Cellular and Gene Therapies Interactive Site Tours Program for Regulatory Project Managers and Reviewers; Information Available to Industry

A Notice by the Food and Drug Administration on 07/15/2024

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

ACTION:

Notice.

SUMMARY:

The Food and Drug Administration's (FDA or the Agency) Center for Biologics Evaluation and Research (CBER), Office of Therapeutic Products (OTP) is announcing the Cellular and Gene Therapies Interactive Site Tours Program (the Interactive Site Tours Program). This program is

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intended to give CBER regulatory project managers and/or reviewers an opportunity to tour biotechnology manufacturing facilities developing cellular and gene therapy products, and to exchange regulatory experiences with their industry counterparts. With this program, CBER intends to enhance review efficiency and quality by providing CBER staff with a better understanding of the biotechnology manufacturing industry and its operations. The purpose of this notice is to invite companies developing cellular and gene therapy products interested in participating in this program to contact OTP for more information.

DATES:

Companies may send proposed agendas to the Agency by August 14, 2024.

FOR FURTHER INFORMATION CONTACT:

Lori Tull, Office of Review Management and Regulatory Review, Office of Therapeutic Products, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-8361, *Lori.Tull@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

DOCUMENT DETAILS

Printed version:
PDF

Publication Date:
07/15/2024

Agencies:
Department of Health and Human Services
Food and Drug Administration

Dates:
Companies may send proposed agendas to the Agency by August 14, 2024.

Document Type:
Notice

Document Citation:
89 FR 57417

Page:
57417-57418 (2 pages)

Agency/Docket Number:
Docket No. FDA-2024-N-2908

Document Number:
2024-15351

DOCUMENT DETAILS

DOCUMENT STATISTICS

Page views:
222
as of 07/20/2024 at 4:15 am EDT

DOCUMENT STATISTICS

ENHANCED CONTENT

regulations.gov

Cellular and Gene Therapies Interactive Site Tours Program for Regulatory Project Managers

Under section 351 of the Public Health Service Act (PHS Act), FDA is authorized to license biological products if they have been demonstrated to be "safe, pure, and potent." CBER is one of two Centers at FDA that regulates biological products for human use under applicable statutory provisions of the PHS Act and the Federal Food, Drug, and Cosmetic Act (FD&C Act). Section 3033 of the 21st Century Cures Act (Cures Act) (Pub. L. 114-255), was signed into law on December 13, 2016, and amended section 506 of the FD&C Act to specifically address the expedited development and review of certain regenerative medicine therapies, including cell therapies, therapeutic tissue engineering products, and human cell and tissue products.

An important part of CBER's commitment to make safe and effective biological products available to all Americans is optimizing the efficiency and quality of the biologics review process. To support this goal, CBER has initiated various training and development programs to promote high performance in its regulatory project management and review staff. OTP seeks to enhance review efficiency and review quality by providing staff with a better understanding of the biotechnology industry and its operations. To this end, CBER/OTP is offering regulatory project managers and reviewers the opportunity to tour biotechnology manufacturing facilities. The goals are to provide the following: (1) firsthand exposure to industry's product development processes and (2) a venue for sharing information about project management best practices (but not product-specific information) with industry representatives.

II. The Interactive Site Tours Program

In this program, which may last a few days, a small group of OTP regulatory project managers and/or reviewers, potentially also including senior level staff, can observe operations of biologics manufacturing and/or packaging facilities, pathology/toxicology laboratories, and regulatory affairs operations. Neither this tour nor any part of the program is intended as a mechanism to inspect, assess, judge, or perform a regulatory function, but is meant rather to provide an avenue for open dialogue between CBER/OTP staff and industry representatives. During the Interactive Site Tours Program, regulatory project managers and reviewers may also participate in daily workshops with their industry counterparts, focusing on selective regulatory issues important to both OTP staff and industry. The primary objective of the daily workshops is to understand the team approach to biological product development, including discovery, nonclinical and clinical evaluation, postmarketing activities, and regulatory submission operations. The overall benefit to regulatory project managers and reviewers will be exposure to project management, team techniques, and processes employed by the biotechnology industry. By participating in this program, the regulatory project managers and reviewers will gain a better understanding of industry processes and procedures.

III. Site Selection

All travel expenses associated with the Interactive Site Tours Program will be the responsibility of OTP; therefore, selection of facility tour sites will be based on

the availability of funds and resources for the program. Selection will also be based on firms having a favorable facility status as determined by FDA's Office of Regulatory Affairs District Offices in the firms' respective locations. Firm participation in the program is limited to companies developing cellular and/or gene therapy products. Firms that want to learn more about this opportunity or that are interested in offering a site tour should respond by sending a proposed agenda via email directly to Lori Tull (see **DATES** and **FOR FURTHER INFORMATION CONTACT**).

Dated: July 9, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024-15351 Filed 7-12-24; 8:45 am]

BILLING CODE 4164-01-P