OFFICE OF EXECUTIVE PROGRAMS

Procedures for Assessments Performed by the Quality Assurance Staff

CONTENTS

PURPOSE

- This MAPP describes the policy and procedures by which the Center for Drug Evaluation and Research (CDER) Quality Assurance Staff (QAS) initiates, conducts, and completes quality assurance (QA) assessments of Center-wide programs and processes, including preparation of the assessment plan, data collection, analysis, dissemination of a final report, and follow-up, if needed.

BACKGROUND

- Since the implementation of the Prescription Drug User Fee Act (1992) and other legislative initiatives (e.g., the Best Pharmaceuticals for Children Act), CDER has embarked on many efforts to (1) improve its overall timeliness in taking action on both new drug applications and supplemental new drug applications, and (2) enhance quality and efficiency. To facilitate this effort, many new processes and procedures have been implemented across the Center.

  In 1998, Dr. Jane Henney, then FDA Commissioner, established a task force to evaluate the system for managing the risks of FDA-approved medical products. In May 1999, the Task Force on Risk Management published a report to the Commissioner entitled *Managing the Risks From Medical Product Use.* One of the recommendations of the report was to "initiate steps to have each Center establish separate QA/QC units to support the QA/QC system as a normal part of all activities."

  This directive further fostered the development of the already existing CDER QA program, which had been established in April 1999. In November 2001, the staff was renamed Review Standards Staff and was made responsible for overseeing the implementation of Good Review Practices (GRPs) and initiating a risk management plan. The QAS was formally reorganized and renamed in February 2003, with a shift of focus back to quality assurance across the entire Center.

This reorganization resulted in a new mission for QAS: to evaluate, assess, analyze, and prepare quality assurance assessment reports on Center-wide programs and processes. QAS also highlights current best practices and provides recommendations for improvements in processes and procedures when needed to enhance Center programs.

DEFINITIONS

- **QA Assessment Plan:** The plan prepared by QAS in conjunction with the organizational unit lead staff member to outline the scope of the assessment and the strategy by which it will be completed.

- **QA Assessment Report:** The final report generated by the QAS, which includes an executive summary, a report of findings highlighting the methods used for the assessment, a discussion of the data found, conclusions, and recommendations for consideration.

- **Secure Drive**: A secure network drive where QAS maintains the final report and all data and raw information used in the assessment.

POLICY

- QAS is accountable to CDER's Senior Management Team (SMT) and other internal customers in providing nonbiased quality assurance assessments. This accountability enables QAS to work independently and be removed from organizational relationships to avoid a conflict of interest when preparing assessments.

RESPONSIBILITIES AND PROCEDURES

- **General**

  QAS serves its internal customers in an advisory capacity. The technically trained staff in QAS will, in consultation with the organizational unit, generate quality assurance reports on various business processes and procedures throughout CDER. The overall goal is to provide (1) an analysis of the work being performed in the designated area, (2) an observation of trends, and (3) recommendations, if any, for improvement. An additional goal is to help highlight best practices being used throughout the Center. The report can include, for example, an assessment of:

  (a) The consistency of review practices within and across review divisions
  (b) The use of review templates
  (c) The use of a particular policy or procedure in an organizational unit
  (d) The interaction between a review and consult division

  Throughout the assessment process, QAS will obtain input and assistance from the organizational unit as needed.

The Director, QAS, will:

- Receive all incoming requests for QA assessments to be performed throughout the Center. These requests can come from an organizational unit, the Center Director, or can be identified by the QAS Director based on available information

- Establish priorities of QA assessments to be performed based on Center needs

The QAS Staff will:

- Accept assignments for the Director, QAS

- Determine the existence of any related MAPPs and other relevant background material that may be associated with the particular project to be completed

- Prepare an assessment plan (see Attachment A) based on meetings and communication with the organizational unit to be assessed, through the organizational point of contact (POC), to include:

  Background
  Purpose
  Methodology
  Resources
  Timeline

- Send the assessment plan to the organizational unit POC for comment

- Conduct a pilot assessment, if necessary, and meet with the POC and others from the organizational unit as needed to determine whether this assessment is consistent in scope with the agreed upon assessment plan

- Obtain the raw data necessary to perform the assessment. Obtaining the data could involve generating reports in COMIS, retrieving documents from the Document Room or DFS, and conducting surveys and interviews.

- Examine the raw data in accordance with the assessment plan. Original raw data as well as data extracted for the purposes of the final report are typically maintained in a database such as MS Access or MS Excel.

- Prepare an in-depth assessment report based on the data examined (see Attachment B), to include:

  Cover Page
  Table of Contents
  Executive Summary
  Report of Findings
  Conclusions
  Recommendations for Consideration

- Provide periodic status reports to the POC on the progress of the assessment
- Issue a draft version of the report for the Director, QAS, or designee for input/revision
- After input from QAS Director, issue a draft version of the assessment report to the POC, seeking input on content only. QAS will not alter the documented data based on these comments, but *may* consider examining an additional parameter before finalizing the report.
- Issue the final report to the Director of the relevant Super Office, the Office Director, the Center Director, the POC and immediate supervisor, and the Division Director, if different from the POC's immediate supervisor
- Prepare a presentation, if desired by POC, and present the findings to the organizational unit
- Perform regular follow-up to determine whether the recommendations (if any) were implemented, and whether additional assessments are needed by the organizational unit

The Organizational Unit will:

- Designate a lead individual to be the POC for QAS

The POC for QAS will:

- Provide input to the QA staff member and approve the draft assessment plan before initiation of the assessment
- Assemble and distribute material as agreed upon in the assessment plan
- Renegotiate timelines, if needed
- Coordinate decisions within the organizational unit
- Review the draft QA assessment report for content

EFFECTIVE DATE

The MAPP is effective upon date of publication.

Attachment A

Assessment Plan Template

Background

Precipitating events/rationale for doing assessment

Purpose

Questions to be answered by completing the assessment

Methodology

Manner in which assessment will be performed

Resources

Names of assessors, point of contact, and others, as appropriate

Timeline

Negotiated between POC and QAS based on current workload and priorities

Assessment Product

Final report in both hard copy and electronic version

Attachment B

Final Report Template

Cover Page

Includes title of report, name of organizational unit, name of Assessors, and date completed

Table of Contents

Executive Summary

Brief overview of the purpose and findings in the report (1 page limit)

Report of Findings

Introduction

Methods

Data and Discussion

Conclusions

Recommendations for Consideration

Conclusions and Recommendations MAY BE combined into one section when needed

Attachments