Leveraging SBIA Resources

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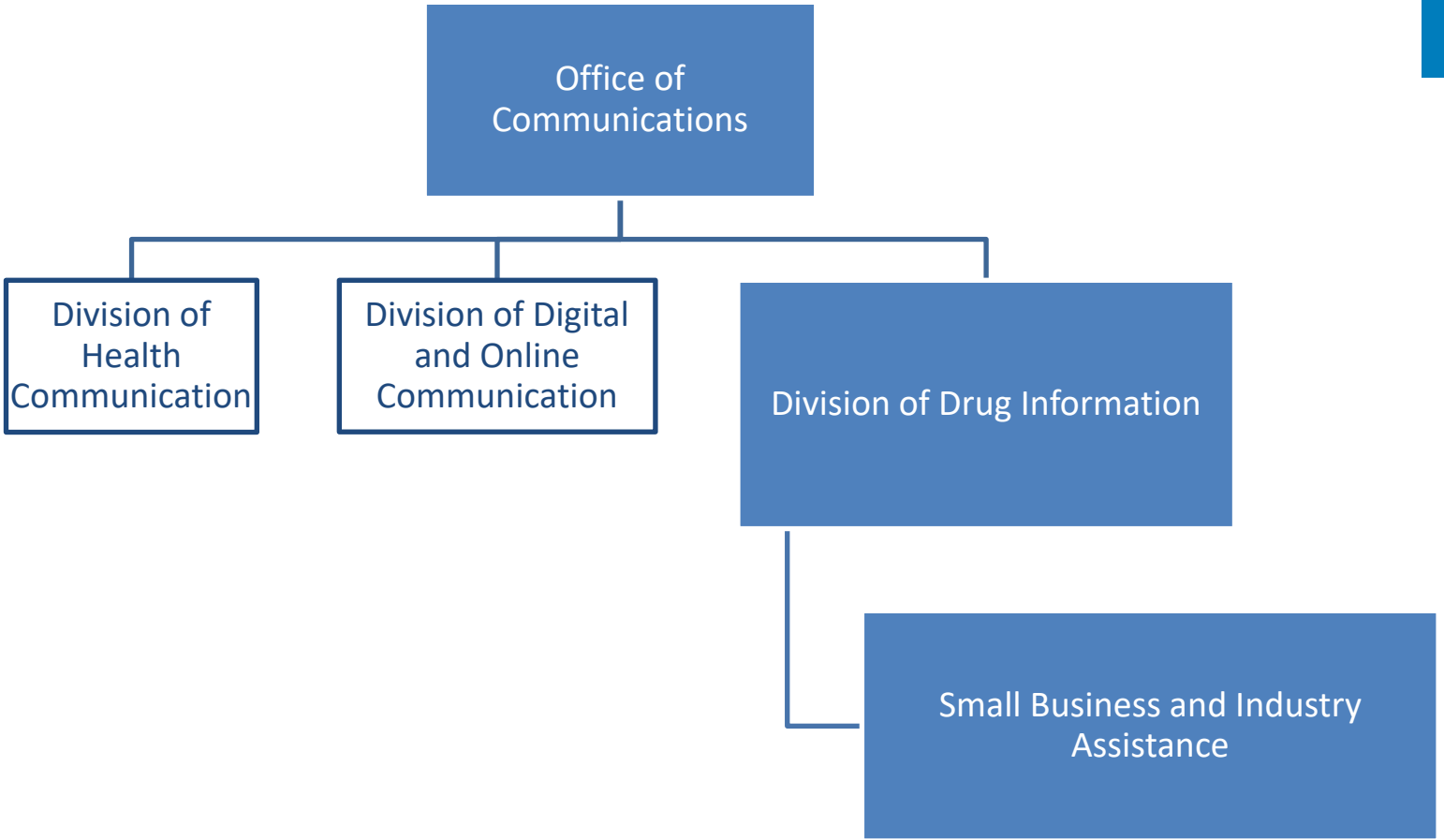
Office of Communications (OCOMM)
CDER | U.S. FDA

REdI Annual Conference – June 6-10, 2022

Learning Objectives

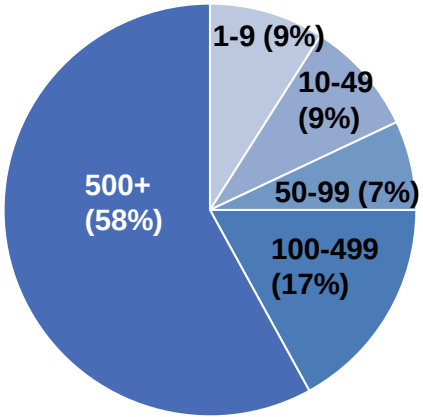
- Locate the SBIA webpage and identify the resources it provides.
- Identify three services SBIA offers to assist the pharmaceutical industry.
- Understand how to register for SBIA events and find recordings of past events.

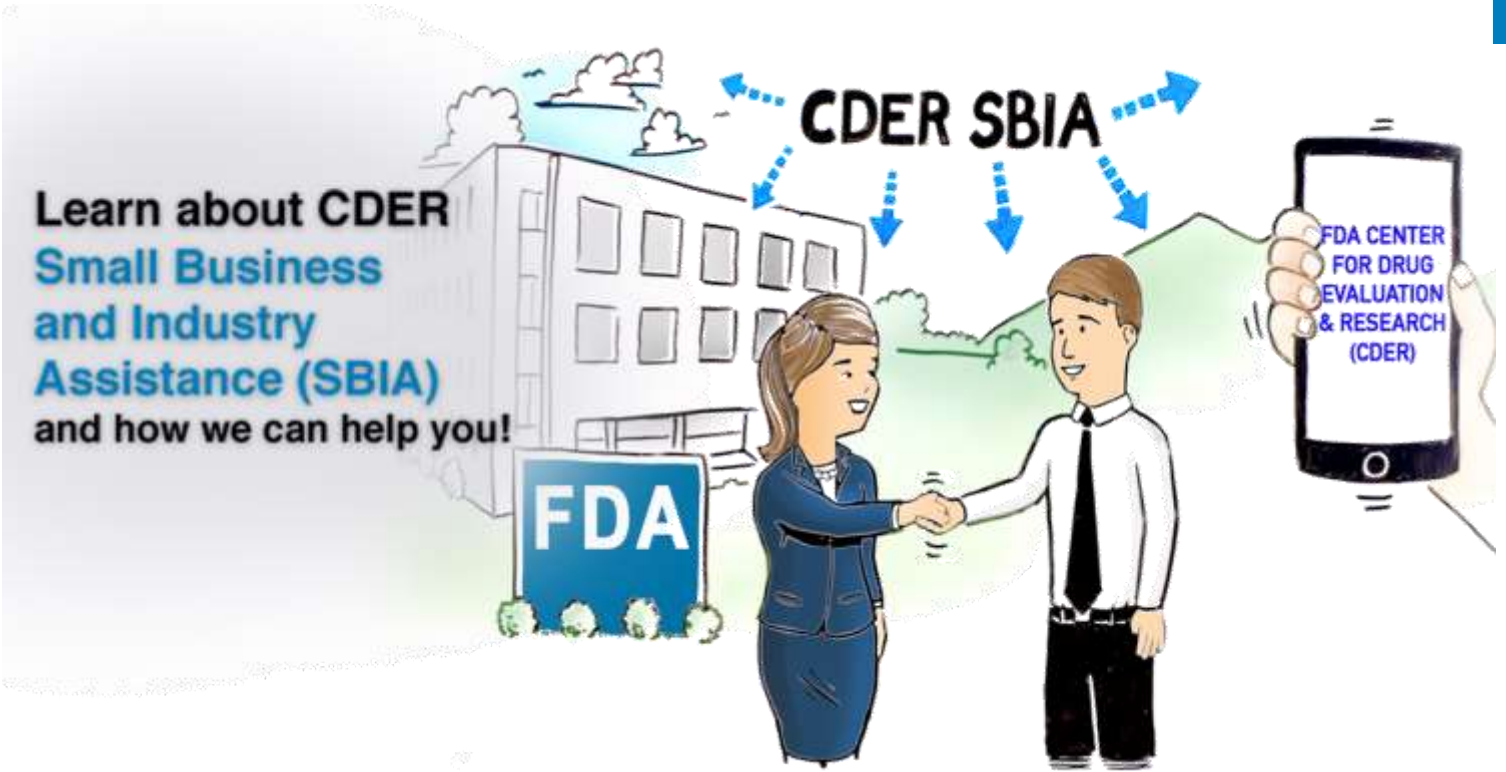

Office of Communications
Division of Health Communication
Division of Digital and Online Communication
Division of Drug Information
Small Business and Industry Assistance

SBIA Mission

- Provide immediate access to resources, education & training
- Allowing for a more clearly informed and efficient developmental process
- Aligned with CDER's goal of helping to ensure the approval safe and effective human drugs and biopharmaceuticals

SBIA Audience




Learn about CDER
Small Business
and Industry
Assistance (SBIA)
and how we can help you!
CDER SBIA
FDA
FDA CENTER
FOR DRUG
EVALUATION
& RESEARCH
(CDER)

Direct Communications Services

Industry of any size can contact SBIA

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

Monday – Friday, 8 AM – 4:30 PM ET

In 2021, SBIA responded to:
8,881 Inquiries
via email, phone, letters, social media

Workshops and Conferences


FDA
CDER SMALL BUSINESS
AND INDUSTRY ASSISTANCE
WEBINARS
www.fda.gov/CDERSBIALearn

Register for Upcoming Events

Date	Time	Event	Location
June 6-10, 2022	8:30 AM - 4:50 PM	Regulatory Education for Industry (REdI) Annual Conference 2022	Webinar
May 24-25, 2022	1:00 PM - 4:00 PM	Quality Management Maturity Workshop	Webinar

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

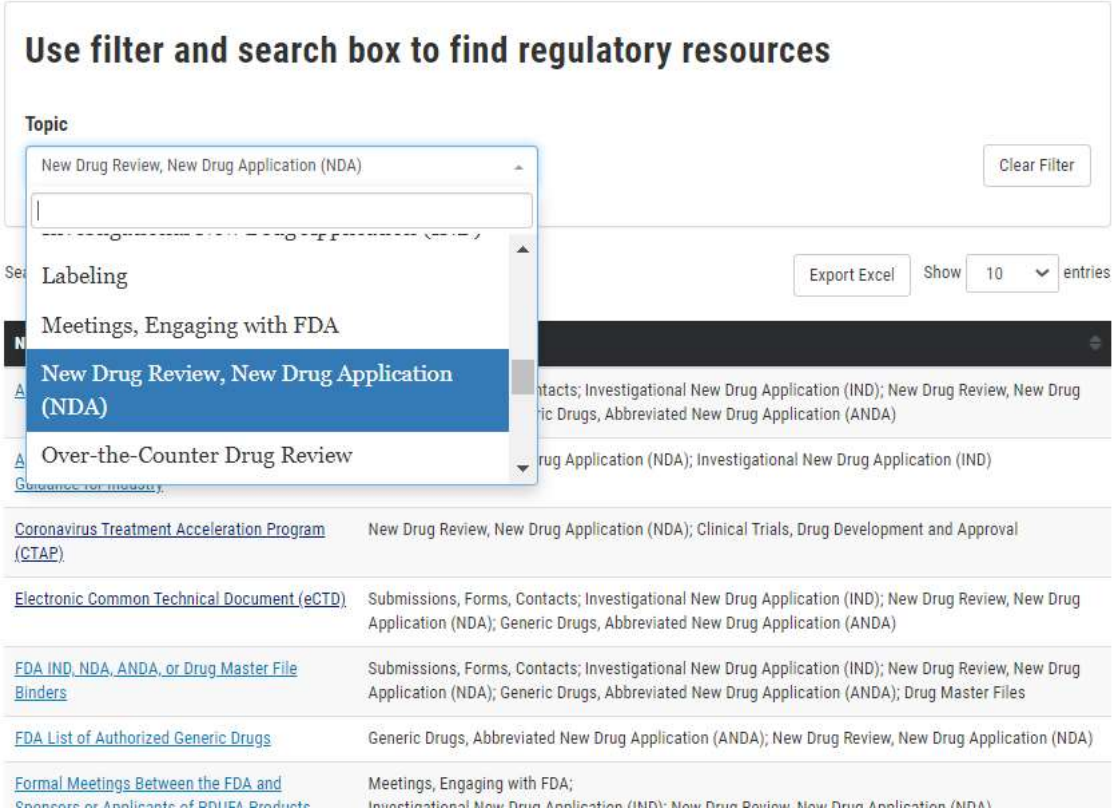
SBIA Learning Library on YouTube

Browse conference and webinar recordings on YouTube

www.fda.gov/cdersbia

Search for Regulatory References | Drugs

Share | Tweet | LinkedIn | Email | Print



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
Regulatory Education for Industry (REdI) Annual Conference 2022	Conference	6/6/2022	Biosimilars, Drug Development, DSCSA, FDA Meetings/Communications, Inspections, NDA, New Drug Development, Regulatory Submissions, Resources, Safety
Quality Management Maturity Workshop	Webinar	5/24/2022	Drug Quality
US-Canada Regional ICH Consultation	Webinar	5/11/2022	Clinical Trials and Research, International, New Drug Development
FDA Workshop on the Role of Phytosterols in PNALD/IFALD	Webinar	5/6/2022	Drug Development

www.fda.gov/cdersbialearn

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

Accompanied by an audio podcast

www.fda.gov/cdersbiachronicles

CDERLearn

Web-based learning tutorials aimed at educating small pharmaceutical business and industry 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

CDER SBIA Learning Library

Share | Tweet | LinkedIn | Email | Print

Visit the CDER Small Business and Industry Assistance Webpage

Subscribe for Industry News Updates

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 2021, 2020, 2019, 2018, and 2017 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 2021 Presentations

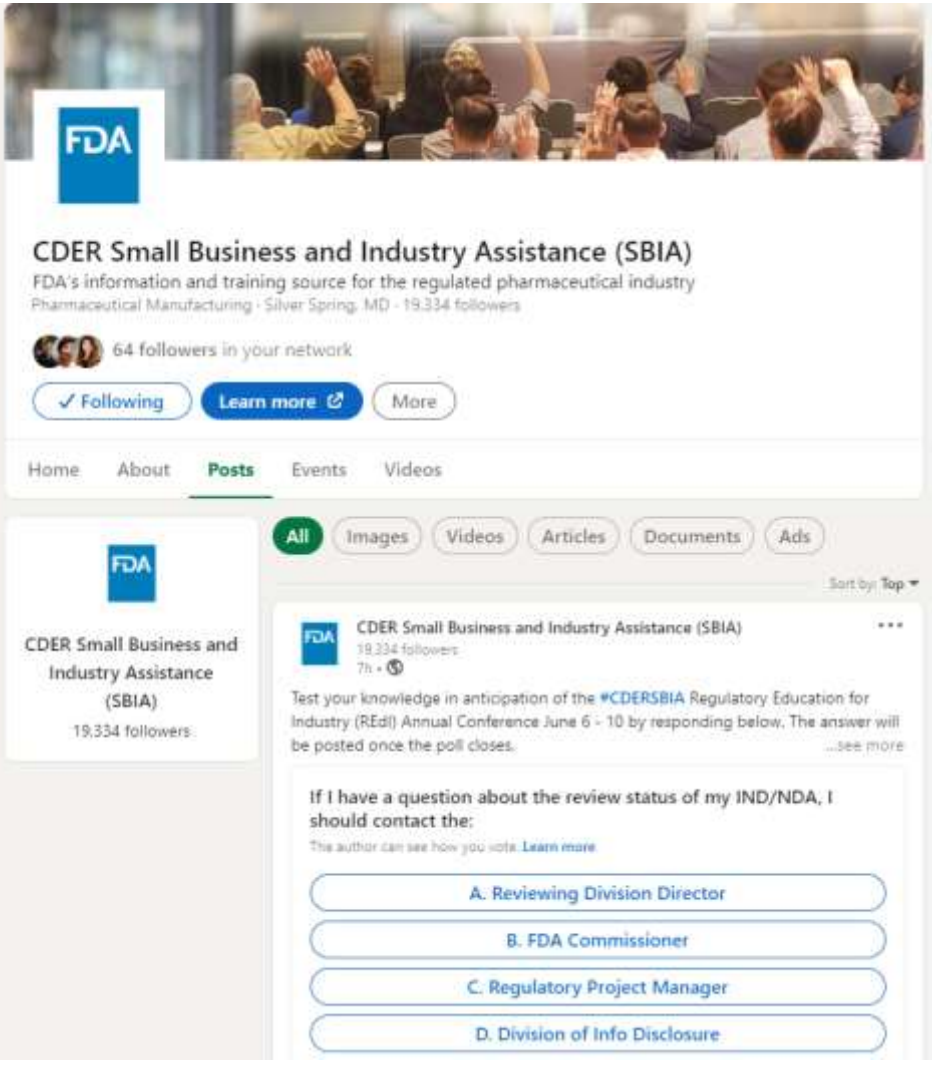
1. Drug Master File (DMF) Submissions on New FDA Form 3938

2. Timeline for the Drug Master Review Process
3. Risk Evaluation and Mitigation Strategies (REMS) Compliance Program
4. More 2021 recordings...

Most Viewed 2020 Presentations

YouTube → FDA → Playlists →

CDER Small Business and Industry Assistance



https://www.linkedin.com/showcase/cder-small-business-and-industry-assistance

SBIA Email Subscription

FDA | Small Business and Industry Assistance

CONFERENCES

Regulatory Education for Industry (REdI)

Annual Conference

June 6-10, 2022

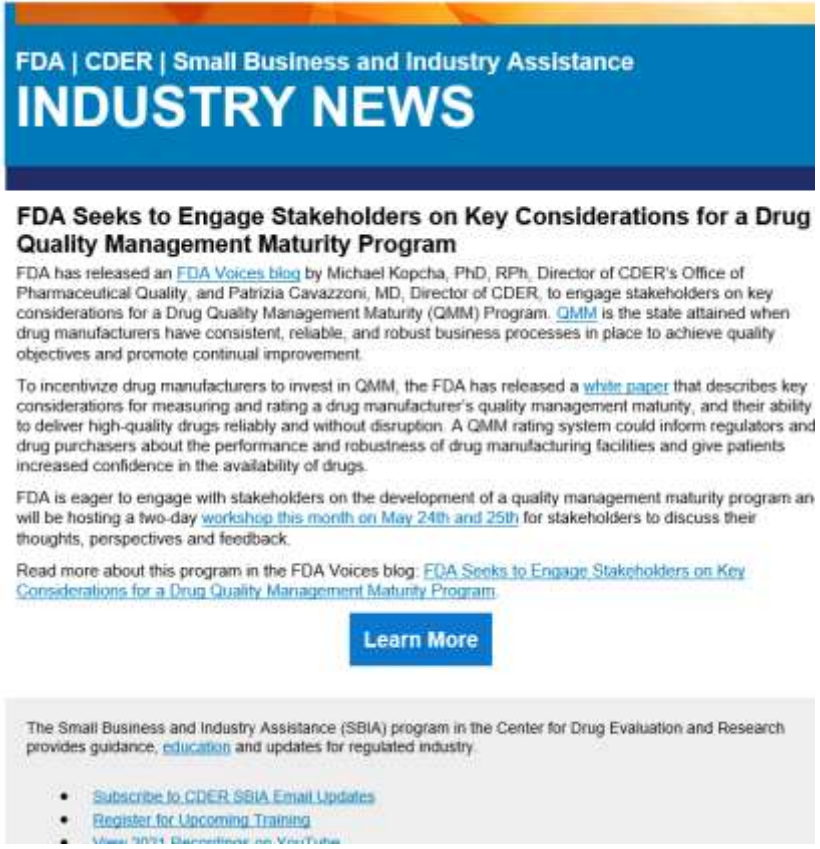
Registration

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.

Test your pre-conference knowledge on LinkedIn:

CDER Poll CDRH Poll CBER Poll



FDA | CDER | Small Business and Industry Assistance

INDUSTRY NEWS

FDA Seeks to Engage Stakeholders on Key Considerations for a Drug Quality Management Maturity Program

FDA has released an FDA Voices blog by Michael Kopcha, PhD, RPh, Director of CDER's Office of Pharmaceutical Quality, and Patrizia Cavazzoni, MD, Director of CDER, to engage stakeholders on key considerations for a Drug Quality Management Maturity (QMM) Program. QMM is the state attained when drug manufacturers have consistent, reliable, and robust business processes in place to achieve quality objectives and promote continual improvement.

To incentivize drug manufacturers to invest in QMM, the FDA has released a white paper that describes key considerations for measuring and rating a drug manufacturer's quality management maturity, and their ability to deliver high-quality drugs reliably and without disruption. A QMM rating system could inform regulators and drug purchasers about the performance and robustness of drug manufacturing facilities and give patients increased confidence in the availability of drugs.

FDA is eager to engage with stakeholders on the development of a quality management maturity program an will be hosting a two-day workshop this month on May 24th and 25th for stakeholders to discuss their thoughts, perspectives and feedback.

Read more about this program in the FDA Voices blog: FDA Seeks to Engage Stakeholders on Key Considerations for a Drug Quality Management Maturity Program.

Learn More

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

- Subscribe to CDER SBIA Email Updates
- Register for Upcoming Training
- View 2021 Recordings on YouTube

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

- 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