MEDIMARK® EUROPE NEWS **January 07, 2010**

European Commission Publishes New MEDDEV Guidelines

The end of 2009 turned out to be a very prolific period for the publication of new or updated guidelines. The documents published in December explain or incorporate changes introduced by Directive 2007/47/EC amending Council Directive 90/385/EEC and Council Directive 93/42/EEC, which will be applicable on March 21, 2010. The first issue of the MediMark Europe News in 2010 seems like a perfect opportunity to raise awareness of three new EC guidelines related to quality systems.

MEDDEV. 2.7.1 Rev.3
Clinical Evaluation: A Guide for Manufacturers and Notified Bodies is a revision of an earlier document published in April 2003 as MEDDEV 2.7.1. It incorporates changes introduced by Directive 2007/47/EC. Even though it was published in December 2009, it states that the gradual implementation of the guidelines will end on March 20, 2010!
The guide describes three main stages:

1. Sources of data/documentation used in a clinical evaluation (Stage 1)
2. Appraisal of clinical data (Stage 2)
3. Analysis of clinical data (Stage 3).

The annexes are very informative, especially Appendix A: A Possible Format for the Literature Search Report and Appendix E: A Possible Format for a Clinical Evaluation Report. The guide also includes Appendix F, a clinical evaluation checklist that your notified body's auditor will use to evaluate this important part of a technical file.
A PDF of the 43-page document can be downloaded from http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf.

MEDDEV 2. 1/3 rev 3
This document applies to borderline products, drug-delivery systems, and medical devices that incorporate, as an integral part, an ancillary medicinal substance or ancillary human blood derivative. The third revision will become effective on March 21, 2010, as it includes amendments introduced by Directive 2007/47/EC. Editorial corrections on C.4.h were published on December 22, 2009.
As in revision 2, the document provides useful examples of drug-delivery products and medical devices that incorporate, as an integral part, an ancillary medicinal substance, which are regulated either as medicinal products or as medical devices. The section concerning the consultation procedure related to devices incorporating, as an integral part, an ancillary medicinal substance or ancillary human blood derivative has been updated to reflect changes introduced by Directive 2007/47/EC.
The 21-page document can be downloaded as a PDF file at http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_1_3_rev_3-12_2009_en.pdf

MEDDEV 2.12-1 rev 6
Revision 6 of MEDDEV 2.12-1, Guidelines on a Medical Devices Vigilance System, incorporates technical modifications to Annex 3 (Report Form - Manufacturer's Incident Report). The April 2007 version of MEDDEV 2.12-1 remains otherwise unchanged.

It is important to remember that reference to this new version shall be included in the manufacturer's and authorized representative's vigilance systems. Revised Annex 3 will be applicable on March 20, 2010.
You can download a PDF of Revision 6 at http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_12_1-rev_6-12-2009_en.pdf. A Word version of Annex 3 can be accessed at http://ec.europa.eu/enterprise/sectors/medical-devices/documents/guidelines/index_en.htm

Various other guidance documents were published in 2009. Here are the three most important, in our opinion:

1. Interpretative Document of the Commission's Services, June 2009, Implementation of Directive 2007/47/EC Amending Directives 90/385/EEC, 93/42/EEC, and 98/8/EC. Download at http://ec.europa.eu/enterprise/sectors/medical-devices/files/meddev/2_7_1rev_3_en.pdf.
2. Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices Version 1.5 (09-2009). Download at http://ec.europa.eu/enterprise/sectors/medical-devices/files/wg_minutes_member_lists/version1_5_borderline_manual_en.pdf.
3. Guidance Notes for Manufacturers of Class I Medical Devices 2009-06-03 MDEG – 2009–12-01 MSOG Class I_Guidance. Download at http://ec.europa.eu/enterprise/sectors/medical-devices/files/guide-stds-directives/notes-for-manufacturers-class1-09_en.pdf.

We will update within the next weeks the MediMark vigilance procedures to incorporate the new incident/FSCA forms given in the Revision 6 of MEDDEV 2.12-1.

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