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Prepare To Go Paperless

If you're looking to streamline your record-keeping and reporting practices, electronic records management systems can help. A recent calibration management initiative at Schering-Plough underscores the point.

Article written by Editor in Chief Tom von Gunden - ***Pharmaceutical Online***

Schering-Plough has made the transition to a paperless system for managing instrument calibration records. Frankly, I applaud this initiative. Given the pharmaceutical manufacturing industry's relatively cautious approach to adopting electronic records-keeping systems, Schering-Plough's decision to dispense with paper in the critical (in terms of GMP) arena of calibration is significant. If nothing else, it suggests that the FDA's reinterpretation of the scope and application of 21 CFR Part 11 — emphasizing risk-based, validation-related processes — will accelerate change. By narrowing the parameters regarding which records, processes, and systems Part 11 affects, the reinterpretation invites companies to more selectively pinpoint critical areas for a transition to electronic records and signatures.

But, the paperless calibration-management initiative at Schering-Plough reveals more than just an FDA-supported willingness to rethink records-keeping approaches. It also shows the company proactively seeking efficiency gains, as well as increased assurances of process control.

As I learned in a recent conversation with Schering, it is already achieving reductions in the space, time, and labor commonly associated with maintaining calibration records. Additional operational benefits include streamlined workflows for calibration approvals; tightened change control; and centralized, standardized system administration.

It's good to see Schering-Plough (or any pharmaceutical company, for that matter) reap benefits like these. After all, many organizations in other vertical industries, including other types of manufacturers, are already accustomed to using electronic records management systems to manage both critical and non-critical information. And, in those industries, compliance-based concerns have tended, ironically, to prompt adoption at faster rates than in the highly regulated yet seemingly more change-reluctant pharmaceutical industry.

When I chatted with the folks from Schering-Plough, they were obviously thrilled with the success of the project. In just 18 months from project inception (in pharma time, that's nearly overnight), Schering moved all calibration record-keeping activities, across multiple facilities, to a single electronic platform. The system it chose was ProCalV5 calibration software from Prime Technologies. Joining me for the conversation about the implementation at Schering were Louis Mezzina, manager of subcontract services; Lorenzo Forlini, calibration systems engineer; and Al Martino, principal engineer of computerized maintenance systems. All have been involved, in some capacity, with electronic records management and workflow processes steered by ProCal.

Earmarking the calibration process for transformation was no small decision. Mezzina confirmed the criticality of records in this area. "Calibration is the foundation of all the practices we have at Schering. It supports early discovery, API development, manufacturing, quality testing, and so on," Mezzina asserted. "When you qualify a piece of equipment, you're relying on values from a calibrated instrument. To maintain control of your processes, it's crucial to have accurate record keeping, efficient workflow, and timely alerts regarding calibration and qualification. After all, a problem with just one instrument could affect many batches."

Before it installed the new system, Schering had been creating and maintaining calibration records on paper forms — typical of traditional industry practice. As is the case with any paper-based system, large volumes of records can require significant effort from the people involved in routing documents and managing the archive. For an instrument to receive calibration approval, the form associated with that instrument has to be reviewed and signed by four people, from four different areas of responsibility. Each day, Schering performs approximately 125 calibrations or updates. Each month, it pulls the master records for more than 2,000 instruments so that technicians can perform calibration checks according to schedule. By the time the company decided to bring in an electronic system, the company was maintaining a paper file repository containing more than 30,000 calibration records.

The ProCal-based electronic system eliminated the need for a paper repository. It also greatly streamlined the process of capturing calibration information and approval signatures that must be included in the master record. One key component is the software's workflow functionality. Check-in/check-out protection, for instance, ensures document change control: Only one calibration record for a particular piece of equipment can be open for data input at the same time.

Mezzina also noted that the electronic system supports the company's calibration maintenance. "The system alerts us when calibrations are due or overdue. That helps when we assign strategies and resources for scheduling calibrations," Mezzina explained. "Plus, since we outsource our calibrations, invoicing for those services is done in a much more timely fashion. We can run reports that show exactly which instruments were calibrated in a particular billing period."

Schering-Plough is clearly reaping benefits from installing the electronic system. I was glad to learn, too, that users made a smooth transition to the new way of creating and managing calibration records. I had been imagining, for instance, some uneasiness about dispensing with the traditional clipboards and paper forms. According to Mezzina, one key to getting everyone up-and-running on the electronic system was mobility. In fact, the mobility factor strongly influenced Schering's choice of software. "ProCal is specifically designed to run on a mobile platform," he said. "Once people saw that using mobile PCs instead of carrying clipboards gave them increased access to information and actually aided the data entry process, they embraced the new system. They saw how it could make them more effective."

The story I got from Schering stands, in my mind, as a strong testimonial for going paperless, at least in the area of calibration management. It's also a clear example of how adopting new technology can drive process improvement, something your organization strives to achieve, I'm sure. Process improvement is something the FDA wants to see, as well. The issuing of the PAT (process analytical technology) guidance is one important sign. The interpretation of how 21 CFR Part 11 applies to critical, risk-based processes is another. Yes, electronic records-keeping systems and practices will exert a steadily growing force on quality monitoring for pharmaceutical manufacturing. Put in terms of old technology, the writing's on the wall.

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