

# OMB-17-08 ANNUAL REPORT

*Fiscal Year: 2019*

## General Report

The Food and Drug Administration (FDA) hosted one conference with expenditures greater than \$100,000 this fiscal year. Conference sponsor included the Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH). Conference topics included the following: Navigating the World of Combination Products, Regulatory Highlights for Biosimilars and Interchangeables, Quality System Regulation and ISO 13485 Comparison: Corrective and Preventive Action (CAPA) Requirements and Building Quality Clinical Data into Premarket Approval Applications (PMAs). This course was designed to provide participants with a strong, foundation in understanding the FDA’s drug and medical device regulatory requirements.

## Narrative Report

See below for a summation of all conference expenditures for FY 2019.

<b>Total Conference Expenses (in dollars)</b>	<b>\$138,479</b>
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## Basic Information

Conference Title	<b>FDA Small Business Regulatory Education for Industry (REdI) Conference May 2019</b>
Applicable Conference Type	Scientific, FDA Hosted/Sponsored/Co-Sponsored
Conference Location	Revere Hotel Boston, Massachusetts
Conference Start Date	Wednesday, May 29, 2019
Conference End Date	Thursday, May 30, 2019



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## Cost and Attendee Information

Total agency cost of the conference	\$138,479
Total number of individuals whose travel expenses were paid by the agency	21

## Explanation of how the conference advanced the mission of the agency

This conference advanced the mission of the FDA because the framework was designed to provide participants with a strong foundation in understanding the FDA's drug and medical device regulatory requirements. Attendees left with a set of tools to assist in preparing regulatory filings and interacting with the FDA. FDA speakers were available to answer questions one-on-one at the end of each day.