PROJECT MANAGEMENT

Regulatory Project Management Site Tours and Regulatory Interactions Program: Pharmaceutical Company Selection

CONTENTS

PURPOSE

- This MAPP outlines the policies and procedures for selecting pharmaceutical companies for participation in the Regulatory Project Management Site Tours and Regulatory Interactions Program in the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- From 1999 to 2001, CDER's Project Management Training and Certification Subcommittee of the Regulatory Project Management Coordinating Committee (RPMCC) piloted a successful pharmaceutical industry site tour program for regulatory project managers. Following completion of the pilot program, the RPMCC agreed to continue the program for regulatory project managers as part of their professional training and development.

- The goals of the program are to provide (1) firsthand exposure to industry's drug development processes, (2) a venue for sharing information about regulatory project management (but not drug-specific information), and (3) an opportunity for CDER's regulatory project managers to fulfill an industry site tour requirement as part of CDER's Regulatory Project Management Certification Program.

REFERENCE

- *Federal Register* notice, "Training Program for Regulatory Project Managers: Information Available to Industry" (67 FR 48921, July 26, 2002)

ORGANIZATION

RPMCC oversees the Regulatory Site Tours Subcommittee (RSTS). RSTS oversees the Regulatory Project Management Site Tours and Regulatory Interactions Program.

POLICY

- A notice will be issued annually in the *Federal Register* announcing the Site Tours Program, based on available funding. All interested companies may apply for the Site Tours Program during the response period specified in the *Federal Register* notice.

- Tours will be fully funded through CDER's RPMCC budget. All companies 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.

- Priority consideration will be given to companies whose proposed program includes a tour of their manufacturing facilities and those companies that have not participated in the Site Tours and Regulatory Interactions Program within the last 3 fiscal years.

- The selection process will include consultation with CDER's Office of Compliance on the compliance status of the companies applying. The report from the Office of Compliance will be considered in selecting companies and alternates for participation in the Site Tours and Regulatory Interactions Program.

- In the event that a selected company is unable to participate, the first alternate company will be contacted. Up to three alternates may be identified during the selection process.

RESPONSIBILITIES

The Chair of the Regulatory Project Management Site Tours and Regulatory Interactions Program will:

- Coordinate the overall Site Tours and Regulatory Interactions Program with participating pharmaceutical companies. Specific duties include:

- Chairing internal meetings
- Drafting the annual *Federal Register* notice
- Consulting with the Office of Compliance
- Selecting pharmaceutical companies
- Communicating with the RPMCC and Training and Certification Subcommittee

The Regulatory Site Tours Subcommittee will:

- Assist the Chair in coordinating the overall Site Tours and Regulatory Interactions Program with participating pharmaceutical companies
- Participate in internal meetings and assist with generating the annual *Federal Register* notice
- Participate in pharmaceutical company selection, and assist with coordinating the Site Tours Program

The Office of Compliance will:

- Screen companies for any compliance issues

The Training and Certification Subcommittee will:

- Support the RSTS
- Communicate with the RPMCC about funding available for the Site Tours Program

The Regulatory Project Management Coordinating Committee will:

- Determine the fiscal year budget for the RSTS

PROCEDURES

After the response period announced in the *Federal Register* closes, the RSTS will:

- Compile a list of companies responding to the FR notice
- Review companies based on available RPMCC funding and resources
- Consult the Office of Compliance
- Notify companies and alternates of their status
- When originally selected company(ies) cannot take part in the program, notify alternate company(ies) of the opportunity to participate
- Following the selection of companies, the RSTS will finalize site tour dates and program agenda

EFFECTIVE DATE

This MAPP is effective upon date of publication.