SMG 2020.2

FDA STAFF MANUAL GUIDES, VOLUME III - GENERAL ADMINISTRATION

FDA OFFICIAL COUNCILS AND COMMITTEES

Collaborative Quality System Feedback Process for Office of Regulatory Affairs (ORA), Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) and Center for Food Safety and Applied Nutrition (CFSAN)

Effective Date: 06/13/2016

1. PURPOSE

The purpose of this document is to establish a process for ORA, CDER, CVM and CFSAN to share and respond to internal and external feedback that require or would benefit from coordination. This SMG focuses on the coordination and interaction between the offices within the FDA to address feedback regarding their processes, products and services, for example, reviews, establishment evaluations, inspections, and recalls.

2. POLICY

This agreement applies to ORA, CDER Office of Compliance (OC), CDER Office of Pharmaceutical Quality (OPQ), CDER Office of Translational Sciences - Office of Study Integrity and Surveillance (OTS-OSIS), CVM and CFSAN. ORA, CDER (OC, OPQ and OTS-OSIS), CVM and CFSAN will collaborate in order to ensure that feedback by either is handled as needed in order to support transparency and continual improvement. This SMG does not apply to internal personnel and budget issues.

3. BACKGROUND

Each of the offices involved with this SMG has developed or committed to developing a Quality Management System (QMS) designed to ensure the quality of their work processes, products and services related to regulated product quality. Each QMS incorporates the office's procedures for receiving and managing feedback related to these processes, products and services.

However, since some feedback on FDA processes, products and services overlaps organizational boundaries, it is appropriate to develop procedures for cross-office collaboration in responding to such feedback. This SMG is designed to fulfill this need for ORA, CDER (OC, OPQ and OTS-OSIS), CVM and CFSAN. It is anticipated that the system established by this SMG will promote and improve cross-office collaboration on issues such as facility inspections, establishment evaluations, chemistry, manufacturing and controls (CMC)/product quality reviews, and current good manufacturing practices (CGMPs) determinations and may be expanded as needed.

This SMG meets the requirements of FDA SMG 2020 *FDA Quality System Framework for Internal Activities* and is compatible with best practices set out in the International Standard ISO 10002, *Quality management – Customer satisfaction – Guidelines for complaints handling in organizations*.

4. RESPONSIBILITIES

4.1 Each office shall have an established process for handling feedback.

4.2 The offices covered by this SMG shall:

4.2.1 Perform initial assessments of internal or external feedback according to office procedures.

4.2.2 Share feedback with other offices as appropriate.

4.2.3 Collaborate with other offices in responding to the feedback.

4.2.4 Meet at least annually with the other offices to review the operation of this SMG.

4.2.5 Integrate with internal QMS, including training.

4.3 The Office of Communications, Quality, and Program Management (OCQPM), Quality Management System Staff (QMSS), is the main point of contact for the Office of Regulatory Affairs (ORA).

4.4 The Office of Center Director (OCD), Quality Management Team (QMT) is the point of contact to handle and process feedback for CFSAN.

5. PROCEDURES

5.1 Intake

5.1.1 One of the offices covered by this SMG obtains feedback related to an FDA process, product or service.

5.1.2 The office acknowledges feedback according to its standard procedure.

5.1.3 The office performs initial assessment to determine if:

- Feedback is specific to the receiving office, or if it requires or would benefit from coordination between two or more offices.
- Feedback is within the scope of this SMG.

5.1.4 If the feedback is office-specific, the office applies their internal standard procedures for managing feedback per its QMS.

5.1.5 If the feedback is not within scope of this SMG, the office responds to the initiator of the feedback and/or forwards the feedback to the appropriate office according to internal QMS procedures.

5.2 Information sharing

5.2.1 If the feedback has been determined to be relevant to multiple offices, the receiving office shares the information included as Attachment A[1] with the relevant offices, along with the results of the initial assessment.

5.2.2 Feedback shall be shared across offices by means of email boxes accessed routinely by respective office quality staff (the email addresses are maintained on the FDA intranet websites) or the use of shared electronic space.

5.3 Action

5.3.1 Representatives of the involved offices meet to evaluate the feedback, identify a root cause (if applicable), assign a lead office,

[1] Attachment A includes initial expectations of typical information to be shared.

and plan appropriate solutions, or other activities including assignment of actions by office.

5.3.2 Offices implement the solutions, or other activities, in accordance with the plan which may include collaboration with other FDA offices.

5.3.3 The lead office communicates with the initiator of the feedback about the status of the response.

5.3.4 When the response has been completed, the lead office formally closes the action and files a record of the action on a common system.

5.4 Management Review

5.4.1 Representatives from each office will meet at least annually to review the operation of this collaborative feedback system.

5.4.2 In addition, each office will periodically evaluate this collaborative feedback process as part of its own ongoing management review system.

6. DEFINITIONS

6.1 Feedback: Information and ideas, including complaints, from internal and external customers about FDA's processes, products, or services. These may include recognition of high quality work or failure to meet a requirement or expectation.

7. REFERENCES

7.1 FDA SMG 2020, FDA Quality System Framework for Internal Activities.

7.2 International Standard ISO 10002, Quality management – Customer satisfaction – Guidelines for complaints handling in organizations.

8. EFFECTIVE DATE

June 13, 2016.

9. DOCUMENT HISTORY - SMG 2020.2, Collaborative Quality System Feedback Process for Office of Regulatory Affairs (ORA), Center for Drug Evaluation and Research (CDER), Center for Veterinary Medicine (CVM) and Center for Food Safety and Applied Nutrition (CFSAN)

STATUS (I, R, C)	DATE APPROVED	LOCATION OF CHANGE HISTORY	CONTACT	APPROVING OFFICIAL
Initial	08/14/2013	N/a	Karen Masley-Joseph, QMS Staff, ORA	Melinda Plaisier, Assoc. Commissioner for Regulatory Affairs
Revised	01/21/2016	N/a	Quality Management System Staff, ORA	Melinda Plaisier, Assoc. Commissioner for Regulatory Affairs

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Example Information types

The following lists are included to show the types of information that are expected to be shared in the collaborative process.

Information regarding the Collaboration process

- Offices sharing information
- Quality staff responsible
- Date entered into collaborative process
- Possible assignment among offices

Information regarding the feedback under consideration

- Date feedback originally obtained

- Additional contact for subject matter expertise

- Type of feedback, e.g., complaint internal/external; positive feedback; suggestion; audit findings

- Process/product/service involved, e.g.,
  - Consults
  - Defect and incident reports
  - Emergency management
  - External inquiries
  - Guidance, policy, procedures
  - Inspection conduct
  - Inspection prep
  - Inspection schedule
  - Inspection write-up
  - Internal quality management activities
  - Laboratory analysis
  - Product review
  - Recall
  - Registration
  - Regulatory action
  - Work plan