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SPECIAL REPORT: E-RECORD GUIDANCE MAY ADD COMPLIANCE REQUIREMENTS

The fourth of the FDA's six planned Part 11 guidances covers the agency's expectations on the maintenance of electronic records. The document identifies not only how electronic records should be maintained, but also spells out the roles and responsibilities of specific personnel at your company.

In this special report, *Part 11 Compliance Report* asked three leading consultants to walk us through the guidance and highlight where changes occur and how they can impact FDA-regulated drug and device firms.

Participating in *PCR's* expert panel were: Rita Geiger, president and chief executive officer of InfoStrength; Ty Mew, president of Ofni Systems; and consultant and former FDA reviewer Joshua Sharlin.

The "Draft Guidance for Industry, Electronic Records; Electronic Signatures, Maintenance of Electronic Records; Availability" contains several changes that could make compliance more difficult for regulated firms, the experts noted. In general, the requirements are tougher than they had been in terms of standard operating procedure (SOP) demands, for example.

Changing Technology

"It's not surprising that a lot of procedural elements are required," Geiger said. "Established quality procedures that are properly maintained and followed provide repeatability and accountability for actions." That also translates into additional costs in time and resources for regulated firms, she added.

Mew said he was heartened to see that the guidance recog-

(See **GUIDANCE**, Page 2)

GENOMICS FIRM INSTALLS NEW PART 11-COMPLIANT SYSTEM

After a rigorous three-month search and tough testing for three finalists, Exelixis has installed its new Part 11-compliant system. Kimberly Manhard, vice president of regulatory affairs, said the genomics firm was lucky in that it did not have any legacy systems or legacy data to wrestle with.

Exelixis selected Livelink from OpenText in late June, bought it in July and completed the installation in the final weeks of August. The company will deploy its Part 11 system Sept. 30, thereafter using it as the official repository for all mandated records, Manhard said.

Livelink is a collaboration and knowledge management software system that includes real-time and asynchronous team collaboration, knowledge/document and records management, business process automation, enterprise group scheduling and information retrieval services.

“We looked at three systems seriously from a drug development, bioinformatics and bibliomics user standpoint, and Livelink was the best system for all three groups,” Manhard said.

Exelixis put all three vendor finalists through tough on-site testing, and Manhard said the race was close, but OpenText – as opposed to another finalist, Documentum – offered excellent out-of-the-box functionality that lowered installation costs. In fact, installation and validation of the IQ and OQ modules was handled within two weeks, Manhard said, noting that she’d seen installations take months.

Training Important

Manhard said Exelixis went with OpenText’s Livelink because the system is well laid out and easy to learn. These features were demonstrated during a single-day of training for the dozen Exelixis system users, she said. Even the more intense three-day training session for the subset of heavier system users went smoothly, she reported.

Industry observers have noted that Livelink is becoming a popular choice for Part 11 compliance. Consultant Debbie Fulton Egbert told *Part 11 Compliance Report* earlier this month that one of her clients also chose that system (*PCR*, 9/4, Page 1).

Exelixis is a genomics-based company focused on the discovery and development of innovative new drugs for cancer and other major human diseases. Most of its employees are engaged in research.



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