

## § 26.31

### 4. Quality Assurance System

—Pharmacovigilance programme  
—Surveillance/monitoring of implementation of corrective action

### 5. Contact Points

For the purpose of subpart A of this part, the contact points for the alert system will be:

#### A. For the European Community:

the Executive Director of the European Agency for the Evaluation of Medicinal Products, 7, Westferry Circus, Canary Wharf, UK - London E14 4HB, England. Telephone 44-171-418 8400, Fax 418-8416.

#### B. For the United States :

Biologics: Director, Office of Compliance and Biologics Quality (HFM-600), 1401 Rockville Pike, Rockville, MD 20852, phone: 301-827-6190, fax: 301-594-1944.

Human Drugs: Director, Office of Compliance (HFD-300), 5600 Fishers Lane, Rockville, MD 20857, phone: 301-827-8910, fax: 301-827-8901.

Veterinary Drugs: Director, Office of Surveillance and Compliance (HFV-200), MPN II, 7500 Standish Pl., Rockville, MD 20855-2773, phone: 301-827-6644, fax: 301-594-1807.

[63 FR 60141, Nov. 6, 1998, as amended at 69 FR 48775, Aug. 11, 2004]

## Subpart B—Specific Sector Provisions for Medical Devices

### § 26.31 Purpose.

(a) The purpose of this subpart is to specify the conditions under which a party will accept the results of quality system-related evaluations and inspections and premarket evaluations of the other party with regard to medical devices as conducted by listed conformity assessment bodies (CAB's) and to provide for other related cooperative activities.

(b) This subpart is intended to evolve as programs and policies of the parties evolve. The parties will review this subpart periodically, in order to assess progress and identify potential enhancements to this subpart as Food and Drug Administration (FDA) and European Community (EC) policies evolve over time.

### § 26.32 Scope.

(a) The provisions of this subpart shall apply to the exchange and, where appropriate, endorsement of the following types of reports from con-

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formity assessment bodies (CAB's) assessed to be equivalent:

(1) Under the U.S. system, surveillance/postmarket and initial/preapproval inspection reports;

(2) Under the U.S. system, premarket (510(k)) product evaluation reports;

(3) Under the European Community (EC) system, quality system evaluation reports; and

(4) Under the EC system, EC type examination and verification reports.

(b) Appendix A of this subpart names the legislation, regulations, and related procedures under which:

(1) Products are regulated as medical devices by each party;

(2) CAB's are designated and confirmed; and

(3) These reports are prepared.

(c) For purposes of this subpart, equivalence means that: CAB's in the EC are capable of conducting product and quality systems evaluations against U.S. regulatory requirements in a manner equivalent to those conducted by FDA; and CAB's in the United States are capable of conducting product and quality systems evaluations against EC regulatory requirements in a manner equivalent to those conducted by EC CAB's.

### § 26.33 Product coverage.

(a) There are three components to this subpart each covering a discrete range of products:

(1) *Quality System Evaluations.* U.S.-type surveillance/postmarket and initial/preapproval inspection reports and European Community (EC)-type quality system evaluation reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.

(2) *Product Evaluation.* U.S.-type premarket (510(k)) product evaluation reports and EC-type-testing reports will be exchanged only with regard to those products classified under the U.S. system as Class I/Class II-Tier 2 medical devices which are listed in Appendix B of this subpart.

(3) *Postmarket Vigilance Reports.* Postmarket vigilance reports will be exchanged with regard to all products regulated under both U.S. and EC law as medical devices.