Subject: **Charter of the Council on Pharmaceutical Quality**

(An FDA Management Council Subcommittee)

SECTIONS

1. PURPOSE

To facilitate FDA's modernization of the regulation of pharmaceutical manufacturing and product quality, the FDA Management Council establishes a Council on Pharmaceutical Quality (herein referred to as Council). This charter describes the duties and responsibilities of the Council, the organization of its membership, and its operating procedures. This charter also sets forth information on the roles and responsibilities of expert working groups deemed necessary by the Council to accomplish the goals and objectives it establishes.

2. BACKGROUND

More than 40 years ago, Congress required that all drugs must be produced in accordance with Current Good Manufacturing Practice (CGMP). This requirement was intended to address significant concerns about substandard drug manufacturing practices by applying quality assurance and quality control principles to drug manufacturing. The last comprehensive revisions to the regulations implementing CGMP requirements occurred almost 25 years ago. In addition, pre-market approval requirements to ensure the quality of approved drugs pertaining to chemistry and manufacturing controls, have also been in effect for many years.

As the 25th anniversary of the last major revisions to the drug CGMP regulations approached, the Agency believed that it needed to step back and evaluate the currency of both the CGMP program and the pre-market review of chemistry and manufacturing issues. In August 2002, FDA announced its undertaking of a significant new two-year long initiative to enhance the regulation of pharmaceutical manufacturing and product quality and to bring a 21st century focus to this FDA responsibility. The initiative was intended to build on the many successes of the inspection and review programs and help them continue to be successful in the future by keeping pace with advances in pharmaceutical science and manufacturing technologies.

The initiative known as *Pharmaceutical CGMPs for the 21st Century: A Risk-Based Approach*, focused on FDA's current good manufacturing practice (CGMP) program, the scope of which included veterinary drugs and human drugs, and select human biological drug products such as recombinant therapeutics and vaccines.

It was designed to improve public health promotion and protection by focusing on three major goals intended to augment FDA's pharmaceutical product quality assurance programs across the board.

- The first goal intended to enhance the focus of the agency's CGMP requirements more squarely on potential risks to public health, by providing additional regulatory attention and agency resources on those aspects of manufacturing that pose the greatest potential risk.

FDA's product quality regulatory system was established many decades ago, with incremental adjustments occurring over the years. However, significant changes in the pharmaceutical environment have occurred in the last several decades that warranted a systematic reappraisal of FDA's approaches to product quality regulation. These changes include: more approved medicines that have a greater role in healthcare, advances in pharmaceutical sciences and manufacturing technologies, advances in science and management of quality, application of biotechnology and globalization of industry. However, due to resource constraints, FDA's capacity to conduct on-site inspections of manufacturing sites for many human drugs and its compliance policies have not kept pace with the changes. Therefore, the agency has reappraised its product quality regulatory system so that it can do its job better in the face of stagnant or diminishing resources. The principles that guided the implementation of the reappraisal include a more systematic and rigorous risk-based orientation; regulation based on all applicable science; international cooperation; strengthening of public health protection; and coordinating and adapting a quality system that establishes core quality requirements for all regulated medical products.

- The second goal intended to help ensure that FDA's essential work in establishing and enforcing pharmaceutical product quality standards does not impede innovation and the introduction of new manufacturing technologies in the pharmaceutical industry.

- The third goal was implemented to enhance the consistency and predictability of FDA's approach among the FDA's centers and field components.

The initiative sought to better integrate quality systems and risk management approaches into the existing programs and encourage industry adoption of modern and innovative manufacturing technology. The initiative also intended to enhance the integration of the pre-approval review and CGMP programs and achieve more consistent application across agency organizational components. In addition, the initiative utilized existing and emerging science and analysis to ensure that limited resources are best targeted to address important quality issues, especially those associated with predicted or identifiable health risks.

The Initiative has been overseen by a steering committee with representation from the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, the Office of Regulatory Affairs and the Office of the Commissioner. Over the life of the initiative, the steering committee has established working groups comprised of agency experts from various areas of scientific and regulatory practice. These groups have shaped and implemented the initiative to achieve the goals and objectives outlined at the onset.

Although there have been significant accomplishments in two years, there are goals that have been identified but have not yet been fully achieved and new challenges are likely to arise. In order to continue the progress that has been made during the CGMP Initiative, as well as stay abreast of continuing advances in technology and improve our understanding of the elements that constitute good quality and the needs of both the review and GMP programs to support this, it is necessary to establish a Council on Pharmaceutical Quality, a subcommittee to the FDA Management Council.

3. SCOPE

a). The Council on Pharmaceutical Quality reports directly to the FDA Management Council through the Council Chair or Executive Secretary**.** The Council will serve as the guiding body on activities and policy development related to the modernization of the regulation of cross-center and ORA pharmaceutical manufacturing and product quality. The Council also serves as a resource to the FDA Management Council, and to the agency in general, on matters relevant to this subject.

b). The applicability of Council activities to a specific product area will require concurrence of the Center with regulatory responsibility for that area, as well as the concurrence of ORA when applicable. In certain cases, (e.g. Part 11) the scope of the Council work may extend beyond pharmaceutical quality, with the concurrence of the Management Council.

c). It is not within the scope of the Council to overrule the decision of a Center or ORA on a particular regulatory or policy matter (except as a part of previously agreed to dispute resolution procedures) or to prevent implementation of Center-specific programs.

4. ORGANIZATION and RESPONSIBILITIES

4.1 The Council is responsible for:

a). Identifying, coordinating, prioritizing, developing and implementing agency activities and policy relating to the modernization of the regulation of cross-Agency pharmaceutical manufacturing and product quality for select Agency products;
b). Identifying training needs and opportunities related to implementing relevant activities;
c). Overseeing implementation of cross-center and ORA quality systems for relevant regulatory programs;
d). Developing agency-wide communications on product quality issues;
e). Nominating liaison members for participation in relevant activities outside of the agency;
f). Overseeing FDA's international negotiations on product quality regulation;
g). Overseeing the expert working groups.

4.1.1 Responsibilities of Council members:

a). Representing their organizational unit's views on issues under consideration by the Council;

b). Serve as the focal point of contact for communicating with their organizational unit, including their senior managers about the deliberations of the Council and obtaining their input;
c). Nominating representatives from their organizational unit to participate in working groups to implement activities deemed necessary by the Council to meet its goals and objectives;
d). Identification of agenda items;
e). Regular attendance at meetings. If a member cannot attend a meeting, an alternate may be designated. The alternate must be able to represent the organization and vote in place of the member.

4.1.2 Responsibilities of the Council Chairperson:

a). Directing the activities of the Council;
b). Apprising the FDA Management Council and Executive Secretary of progress and activities;
c). Representing the Council on Pharmaceutical Quality to the FDA Management Council;
d). Recommending formation of relevant work groups.

4.1.3 Responsibilities of the Project Manager:

a). Suggesting agenda items as appropriate;
b). Arranging and organizing meeting logistics;
c). Distributing documents relevant to the activities of the Council;
d). Serving as the focal point for the working groups;
e). Noting action items generated during the meetings of the Council and following-up on those action items;
f). Preparing documents and papers as requested by the Chair.

4.1.4 Responsibilities of working groups and their members:

a). Development of project plans that include timelines and updating the Council at regular intervals as designated by the Council;
b). Confirming its objectives with the Council;
c). Defining member responsibilities;
d). Providing work products to the Council in a timely manner;
e). Respond to questions from the Council on specific issues;
f). Advising and assisting the Council in responding to agency staff;
g). Members should represent their organizational unit's views to the work group and communicate discussions of the work group to their FDA organizational unit.

4.2 The Council on Pharmaceutical Quality is organized as follows:

4.2.1 The Council is comprised of no more than four representatives each from the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, the Office of Regulatory Affairs, and the Office of the

Commissioner, including the Office of the Chief Counsel. The Council is supported by a project manager.

4.2.2 Other participants, observers, and consultants from within the agency and from other Federal government organizations may participate, when appropriate, in the activities of the Council at the discretion of the Chair or the FDA Management Council.

4.2.3 Working groups may be established under the following circumstances:

a). The Council identifies a specific need;
b). The FDA Management Council directs the Council on Pharmaceutical Quality to establish a new work group to achieve specific objectives or for a specific project.

4.2.4 Working group organization:

a). Each working group will have a Chairperson or Co-Chairpersons who will direct the group's activities;
b). The working group Chairperson or Co-Chairpersons and members are nominated by the Council 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). Working groups may solicit assistance from other groups within the agency to provide needed expertise;
d). At least one member of the Council will serve on each working group to provide continuity and ensure the adherence to the goals and objectives related to the modernization of the regulation of pharmaceutical manufacturing and product quality.

4.2.5 Working groups will have a finite lifetime which will be determined according to their project plans and timelines and will adjourn when:

a). They have successfully completed their goal, however;
b). if additional related work is required from the group as determined by the Council on Pharmaceutical Quality or FDA Management Council, the lifetime of the working group can be extended to accomplish these tasks.

5 PROCEDURES

5.1 In performing these responsibilities, the Council 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). Facilitate public discussion and input to cross-cutting GMP issues, including policy, science and technology aspects;
c). Establish and oversee work groups for the purposes of fulfilling the Council's responsibilities;
d). Review and concur with work products (e.g. documents or recommendations) of the work groups before they are circulated for FDA Management Council concurrence;
e). Communicate recommendations, decisions and actions to FDA Management Council, senior management, staff and other interested parties;
f). Provide input and work with other committees or agency components as necessary on matters which may impact or intersect with the established goals and objectives;
g). Develop and have approved by the FDA Management Council a work plan to achieve the goals and responsibilities of the Council. Major alterations to the work plan should be approved by the Management Council.

5.2 Council Leadership:

a). The Council is led by a chairperson who is appointed by the Commissioner.

5.3 Council Meetings:

a). Meetings are held as frequently as necessary, but not more than once per week, in order to accomplish the goals and objectives set forth.
b). Deliberations of the Council will generally be brought to closure by consensus. If consensus cannot be obtained, a majority opinion will be sought: each organizational unit will be entitled to one vote. If an organizational unit continues to be opposed to a majority recommendation, an option paper will be developed and presented to the FDA Management Council, followed by the Commissioner for a final decision.

6. RECORDS

a). The Chair and the project manager will assure that the activities of the Council including recommendations, decisions, issues, action items, and other pertinent materials attributable to the Council are documented and communicated to senior management and relevant staff, as appropriate.
b). The Council will review this Charter at least annually based on experience gained by the Council and revise it as needed.

7. *REFERENCES*

August 21, 2002 Concept Paper: Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach (A science and risk-based approach to product quality regulation incorporating an integrated quality systems approach)

February 20, 2003: Summary Progress Report

September 3, 2003: Pharmaceutical CGMPs for the 21st century — A Risk-Based Approach, Second Progress Report and Implementation Plan

September 2004: Pharmaceutical CGMPs for the 21st Century – A Risk-Based Approach, Final Report – Fall 2004

Document history

VERSION #	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	NAME, TITLE & ORGANIZATION	
				CONTACT	APPROVING OFFICIAL
1.0	initial	09/27/2004	n/a	FDA Council on Pharmaceutical Quality	Janet Woodcock, Chair, FDA Management Council

Drafted: MHess
Edited: JWoodcock/9.2.04
Revised: MHess/9.3.04
Edited: JTaylor/9.8.04/HWinkle/9.9.04/CBER/9.9.04/
Concurrence: CVM/9.9.04/CDER Compliance/9.14.04
Revised: MHess/9.14.04