

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Certifier R. VEDESMA

Food and Drug Administration

Training Program for Regulatory Project Managers; Information Available to Industry

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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**SUMMARY:** The Food and Drug Administration (FDA), Center for Drug Evaluation and Research (CDER), is announcing the continuation of the Regulatory Project Manager Site Tours. This training program, initiated in 1999, gives CDER's regulatory project managers an opportunity to tour pharmaceutical facilities. The program provides regulatory project managers and their industry counterparts an opportunity to share their regulatory experiences. The program is intended to enhance review efficiency and quality by providing CDER staff with a better understanding of the pharmaceutical industry and its operation, and to improve communication and cooperation between CDER staff and industry. The purpose of this notice is to invite pharmaceutical companies interested in participating in these programs to contact CDER.

**DATES:** Pharmaceutical companies may submit proposed agendas by [*insert date 45 days after date of publication in the Federal Register*].

**FOR FURTHER INFORMATION CONTACT:** Sean J. Belouin, Center for Drug Evaluation and Research (HFD-530), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-2481, FAX 301-827-2523, e-mail: BELOUINS@cder.fda.gov.

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**SUPPLEMENTARY INFORMATION:****I. Background**

An important part of CDER's commitment to make safe and effective drugs available to all Americans is optimizing the efficiency and quality of the drug review process. To support this primary goal, CDER has initiated various training and development programs to promote high performance in its regulatory project management staff. CDER seeks to significantly enhance review efficiency and review quality by providing the staff with a better understanding of the pharmaceutical industry and its operations. To this end, CDER is continuing the Regulatory Project Manager Site Tours to give regulatory project managers the opportunity to tour pharmaceutical facilities. The goals are to provide: (1) Firsthand exposure to industry's drug development processes, and (2) a venue for sharing information about project management procedures (but not drug-specific information) with industry representatives.

**II. Regulatory Project Manager Site Tours and Regulatory Interactions**

In this program, over a 2- to 3-day period, small groups (five or less) of regulatory project managers, including a senior level regulatory project manager, may observe operations of pharmaceutical manufacturing, packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. The purpose of this tour, or any part of the program, is meant to improve mutual understanding and to provide an avenue for open dialogue.

During the site tours, regulatory project managers and their industry counterparts will also participate in daily workshops focusing on selective regulatory issues important to both CDER staff and industry. The primary

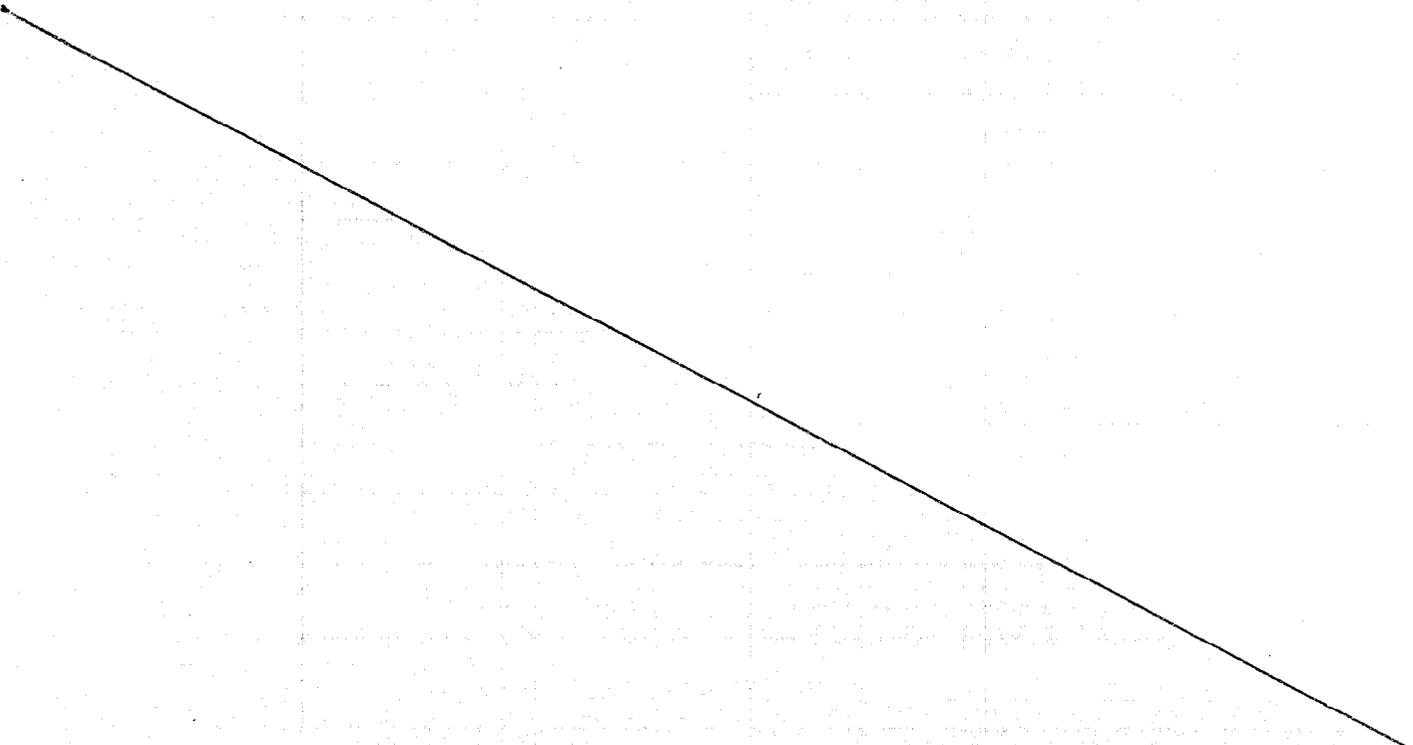
objective of the daily workshops is to learn about the team approach to drug development, including drug discovery, preclinical evaluation, project tracking mechanisms, and regulatory submission operations.

The overall benefit to regulatory project managers will be exposure to project management team techniques and processes employed by the pharmaceutical industry. By participating in this program, the regulatory project manager will grow professionally by gaining a better understanding of industry processes and procedures.

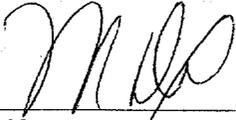
### **III. Site Selection**

All travel expenses associated with the site tours will be the responsibility of CDER, therefore, selection of potential facilities will be based on available resources for this program.

If your firm is interested in offering a site tour or learning more about this training opportunity, please submit a proposed agenda to Sean J. Belouin (see **FOR FURTHER INFORMATION CONTACT**).



Dated: 7/17/02  
July 17, 2002.



Margaret M. Dotzel,  
Associate Commissioner for Policy.

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