number will grow significantly during the remainder of the roll out phase.

CONCLUSION

"The FDA's primary goal is to protect the public. With electronic systems, medical device companies can report problems in the field and take corrective actions much more quickly and efficiently as opposed to paper systems, which can take months," said Miles.

"Being able to capture, manage and trend information during all stages of the product life cycle in an electronic system will allow you to quickly assemble valuable information needed when making corrective action or quality-related changes. These types of changes may not only affect safety and effectiveness, but also productivity and profitability within an organization."

With the FDA increasing its focus on compliance and CAPA issues, organizations can no longer set aside their plans to convert from paper to much more efficient electronic systems. Recent FDA fines to medical device companies have run into the hundreds of millions of dollars. Failure to address quality or manufacturing issues not only will result in FDA warnings or possible recalls, but also class action lawsuits filed by consumers that become victim defective medical devices. A global CAPA solution can provide information and visibility throughout the entire organization in real time, and is no longer isolated to the quality assurance department. Problems can be resolved much faster before they become a major liability.

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