Medical Device Subteam Meeting Minutes
Teleconference
24 February 2011

Attendees:

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* Facilitator and meeting minutes

Agenda:

I. The meeting minutes from February 10, 2010 were approved as written.

II. Announcements

There will be an SPL Technical Team meeting on Monday, February 28th. Agenda will include mostly SPL drug-related implementation issues. Technical issues pertaining to implementation of SPL for all regulated products (drugs, biologics, devices, etc.) will continue to be discussed in the SPL Technical Team meeting which meets every other Monday. If you are receiving meeting invitations for this meeting (Medical Product Information), you will be getting meeting invitations for the Monday meeting as well. The same call-in number and conference code are used.

III. XFORMS testing

As discussed during the last meeting, we are seeking volunteers to test the new XFORMS SPL editing tool. So far, we have nine volunteers. There is room for more. So if you have an interest, please join the group.

Testing plan:

1. The pilot test will start after the XFORMS demonstration on February 24th.
2. There is interested in getting feedback on all SPL doctypes (drugs, devices, and biologics). If you are testing devices, try sampling a variety of device types (catheter, stent, ICD, ICD w/ accessories, combination products (such as pre-filled syringe, drug-device kit, etc.). For devices, it would nice to have both "UDI submission" and "Medical Device Home Use" submission types.
3. Try to find any software bugs, comment on features that you like or dislike, or make suggestions for possible features.
4. There will be two weeks to submit comments.
5. No format to follow while conducting the review.
6. Send your comments to me (myron.finseth@medtronic.com). I will collate all comments, re-route them to all participants for final edits, and then send them off to Gunther and Lonnie Smith at the FDA when complete.
7. E-mail me with general questions. For technical questions, e-mail Gunther (gunther@pragmaticdata.com).

IV. XFORMS demonstration (Gunther Schadow)

To get to the web-based tool, you will need to register at the Pragmatic Data website.
http://pragmaticdata.com

Once registered, the tool is located at:

http://pragmaticdata.com/spl/form/

Notes from the demonstration:

1. The tool is offered as a web-based editor. You can load and save files to your local drive using the software that is located on the Pragmatic server. The web-based editor will always be the latest version of the tool. It can be used with Internet Explorer 6.x and up with some issues (better to use version 7.x or 8.x), Google Chrome, Firefox, and Safari. Gunther is interested in people trying out all types of web browsers.
2. The tool includes templates for device and drug submissions (Home Use Medical Devices, UDI submission, Labeler Code Request, Establishment Registration, Drug listing, Substance Indexing.
3. Gunther wanted to make clear that we still do not know what the FDA's UDI requirements will be. The XFORMS tool is just a "playground", or an example of Gunther's "crazy ideas" for the industry to use for experimentation. The Proposed Rule is expected to be posted in late June.
4. Technical problems you may experience with the tool might be solved by clearing all "temp internet file" caches.

5. You can edit the xml source text/code using the “XML view” feature.
6. The discussion of validation tools may be a good subject to consider for future meetings.

Additional notes on the testing:

7. The group encouraged participants to share sample SPL files with the group. Send your samples to me (Myron) and I will distribute them to the rest of the participants when the comments are submitted.

V Next meeting is tentatively schedule for March 10th, 2011 (10:30 a.m. eastern)