Preparing for eMDR

On February 13, 2014, FDA issued the final rule for eMDR. The rule is effective on August 14, 2015.

For the manufacturer, the eMDR set-up on the surface can be simple, but there are a lot of details. The overall approach has four basic steps:

- Update MDR procedures to utilize electronic transmission.
- Implement a method to format the MDR information in the eMDR format.
- Implement a method to transmit the information in the eMDR format to the FDA's Electronic Submission Gateway (ESG).
- Review the acknowledgements that the FDA sends and keep them as quality records to demonstrate that the MDR was loaded into the database.

Update MDR Procedures

While the information required in an MDR has not changed, the transmission method has. This means the procedures that describe investigations, deliberations, *etc*. remain unchanged. As a number of pre-eMDR Warning Letters show, however, FDA expects the procedure to include instructions to obtain the 3500A form, instructions to fill it out, and instructions, including the mailing address, on how to send it.

Under eMDR, there is no form, as such, to obtain. Instead, it is only an electronic record, using the appropriate software package, and sends it electronically to FDA. As a result, this portion of the procedures needs to be revised, approved, and issued. In addition, employees need training on the new methods, which will generate training records.

§803.12(a) requires the manufacturers and importers submit initial, supplemental, or follow-up reports to FDA in an electronic format. This is a change for the current regulation that requires submissions to FDA, CDRH, Medical Device Reporting, P.O. Box 3002, Rockville, MD 20847-3002.

The set of Acknowledgements, described below, become quality records stored in the MDR Event File. Therefore, any references to the event file's content must also be updated.

Implement the Software to Generate the Report

The manufacturer has two choices.

Small volume reporters will use the free software package from FDA call eSubmitter. It generates one MDR at a time from data the reporter keys in.

Large volume reporters will need to build or buy a software package that produces the reports in the HL7 Individual Case Safety Report (ICSR) format. This method can create MDRs in batches using information from an existing database.

Implement a Method to Transmit the Report
With the files produced, the manufacturer must transmit them to FDA's Electronic Submission Gateway (ESG).

For low volume reporters the choice will be a WebTrader set up with FDA. High volume reporters can use any B2B or EDI solution that is AS2 compliant. This is Applicability Statement 2, which is an electronic submission protocol that uses HTTP/HTTPS for communications.

In either case, the manufacturer must go through a number of steps.

- Ask FDA for a Test Account to demonstrate the proper capability
- Send a letter of nonrepudiation to FDA that states the electronic signatures in the files are valid as handwritten signatures.
- Obtain personal digital certificates for each person submitting files. This sets up a public key/private key encryption system.
- Generate test files. The number and type of files depends on the transmission method.
- Submit the test files and receive a report that the tests were successful.
- Migrate from the Test Account to a Production Account.

Review and Store Acknowledgements
When the manufacturer sends the files to ESG using a Production Account, they follow a process to load into the MDR database.

When ESG receives the files it sends Acknowledgement #1 with the date and time of receipt. Assuming the subsequent steps are successful, this is the date and time of submission.

ESG will send the files to CDRH and send Acknowledgement #2 to the manufacturer.

CDRH will receive the files, perform error checks, and, if successful, load them into the MDR database. If the files don't pass the error checks, CDRH will generate an error report. In either case, CDRH sends Acknowledgement #3.

If there are errors, the manufacturer fixes them and resubmits. This starts the acknowledgement process again.

When Acknowledgement #3 shows the files were successfully loaded, the set of three Acknowledgements become quality records sorted in the MDR Event File.