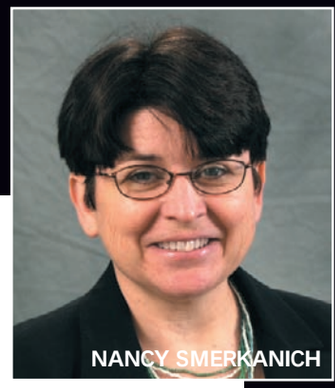
Contributed by Nancy Smerkanich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REGULATORY UPDATE ON THE FDA PUBLIC HEARING

The U.S. Food and Drug Administration (FDA) called a Part 15 (21 CFR Part 15) hearing on Dec. 18, 2006, primarily as "a listening exercise" to gather information so that the agency could move forward to "an all electronic submission environment and electronic data exchange platform," as Former Deputy Director of the FDA Dr. Janet Woodcock said. Recently, Dr. Woodcock, who is now deputy commissioner for operations for the FDA, also stated that the FDA will take a stepwise approach to implementation of these initiatives. One of the presenters, however, paraphrasing Shakespeare said, "We came not to praise paper, but to bury it."

The FDA also promised swift action (i.e., final rule making) coming out of this meeting. The 14 presentations were made by a variety of stakeholders, representing industry, vendors, and professional groups (PhRMA). All of the presentations were directed to a panel, including, among others, Dr. Woodcock, Dr. Randy Levin, and Dr. Armando Oliva from FDA/CDER, and representatives from the NIH, the NCI, and the FDA's legal counsel.

INDUSTRY FEEDBACK

Dr. Al Edwards from TAP Pharmaceuticals was the first presenter at the conference, and he shared the experience of his company, not just in moving to electronic submission but to the electronic common technical document (eCTD) for all of TAP's active applications. Dr. Edwards highlighted the benefits of this submission format as well as the challenges, including, but not limited to, establishing and retaining trained staff to perform the kind of skills required to work in an all-electronic environment.

A number of other presentations focused on specific tools or platforms that exist to support electronic data collection, data, and document standardization, as well as data exchange. A diverse group of stakeholders, including representatives from industry, academia, and patients, presented on the CRIX Project (the Clinical Research Information eXchange); they shared their insights into the collection of clinical investigation materials and warehousing. Another presentation focused on data standards (CDISC) and representatives from PhRMA shared their vision of a five-year implementation period for this type of change. One of the final presentations of the day was made by a representative of the Regulated Product Submission group, associated with HL7, who outlined for the panel and attendees the future of all regulatory submissions, which is a messaging standard for all of the areas under the FDA umbrella and one that is based on XML technology, similar to eCTD.

I should mention here that I also had the opportunity to present at this meeting. My presentation was based on the results of an informal survey conducted as part of an e-mail blast sent to Octagon's regulatory contact list announcing the meeting; an overwhelming response was received primarily from small pharmaceutical companies asking that their concerns be expressed. Our survey asked five questions, many of which were taken directly from the Docket, about transitioning to and implementing electronic submissions. The questionnaire also provided for an open comments area, which was greatly used.

Across all respondents, there was a 50/50 split among those who had moved to providing electronic submissions vs. those who had not. Among respondents who had not made the transition there was a consistent set of reasons: time, costs, expertise, training, resources, and process change. For the companies that had moved to electronic submission they cited the following benefits: ease of use/review, speed (compilation), accuracy, compatibility, harmonization, document standards, and document reuse.

The presentation also provided a time and cost comparison between paper and electronic based on our experiences. This model based on our outsourcing model, which takes into account the use of validated tools, a pressure-tested process, and trained staff, consistently shows that as submission size increases the cost and time to compile the dossier goes down. Overall, the conclusion I was able to draw was that despite the challenges and impediments of implementing an electronic submission solution, the benefits are worth it.

A REGULATORY CRYSTAL BALL

During the course of the hearing only the panel was allowed to ask questions, and at the conclusion of the meeting those present were allowed to make comments that would be entered into the transcript. The panel seemed very interested in a couple of points: first, the presenter's views of mandates for electronic submissions vs. incentives and second, profit vs. nonprofit models for the hosting environments. Clearly, the agency is considering these options as it moves forward on its own e-initiatives.

If there were such a thing as a "regulatory crystal ball" that would allow us to make predictions on the future of FDA submissions, a number of things might become clear, based on this meeting and other recent activities:

- The FDA is clearly moving to mandate eCTD.
- The FDA is clearly moving to mandate CDISC formatted data.
- Beyond eCTD, the FDA is moving to require postmarket surveillance.
- The FDA is interested in using a hosted environment for these initiatives.
- The FDA will, at some point in the not so distant future (my money is on by 2010), not accept paper for submissions.

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