
POLICY AND PROCEDURES

PROJECT MANAGEMENT

**Regulatory Project Management Site Tours and
Regulatory Interactions Program**

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PURPOSE

- This MAPP describes the Regulatory Project Management Site Tours and Regulatory Interactions Program (the Site Tours Program) in the Center for Drug Evaluation and Research (CDER), including the overall oversight of the program. This MAPP also outlines the policies and procedures for selecting pharmaceutical companies for participation in the Site Tours Program.

BACKGROUND

- From 1999 to 2001, CDER’s Training and Certification Subcommittee of the Regulatory Project Management Coordinating Committee (RPMCC) piloted a successful pharmaceutical company 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:
 - Firsthand exposure to the industry’s drug development processes
 - A venue for sharing information about regulatory project management (but not drug-specific information)

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- 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
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ORGANIZATION

- The RPMCC oversees the Training and Certification Subcommittee where the Regulatory Site Tours Subcommittee (RSTS) resides. The RSTS oversees the Site Tours Program.
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POLICY

- An annual notice announcing the Site Tours Program and how to apply will be issued in the *Federal Register*. 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 to those companies who have not participated in the Site Tours Program within the last 3 fiscal years.
 - The selection process will include confirmation from CDER’s Office of Compliance and from the chair of the RSTS that the companies that have applied do not have outstanding actions from the Office of Compliance and that they are not in arrears for user fees. These factors will be considered in selecting companies and alternates for participation in the Site Tours 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.
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RESPONSIBILITIES

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

- Coordinate the overall Site Tours Program with participating pharmaceutical companies. Specific duties include:
 - Chairing internal meetings
 - Drafting the annual *Federal Register* notice
 - Consulting with the Office of Compliance
 - Reviewing the Arrears List to ensure that user fees have been paid
 - Selecting pharmaceutical companies
 - Communicating with the RPMCC and the Training and Certification Subcommittee

The Regulatory Site Tours Subcommittee will:

- Assist the Site Tours Program chair in coordinating the overall Site Tours 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 both during the initial site selection phase of the program and again approximately 30 days before the date of the site tour

The Training and Certification Subcommittee will:

- Support the RSTS
- Communicate with the RPMCC about available funding 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 that responded to the *Federal Register* notice
 - Review companies based on available RPMCC funding and resources
 - Consult the Office of Compliance
 - Review the user fees Arrears List
 - 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 confirm the site tour dates, finalize the program agenda, and facilitate all logistics for the site tour participants

EFFECTIVE DATE

This MAPP is effective upon date of publication.