Leveraging Small Business and Industry Assistance (SBIA) Resources

Renu Lal, PharmD, BCACP

Lieutenant Commander, U.S. Public Health Service

CDER Small Business and Industry Assistance (SBIA)

Division of Drug Information (DDI)

Office of Communications (OCOMM)

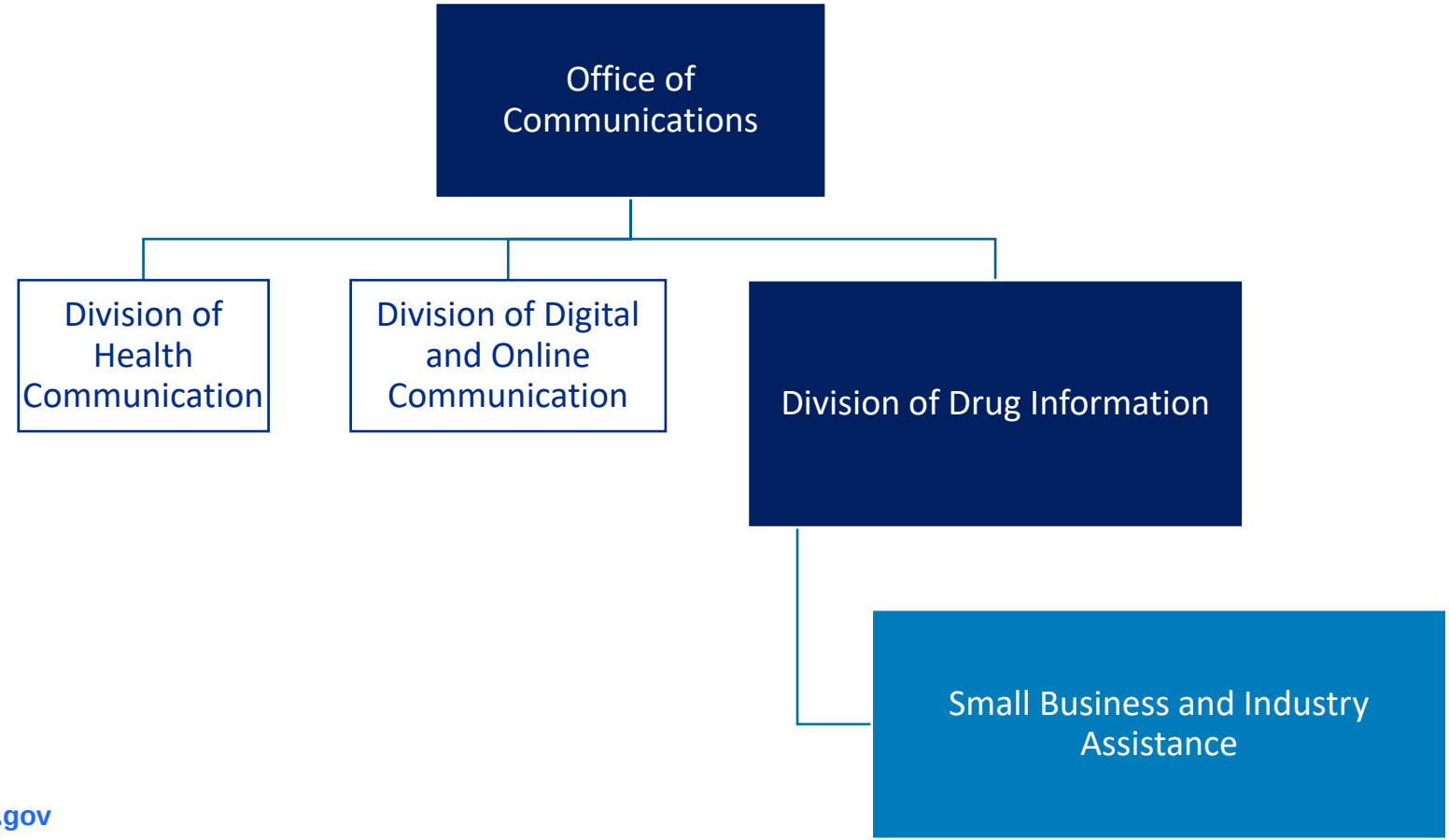
CDER | U.S. FDA

REdI Annual Conference – June 2023

Objectives

- Locate the SBIA webpage and identify the resources it provides
- Identify three services SBIA offers to assist the pharmaceutical industry
- Understand how to register for SBIA events and find recordings of past events

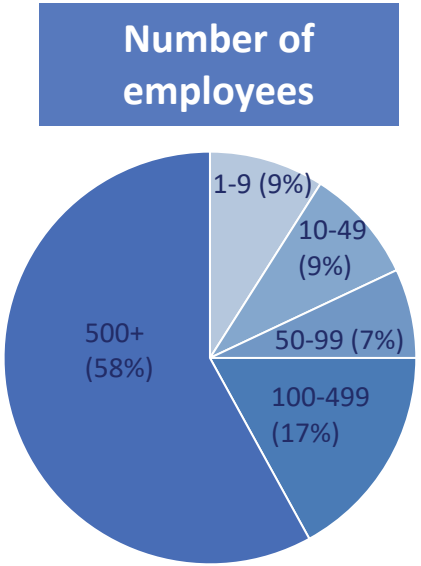
Organizational Structure



SBIA Mission

- ✓Provide industry stakeholders with immediate access to resources, education & training
- ✓Allow for a more clearly informed and efficient developmental process
- ✓Align with CDER's goal of approving safe and effective human drugs and biopharmaceuticals

SBIA Audience



Resources

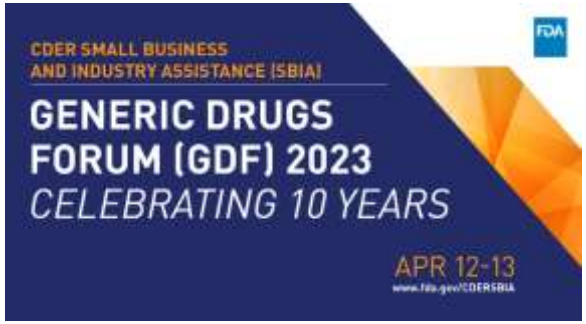
- Direct Communication Services
- Webpages
- Training Resources
- News and Updates

Direct Communications Services

- **Phone:** 301-796-6707 | 866-405-5367
- **Email:** CDERSBIA@fda.hhs.gov

(Monday – Friday 8 AM – 4:30 PM ET)

Training: Workshops and Conferences



Training: Webinars

Training:
SBIA Chronicles

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

Accompanied by an audio podcast

www.fda.gov/cdersbiachronicles

Webpages

www.fda.gov/cdersbia

CDER Small Business & Industry Assistance (SBIA)

A Comprehensive Resource for Information on Human Drug Development in Regulation

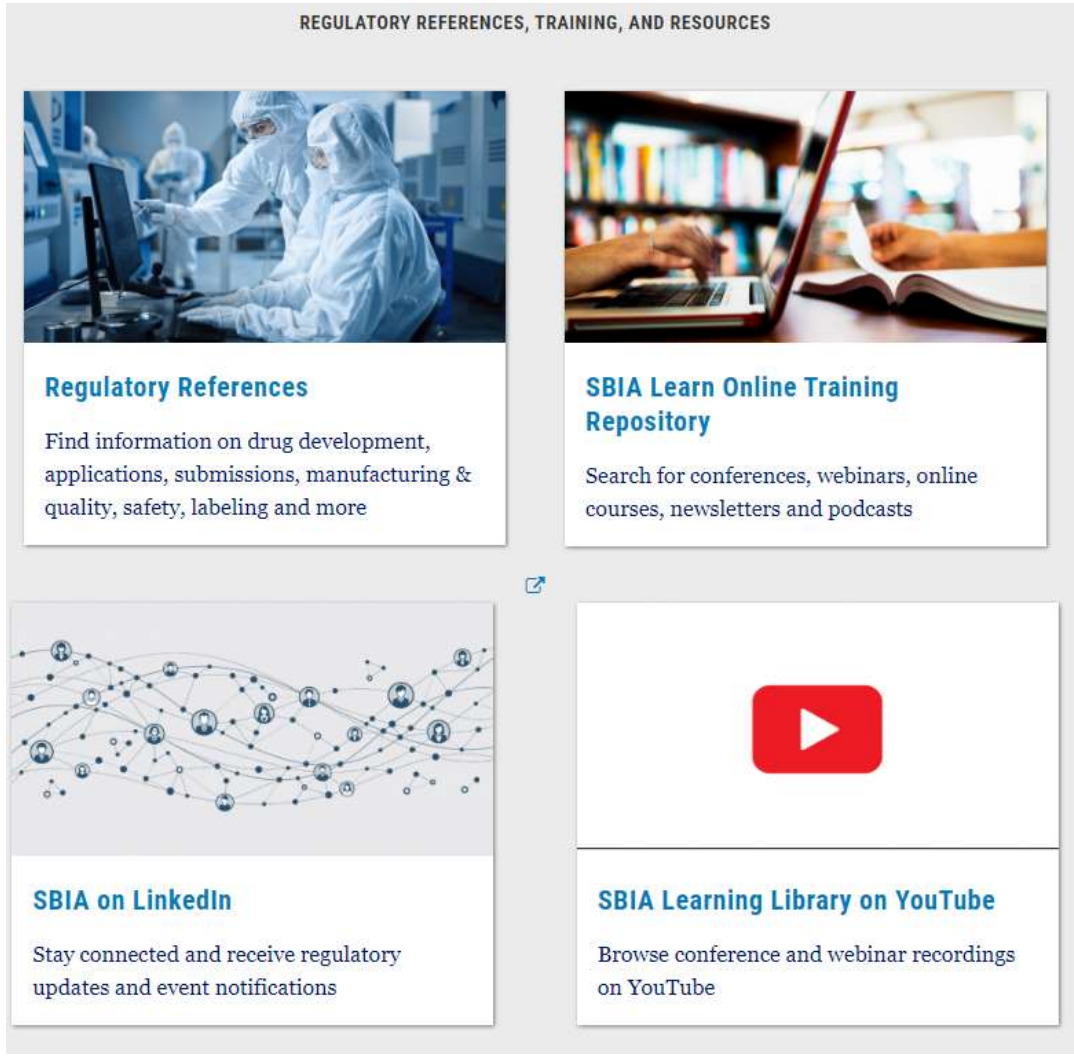
Subscribe to Email Updates | Share | Tweet | Linkedin | Email | Print

Register for Upcoming Events

Date	Time	Event	Location
June 5-9, 2023	8:40 AM - 4:30 PM	Regulatory Education for Industry (REdI) Annual Conference 2023	Conference
May 24, 2023	9:00 AM - 2:00 PM	An Update on Field Alert Reports (FAR) and Biological Product Deviation Reports (BPDR)	Webinar
May 16, 2023	1:00 PM - 2:00 PM	OTC Monograph Drug User Fee Program (OMUFA): Understanding FY 2023 User Fees and Registration	Webinar
May 15, 2023	1:00 PM - 4:30 PM	A Deep Dive: GDUFA III Scientific Meetings	Webinar
May 2, 2023	1:00 PM - 3:30 PM	Navigating the First ICH Generic Drug Draft Guideline "M13A Bioequivalence for Immediate-Release Solid Oral Dosage Forms"	Webinar

Webpages

www.fda.gov/cdersbia



Webpages

www.fda.gov/cdersbia

Regulatory References

Find information on drug development, applications, submissions, manufacturing & quality, safety, labeling and more

Search for Regulatory References | Drugs

Share | Tweet | LinkedIn | Email | Print

Use filter and search box to find regulatory resources

Topic

New Drug Review, New Drug Application (NDA)

Clear Filter

- Labeling
- Meetings, Engaging with FDA
- New Drug Review, New Drug Application (NDA)
- Over-the-Counter Drug Review

Export Excel | Show 10 entries

	ntacts; Investigational New Drug Application (IND); New Drug Review, New Drug ric Drugs, Abbreviated New Drug Application (ANDA)
	rug Application (NDA); Investigational New Drug Application (IND)
Coronavirus Treatment Acceleration Program (CTAP)	New Drug Review, New Drug Application (NDA); Clinical Trials, Drug Development and Approval
Electronic Common Technical Document (eCTD)	Submissions, Forms, Contacts; Investigational New Drug Application (IND); New Drug Review, New Drug Application (NDA); Generic Drugs, Abbreviated New Drug Application (ANDA)
FDA IND, NDA, ANDA, or Drug Master File Binders	Submissions, Forms, Contacts; Investigational New Drug Application (IND); New Drug Review, New Drug Application (NDA); Generic Drugs, Abbreviated New Drug Application (ANDA); Drug Master Files
FDA List of Authorized Generic Drugs	Generic Drugs, Abbreviated New Drug Application (ANDA); New Drug Review, New Drug Application (NDA)
Formal Meetings Between the FDA and	Meetings, Engaging with FDA;

Webpages

www.fda.gov/cdersbialearn

SBIA Learn Online Training Repository

Search for conferences, webinars, online courses, newsletters and podcasts

CDER Small Business and Industry Assistance (SBIA) Learn

Online Training Repository

Subscribe to Email Updates | Share | Tweet | LinkedIn | Email | Print

The table below lists SBIA multimedia training resources, including conference/webinar presentations and recordings, online courses, newsletters and podcasts. Explore the SBIA recordings on YouTube to browse by most popular videos and see upcoming events for a list of future live events.

SBIA Recordings on YouTube | Upcoming SBIA Events

Use filters and search box to find resources

Advanced search (combine topic and search terms)

Topic | **Type**

Clear Filters

Search: | Export Excel | Show 10 entries

Summary	Type	Issued/Updated	Topic
Decentralized Clinical Trials (DCT) Draft Guidance	Webinar	6/20/23	Clinical Trials and Research, IND, New Drug Development
Overview: Clinical Pharmacology Considerations for Food Effect Studies	Webinar	6/15/23	Drug Development, Regulatory Submissions
Regulatory Education for Industry (REdI) Annual Conference 2023	Conference	6/5/23	BLA, Chemistry Manufacturing and Controls (CMC), Digital Health Technologies, Drug Development, FDA Meetings/Communications, IND, NDA, New Drug Development, Real World Evidence, and Regulatory Submissions

Webpages

SBIA Learning Library on YouTube

Browse conference and webinar recordings on YouTube

→ FDA → Playlists → CDER Small Business and Industry Assistance

CDER SBIA YouTube Learning Library

Subscribe to Email Updates | Share | Tweet | Linkedin | Email | Print

FDA's CDER Small Business and Industry Assistance (SBIA) is making available our YouTube learning library - now hundreds of our recordings are readily accessible.

Bookmark and share 2022, 2021, 2020 recordings of webinar and conference presentations. New content will be posted on SBIA's LinkedIn page, and top viewed presentations will be updated quarterly. The subject matter expert presentations are intended to educate and help industry navigate FDA policies and procedures.

Register for upcoming CDER SBIA webinars and conferences to learn directly from FDA subject matter experts and earn free continuing education.

Most Viewed 2022 Presentations

1. FDA Clinical Investigator Training Course (CITC) 2022

2. FDA NanoDay Symposium 2022
3. DMF Workshop: GDUFA III Enhancements and Structured Data Submissions – Session 3
4. More 2022 Recordings...

Webpages

CDER Small Business and Industry Assistance

CDER Small Business and Industry Assistance (SBIA)

FDA's information and training source for the regulated pharmaceutical industry

Pharmaceutical Manufacturing · Silver Spring, MD · 27,212 followers

✓ Following | Learn more | More

Home | About | Posts | Events | Videos

CDER Small Business and Industry Assistance (SBIA)
27,212 followers

All | Images | Videos | Articles | Documents | Ads

Sort by: Top

CDER Small Business and Industry Assistance (SBIA)
27,212 followers
1w •

Test your knowledge! The answer will be posted once the poll closes.

What is the most significant difference between recommendations in M13A ...see more

What is the most significant difference between recommendations in M13A as compared to FDA's current draft guidance on BE for ANDAs?

The author can see how you vote. Learn more

A. (See above for options)

B. (See above for options)

C. (See above for options)

D. (See above for options)

News and Updates: Email Subscriptions

FDA | Small Business and Industry Assistance (SBIA)

Regulatory Education for Industry (REdI) Annual Conference

JUNE 5 - 9, 2023

No Fee Registration

Agenda

Learn directly from the FDA's regulatory experts in medical product centers: drugs, devices, and biologics. This course is designed to provide participants with a strong, basic foundation in the FDA's regulatory requirements, and also create awareness of current activities.

Plenary Session Faculty



FDA | CDER | Small Business and Industry Assistance

INDUSTRY NEWS

FDA Publishes Final Question-and-Answer Guidance on a Risk-Based Approach to Monitoring Clinical Investigations

Today, the U.S. Food and Drug Administration published a final guidance for industry, "A Risk-Based Approach to Monitoring of Clinical Investigations – Questions and Answers."

The purpose of the guidance is to provide industry with recommendations on implementing a risk-based approach to monitor investigational studies on human drugs, biologics, medical devices, and combinations of these products. It expands on FDA's 2013 guidance for industry "Oversight of Clinical Investigations – A Risk-Based Approach to Monitoring" with additional recommendations to facilitate and encourage sponsors to implement risk-based monitoring. This guidance complements and does not supersede the 2013 guidance.

The new guidance focuses on FDA's recommendations for planning a monitoring approach, developing content for monitoring plans, and addressing and communicating results from monitoring. The questions and answers in this guidance strive to help sponsors plan and use risk-based approaches to monitor clinical investigations.

Revisions to the draft guidance included changes made in response to public comments that requested clarification of some of FDA's recommendations for planning and implementing risk-based approaches to monitor clinical investigations.

Sponsors must monitor their clinical investigations, but they have flexibility in how they do so. FDA believes risk-based monitoring can allow sponsors to identify and address issues that could affect processes that protect human research participants and clinical trial integrity during clinical investigations.

The Small Business and Industry Assistance (SBIA) program in the Center for Drug Evaluation and Research provides guidance, education and updates for regulated industry.

Challenge Question #1

In which of the SBIA resources can you find a database of searchable FDA webpages relating to drug development?

A. Regulatory References

B. SBIA Learn Online Training Repository

C. Calendar of Upcoming Events

D. SBIA Learning Library on YouTube

Challenge Question #2

Which of the following statements is NOT true?

A. You can stay connected with the latest regulatory information and offerings by subscribing to the SBIA listserv and following SBIA on LinkedIn.

B. Industry stakeholders may call or email SBIA directly.

C. SBIA's services are only available to companies with less than 500 employees, including affiliates.

D. SBIA offers many free conferences, webinars and workshops on various regulatory topics.

Summary and Action Items

- Email or call SBIA with your regulatory questions

  CDERSBIA@fda.hhs.gov | 866-405-5367 or 301-796-6707

- Bookmark www.fda.gov/cdersbia and www.fda.gov/cdersbialearn
- Browse the CDER SBIA playlists on FDA's YouTube channel
- Follow us on LinkedIn
- Subscribe to the SBIA listserv