Questions and Answers on Current Good Manufacturing Practices, Good Guidance Practices, Level 2 Guidance

General

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1. Are USP general chapters above <999> considered equivalent to FDA guidance? What are their purpose and how should manufacturers use these informational chapters?

No, FDA is the only source of policy on pharmaceutical CGMPs and quality. CGMP requirements are found in statutes and regulations, and FDA's current thinking on these requirements is explained in the Agency's guidance documents.

The USP is a private, non-governmental organization. While products labeled as USP are required to meet the criteria in product monographs when tested by the methods of analysis outlined in the tests and assays section, the suggestions found in General Chapters above <999> are only informational. The views expressed in these chapters are solely USP's. As with all information sources, these chapters might include some recommendations that may help a firm meet CGMPs.

References:

- Food Drug & Cosmetic Act
- United States Pharmacopeia

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2. How does one comment on FDA's proposed guidance documents? How about USP proposals?

Both USP and FDA have mechanisms in place for interested parties to make comments on

proposed documents.

1. Guidance Documents

FDA's proposed guidance documents are written using good guidance practices and published for comment per 21 Code of Federal Regulations 10.115. They are easily accessible to the public via our Web site and through the *Federal Register* Web site (http://www.gpoaccess.gov/fr/index.html). FDA's Division of Dockets Management (DM) is the office responsible for receiving all comments on proposed guidance. Interested parties can read and submit comments via FDA's Dockets Management Web site (http://www.fda.gov/ohrms/dockets/default.htm). FDA reviews all received public comments, makes appropriate modifications, and publishes a final document.

2. USP Monographs

USP publishes proposed chapters or monographs in the Pharmacopeial Forum, a publication that is issued bimonthly. USP subscribers have access to these publications, and can send comments (within a 90-day post publication comment period) for consideration by the USP. Finalized proposals (official revisions, new chapters or monographs) are published in subsequent supplements to, or editions of the Pharmacopeia.

References:

United States Pharmacopeia

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