SMG 2010.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

FDA QUALITY RESOURCE GUIDANCE TEAM

Effective Date: 08/19/2004

1. PURPOSE.

To provide the FDA with quality system design and implementation information, the FDA Management Council establishes a subcommittee to act as an agency resource. This charter describes the duties and responsibilities of the FDA Quality Resource and Guidance Team (QRGT), the organization of its membership, and its operating procedures. This charter also explains the method for establishing expert working groups (work groups) within the QRGT and the responsibilities, organization, and operating procedures of the work groups.

2. BACKGROUND.

In June 2003, as part of FDA's current Good Manufacturing Practices (CGMP) Initiative (http://www.fda.gov/cder/gmp/index.htm), the FDA formed a Quality System Framework Subcommittee (QSFS), composed of representatives from five out of six of the FDA Centers (CDER, CBER, CVM, CDRH, CFSAN), ORA, and the Office of the Commissioner. The QSFS was charged with developing a quality system framework ("Report on FDA Quality System Framework for Pharmaceutical Product Quality Regulation Activities", December 2003) for FDA pharmaceutical product quality regulatory activities. The charge included:

- defining terms related to quality to ensure common understanding without using jargon,

- describing a basic framework to be used by FDA managers to develop quality systems, and

- providing implementation suggestions.

While the mission of the QSFS emerged from the CGMP Initiative, the ideas, principles, and models discussed could also prove helpful to other FDA components seeking to improve the quality of their own services and products.

A number of FDA programs have already committed to implementing quality systems. Examples include ORA's Quality Control and Quality Assurance (QCQA) initiative, the CGMP Steering Committee, the medical product review programs as part of the Improving Innovation in Medical Technology initiatives, and CBER's Laboratory Quality System Initiative. The Office of the CIO has committed to using the Capability Maturity Model (CMM) for software development, based on concepts closely akin to a quality system.

In some instances, perhaps due to resource constraints, many FDA components have implemented elements of quality systems within individual programs, rather than a comprehensive quality system. For example, CDRH has developed performance metrics using a scorecard approach, the PDUFA programs have concentrated on "process management" and training, and ORA (in addition to laboratory quality systems) is developing a comprehensive, up-to-date set of procedure manuals.

However, until now there has not been an integrated, agency-level effort or focus on quality systems.

At its March 18, 2004 meeting, the QSFS proposed, and the Management Council adopted, the FDA Quality Systems Framework. To implement the Framework, the Management Council the agency would need to prepare an inventory of FDA quality systems activities, Staff Manual Guides for the Quality System Framework and a document outlining the scope of activities for which FDA would implement quality systems and to which FDA would be held publicly accountable.

The Management Council has therefore decided to establish the Quality Resource and Guidance Team (QRGT). As the agency proceeds to develop policies and procedures applicable to the development of internal quality systems, the QRGT will provide a recognizable structure where quality system design and implementation information can be made available.

3. SCOPE.

a. The QRGT reports directly to the FDA Management Council through the Council Chair or Executive Secretary. The QRGT serves as a resource to the FDA Management Council, and to the agency in general, on quality systems. Its specific duties and responsibilities may evolve as the agency gains experience in the use of the quality systems.

b. It is not within the scope of the QRGT to pursue design or implementation of specific quality system activities within any Center or Office unless directed to do so by the FDA Management Council.

4. ORGANIZATION AND RESPONSIBILITIES.

4.1 - The QRGT is responsible for:

a. Identifying and proposing future projects for the budgeting process for final recommendation by the FDA Management Council;

b. Proposing agency-wide applications of quality systems;

c. Identifying information and providing guidance for implementing quality systems including the Quality Systems Framework (projects may be within a Center/Office or may be cross-cutting);

d. Managing, in conjunction with the Staff Manual Guide Staff, the FDA Quality System Framework and quality system-related staff manual guides;

e. Identifying training needs and opportunities related to implementing quality systems;

f. Advising and consulting with Center/Office training units regarding quality system training needs and resources;

g. Identifying, coordinating, prioritizing and developing agency policy required for achieving quality systems standardization;

h. Developing agency-wide communications on quality system issues, including a web site, contact list, list-serve-chat room, and an activity inventory;

i. Providing a forum to discuss specific quality system design or implementation issues;

j. Nominating liaison members for participation in quality system initiatives outside the agency, which impact or describe internal quality system activities.

4.1.1 - The QRGT members are responsible for:

a. Representing their views to the QRGT;

b. Communicating QRGT activities to their respective FDA organizations and obtaining input from their organizations for communication to the QRGT;

c. Attending the QRGT meetings.

4.1.2 - The Chairperson is responsible for:

a. Directing the activities of the QRGT;

b. Coordinating the collection, management and dissemination of QRGT recommendations, decisions, actions and other information related to the responsibilities of the QRGT;

c. Keeping the FDA Management Council Chair and Executive Secretary informed of QRGT progress/activities;

d. Represent QRGT to the FDA Management Council when invited;

e. Recommending formation of relevant work groups;

f. Overseeing the activities of the work groups.

4.1.3 - The Vice-Chairperson is responsible for

a. Representing the Chair in his/her absence;

b. Performing duties delegated by the Chairperson.

4.1.4 - The executive secretary is responsible for the following:

a. Preparing agendas and meeting minutes of each QRGT meeting;

b. Arranging and organizing meeting logistics;

c. Distributing documents to QRGT members;

d. Maintaining records of QRGT activities (i.e. training activities);

e. Ensuring accuracy of QRGT documents.

4.1.5 - Each work group supports the QRGT in its area of expertise. This includes:

a. Advising and assisting the QRGT in responding to agency staff;

b. Developing policies and procedures for the QRGT (when developing policies and procedures, the work group should actively gather input from others in the agency);

c. Responding to questions from the QRGT on specific issues;

d. Documenting meetings with brief minutes.

4.1.6 - Work groups are responsible for:

a. Confirming its objectives with the QRGT;

b. Defining member responsibilities;

c. Providing work products to the QRGT in a timely manner.

4.1.7 - Work group members are responsible for:

a. Representing their views to the work group;

b. Communicating the discussions of the work group to their FDA organizational unit management and obtaining input from them for communication to the work group;

c. Attending the work group meetings.

4.2 - The QRGT is organized as follows:

4.2.1 - Each of the organizations on the FDA Management Council is entitled to appoint at least one member to the QRGT. Members will serve a minimum two-year term but may be re-appointed.

4.2.2 - Other participants, observers, and consultants from within the agency and from other federal government organizations may participate in QRGT activities at the discretion of the Chair and Vice-Chair or the FDA Management Council.

4.2.3 - Work groups may be established under the following circumstances:

a. The FDA Management Council directs the QRGT to establish a new work group to achieve specific objectives or for a specific project.

b. The QRGT identifies a specific need, which could be best addressed by a few members with particular expertise, familiarity or interest in the subject.

4.2.4 - Work groups will have a limited lifetime and will adjourn when:

a. They have successfully completed their goal or;

b. Additional work is not required from the work group as determined by the QRGT or FDA Management Council.

4.2.5 - Work group organization:

a. Each work group will have a Chairperson who will direct the group's activities.

b. The work group chairperson and members are selected by the QRGT from among a list of volunteers or by recommendation. Member selection is based on Center/Office affiliation, qualifications, expertise, and ability to contribute to the work group.

c. Some work groups may contain representatives from other groups within the agency to provide needed expertise.

d. A member of the QRGT will serve on all work groups to provide continuity.

e. Work group membership will generally be kept small (no less than three, no more than eight members).

5. PROCEDURES.

5.1 - In performing these responsibilities the QRGT will:

a. Oversee the preparation of documents intended to communicate and implement consistent, standard policies and procedures related to quality system design and implementation for internal and external use;

b. Establish and oversee work groups for the purposes of fulfilling the QRGT's responsibilities;

c. Review work products (e.g. documents or recommendations) of the work groups before they are circulated for FDA Management Council concurrence;

d. Promote and coordinate workshops and extramural activities, and recommend studies intended to facilitate development or communication of issues related to agency internal quality systems;

e. Maintain records of QRGT recommendations, decisions, and actions;

f. Communicate recommendations, decisions and actions to senior management, staff and other interested parties;

g. Provide input to and work with other committees or agency components as necessary to achieve FDA quality-related goals.

5.2 - QRGT leadership:

a. A rotating Chairperson, serving a six-month term, is elected by the QRGT and ratified by the FDA Management Council;

b. A rotating Vice-Chairperson, serving a six-month term, is elected by QRGT;

c. A rotating executive secretary, serving a six-month term is elected by the QRGT.

5.3 - QRGT meetings:

a. Are held monthly, more frequently if needed;

b. Are announced at least one week prior to the scheduled date;

c. Are summarized in writing within two weeks after they are held, reviewed and approved at the next meeting.

5.4 - Meeting agenda:

a. Proposed agenda items may be submitted by any agency staff to the QRGT e-mail box, through the QRGT web site, or to any member of the QRGT, who forwards it to the Chair and Vice-Chair;

b. The Chair and Vice-Chair will determine if an item will be submitted to the QRGT members and included on the agenda;

c. The decision regarding inclusion of an item on the QRGT agenda is communicated to the individual who submitted the proposal.

5.5 - Voting:

For issues where consensus is not obtained, at the decision of the Chair, the QRGT may vote. Votes are distributed one per agency component represented on the FDA Management Council. Votes are carried by a simple majority of the votes cast. Ties fail. Voting is conducted via e-mail over a minimum of a 3-day period. Balloting is conducted by the Executive Secretary of the FDA Management Council.

6. RECORDS.

a. The Chair and Vice-Chair will assure that QRGT activities including recommendations, decisions, issues, action items, meeting summaries and other pertinent materials attributable to the QRGT are documented and communicated to senior management and relevant staff, as appropriate, in a timely manner.

b. The QRGT web site will generally make these records available to agency staff.

c. At a minimum, minutes record attendees, issues presented, decisions made, the rationale for those decisions, and any outstanding action items.

d. This Charter is reviewed at least annually based on experience gained in the use of the QRGT and revised as needed.

7. EFFECTIVE DATE.

The effective date of this guide is August 19, 2004.

8. Document History -- SMG 2010.1 FDA Quality Resource Guidance Team

VERSION #	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	07/01/2004	N/a	FDA Quality Resource Guidance Team	Janet Woodcock, Chair, FDA Management Council