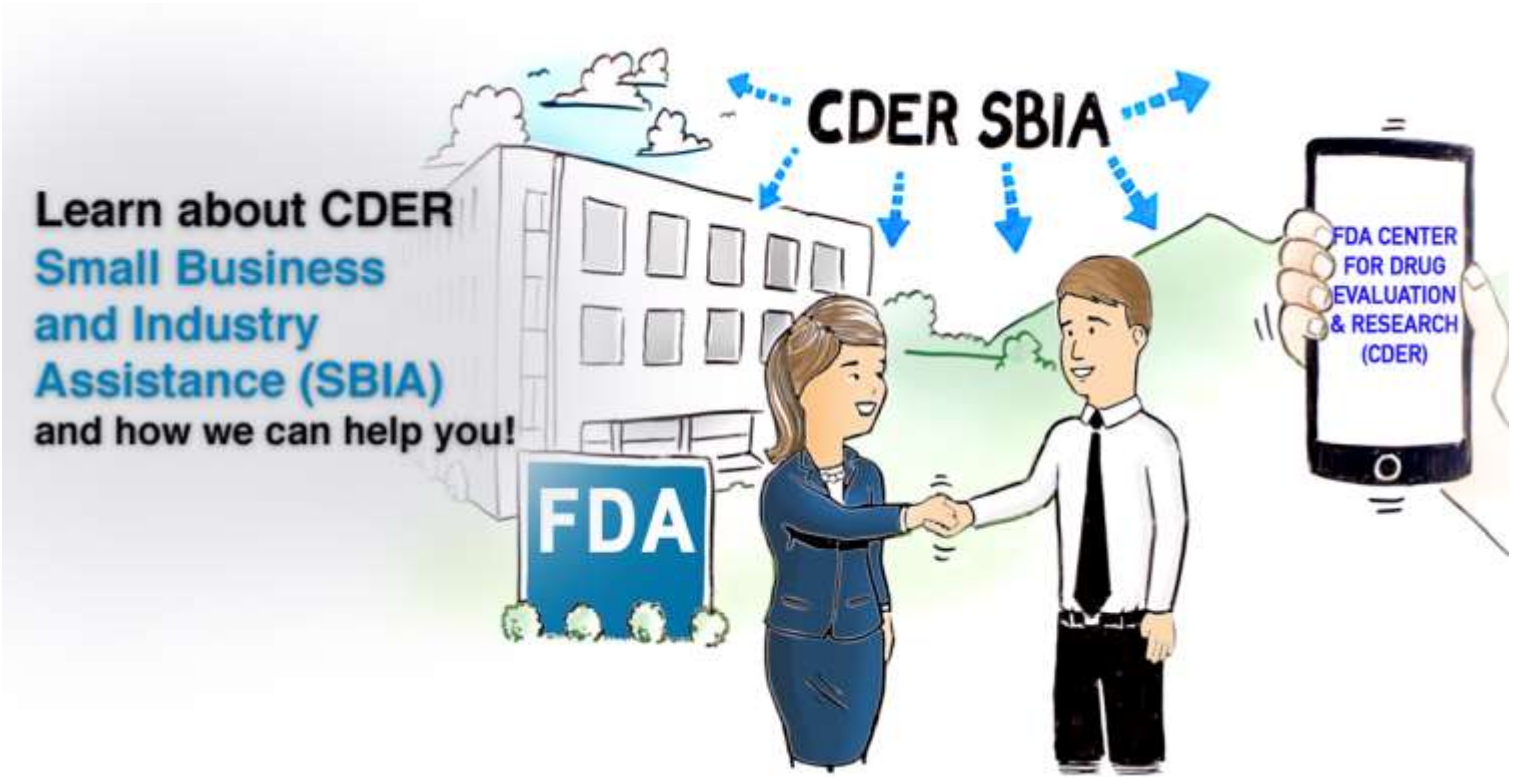
Leveraging Small Business and Industry Assistance (SBIA) Resources

Renu Lal, PharmD, BCACP
Lieutenant Commander, US Public Health Service
Team Lead | Division of Drug Information
Deputy Director | SBIA
Office of Communications
CDER | US FDA

REdI Annual Conference – May 30, 2024

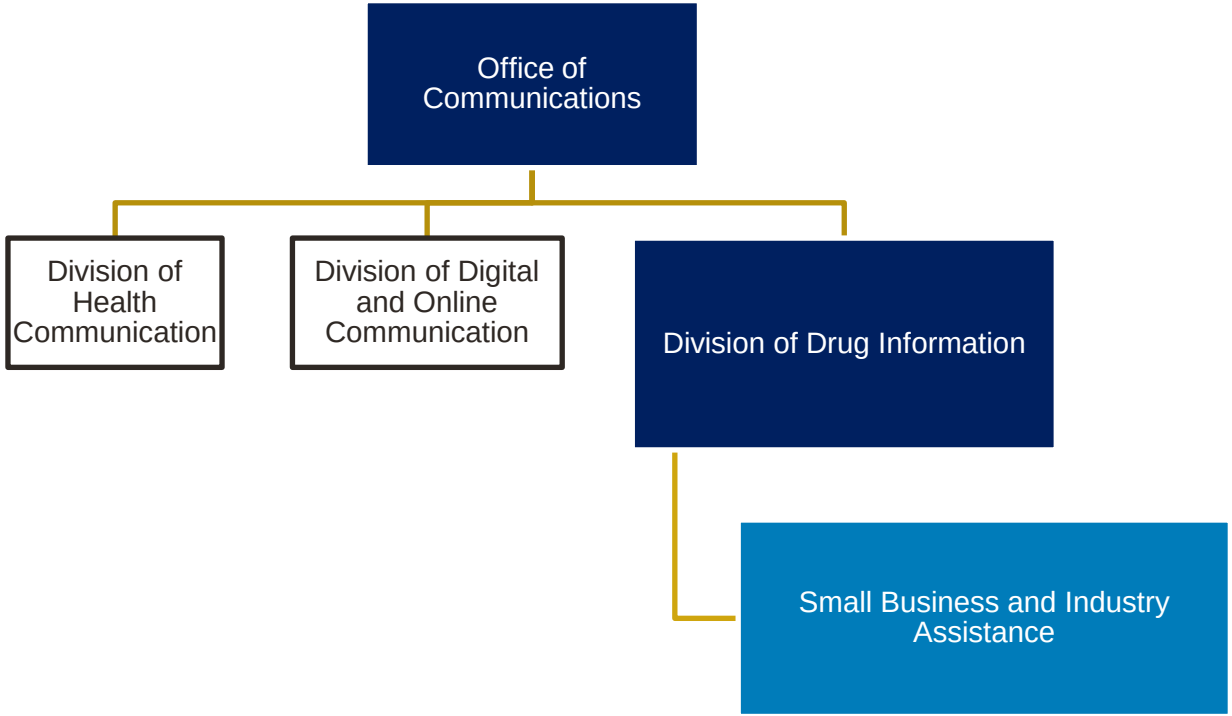


fda.gov/cdersbia

Learning Objectives

- Locate the SBIA webpage and identify 3 resources SBIA offers that can help YOU
- Understand how to register for SBIA events and find recordings of past events

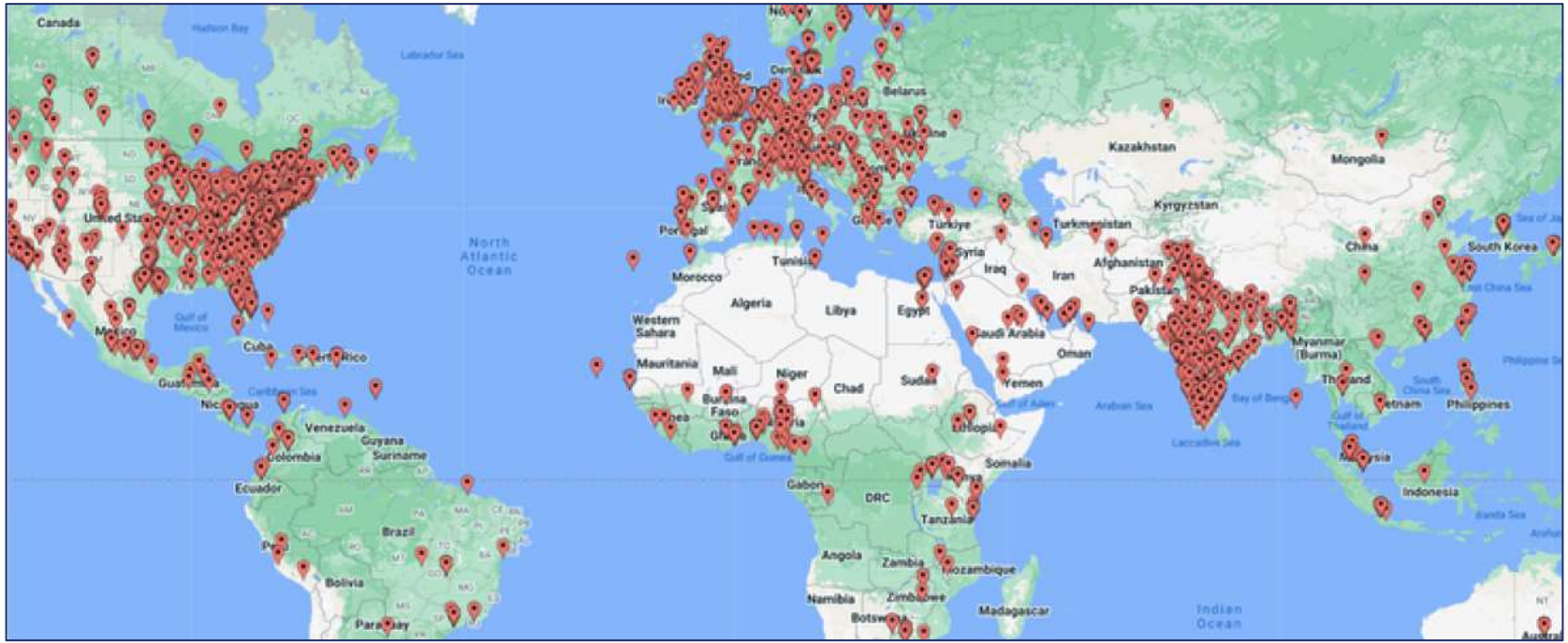
Organizational Structure



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

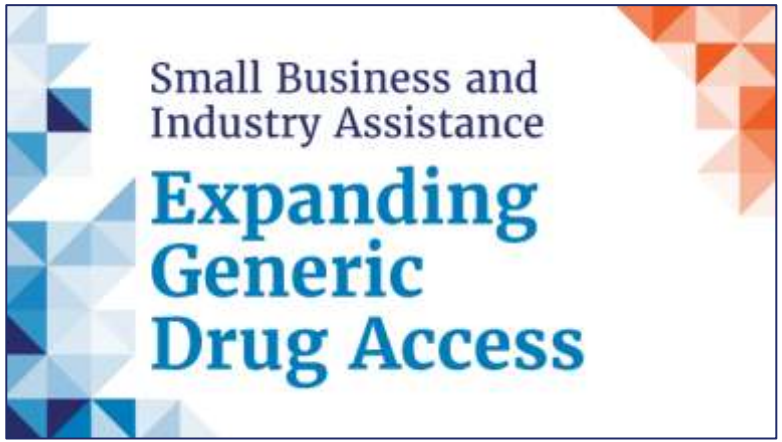
Direct Communications Services

- **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



fda.gov/cdersbia

Training: SBIA Chronicles

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

www.fda.gov/cdersbiachronicles

CDER Small Business & Industry Assistance (SBIA)

A Comprehensive Resource for Information on Human Drug Development in Regulation

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

www.fda.gov/cdersbia

Register for Upcoming Events

Date	Time	Event	Location
April 10 - 11, 2024	8:30 am - 5:00 pm	Generic Drugs Forum (GDF) 2024: Regulatory Considerations to Enhance Generic Drug Access	Conference
April 25, 2024	1:00 pm - 4:00 pm	Facilitating Generic Drug Product Development through Product-Specific Guidances	Webinar
May 9, 2024	1:00 pm - 3:30 pm	Redesigned Pre-Submission Meetings in GDUFA III: Benefits for ANDA Submission and Approval	Webinar
May 16, 2024	1:00 pm - 2:30 pm	Statistical Considerations for Premarketing Risk Assessment	Webinar
May 29-30, 2024	8:30 am - 4:30 pm	Regulatory Education for Industry (REdI) Annual Conference 2024: Innovation in Medical Product Development	Conference

REGULATORY REFERENCES, TRAINING, AND RESOURCES

Regulatory References

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

SBIA Learn Online Training Repository

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

SBIA on LinkedIn

Stay connected and receive regulatory updates and event notifications

SBIA Learning Library on YouTube

Browse conference and webinar recordings on YouTube

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

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;

Regulatory References

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

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

SBIA Learn Online Training Repository

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

www.fda.gov/cdersbialearn

Poll: Improving CDER SBIA Learn

Would *fda.gov/cdersbialearn* be more helpful if there was an option to:

A. Filter by multiple tiers of topics (Broad to Specific)

B. Filter by competency level (basic, intermediate, advanced)

C. A & B

In-Person: *Show of Hands*

Online Login 1: *Respond to Poll*

1. 

A Deep Dive: FDA's Model-Integrated Evidence (MIE) Industry Meeting Pilot Program fo
U.S. Food and Drug Administration • 3.8K views • 3 months ago

2. 

FDA-MHRA-HC 2024 Joint Symposium (Day 1)
U.S. Food and Drug Administration • 16K views • Streamed 3 months ago

3. 

FDA-MHRA-HC 2024 Joint Symposium (Day 2)
U.S. Food and Drug Administration • 7K views • Streamed 3 months ago

4. 

FDA-MHRA-HC 2024 Joint Symposium (Day 3)
U.S. Food and Drug Administration • 7K views • Streamed 3 months ago

5. 

Good Clinical Practice & Pharmacovigilance Compliance Symposium Day One – AM
U.S. Food and Drug Administration • 1.3K views • 2 months ago

6. 

Good Clinical Practice & Pharmacovigilance Compliance Symposium Day One – PM
U.S. Food and Drug Administration • 754 views • 2 months ago

7. 

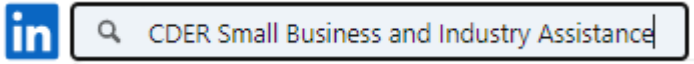
Good Clinical Practice & Pharmacovigilance Compliance Symposium Day Two – AM
U.S. Food and Drug Administration • 1.2K views • 2 months ago

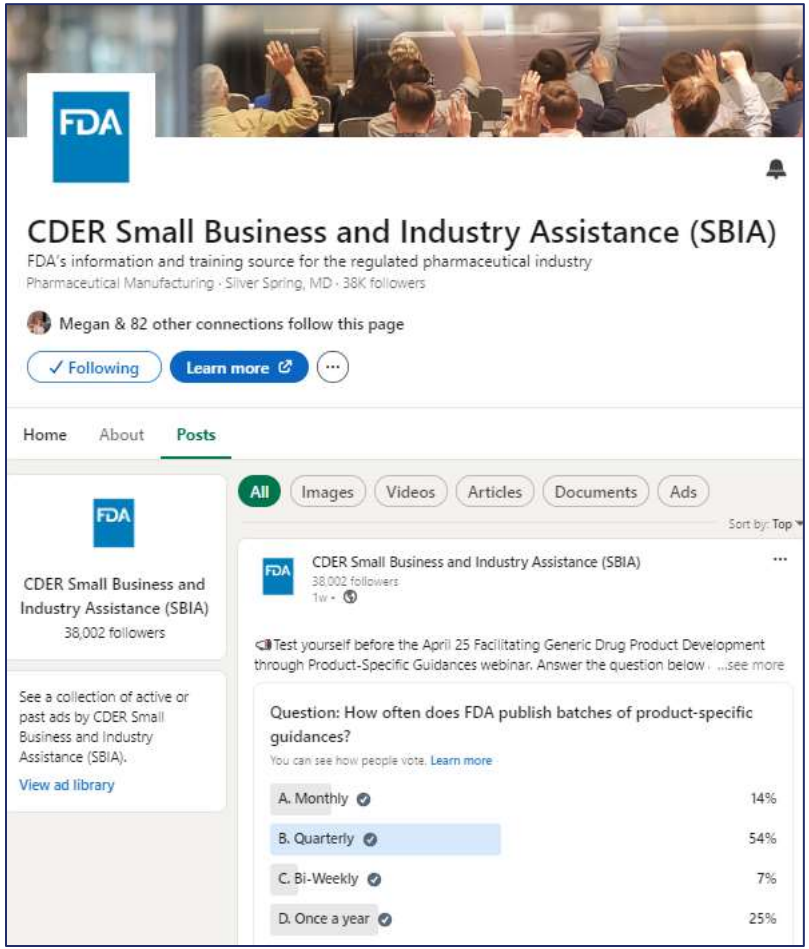
FDA

SBIA Learning Library on YouTube

Browse conference and webinar recordings on YouTube

FDA → Playlists → CDER Small Business and Industry Assistance


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 · 38K followers
Megan & 82 other connections follow this page
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View ad library
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1w
Test yourself before the April 25 Facilitating Generic Drug Product Development through Product-Specific Guidances webinar. Answer the question below · ...see more
Question: How often does FDA publish batches of product-specific guidances?
You can see how people vote. Learn more
A. Monthly 14%
B. Quarterly 54%
C. Bi-Weekly 7%
D. Once a year 25%


SBIA on LinkedIn
Stay connected and receive regulatory updates and event notifications

News & Updates: Email Subscriptions

FDA | CDER | Small Business and Industry Assistance

CONFERENCES

Regulatory Education for Industry (REdI) Annual Conference 2024

Innovation in Medical Product Development

Hybrid

May 29 – 30 | 8:30 AM - 4:30 PM ET

No Fee Registration

SHARE

DRUGS, DEVICES, AND BIOLOGICS

TRACKS WILL OFFER AN OPPORTUNITY FOR 1:1 QUESTIONS FOR ONSITE ATTENDEES

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.



FDA | CDER | Small Business and Industry Assistance

INDUSTRY NEWS

FDA establishes CDER Center for Clinical Trial Innovation (C3TI)

Today, FDA's Center for Drug Evaluation and Research (CDER) announced the launch of the CDER Center for Clinical Trial Innovation (C3TI). C3TI's mission is to promote CDER clinical trial innovation activities through enhanced communication and collaboration, both internally within CDER and externally.

"CDER's long-standing efforts to embed innovation in clinical trial design and conduct into our regulatory work have been crucial in bringing new therapies to areas of unmet medical need," said Patrizia Cavazzoni, M.D., director of CDER. "We are eager to build on this foundation by launching C3TI to further spur the adoption of clinical trial innovation across industry and within CDER."

For years, CDER has championed innovation, and our activities to foster and support innovation span drug development programs, therapeutic areas, and disciplines. These CDER efforts have led to improvements in the design and conduct of clinical trials that are intended to efficiently generate evidence on the safety and effectiveness of new therapies in ways that meet the growing demands of drug development.

Recently, we sought to understand the impact of these efforts by holding interviews, listening sessions, and a public workshop with both internal and external parties, and soliciting comments to a public docket. Based on these engagements, we recognize an opportunity to enhance the implementation of our innovative efforts and maximize the impact on drug development.

C3TI will be a central hub within CDER that supports innovative approaches to clinical trials that are designed to improve the efficiency of drug development. C3TI will facilitate the sharing of lessons learned across CDER's existing clinical trial innovation initiatives and will communicate and collaborate with external parties. C3TI will also manage a demonstration program that will expand opportunities for sponsors of innovative clinical trials to interact with CDER staff and for these trials to serve as case examples to spur further implementation. The three initial project areas under the C3TI Demonstration Program are 1) point-of-care or pragmatic trials; 2) Bayesian analyses; and 3) trials using selective safety data collection.

This new center within CDER will enable both internal and external parties to access information on clinical trial innovation efforts more easily, engage in collaborations, identify resources that can further support the use of innovative modalities, and identify development programs where a concerted approach to the use of clinical trial innovations would be impactful. The goals of these efforts are to assist those involved in clinical research in staying current with clinical trial innovations, improve the efficiency and effectiveness of clinical trials, help increase the participation of diverse populations in clinical trials, and, in turn, accelerate the development of safe and effective new drugs.

For more information about C3TI, including how to participate in a project in the C3TI Demonstration Program, explore the C3TI webpage. Visit the CDER Conversation with Dr. Kevin Bugin, deputy director for operations in CDER's Office of New Drugs and lead for C3TI to learn more about the impetus for establishing C3TI and the center's forward-facing goals and objectives.

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

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

Resources

SBIA webpage

SBIALearn

YouTube

SBIA LinkedIn

Email updates

fda.gov/cdersbia

Summary and Call to Action

- 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

CDER SBIA Learn Feedback

Do you have suggestions for improvements on the usability *fda.gov/cdersbialearn* ?

In-Person: *Please share them with me sometime today*

Online Login 1: *Enter your suggestions into the Poll question*