POLICY AND PROCEDURES

OFFICE OF THE CENTER DIRECTOR

Prioritization of Requests for Training and Visits by Foreign Regulatory Agencies and International Regulatory Organizations

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PURPOSE

This MAPP describes how the Center for Drug Evaluation and Research (CDER) prioritizes requests for visits and training by representatives from foreign regulatory agencies, as well as international standards development organizations and other international regulatory organizations.

BACKGROUND

CDER exchanges scientific, clinical, and technical information as well as the policies and procedures FDA uses to regulate products with other countries. CDER staff have briefed international visitors on a variety of topics including the Agency's organization, procedures and other regulatory processes, research programs, and international initiatives. Visitors return to their countries with a greater understanding of FDA's regulatory requirements, and take home new ideas and methods for solving health and regulatory issues in their own organizations or countries.

Working with FDA's Office of Global Policy and Strategy (OGPS), and the Office of Security Operations (OSO), CDER's International Program (IP) staff responds to

requests for visits and training on regulatory issues by foreign regulators on a case-by-case basis. CDER IP staff consolidate and manage international training and visit requests to minimize the disruption to the CDER review staff. In general, foreign regulator visits and trainings are kept to a minimum to avoid disruption of the CDER review process. CDER staff are encouraged to consider all virtual meeting options before proposing or accepting any in-person visit or training. A visit is considered any in person meeting between a foreign regulator or other international regulatory organization and FDA staff, at an FDA facility.

POLICY

- All training and visitor requests made by foreign regulators are coordinated by CDER's IP staff in consultation with the FDA's OSO, OGPS, and the host CDER Office.
- If training or visits are to occur, the requestor must qualify as a foreign government official under 21 CFR 20.89 and secure the proper clearance requirements outlined by the OSO's Visitor Access Management (VAM) Standard Operating Procedures (SOP).
- The value of the training or visit, the cost of CDER expending resources on the training, the relevance of CDER's system to the visitors country's system are considered. Mutual benefits should be apparent for both CDER and the requesting authority.
- As part of this coordination, CDER IP staff recommend the requestor consider all-virtual meeting options before referring an in-person visit to the relevant host CDER office. If a foreign regulator still wishes to pursue an in person visit or training, the hosting CDER office director or division director makes the final determination of the request.
- If the CDER office agrees to host a visit or training, CDER IP staff liaises directly with the foreign visitors, submits the visitor's relevant personal information to the OSO for a background check, and helps to lead the logistical coordination of the visit.
- CDER IP staff ensure foreign regulators receive OSO's clearance to proceed with an in-person visit. A visit cannot take place without OSO clearance.
- Foreign visitors are denied access to FDA technology systems, FDA computers, telephones, external drives, private offices, labs, and all confidential or sensitive documents. Access to FDA labs will need to be cleared with the OSO and is granted on a case-by-case basis.
- Foreign visitors are authorized to use the guest IT network (not the FDA internal network), to provide presentations.

- If an individual is staying for longer than 30 days, and if CDER wishes to provide the visitor with FDA IT access, based on Homeland Security Presidential Directive (HSPD) 12, the visitor must go through the background check process to obtain a Personal Identity Verification (PIV) card.
- Visit and training requests by foreign regulators are sent to CDERINTLEXEC@fda.hhs.gov. CDER IP staff reviews the following details:
    - What specific government or organization are they representing? Include organization's name, the departments, and suboffices.
    - What are the shared goals of the visit or training?
    - The full list of visitors. Include names, titles, positions, and contact information.
    - The desired timeframe and duration of the visit or training.
    - The specific subject matter experts (SMEs) and offices the requestor wants to meet with.
- All official FDA meetings and trainings are in English. Foreign regulators should provide their own translators and interpreters, if needed. All translators and interpreters need to be cleared by FDA's OSO.
- Security screenings and clearance requirements are met in advance of visits by any foreign regulatory agency representative.

Visits of longer than one month are referred to FDA's OSO for clearance and OGPS is notified.

RESPONSIBILITIES

All CDER staff:

- Forward all requests for visits or training to the Associate Director for Strategic Initiatives, and CDERINTLEXEC@fda.hhs.gov via email, as early as possible and within 7 days of receipt.
- Protect confidential, commercial, and trade secrets, and other privileged information from unauthorized disclosure. When working with international visitors, be familiar with the procedures for identifying and safeguarding confidential commercial and trade secret information.
- When appropriate, brief the international visitors on the restricted access they have to FDA property, IT systems, and confidential commercial information, and inform them of the need to secure OSO clearance to access an FDA facility.

- Enforce restrictions of international visitor access to FDA systems and some facilities. Visitors are not allowed any access to FDA computers, telephones, external drives, private offices, labs, or any confidential or sensitive documents.
- Be familiar with FDA OSO's training on access restrictions for international visitors.

CDER IP Staff:

- Coordinates and clear all requests for training and visits by officials of foreign regulatory agencies and international regulatory organizations in consultation with the hosting CDER office and FDA's OSO.
- Collaborate with FDA's OGPS to triage international visitor and training requests, to consolidate them as much as possible, to conserve center resources.
- Recommend consideration of all-virtual meeting options before proposing or accepting an in person visit. This will reduce the number of resources expended for each visit or training and provide CDER staff with greater flexibility when engaging in these meetings and trainings.
- Refer requests for training and visits for longer than one month to the OSO to ensure all appropriate security screenings and clearance requirements are met.
- Complete the host and escort training and registration, located on the OSO SharePoint Online home page, prior to each international visit. Unless the host CDER office has staff present, who has completed OSO's host and escort training, CDER's IP staff will need to escort the foreign visitors, until they leave FDA's campus.
- Ensure all requirements and deadlines, described in the OSO Visitor Access Management SOP, are met.
- Liaise directly with the foreign visitors or trainees to ensure the orderly logistical management of the visit. This includes providing the visiting officials with information leading up to the meeting, sharing important information related to the meeting, and key restrictions of their visit, providing escorting instructions, and addressing all questions and requests from the foreign officials.

CDER Super Office Director (or designee):

- Decides whether to accept or reject requests for training and visits by foreign regulatory agencies and international regulatory organizations, based on the following criteria:
    - Mutual public health, scientific, technical, clinical and regulatory interest.
    - Limited resources, availability, or interest from FDA staff.

- Competing public health priorities.
- Whether CDER staff see reciprocal value in the visit.

- Communicates decision to IP staff.

CDER Host Offices:

- Provide a response to requests for visit, within 10 business days. Directs the response to CDER IP staff at CDERINTLEXEC@fda.hhs.gov.
- Provide CDER IP staff with any follow up information relevant to the training or visit to ensure smooth coordination.
- Copy CDERINTLEXEC@fda.hhs.gov inbox on all correspondence with foreign visitors.

PROCEDURES

1. Requests for training and visits are forwarded to CDER's IP staff via email at CDERINTLEXEC@FDA.hhs.gov. CDER's IP staff coordinates all requests, via email, and forwards them for consideration to the proposed host offices targeted for the training or visit. In parallel, CDER IP staff forwards the request to OGPS's Office of Global Operations (OGO) for feedback or concerns related to the request. Information received from OGPS is forwarded to the relevant office or division for consideration. If no response is received from the OGPS OGO in 5 business days, CDER IP staff will proceed with processing the request based on the decision of the proposed host offices to accept or decline the request.

2. The CDER office or division director (or designee) of the host office targeted for the visit accepts or declines the visit request from the foreign regulatory organization based on the following criteria:
    a. Mutual public health, scientific, technical, clinical and regulatory interest
    b. Limited resources, availability, or interest from FDA staff.
    c. Competing public health priorities.
    d. Whether CDER staff see reciprocal value in the visit.

    The decision to accept or to decline the request is communicated to the CDER IP staff via email.

    - If the potential hosting CDER office declines the visit request, CDER IP staff informs the requestor within 5 business days of the receipt of the CDER office's determination.

- If the potential hosting CDER office agrees to the visit, CDER's IP staff informs the requestor via email within 5 business days of the receipt of CDER office's determination.
- If CDER agrees to the visit, CDER's IP staff then gathers the required information from the foreign regulator to process OSO clearance of each visiting individual.

3. CDER IP staff lead the coordination of the visit between the host office and the foreign visitors, including:
    a. Sharing all relevant information related to the logistics of the visit and associated meetings and trainings, including hybrid meetings.
    b. Informing the visitors of FDA escorting requirements, on-site restrictions, and addressing all requests and questions from the foreign official(s).
    c. Disseminating key meeting and training information and materials including agendas and lists of FDA foreign official attendees.
    d. Ensuring the safe departure of foreign visitors from FDA buildings and facilities after concluding the meeting or training.
4. CDER's IP staff refers requests for training and visits for longer than one month to OSO, and notifies OGPS of the request. This ensure all appropriate security screenings and clearance requirements are met.
5. Before any training or visit occurs, CDER IP staff ensure all requirements and deadlines, described in the Visitor Access Management (VAM) SOP, are met.

REFERENCES

- 21 CFR 20.89. Communications with Foreign Government Officials. 2012. DHS, 2004. Homeland Security Presidential Directive 12: Policy for a Common Identification Standard for Federal Employees and Contractors.

DEFINITIONS

Foreign Government Official: Under 21 CFR 20.89, (e) the term "official of a foreign government agency" includes, but is not limited to, employees (whether temporary or permanent) of and agents contracted by the foreign government, or by an international organization established by law, treaty, or other governmental action and having responsibility to facilitate global or regional harmonization of standards and requirements in FDA's areas of responsibility or to promote and coordinate public health efforts.

Training: For the purpose of this MAPP, training includes education that results in skill, knowledge, and experience relate to CDER's regulatory processes and procedures. Training generally lasts less than one month.

Visit: For the purpose of this MAPP, a visit is an in person meeting between the requesting organization and CDER representatives at an FDA facility. The objective of the meeting is to obtain an overview of CDER's regulatory processes and procedures. Visits by foreign government officials are generally less than one week.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
5/30/00	n/a	Initial issuance
11/09/22	1	• Updated Office names, titles, and processes. • Updated technology requirements, IT security requirements, and available trainings. Accounted for virtual options. • Added one reference.