SOPP 8115: Regulatory Site Visit Training Program

Version #2

Effective Date: November 22, 2005

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1. Purpose

This document describes the policy and procedures the Center for Biologics Evaluation and Research (CBER) staff are to follow to participate in the Regulatory Site Visit Training Program (RSVP). This document also describes the process for selecting biological companies for participation in the RSVP.

2. Definitions

Regulatory Site Visit - A Regulatory Site Visit is a training opportunity in which CBER personnel visit biologics facilities to learn about and observe biologics industry operations such as manufacturing, packaging, pathology/toxicology laboratory testing, or regulatory affairs operations. These training visits, or any part of the program, are not intended as a mechanism to inspect, assess, judge or perform a regulatory enforcement function, but are meant to improve mutual understanding and provide an avenue for open dialogue between the biologics industry and CBER.

Lead Office - The Lead Office for coordinating the RSVP is the Office of Communication and Manufacturers Assistance (OCTMA). The Division of Manufacturers Assistance and Training (DMAT) within OCTMA has primary responsibility for managing the RSVP.

Coordinating Office - The office with the primary responsibility for selecting the facility being visited is the Coordinating Office. For example, the Office of Vaccines Research and Review (OVRR) is likely to be the coordinating office for any site visits to vaccine manufacturing facilities. The Coordinating Office will work closely with DMAT to ensure successful and valuable site visits.

Participating Office - Any office providing personnel to participate in the site visit is a participating office. The participating office may be the same as the coordinating office.

Participating Industry - Any biologics industry member that responded to the Federal Register notice announcing the RSVP and submitted a request to CBER to participate in the RSVP is considered a participating industry.

3. Background

CBER regulates biological products including blood and blood products, biological devices, vaccines, and cellular, tissue, and gene therapy products. Committed to advancing the public health through innovative regulations that help ensure the safety, effectiveness and timely delivery of biological products to patients, CBER has initiated various training and development programs to promote high performance by its regulatory and research review, compliance, and regulatory project management staffs. Since CBER seeks to continuously enhance and update regulatory efficiency, the Center is initiating the RSVP to provide CBER

staff the opportunity to visit biologics manufacturing facilities to observe first hand the industry's development and manufacturing processes and thereby obtain a better understanding of the biologics industry and its operations. Furthermore, this program is intended to improve CBER's understanding of current practices, regulatory impacts and needs, and improve communication between CBER staff and industry.

4. Policy

It is CBER's policy to continuously improve its regulatory practice and to provide staff with the training necessary to discharge their responsibilities efficiently and effectively. The RSVP will be available to review, compliance and project management staff only. Selected staff may spend one day or more at a facility learning about product development and manufacturing processes. It is CBER policy that this program is intended to be a training exercise and not a compliance effort.

5. Responsibilities and Procedures

Office of Communication, Training and Manufacturers Assistance, Division of Manufacturers Assistance and Training (OCTMA/DMAT) will:

- Coordinate the overall Regulatory Site Visit Training Program (RSVP).
- Draft the annual Federal Register notice and submit for publication.
- Work with Dockets Management on collecting responses to the Federal Register notice.
- Coordinate with appropriate CBER Offices the selection of companies from those who respond to the Federal Register Notice.
- Consult with the Office of Compliance and Biologics Quality, Division of Case Management (OCBQ/DCM) regarding compliance checks.
- Review the program agenda submitted by the requesting firm with the relevant Office Director, or the Director's designee, and the Associate Director for Review Management, CBER.
- Communicate planned site visits with ORA Headquarters and the appropriate ORA District Office, Director, Inspections Branch (D-IB) through OCBQ/Division of Inspections and Surveillance, Program Surveillance Branch (DIS/PSB).
- Schedule CBER staff pre-site visit training with the Division of Disclosure and Oversight Management (OCTMA/DDOM).
- Evaluate the program with Coordinating Offices, Participating Offices and with the participating industry.

OCTMA/Division of Disclosure and Oversight Management (DDOM) will:

- Provide pre-site visit training for CBER staff participating in the RSVP regarding:
    - Disclosure requirements under the Freedom of Information Act (FOIA) and Privacy Act (PA).
    - "Forbidden" issues during training visit (do not conduct an inspection; discussing regulatory issues).
    - Inappropriate disclosures regarding FDA pending policy development.

Office of Compliance and Biologics Quality, Division of Case Management (OCBQ/DCM) will:

- Check available information to determine if the proposed facility has outstanding compliance actions by performing an initial compliance check once the list of applicants is received from OCTMA, and then another check within 2 weeks of the actual visit.

OCBQ/Division of Inspections and Surveillance, Program Surveillance Branch (DIS/PSB) will:

- Notify ORA D-IB of selected sites when the general schedule becomes available. The ORA D-IB will be notified again approximately 2 weeks in advance of a confirmed scheduled visit. The ORA D-IB will be invited to contact OCBQ/DIS/PSB immediately if they know of any reason (e.g., compliance problems or scheduled inspections) that might create a conflict with the site visit.
- Provide OCTMA with necessary information with regard to status of chosen sites.
- Provide consultation by phone if during a site visit a CBER participant has questions regarding a manufacturing practice which they find questionable. If necessary, OCBQ/DIS will coordinate information exchange with ORA, the proper District Office and OCTMA.

Director, Inspections Branch (D-IB) should:

- Provide feedback to OCBQ/DIS/PSB in a timely manner relevant to the compliance status of a chosen site.

Coordinating and Participating Offices will:

- Coordinate planned site visits with OCTMA.
    - agenda
    - logistics
    - Make all travel arrangements for participants.
- Fund the travel for individuals participating.

6. Procedures

- A Federal Register notice will be issued annually announcing the RSVP, based on available funding. All interested facilities may apply for the RSVP during the response period specified in the Federal Register notice.

- All facilities that apply in response to the Federal Register notice will be considered. Selection will be based on the availability of funds and resources for each fiscal year and suitability of the site for training.

- After the response period announced in the Federal Register closes, DMAT will:

    - Compile a list of facilities responding to the Federal Register notice;

    - Consult OCBQ/DCM to assure there are no outstanding compliance actions against the facility;

    - Notify facilities their letter of interest was received;

    - Work with ORA through OCBQ/DIS/PSB to determine if a site visit will coincide with or have an impact on a planned inspection;

    - Coordinate plans for site visits with the volunteer facilities;

    - Work with coordinating and participating offices to finalize site visit and program agenda;

        - Forward list of approved sites with proposals to coordinating office(s)

        - Request reply as to interest from offices no later than 2 weeks after receiving list

        - Once interest has been determined, notify participating industry

        - Request proposed detailed agenda from sites

        - Forward agenda to coordinating office(s) and Associate Director for Review Management, CBER for consideration

        - If agenda is acceptable, notify sites. If agenda is not acceptable, work with site contact, coordinating office, and Associate Director for Review Management, CBER to finalize

        - Work with site contact and coordinating office to determine logistics of visit

        - Schedule participants for pre-site visit training

- Provide a schedule of planned site visits to OCBQ/DIS, Associate Director for Review Management, CBER and/or DCM.

- The selection process will include consultation with OCBQ on the compliance status of the facility(ies) applying. The report from OCBQ will be considered in selecting sites for participation in the RSVP.

7. Effective Date

November 22, 2005

8. History

Written/Revised	Approved	Approval Date	Version Number	Comment
OCTMA/DMAT	Robert A. Yetter, PhD	November 22, 2005	2	Revision to Appendix
OCTMA/DMAT	Robert A. Yetter, PhD Jesse Goodman, MD	August 3, 2005	1	Reclassification of SOPP 7305
OCTMA/DMAT	Mark Elengold Joseph Biviano Mary Mey	July 2, 2004	0	Original SOPP 7305

9. Appendix

Guidelines / Instructions for Participants (PDF - 21KB) Appendix 1