

Part 11

COMPLIANCE REPORT®

Monitoring FDA-related Technology Initiatives

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FDA CRAFTING PART 11 GUIDANCE COVERING CLINICAL TRIAL DATA

The FDA is crafting a new guidance to address the use of computerized systems in clinical trials, a move that could help the agency establish a consistent, risk-based approach to Part 11 for all segments of the pharmaceutical industry.

“We are working on a draft guidance that will supersede the existing guidance on computer systems and clinical trials,” FDA spokeswoman Christine Parker told *PCR*. The existing guidance, entitled “Computerized Systems Used in Clinical Trials,” was issued by the agency in April 1999. Parker explained that the changes are being made primarily to “incorporate information about the agency’s latest thinking on Part 11.”

(See **GUIDANCE**, Page 2)

METRICSTREAM USES FRAMEWORK TO MANAGE SYSTEMS VALIDATION

Information systems validation can be a frustrating endeavor for FDA-regulated companies, particularly because the FDA has not spelled out in its guidances on Part 11 how to perform such validation.

One way of cutting through the uncertainty is to employ a comprehensive strategy that ensures all of the company’s systems are properly validated. Software solutions developer MetricStream has developed one such strategy based on a five-step validation framework and the use of quality management systems to ensure full compliance.

PCR recently spoke with MetricStream Chief Executive Officer Shellye Archambeau about the company’s recommended framework and other validation issues.

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The new document is expected to translate into the clinical context many of the policies enunciated in the Part 11 guidance released last August, such as risk-based management and systems and process validation. Parker gave no date for the release of the guidance, but some industry officials are predicting it could come before the end of the summer and may even be a harbinger of broader action on Part 11.

The guidance will be welcomed by the clinical community, which views Part 11 as a particularly hot issue. “We are anxiously awaiting the guidance,” said Douglas Peddicord, executive director of the Association of Clinical Research Organizations (ACRO). Peddicord acknowledged he had no inside information about when the guidance would be released. However, “the cancellation of the Part 11 meeting certainly made the FDA’s task ... more difficult,” he offered, noting the agency has had to forge the guidance using a paper rather than the collaborative process the public meeting would have afforded.

“The clinical area has always been a problem for the FDA,” said Martin Browning, president and co-founder of EduQuest, a provider of classroom-based training and regulatory compliance consulting. Outside of a “couple of nuances,” the Part 11 specifications are clearly required of device and pharmaceutical manufacturers, he said, but, in the clinical and nonclinical areas, “the regulations are not as explicit, and there is a lack of guidance.”

Browning left the FDA in 1995 after serving for 22 years as a local, national and international expert investigator and then as a special assistant to the associate commissioner for regulatory affairs. During his time at the FDA, Browning was vice chairman of the Electronic Records and Signature Working Group that drafted the 21 CFR Part 11 regulations.

ACRO’s Desires

The predicate rules, systems validation and risk-based management are all high on the list of issues ACRO members want addressed, said Peddicord. “Unlike the predicate rules for GMP [good manufacturing practices] and GLP [good laboratory practices], good clinical practices [GCP] do not clearly identify records to be maintained or signed. As a result, there has been industrywide confusion and variability in interpretation as to the applicability of Part 11 and exactly which GCP requirements constitute ‘predicate’ rules,” Peddicord said in comments the organization filed with the FDA in July.

In addition, “the GCP regulations would do well to require validation of systems and processes in a way similar to the way GMP processes are,” Peddicord added. ACRO also urged the FDA to “publish meaningful guidance in regard to risk assessment and risk management vis-à-vis the requirements of Part 11,” noting that the FDA’s “discussion of risk-based approaches has been focused largely on GMP issues.”

The FDA is more than likely to fulfill the last request, according to Ludwig Huber, worldwide product marketing manager at Agilent Technologies.

(See **GUIDANCE**, Page 8)



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METRICSTREAM, from Page 1**Q: What is systems validation?**

Archambeau: Validation is the process of compiling written verification of all system functions and the performance of those functions to system specifications. It also involves substantiating, in writing, data integrity and system maintenance. That written documentation must be aligned with the industry standards and regulatory laws that guide the FDA in its evaluation and enforcement of compliance. To successfully manage compliance, each regulated system must be proven to operate in accordance with its intended use and design, and all documentation supporting that evidence must be FDA-acceptable.

Q: What systems need to be validated and why?

Archambeau: Part 11 requires that all systems that govern any cGxP process, including good manufacturing practices, good laboratory practices and good clinical practices be validated to ensure that the products manufactured by pharmaceutical, biotech and medical devices companies meet specific requirements for identity, strength, quality and purity. The FDA has issued very comprehensive guidance about this; however, the agency hasn't spelled out how to accomplish it, and I think that has been a source of frustration for many companies.

Q: With this uncertainty, what is the best way to approach validation?

Archambeau: There are a number of strategies out there. We have developed, for example, a five-point framework for validating systems that is comprehensive and applicable to both off-the-shelf and homegrown software solutions. This framework ensures that the software being deployed is most likely to be compliant with FDA requirements and will continue to sustain the compliance over time.

The framework includes the following steps:

- (1) Make sure software complies with basic Part 11 electronic signature and auditability requirements;

- (2) Follow a clearly defined software development life cycle process to ensure quality and prevent software defects. This includes a number of provisions, such as ensuring that all system requirements are clearly defined and approved before any design or coding effort starts;
- (3) Make sure the systems are housed in secure facilities to prevent any unauthorized access to software and computer rooms;
- (4) Guarantee that the company's software developers, designers and quality assurance engineers are adequately trained to perform the technical aspects of their jobs and that the company has training policies to ensure the team will continue to have the right skills on an ongoing basis to do their job; and
- (5) Finally, make certain the system is validated to accomplish its intended use.

Q: What are the challenges of implementing this type of strategy?

Archambeau: For organizations taking this on, the devil is in the details. They have got to document, manage and ensure that requirements, such as the necessary team training, have actually transpired. We recommend that companies look at using a quality management system (QMS) to administer this process because there is too much detail to manage on a full-time basis. The QMS serves as a system-of-record for the systems validation project. All documents including standard operating procedures, specifications and test plans are stored in its repository. By using a QMS, companies ensure that the ongoing and proactive audit and corrective action process is systematized and provides the basis for lowering the cost of compliance.

Q: How long does the process take?

Archambeau: We've had validations that have taken a couple of weeks and some that take as long as three months. It depends on the complexity of the software that is being implemented, the scope of the solution being deployed and the number of touch-points with other systems.

For more information about Archambeau and MetricStream, go to <http://www.metricstream.com>.

LEGAL BARRIERS MAY IMPEDE HEALTH IT PLAN, SAYS GAO

PhRMA is keeping a close eye on the ways in which HHS is developing its heavily touted health information technology initiative, especially in terms of the initiative's potential impact in the area of clinical trials, according to the trade group's associate vice president of U.S. regulatory affairs.

"We have been involved in a number of [health IT] initiatives," PhRMA's Alan Goldhammer said. The association is paying very close attention to the standards being developed for the health IT initiative to ensure that they are compatible with drugmakers' existing systems, such as those used to automate clinical trial processes. To facilitate this, PhRMA is working with standards developer Health Level 7 to help craft the standards for the health IT infrastructure, he said.

The HHS health IT program has been steadily gaining momentum since the beginning of the year. In April, President Bush signed an executive order — dubbed "Incentives for the Use of Health Information Technology" — calling for broad-based use of electronic medical records within 10 years, and in late July, HHS Secretary Tommy Thompson issued a strategic plan aimed at pushing that effort forward (*PCR*, Aug. 4, Page 1).

The initiative is part of an overall vision for the electronic interchange of data that would reach from electronic track-and-trace technology designed to prevent the counterfeiting of prescription drugs to electronic prescribing, which pharmaceutical manufacturers are studying to try to determine potential dangers, as well as possible opportunities to enhance their sales and marketing efforts.

(See **GAO HIT**, Page 5)

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GAO HIT, *from Page 4*

In the short term, however, the initiative, which is likely to have its most immediate impact on other sectors of the healthcare industry, will have to overcome a number of thorny legal barriers that extend beyond security and privacy concerns, according to recently released report from the Government Accountability Office (GAO).

While HHS is moving full speed ahead on the health IT initiative, the GAO contends that there are still many hurdles to blocking development of such a plan. "Various laws present barriers to adoption of health (information technology), and at the time of our review, HHS' efforts to address these barriers had been limited in scope," the watchdog agency said in a Aug. 13 letter to Sen. Judd Gregg (R-N.H.), who had called for the report.

Numerous Barriers

The challenges detailed in the report, entitled "HHS' Efforts to Promote Health Information Technology and Legal Barriers to Its Adoption," look beyond legal issues associated with privacy and security of health data to a series of the laws covering fraud and abuse, antitrust, federal income tax, intellectual property, malpractice and state licensing. "Because these laws frequently do not address health IT arrangements directly, healthcare providers are uncertain about what would constitute violations of the laws or create a risk of litigation," the report states. The GAO noted that because of these uncertainties, "healthcare providers are reluctant to take action and make significant investments in health IT."

HHS has tried to "address some of the legal barriers posed by the fraud and abuse laws, but experts told us these efforts have not been sufficient to overcome the reluctance of the providers," the GAO reported.

In the area of fraud and abuse, for example, the GAO said the Physician Self-Referral (Stark) Law and the Anti-kickback Law could hinder the establishment of arrangements between providers such as the provision of IT resources—that would otherwise promote the adoption of health IT. The report goes on to assert that some experts have

suggested that certain arrangements that could be used to promote the adoption of health IT may violate antitrust laws.

"An official from the Department of Justice told us that to the extent that the benefits of such arrangements can be shown to outweigh any anti-competitive impact, they are not likely to violate federal antitrust laws," said the GAO. "However, given the uncertainty about the impact of health IT arrangements on competition and what constitutes a violation, antitrust laws still present a barrier to the adoption of health IT."

The GAO also warned that some hospitals could lose their tax-exempt status by providing IT resources to physicians, explaining that "tax-exempt organizations that provide financial or other benefits to private individuals may jeopardize their tax-exempt status." Furthermore, the GAO said some experts are concerned that any charges tax-exempt hospitals impose on others for using IT resources that the hospitals have financed and developed may be taxable.

Copyright Concerns Likely

Another pressing issue, according to the GAO, is that the health IT plan could pose copyright issues. "Hospitals and other entities that are investing ... significant financial resources in the development of health IT systems are [also] concerned that copyright protections applicable to such systems may be inadequate to prevent unauthorized use and they will be unable, as a result, to recoup their investments," the report said.

On another front, "some physicians are concerned that the more information they have access to through health IT, the more information they will be held responsible for knowing and that this will increase their risk of being held liable for malpractice." Generally, doctors are responsible for obtaining "relevant information from patients to provide proper treatment, and the adoption of health IT may make it easier for physicians to obtain all relevant information and provide better care, which may reduce the risk of malpractice."

For further information, the GAO report can be accessed at <http://www.gao.gov/new.items/d04991r.pdf>.

LILLY TO POST TRIAL DATA ON UPDATED WEBSITE

Eli Lilly is revamping its Lillytrials.com website to include a detailed registry of all clinical trials sponsored by the company.

The move to add more information to the company's website — designed to provide clinical trial and health-related information to patients and healthcare professionals — comes at a time of increased pressure from lawmakers to publicly release the outcomes of all clinical trials. Lilly said the overhaul will be completed in the fourth quarter.

The registry will include all results from the company's Phase I through Phase IV clinical trials on the registry, including initiation data of all Phase III and Phase IV studies. Predefined and secondary outcome measures specified in clinical study protocols will be published, as well as additional safety and efficacy results that affect patient care, the company said.

Results that do not support the hypothesis being tested or that are contrary to the expected outcome will be disclosed in the registry as well, Lilly said.

"Lilly understands that patients, customers and critics are looking for transparent answers that provide value to the healthcare decision-making process," said Sidney Taurel, Lilly's chairman, president and chief executive officer.

Lilly's new data standards will cover all clinical trials completed after July 1. The registry will also be populated with results of core safety and efficacy information of marketed products approved since July 1, 1994. Lilly said it would assign an independent third party to audit and verify adherence to its disclosure standards.

Lilly's announcement comes amid growing controversy over the suppression of negative clinical trial data. Delays by pharmaceutical manufacturers in reporting the results of clinical drug trials to a federal internet database have led several senators to call for the creation of a national registry of drug trials that would considerably expand the scope of the existing database at clinicaltrials.gov (PCR, July 21, Page 5).

Last month, PhRMA adopted voluntary guidelines asking pharmaceutical companies to make all clinical trial data publicly available, whether the results are positive or negative.

Those familiar with the clinical trials process believe Lilly is pursuing the wisest course by making its trial results public.

"Lilly's bold step sets the bar at a new and high level," said Susan Torroella, chief executive officer of Columbia MedCom Group, a company that provides accreditation and medical marketing services to healthcare businesses. "All others should follow suit, and are suspect if they do not."

"Studies that are buried and hidden and not available to the public do physicians, patients and educators a grave disservice," Torroella continued. "PhRMA's new statement, and in particular, bold steps like Lilly's, need to be the norm, not the exception."

To view Lilly's clinical trials registry, go to <http://www.lillytrials.com>.

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GUIDANCE IN WORKS FOR SOFTWARE PATCHING

The FDA has started drafting a new guidance to address medical device security, particularly as it relates to software security patches.

Expected to be issued within the next six months, the guidance will detail how the FDA expects manufacturers to keep their products up to date with security patches, which are designed to guard software against viruses and other electronic threats. FDA Deputy Director Brian Fitzgerald outlined the security initiative at the recent 2004 VA Information Technology Conference, an event organized by the Veteran Affairs Department.

Fitzgerald told conference attendees that the guidance will be designed to help manufacturers achieve “technical excellence,” including enhanced testing to improve patching of networkable devices. As part of its initiative to enhance device security, Fitzgerald said the FDA may begin withholding regulatory approvals from firms with poor histories of patching their devices.

Hospitals Express Concern

The FDA’s efforts on the security front were prompted in part by recent complaints from U.S. hospitals, many of which have been voicing concerns that medical device manufacturers are failing to patch Microsoft Windows-based equipment, such as ultrasound and radiology systems, on a timely basis. Hospital IT executives claim that by not installing critical security patches, their electronic devices may be infected with viruses, which could pose a potential safety hazard to patients.

“We have machines that are constantly getting infected with viruses and it’s becoming a real problem because we can’t do anything to plug these security holes. We’re at the mercy of the manufacturer,” said a Massachusetts hospital executive, who wished to remain anonymous. “There have been no patient injuries as a result of

the viruses, but they have caused problems with some equipment.” The executive explained that some virus-affected devices no longer are able to transmit information to bedside screens.

In an effort to take matters into their own hands, some hospital IT administrators have started installing patches to device software themselves, but such action can get them in hot water with equipment providers. “We haven’t gotten to that point yet, because our equipment contracts with certain vendors would be voided if we do it on our own,” the Massachusetts executive said. “That’s too much of a risk for us to take.”

Patching Challenges

One reason manufacturers are often slow to patch their medical devices is because they are required by federal law to test and then authorize patches released by Microsoft and other software vendors before they can be installed. That process can be time-consuming because it requires additional validation efforts to ensure that the software patch doesn’t interfere with the operation of the device.

“The process of validating a security patch can take as short as a few days or as long as a few months, but in most cases it’s not something that can be done immediately,” said an executive with a device firm that provides radiology equipment to hospitals. “Our most important goals are safety and effectiveness and speed has to take a backseat to that.”

While devicemakers acknowledge that they can be slow in authorizing security patches, they also contend that hospitals and other facilities where electronic devices are used must do a better job with security to reduce network vulnerabilities.

“The security threats don’t start with our equipment, they start with a virus or a worm getting into the hospital’s network,” said the device firm executive. “Our customers have to take steps to ensure that they aren’t leaving their systems open.”

GUIDANCE, *from Page 2*

“It will expand the concepts of risk-based controls to all areas and to legacy systems,” Huber predicted. The guidance will, for example, discuss issues such as limiting system access to authorized individuals and the use of operational system, authority and device checks, as well as training and training records.

Browning noted that given the FDA’s increasing focus on risk assessment, the agency will likely try “to insert the word ‘risk’ in every conceivable location within the guidance.” That approach won’t be effective, however, if the agency doesn’t define what the risks are, he said.

“Unfortunately, [in previous guidances] the FDA has not thoroughly defined what the concept of risk is, and that ... leaves companies in a very awkward position when they try to comply,” Browning said.

“The agency is talking more and more about risk today than ever before, and yet we’ve got medical mistakes as one of the top 10 causes of death in the U.S.,” Browning added. “I’m sorry but a significant number of those medical mistakes are either caused by poor quality software or are not prevented by the poor quality of software,” he added.

Another likely goal of the guidance, predicted Browning, will be building the concept of enforcement discretion. “This is going to be difficult to do because the agency has not developed a lot of guidance relative to clinical data systems or software,” he said. “To build in discretion where there is very little guidance and very little real hard regulatory information is always awkward.”

Huber countered that enforcement discretion will not “play a major role, since enforcement discretion will go away with the final Part 11 rule and the FDA will not want to update the guidance again at that time.”

The April 1999 guidance covering clinical trial data can be accessed at http://www.fda.gov/ora/compliance_ref/bimo/ffinalcct.htm.

To view ACRO’s comments, go to <http://www.fda.gov/ohrms/dockets/dailys/04/july04/071204/04N-0133-emc00058-01.doc>.

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CMS TECHNOLOGY COUNCIL TO FOCUS ON CLINICAL RESEARCH

The Centers for Medicare & Medicaid Services (CMS) has formed a new technology council to boost clinical research efforts for medical technologies and improve Medicare beneficiary access to innovative products.

Formally launched on Aug. 13, the Council on Technology and Innovation will support CMS in its efforts to develop better evidence on the safety, effectiveness and cost of new and approved technologies to help promote their effective use.

The council consists of two working groups: one focused on clinical research activities and the other on product innovation. The clinical research group — dubbed Better Evidence — will identify priorities for Medicare-supported research on treatments for which important questions about their effectiveness or cost persist and where additional or better information to answer these questions could help guide more effective decision making by doctors and patients. The study group will also be tasked with developing study methods for gathering reliable evidence of the clinical benefit of new technologies through simple protocols, registries and other methods.

The second working group — dubbed Effective Innovation — will develop ways to improve the timeliness and efficiency of the coverage, coding and payment processes. CMS said that specific steps to achieve this goal include facilitating greater stakeholder understanding of the coverage processes, ensuring those processes are based on the latest scientific knowledge and creating opportunities for stakeholders to communicate with CMS.

“Many new drugs and devices in development today are based on promising but highly distinctive technologies that may have little precedent,” asserted CMS Administrator Mark McClellan, adding the “Medicare law gives us new opportunities to help patients get the most out of them.” The council will, in turn, “work to anticipate these new technologies and create ways to make their transition to Medicare coverage as predictable and fast as possible,” he noted.

The council will be co-chaired by Herb Kuhn, director of CMS’ Center for Medicare Management, and Sean Tunis, director of CMS’ Office of Clinical Standards and Quality, who will oversee an independent staff of senior level CMS professionals and clinical experts.

CALENDAR

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BRIEFS

GSK Deploys Electronic Data Capture

GlaxoSmithKline has signed a multiyear agreement to use Phase Forward's InForm solution to electronically capture all of its clinical data. Already a customer of Phase Forward's clinical data management solution, Clintrial, GSK plans to use InForm along with Phase Forward consulting and support services for all of its Phase I-IV clinical trials. "This electronic data management initiative promises to be an important tool in managing a larger number of trials while restraining costs," said Ted Chin, GSK eDM project leader and vice president of biometrics and data sciences.

Report Examines Brand Security

Consulting firm Best Practices has released a new report examining how brand security functions are organized and resourced to effectively safeguard against counterfeit products across business units and geographies. Many pharmaceutical companies have begun to crafting comprehensive strategies to fend off the assault from drug counterfeiters, according to the study, entitled "Safeguarding Against Counterfeit Products: Developing the Pharmaceutical Brand Security Function." Best Practices concluded that for many companies the brand security function is centralized but only a few companies have created permanent department whose primary role is to protect their brands from counterfeiters, pharmaterrorism and other illegal operations. Companies profiled in the report include 3M Pharmaceuticals, Abbott Laboratories, Aventis, Merck, Pfizer

and Procter & Gamble. For more information about the report, go to <http://www.best-in-class.com>.

IT Vendors Launch Café Rx

In effort to spur the adoption of electronic prescribing, nine healthcare IT solution providers have joined forces to formed Café Rx. To encourage the adoption of eprescribing, Cafe Rx will provide payers and physicians with successful strategies and best practice models; offer extensive information on eprescribing through its website (<http://www.caferx.org>); launch a program to educate physicians and their office staffs about the value of eprescribing; and support lobbying efforts that urge federal and state governments to adopt eprescribing and electronic medical records.

Mayo Collaborates With IBM

The Mayo Clinic and IBM have launched a broad collaborative effort aimed at using technology to accelerate advances in healthcare, research and education. The goal of the joint effort is to take advantage of an explosion in new medical data to drive tighter linkage between research and the practice of medicine to achieve breakthroughs, according to the organizations. Under the collaboration, Mayo Clinic will become the first medical institution to use IBM's Blue Gene super computer. It will use the super computer to advance its work in molecular modeling for disease research. The organizations are also looking to use technology to map current and historical patient records and link them to new types of medical information.



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