CDER Small Business and Industry Assistance Program Overview

LT Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance
Division of Drug Information
Office of Communications
Center for Drug Evaluation and Research
Food and Drug Administration
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Objective

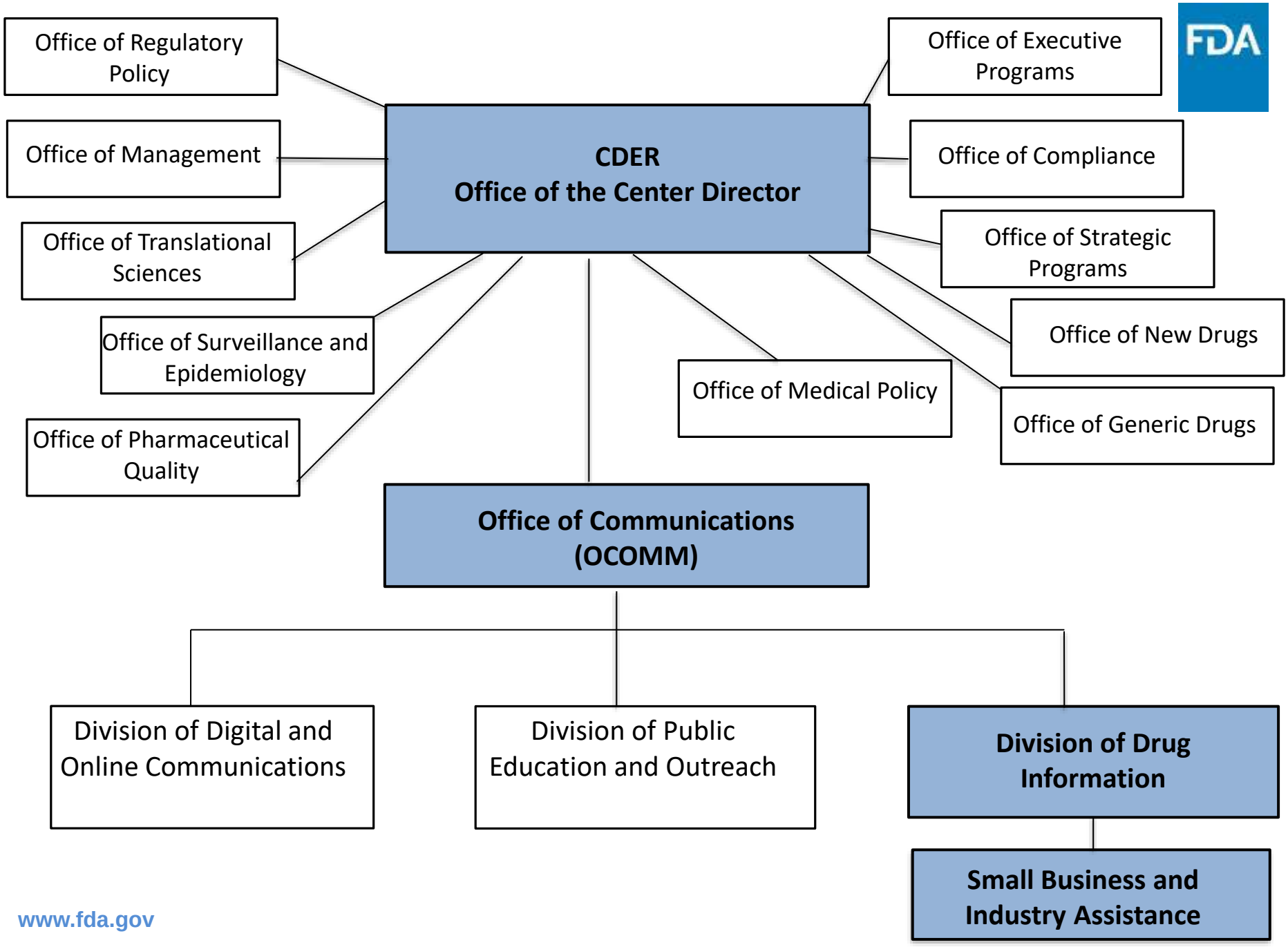
To describe the resources available via CDER's Small Business and Industry Assistance (SBIA) Program.

FDA's Philosophy

Timely interactive communication with sponsors during drug development is a core activity to help achieve our mission to **facilitate the conduct of efficient and effective drug development** programs, which can **enhance public health** by making new safe and effective drugs available to the American public in a timely manner.

SBIA

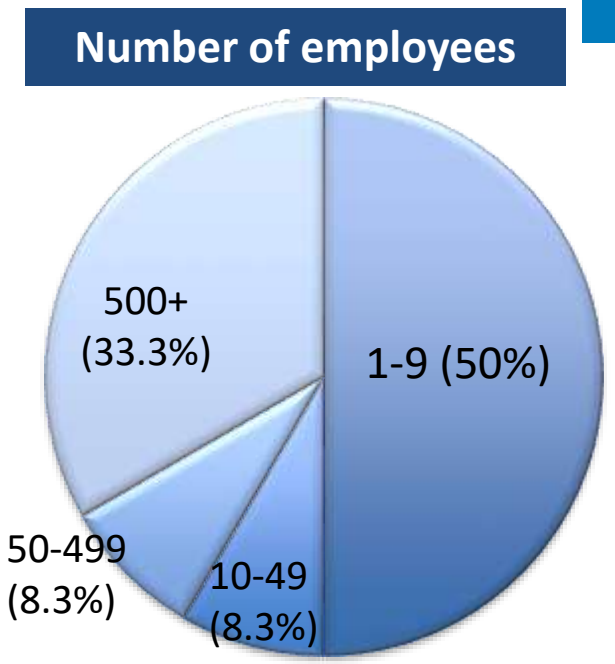
Providing timely and accurate information on human drug development and regulation through engagement with small pharmaceutical business and industry


Office of Regulatory Policy
Office of Management
Office of Translational Sciences
Office of Surveillance and Epidemiology
Office of Pharmaceutical Quality
CDER
Office of the Center Director
Office of Executive Programs
Office of Compliance
Office of Strategic Programs
Office of New Drugs
Office of Medical Policy
Office of Generic Drugs
Office of Communications (OCOMM)
Division of Digital and Online Communications
Division of Public Education and Outreach
Division of Drug Information
Small Business and Industry Assistance

SBIA Audience

Though our focus is on small business, our resources and outreach activities extend to **all of the regulated pharmaceutical industry**, and are not restricted to small business.

The majority of SBIA clientele are located within the U.S. However, our outreach extends globally.

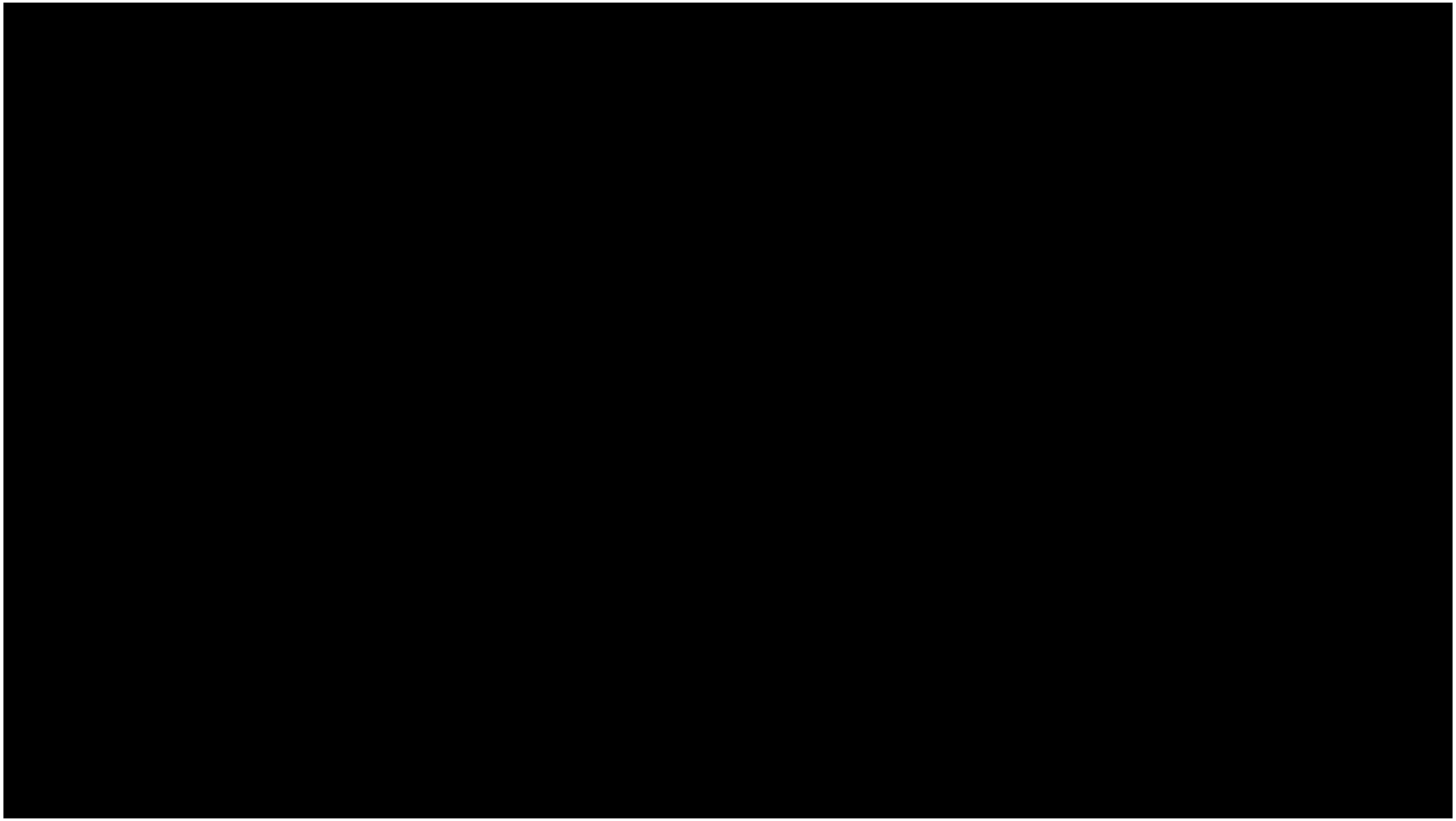


For CDER SBIA purposes, the term "small business" is defined as a business that has fewer than 500 employees, including employees of affiliates. An affiliate is further defined as a business entity that has a relationship with a second business entity if:

- one business entity controls, or has the power to control, the other business entity, or

- a third party controls, or has the power to control, both entities.

Learn about CDER
Small Business
and Industry
Assistance (SBIA)
and how we can help you!



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Direct Communication Services

DDI/SBIA staff respond to public inquiries

No ‘small business qualifications’
Anyone can contact SBIA

In 2019, SBIA responded to:

6,550 Emails
3,773 Phone Calls
18 Correspondence/Letters/Social Media Messages
Total: 10,335 Inquiries

Workshops and Conferences

Webinars

Tool to communicate directly with industry

Extends SBIA's reach globally

YouTube Archives

CDER Small Business & Industry Assistance (SBIA)

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Calendar of Upcoming Events

Date	Event	Location	Event Type
Aug. 25 - Aug. 28, 2020	Regulatory Education for Industry (REdI) Annual Conference	Online	Conference
Sept. 29 - Sept. 30, 2020	Regulatory Education for Industry: Advancing Innovative Science in Generic Drug Development Workshop	Webcast	Workshop

Recent Events and Information

- A Pharmaceutical Quality Webinar for Global Stakeholders (July 23, 2020)
- Regulatory Education for Industry: Regulated Bioanalysis Workshop: Requirements and Expectations (June 30, 2020)
- CDER SEND Common Issues and Policy Update (June 15, 2020)
- Regulatory Education for Industry (REdI): Pharmacovigilance and Risk Management Conference – New Approaches, Tools, and Technologies (June 9-10, 2020)
- Webinar: Monograph reform is here! Learn what to expect and how to prepare (May 29, 2020)
- Still submitting paper to CDER? Send electronically with CDER's NextGen Portal instead! (for submissions not required in eCTD) (May 26, 2020)
- SBIA Webinar: Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency (April 30, 2020)
- SBIA Webinar: Postmarketing Drug Safety Compliance: 2019 Inspection Findings (April 29, 2020)
- SBIA Webinar: Updates on FDA's Drug-Drug Interaction Final Guidances (April 24, 2020)
- Regulatory Education for Industry (REdI): Generic Drugs Forum (April 15-16, 2020)

Drug Development

New Drug Application(NDA)/Biologic License Application (BLA) | Submission of the Marketing Application

Generic Drug Review

Over-the-Counter (OTC) Drug Review

www.fda.gov/cdersbia

CDER SBIA Learn: Webinars, Conferences, Trainings & Upcoming Events

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Welcome to CDER SBIA Learn. We offer a variety of multimedia resources to provide information that is comprehensive, interactive, and easily accessible to small pharmaceutical business and industry. Our offerings are organized by topic below.

SBIA Multimedia Resources and Offerings

Over-the-Counter Drug Regulation

New Drug Development and Safety

Regulatory Submissions

Generic Drugs

Registration and Listing

Drug Supply Chain

Import-Export

Drug Quality

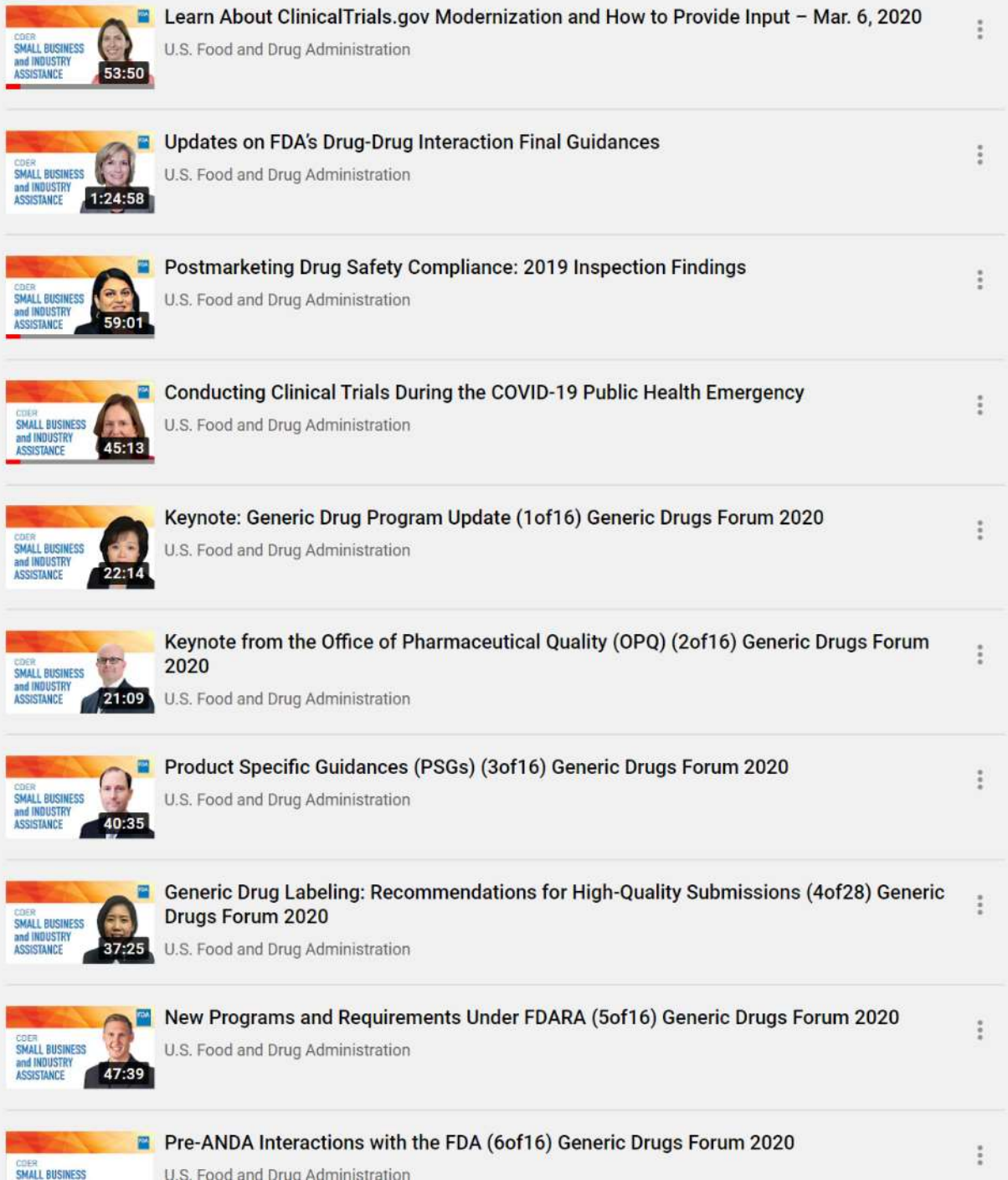
Additional Topics
BioResearch Monitoring Program, Drug Master File, Compounding, Drug Shortages

Related Presentations and Webinars

www.fda.gov/cdersbialearn

YouTube → FDA → Playlists → CDER Small Business and Industry Assistance

- 2020
- 2019
- 2018
- 2017



Short electronic newsletter, highlighting a specific regulatory issue every other month in an easy to read format.

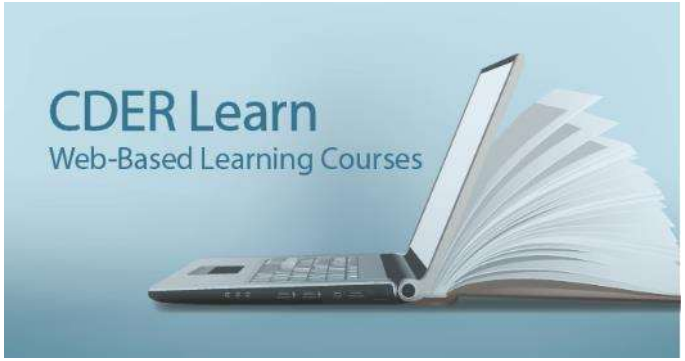
Accompanied by audio podcast downloads

www.fda.gov/cdersbiachronicles

CDERLearn

Web-based learning tutorials on topics relating to drug regulation and review

www.fda.gov/cderlearn



Courses Offered:

Bringing an Over-the-Counter (OTC) Drug to Market

Chemistry, Manufacturing, and Controls (CMC) Perspective of the IND

Electronic Common Technical Document (eCTD)

Engaging with the FDA During New Drug Development

Human Drug Establishment Registration and Drug Listing Compliance

Overview of the Generic Drug User Fee Amendments of 2012 (GDUFA)

GDUFA Self-Identification (SPL) Submission – Part 1

GDUFA Self-Identification (SPL) Submission – Part 2

PRESENTATIONS

Annual Small Business Innovation Research (SBIR)/ Small Business Technology Transfer (STTR) Conferences

National Institutes of Health Commercial Accelerator Program (NIH CAP) and Feed Forward sessions

U.S Patent and Trademark Office

EXHIBITS

The Association of Clinical Research Professionals
BIO
Drug Information Association
Society of Clinical Research Associates

FDA

CDER SBIA email updates:

- New regulations and Federal Register announcements
- New guidance documents
- Upcoming meetings, conferences, and workshops
- Upcoming webinars
- New web-based learning courses

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Get Email Updates: Drugs Small Business and Industry Assistance

Get regular FDA email updates delivered on this topic to your inbox.

www.fda.gov

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Follow us on LinkedIn

Challenge Question

How can one stay in the know about upcoming SBIA conferences, webinars, and news?

A. Sign up for the Small Biz Buzz email updates via www.fda.gov/cdersbia.

B. Bookmark www.fda.gov/cdersbia and continually check the Event Calendar.

C. Follow the Small Business and Industry Assistance LinkedIn page via the link at www.fda.gov/cdersbia.

D. All of the above

CDER SBIA Contact Information:

Phone: 866-405-5367 or 301-796-6707

Email: **CDERSBIA@fda.hhs.gov**

Monday – Friday, 8 AM – 4:30 PM ET

www.fda.gov/cdersbia www.fda.gov/cdersbialearn

SBIA Email Updates:
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SBIA LinkedIn:
https://www.linkedin.com/company/cder-small-business-and-industry-assistance


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ADMINISTRATION