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FDA SUPPLEMENT SPOTLIGHT MAY SHED LIGHT ON PART 11, TOO

The FDA's new final rule establishing regulations to require Current Good Manufacturing Practices (cGMP) for dietary supplements, which become effective August 27, 2007, demonstrates that the agency is becoming more consistent in its approach to data integrity and other rerecord expectations, expert John English tells EDIR.

In his detailed analysis of the new 21 CFR Part 111 regulations, English says the agency is signaling, among other things, that it views inventory control as serious business. English is Manager of Computer Systems Validation with BE&K Bipolar.

"In my opinion, the inventory system is key to a recall," he said. The new Part 111, which allows a three-year

phase-in for smaller companies, requires FDA regulated companies to address key issues, including:

- ▯ Personnel qualification and training records
- ▯ Equipment logs and calibration records
- ▯ Supplier management
- ▯ Deviation and investigation actions/records/follow up
- ▯ Written procedures
- ▯ Complaints management
- ▯ Reporting adverse events to FDA
- ▯ Returned material handling

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SENIOR BUY-IN, DEFENSIBLE PLAN KEYS TO EFFECTIVE COMPLIANCE

You've got to make certain the senior executives are engaged, that you can articulate your compliance philosophy to an FDA inspector, and have a real handle on change management and risk assessment if you want to improve your operational efficiency even as you meet agency

regulations, experts tell EDIR.

"Senior buy-in is absolutely essential," said Paul Fricke, Quality Manager at AssurX and a long-time Quality Assurance professional in

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Did You Hear?...

"The old [Part 11] guidance was almost like an official blog...there were too many ways to interpret it," Sal Lucido, VP AssurX

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several organizations before joining the company last year. “The danger is when departments get out of synch due to lack of top down direction. Compliance spending can become a bottomless pit of money, and still not achieve a state of control” he warns. It happens sometimes because without senior oversight, IT folks can feel like “they are doing something good if they are doing something” without really looking at compliance from a risk assessment perspective.

The FDA’s 21 CFR Part 11 Rule requires all FDA-regulated companies to follow technical and procedural standards for the processing, storage, security, and retention of electronic records and electronic signatures.

Instead, he advises FDA regulated life sciences companies to think long and hard about how they will actually use an electronic record. “How does it relate to the predicate rules” and how directly does it impact the drug product or medical device, Fricke says. And obviously it is important to consider the product itself. A pacemaker is going to demand much higher scrutiny vis-à-vis record integrity than a rubber tip on a crutch, for example.

But it goes beyond understanding how the electronic record impacts the product to how important the product is in connection with a patient’s safety, Fricke noted.

FDA regulated life sciences companies not only need to develop and implement a smart compliance program, they also need to be able to articulate the underlying philosophy and approach of their program in a way that is easy for a FDA inspector to grasp and appreciate, he added.

And with the “new, improved” Part 11 slipping past all of its deadlines (so far), don’t waste too much time waiting for the new rule, said AssurX VP Sal Lucido. “We don’t expect Part 11 next year [or whenever it finally emerges] to be radically different,” he told EDIR. Instead, he expects, and hopes, that the new version will simply clarify some issues and otherwise make it easier to understand the FDA’s expectations.

But the overarching goal behind Part 11 – ensuring electronic data record integrity – shouldn’t change much, if at all, when the new Part 11 is finally issued, Lucido and others have told us. “The old guidance was almost like an official blog,” he said. “There were too many ways to interpret it.”

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That made it tough for well-meaning firms to comply, especially when individual FDA auditors and inspectors didn't always have the same interpretation of what the rule expected, many have told us.

"I hope and think they will tighten that up" as part of the new Part 11, Lucido said.

"Risk assessment is going to be a big part" of any effective compliance program in the future, too, Lucido agreed. "You should evaluate your quality records in light of the impact that data has on your product quality and customer safety. "

Key to that is conducting a gap analysis, experts stress. "It shouldn't take long," Lucido says. At the core, you are looking to determine if your computer system is doing what it is supposed to be doing.

Think also in terms of how well you are able to investigate a complaint or other problem, Fricke suggested. "You need to not only look at what information you capture, but also how you use it," he said.

If you have to investigate a complaint or an otherwise out-of-spec occurrence, you have to be able to make determinations and decisions on a dashboard electronic data information system that is well controlled and maintained, Fricke said.

CAPA CONTROL VITAL

Getting a firm grip on your Corrective and Preventive Action (CAPA) program is crucial, experts tell EDIR. In fact, several former FDAers have told us that when they conducted inspections, CAPA was the "bellwether" they'd focus on to get a feel for how strong the company was in terms of overall compliance. "CAPA should be the hub," echoed Lucido.

An effective CAPA program is tied to a software tool that allows a company to take in issues and incidents from all over its operations – be it audit findings, complaints, 3500a issues and/or internal test failures in manufacturing, for example – and treating the corrective action consistently with the same identified, proven best practices, Lucido said. "You've got to harmonize" your CAPA program, he added.

"A big part of a true CAPA system is to harness your best practices," Lucido said. And that is also part of the business case for compliance. Regulatory demands aside, compliance with Part 11 and related FDA requirements is simply smart business, Lucido and others have told EDIR.

Among other benefits, effective compliance programs and tools help you catch recurring problems faster, and that will save you time, money and reputation. "If you can achieve those things, you improve compliance as well as the bottom line," Lucido said.

SUPPLEMENTS...(From Page 1)

“Most of us don’t work in supplements, but you will find the positions [in the new supplement rule] both familiar and useful,” he said. For starters, the FDA’s new rule is potentially interesting for drug and medical device companies because it also addresses computer error, English said. “Computers can indeed screw up” and the FDA wants regulated companies to have in place “systems to address that,” he added.

The new rule also sheds some additional light on the agency’s thinking about record retrieval, English said. All records or copies must be readily available during the retention period, just as in Part 11. But the new rule also specifies that if you use reduction techniques such as microfiche, you must provide an FDA inspector with a reader along with the actual records.

“It is a more detailed approach, but overall I don’t see it as back breaking,” English said.

The FDA has numerous options to use in seeking remedy against firms/individuals who violate cGMP regulations. Penalties can range from warnings to injunction, seizure, debarment, civil penalties (individual fines may reach up to \$1,000,000), and criminal prosecution (fines/prison). More recent approaches by the FDA include hefty fines (intended to disgorge firms of any profit) and consent decrees.

In recent months, problems with food and supplements have generated media attention and high-profile hearings on Capitol Hill where FDAers have sometimes been grilled, so to speak, for not doing an adequate job protecting consumers. As a result, most consultants and other observers expect the FDA to increase its enforcement efforts in food and cosmetics, and also drugs and medical devices.

Computerized systems are key here, English said. The FDA’s new rule emphasizes the importance of computerized systems in handling inventory and related quality issues, he noted. “In this world of Chinese ingredients, that’s a big deal,” he said.

EDATA REQUIREMENTS...(From Page 5)

- HIPAA, which among other requirements says all covered entities must not only ensure the security and
- appropriate access of edata, but must also maintain it for six years from the date of its creation or from the date for which it was last in effect, whichever is later.
- FDA’s Good Manufacturing Standards, which require retaining all appropriate critical documents, such as development history reports, scale-up reports, process validation reports and training records. All production, control and distribution records must be retained for at least one year after the expiration date of the corresponding batch. For APIs with retest dates, the records must be retained for at least three years after the batch is completely distributed.
- FDA’s Good Laboratory Practice, which controls the documentation records of raw data and specimens pertaining to a non-clinical lab study. In general, it requires many records to be retained for two to five years, depending on the situation.

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EDATA RETENTION REQUIREMENTS ABOUND

A myriad of edata retention compliance programs challenge FDA regulated life sciences companies whether they operate in a single country or internationally, says a new white paper by long-time industry consultant and expert Rebecca Herold.

“Many laws and regulations exist throughout the world that require specific retention time periods and associated safeguards for a wide range of data types,” Herold said. “Organizations need to be aware of these data retention requirements and plan to meet the compliance challenges.”

In addition to the FDA’s Part 11, many companies have to contend with the requirements in domestic and international laws and regulations, including:

- European Union (EU) Data Protection Directive, which mandates that personal data must be accurate and up to date and that organizations not maintain data in a form that identifies specific individuals any longer than necessary for the purposes for which the information was collected or processed.
- Sarbanes-Oxley Act of 2002, which among other requirements expects all audit and review information to be retained in a readily accessible and indelible format for seven years

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EDATA MATTERS

LABTrack Unveils New ENotebook Tool

LABTrack, developer of the LABTrack Electronic Lab Notebook (ELN), just introduced its newest ELN product: LABTrack Personal. LABTrack Personal is designed to provide scientists and engineers with the ability to replace their paper lab notebooks and work sheets with an electronic equivalent. Like the Team and Enterprise editions, LABTrack Personal incorporates a thin client word processor. And LABTrack Personal incorporates the new Smart-xForms technology for storing customized formatted data with searching capabilities supported.

LABTrack Personal runs on Microsoft 2000 Server, 2003 Server, Windows XP Professional, Vista Business and Vista Ultimate PCs. Up to five (5) users may share a LABTrack Personal system using 21 CFR Part 11 compliant user accounts. LABTrack Personal comes with the free MSDE and Oracle XE databases from Microsoft and Oracle respectively. When interfaced to larger SQL Server and Oracle 10g database servers, users can create and store an unlimited number of notebooks and notebook pages. The free databases are limited to 2 GB (MSDE) and GB (Oracle XE). For more info go to www.labtrack.com.

Waters Ships New Publisher Tool

Waters Corporation said recently it was shipping SDMS Vision Publisher for its NuGenesis Scientific Data Management System (SDMS), an erepository that stores and manages all types of scientific data to a centralized database. With Waters Vision Publisher, laboratories can electronically capture primary data from a variety of laboratory devices and instruments and append that information and associated metadata to the experimental record for any investigational or manufactured product be it a promising drug candidate or a newly manufactured lot of product awaiting release, the company said in a press release. With SDMS Vision Publisher, key experimental data becomes part of the permanent record preventing transcription errors, streamlining review and approval processes, accelerating record retrieval, and facilitating audits.

SDMS Vision Publisher is a compliant-ready product that features status-based user access, configurable electronic signature hierarchies, full audit trails, and digital signatures. These features allow QC laboratory managers to follow the real-time status and compliance activities of the laboratory driven by SOP's and test methods. SMDS Vision Publisher uses secure, software-generated, time-stamped audit trails to independently record the date and time of operator entries as well as actions that create, modify, or delete electronic records.

The 21 CFR Part 11 compliant-ready SDMS Vision Publisher includes a number of predefined 'application packages' that utilize forms or templates to guide and enforce laboratory workflow. Entire routine laboratory experiments - such as studies for dissolution, content uniformity, or dynamic generation of test protocols – can be integrated into experimental write-ups automatically, reducing errors and tedious and time-consuming manual steps, maximizing efficiencies in the laboratory.

EtQ Offers New Part 11 Compliant Biometric Capabilities

EtQ has developed the ability for 3rd party Biometric readers to authenticate 21 CFR Part 11 electronic signatures within the EtQ Reliance FDA Compliance Management System, the company said June 28.

Biometrics are technologies that measure and analyze human physical and behavioral characteristics as authentication measures. Fingerprint scanning, retinal scanning, and similar methodologies are used as biometrics to ensure that any authentication to the system is consistent and unique, and eliminates any errors or forgotten passwords.