

SG2 meeting highlights from Ottawa, Canada,
Dates: 18-20 October 2000

Study Group 2 (SG2) along with the other Study Groups of the Global Harmonization Task Force (GHTF), met in Ottawa in conjunction with activities of the 2000 Plenary and specialty meetings of the GHTF. The following information provides the highlights of the SG2 meeting.

The SG2 meeting was Chaired by Dr. Larry Kessler and attended by 18 members of SG2, as well as 14 interested observers from industry and regulatory agencies around the world.

N21: manufacturer reporting

The first order of business, after approval of previous meeting minutes, was to hear an update from participant NCA reps as to what steps have been completed towards the implementation of N21. This documents gives guidance on what does and does not need reported by the manufacturer to the NCA.

Briefly, implementation updates were as follows:

FDA notes that some regulatory changes will be necessary, and proposed changes will need to be published in the Federal Register, with a minimum of 60 days provided for public comment. It is hoped this process will be completed by February 2002.

Canada expects to draft guidance in reference to N21. It is noted that summary reporting and exemptions to reporting pose special challenges. Writing of the guidance has not yet commenced.

Australia is writing medical device law currently. Once the laws are in place, guidance will be drafted referencing N21. Hopefully the new laws, and guidance to N21 will be in place by 2001.

The European Union hoped to publish guidelines in July 2000. This is yet pending, but is imminent. Some reporting exemptions pose special challenges, and require careful language. No date predicted for revisions to the current European reporting guidelines.

Japan cannot currently change medical device laws. Until regulatory changes occur, the Ministry of Health will work with the Federation of Medical Devices Associations to draft guidelines relative to N21. Some reporting exemptions require careful use of language for Japan also.

N20: National Competent Authority Report (NCAR) Exchange Program & N38: Application Requirements to participate in the NCAR program

Kim Dix provided a graphic presentation to illustrate the data from the NCARs exchanged to date. In summary, nine (9) countries have exchanged a total of 86 reports since January 1999. Members identified a variety of issues that need resolution before the program can be expanded, but all participants agree that the information exchanged is very valuable and we want to be able to expand international participation. Some key elements to resolve include (but are not limited to): global assurance of confidentiality of the data in the NCAR, training of new participants, as well as distribution and maintenance of the NCARs and evaluations.

General overview of document status

There are two guidance documents that need minimal and non-substantive changes, then will be ready to be released for public comment. They are:

1. N32: The universal dataset for manufacturer reports to the NCA
2. N36: Manufacturer's trend reporting of adverse events

Additionally, SG2 has generated a number of documents that do not give guidance or make any practice recommendations. These documents are intended to provide background information. There are three documents of this type that will be posted on the SG2 website and updated regularly. They are:

1. N6: Comparison of Regulatory Reporting Systems- updated August 2000
2. N12: SG2 Précis- provides overview of SG2 goals and activities- being updated as of September 2000
3. N30: Known and well-characterized adverse events / periodic summary reporting and reporting exemptions- revised August 2000

Documents still in working draft phase were discussed, with some language suggestions presented and debated. No consensus has yet been reached on the following two documents:

1. N31: Reporting of adverse events associated with use/r error
2. N33: Timeframes for manufacture's reports to NCAs

Also presented during this meeting were:

- Update on the GMDN project
- Update on the EUDAMED project
- To whom manufacturers should report adverse events - conceptualizing a global database, among other things
- TC210 workplan for device problem codes
- How to handle unsolicited NCARs

The next meeting for SG2 will be held in Sunnyvale California at the end of February 2001.

This report submitted on 5 October 2000 by Deb Blum, Exec Sec for SG2. Persons wishing additional details should contact Deb at dyb@cdrh.fda.gov