SMG 2020.1

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

SCOPE OF QUALITY SYSTEM IMPLEMENTATION IN FDA

Effective Date: 10/01/2004

1. PURPOSE.

Implementation of a quality system is a demanding process requiring significant resources, personnel and time, therefore FDA is applying the Quality System Framework (SMG 2020) in a controlled and limited manner. Specific programs are identified in this document for quality system implementation.

2. SCOPE.

The programs listed in this document are those for which a quality system is being implemented according to the FDA Quality System Framework.

2.1 - The programs listed may or may not be FDA-wide.

2.2 - Individual Centers and Offices may direct that additional programs in their Center/Office develop full or partial quality systems based on the Framework.

3. RESPONSIBILITY.

3.1 - Oversight - The FDA Management Council is responsible for

a. approving the addition, modification, or deletion of programs from this Guide's list (Section 4); the Chair of the Management Council is the signature authority.

b. requesting status updates of quality system programs at least yearly.

3.2 - Tracking Implementation - Each Center/Office unit involved in the programs listed in this Guide develops tracking mechanisms within their organization for reporting on status, progress, and issues regarding quality system implementation for the program. The Center/Office Director forwards reports to the Management Council for review.

4. QUALITY SYSTEM IMPLEMENTATION PROJECTS.

4.1 - Regulatory Laboratory Accreditation

a. FDA laboratories that perform regulatory analyses were charged in 1999 with meeting the ISO 17025 standard "General Requirements for the Competence of Testing and Calibration Laboratories" as measured by third party accreditation. (Commissioner Jane E. Henney, M.D., FDA Leadership Council meeting minutes, November 17, 1999)

b. The Office of Science and Health Coordination oversees the FDA Laboratory Accreditation Committee with ORA chairmanship (e-mail: "ORA Lab Accred. Comm." oralabaccred@ora.fda.gov).

c. Participating Center/Offices - Scope of accreditation may vary by organization and/or laboratory.

1. Center for Biologics Evaluation and Research: Office of Blood, Product Testing Staff; Laboratory of Cellular Hematology; Laboratory of Hemostasis; Laboratory of Plasma Derivatives; Office of Compliance and Biologics Quality, Product Release Branch; Office of Vaccines, Analytical Chemistry Staff; Office of Vaccines, Standards and Testing Staff; Laboratory of Immunobiochemistry; Laboratory of Bacterial Polysaccharides; Laboratory of Methods Development and Quality Control; Laboratory of Pediatric & Respiratory Viral Diseases; and Laboratory of Method Development

2. Center for Device and Radiological Health:

3. Center for Drug Evaluation and Research:

4. Center for Food Safety and Applied Nutrition:

5. Office of Regulatory Affairs: Arkansas Regional (Jefferson), Denver, Detroit, Kansas City, Northeast Regional (Jamaica, NY), Pacific Northwest Regional (Seattle), Pacific Southwest Regional (Los Angeles), Philadelphia, San Francisco; San Juan, Southeast Regional (Atlanta); and Winchester Engineering Center (Stoneham, MA).

4.2 - Pharmaceuticals for the 21st Century (CGMP Initiative)

a. The CGMP Steering Committee, chaired by the Deputy Commissioner for Operations, oversees quality system program implementation for selected pharmaceutical product quality regulatory activities.

b. Selected programs (as per final report, September 2004) include

   1. Recalls of pharmaceutical product

   2. Warning letters for pharmaceutical product industry related to CGMP issues

   3. FDA Pharmaceutical Inspectorate, including product specialist teamwork.

   4. Process Analytical Technology Team

   5. Team Biologics quality program

c. Participating Center/Offices - Scope of participation is dependent on the program

   1. Center for Biologics Evaluation and Research

   2. Center for Drug Evaluation and Research

   3. Center for Veterinary Medicine

   4. Office of Regulatory Affairs, and

   5. Office of the Chief Counsel.

4.3 - Innovations in Medicine

a. Pre-approval review (FDA 2003 Strategic Action Plan)

b. Bioresearch Monitoring (BIMO), Good Clinical Practice Program, Office of Science and Health Coordination (FDA 2003 Strategic Action Plan)

4.4 - FDA Office of Management

a. IT Enterprise Architecture - Instituting Enterprise Architecture (EA) as a quality system ensures new and existing IT initiatives meet the requirements of the Agency's program staff as they adapt to new mandates and the ever changing world of technology. Changes that result can then be incorporated more seamlessly, meeting Agency IT needs in a timelier manner.

b. PDUFA III Business/IT Governance - The objectives are to: review, prioritize and fund new PDUFA investments; review and authorize adjustment to existing PDUFA investments; review and authorize PDUFA maintenance and operations funding; and maintain and update the PDUFA IT 5-Year Plan to ensure linkage to Agency strategic goals. The process requires IT projects or initiatives to have made a clear and compelling business case prior to committing resources. It includes steps for monitoring and evaluating progress of approved and ongoing projects by requiring in-process reviews and reviews at critical points throughout the project to evaluate project schedule, cost, risk, and performance information.

5. EFFECTIVE DATE.

The effective date of this guide is October 1, 2004.

6. Document History -- SMG 2020.1, Scope of Quality System Implementation in FDA

VERSION #	STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
1.0	Initial	08/19/2004	N/a	FDA Quality Resource Guidance Team	Janet Woodcock, Chair, FDA Management Council