POLICY AND PROCEDURES

OFFICE OF PHARMACEUTICAL QUALITY

CDER Liaisons to Official Compendia and Standards Development Organizations – Selection Process, Roles, and Responsibilities

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PURPOSE

This Manual of Policies and Procedures (MAPP) establishes policy, responsibilities, and procedures pertaining to CDER employees who agree, with the concurrence of their managers, to serve as FDA Liaisons to standards development organizations (SDOs), including the United States Pharmacopeia (USP). This MAPP also establishes the policy and procedures for leading and administering this Standards Liaison Program (SLP).

The SLP described in this MAPP includes CDER Liaisons to those organizations defined as SDOs in the DEFINITIONS section of this MAPP.

BACKGROUND

In 1996, Congress passed the *National Technology Transfer and Advancement Act* (NTTAA) (PL104-113), codifying an Office of Management and Budget (OMB) directive Circular A119, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities* (OMB Circular A-119), originally issued in 1982.

The NTTAA and OMB Circular A119 establish that Federal Government policy is to use voluntary consensus standards (non-government standards) in lieu of government-unique standards except where those voluntary consensus standards are inconsistent with law or otherwise impractical.

FDA encourages qualified employees to participate in standards development activities, including serving as FDA Liaisons to selected SDOs.

The CDER Office of Pharmaceutical Quality (OPQ), Office of Policy for Pharmaceutical Quality (OPPQ), Compendial Operations and Standards Staff (COSS) is responsible for the management of agency staff selection and the maintenance of participation in standards development activities. Agency staff participate with selected SDOs to develop technical standards in accordance with policies set forth in the NTTAA, the Office of Management and Budget (OMB) Circular A-119, and FDA Staff Manual Guides (SMG) 9100.1.

POLICY

CDER will follow the SMG 9100.1 that sets forth agency program directives regarding standards management to establish a unified approach to standards within FDA. The guide includes a section (5.5.10) outlining the general responsibilities of FDA Liaisons to SDO activities.

OPQ will encourage CDER employees, along with employees from other FDA organizational units, to serve as FDA Liaisons as part of their official duties, as assigned by their management, using official duty time.

Employees serving as FDA Liaisons under policy established in SMG 9100.1 will represent the opinions of the agency to the SDO.

The policies and procedures set forth in this CDER MAPP complement those in the SMG 9100.1 and are applicable to CDER employees appointed as FDA Liaisons to SDOs.

RESPONSIBILITIES

COSS will:

- Lead and coordinate the SLP in CDER, in accordance with this CDER MAPP.

OPPQ Management will:

- Review COSS proposals regarding which SDOs and SDO committees should have CDER Liaisons.
- Approve COSS Liaison proposals or suggest revisions.
- Confirm appointment of CDER candidate Liaisons to SDOs.

CDER Liaisons to SDOs

- SDO committee meetings – Liaisons will:
    - Attend meetings of the SDO committees to which they are assigned and participate in committee activities.
    - Arrange for a substitute, as needed, if unable to attend a committee meeting. Alternatively, Liaisons can request fellow Liaisons, if any, on the committee to cover for them, or request a COSS employee to attend, if needed. Liaisons should help prepare the substitute for the meeting (e.g., with background materials, personal briefing).
- SDO committee activities – Liaisons will:
    - Participate in developing new standards and revising existing standards.
    - Represent CDER policies and positions in the standards development process to ensure standards are relevant to agency-regulated products. Liaisons are not to offer their own personal opinions over those favored by CDER.
    - Communicate, defend, and promote CDER positions to the committee.
    - Pre-review all items to be discussed at meetings and incorporated into briefing books or other materials. If an item is beyond their expertise, they will discuss with management and/or other appropriate FDA employee (e.g., from relevant working groups or subject matter experts) before the committee meets.
    - Determine a CDER position early in the standards development process. Liaisons may request COSS to identify an agency employee who can be consulted, if necessary, to learn about or develop an agency position.
    - Communicate with other Liaisons, as necessary, in advance of an SDO meeting, to ensure that all issues have been addressed and a consistent approach is understood and taken in support of a CDER position. A lead Liaison may be appointed, as needed, for large SDO committees.
    - Meet internally, as needed, with appropriate agency managers and/or subject matter experts before an SDO meeting to ensure proper vetting of agency positions.
- Other Liaison responsibilities – CDER Liaisons will:

- Keep their management and COSS informed of precedent-setting standards issues and progress by providing them a concise "bullet list" or outline summary of relevant information.

- Notify COSS if additional Liaison representation or technical expertise is needed to support standards development activities.

- If serving as Liaison to an SDO technical panel that is advisory to a principal determinative SDO parent committee, provide timely alerts to the agency Liaison serving the principal SDO committee regarding any developing issues that may need to be addressed.

- Take relevant standards-specific training courses coordinated by OPPQ.

- Notify their managers and COSS in writing at any time if they wish to resign their Liaison duties.

- Managers of CDER Liaisons, as approved by their offices, will:

  - Allow Liaisons to attend meetings and, unless COSS is otherwise notified, observe the policies and procedures established by this CDER MAPP.

  - Take into consideration the amount of time employee Liaisons spend working on standards development activities and, to the extent possible, accommodate those activities.

  - Ensure that Liaisons carry out their duties in a professional and responsible way.

  - Recognize the contributions that Liaisons make through their work on standards activities in furthering the FDA/CDER mission.

PROCEDURES

- Selecting Liaisons

  - COSS creates a selection plan in which it recommends to OPPQ management which SDOs, and which of the SDOs' committees, should have CDER Liaisons. COSS also includes in the plan how many CDER Liaisons should participate on each SDO committee and identifies the offices that should be contacted to request Liaison candidates.
  - COSS will base the selection plan on its evaluation of the purpose and scope of the SDO committees, the expertise required to serve on the

committee, input from OPQ/CDER stakeholders, and the importance and relevance of the committee's activities to advancing CDER's mission.

- OPPQ will approve the COSS recommendation, or suggest revisions and create an alternative selection plan.

- After the selection plan is final, COSS will contact the affected CDER offices and request that they select a specified number of qualified employees to serve as Liaisons to the SDO committees identified. COSS will request CDER offices to select candidate employees based on the employee's experience, expertise, current job responsibilities, and other relevant factors. COSS also will inform the offices that it will administer the program according to this CDER MAPP.

    - In the selection process for non-CDER FDA employees to become Liaisons to USP, COSS works with points of contact in other FDA organizational units to obtain their organization's list of selected candidate Liaisons.

- COSS asks CDER office managers to obtain a voluntary agreement from the employee before notifying COSS of their selection as candidate Liaisons.

- COSS will request that CDER office managers respond by e-mail to specify which employees have been selected as candidate Liaisons. COSS will request that points-of-contact (POCs) in other FDA organizational units respond by e-mail to indicate which employees have been selected as candidate Liaisons to USP.

- OPPQ will confirm the appointment of CDER employees as Liaisons to SDOs, and will inform the Liaisons and their managers of the confirmation.

- OPPQ will work with POCs of non-CDER FDA organizational units regarding confirmation of the appointment of non-CDER employees as FDA Liaisons to USP.

- <u>Training Liaisons</u>

    - Once selected, the new CDER Liaisons will attend COSS-provided and/or arranged training. This training will enable the Liaisons to perform their duties efficiently and effectively. Non-CDER FDA Liaisons to USP may also be invited to attend this training.

- The CDER Liaisons will then attend periodic training arranged by COSS. This training will keep the Liaisons informed of any significant changes in the SLP.

- Monitoring Liaisons

  - COSS will monitor the performance of CDER Liaisons, including obtaining feedback from SDOs regarding Liaisons' participation and contributions to the committee(s) the Liaisons serve.

  - COSS may replace a CDER Liaison, in consultation with the Liaison's manager, if it is determined that the Liaison's continued service is not in the agency's, SDO's, and/or the individual's best interest. For non-CDER FDA Liaisons to USP, the COSS will coordinate actions through the Liaison's manager.

REFERENCES

1. SMG 9100.1 - STAFF MANUAL GUIDES, - DEVELOPMENT AND USE OF STANDARDS.
2. CIRCULAR NO. A-119, Revised 1998, *Federal Participation in the Development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities*.
3. P. L. 104-113, *National Technology Transfer and Advancement Act of 1995* (NTTAA).

DEFINITIONS

FDA Liaison – An FDA employee who is assigned, as part of his or her official duties, to represent FDA viewpoints to an SDO (as defined below).

Standard – A document that provides for common and repeated use, rules, guidelines or characteristics for products or related processes and production methods, and related management systems practices. It may also include or deal exclusively with terminology, symbols, packaging, marking or labeling requirements as they apply to a product, process, or production method.

Non-government Standard – A standard as defined above that is developed by a private sector association, organization or technical society which plans, develops, establishes or coordinates standards, specifications, handbooks, or related documents.

Standards Development Organization (SDO) – For purposes of this MAPP, SDOs include the official compendia of the United States (USP, National Formulary, and

Homeopathic Pharmacopoeia of the United States), as well as certain other organizations that develop standards for pharmaceutical quality, such as ASTM International and International Organisation for Standardization. Organizations such as the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (jointly referred to as PIC/S) are not included in the SLP and are therefore not considered SDOs in this MAPP. A complete, current list of SDOs included in the SLP is available from COSS.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
5/13/16	N/A	Initial
5/1/2020	N/A	Administrative: office name change from Compendial Operations and Standards Branch to Compendial Operations and Standards Staff