Division of Industry and Consumer Education (DICE)

2022 OIR Submissions Workshop
April 26, 2022

Ruth Bediakoh
Acting, Senior Consumer Safety Officer
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health (CDRH)

Learning Objectives

- Review background information about DICE
- Discuss available educational resources and how to access them
- Indicate contact information for device regulatory education and assistance

Background Information on DICE

DICE Mission Statement

To educate our stakeholders with understandable and accessible science-based regulatory information about medical devices and radiation-emitting electronic products.

Background Information on DICE

- Division of Industry and Consumer Education (DICE) established to implement the mandate of the 1976 Medical Device Amendments
  - Provide technical and regulatory assistance to small manufacturers of medical devices
- Respond to industry and consumer inquiries
  - Over 15,000 phone calls in FY2021
  - Over 13,000 emails in FY2021

DICE promotional video

DICE Educational Resources

DICE Educational Resources

- **Device Advice**
  - Text-Based Educational information
  - Over 300 pages of premarket/postmarket regulatory information
    - **www.fda.gov/DeviceAdvice**

DICE Device Advice Educational Topics

Premarket

- How do I market a device?
- Device classification
- Premarket applications
- FDA laws, regulations, guidance, and policies

Postmarket

- Quality System
- Medical device reporting
- Recalls and corrections
- Imports/Exports
- Registration and listing

Device Advice – www.fda.gov/DeviceAdvice

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Device Advice: Comprehensive Regulatory Assistance

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Device Advice: Comprehensive Regulatory Assistance

Overview of Device Regulation

How to Study and Market Your Device

Postmarket Requirements (Devices)

Quality and Compliance (Medical Devices)

Human Factors and Medical Devices

Medical Device

COVID-19 Resources

- Contacts for Medical Devices During the COVID-19 Pandemic
- FDA's Role: Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions
- Coronavirus Disease (COVID-19) Emergency Use Authorization (EUA) Information
- Coronavirus Disease (COVID-2019) updates from FDA

CDRH Operating Status During COVID-19

- **CDRH Document Control Center (DCC):** Open. Will continue to process submissions. DCC Contact Information and Address.
- **CDRH Reviews:** Ongoing.
- **Marketing Submissions Currently On Hold:** See Question/Answer of FDA Guidance on "Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications for Medical Devices"

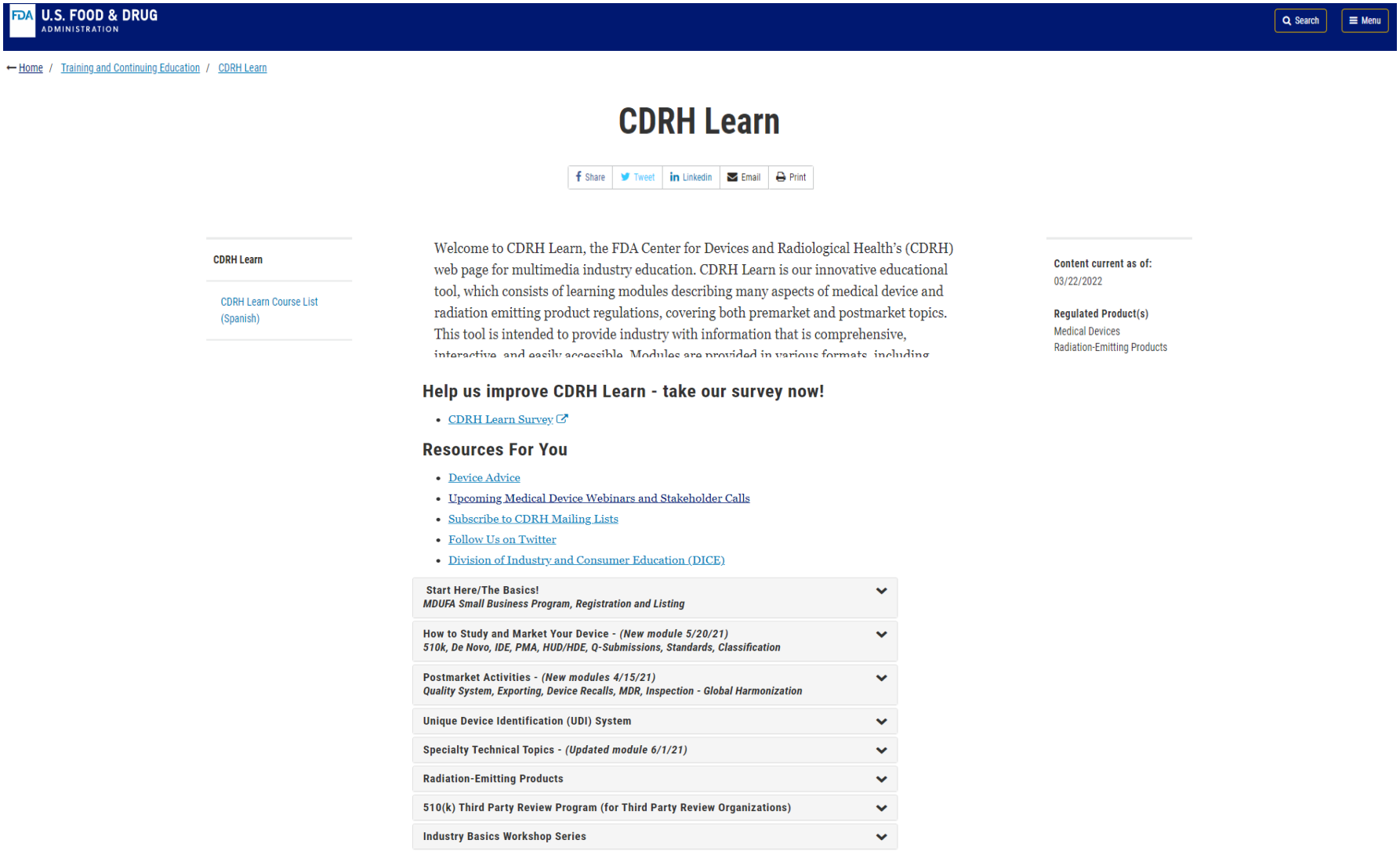
Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory

Content current as of:
06/23/2021

DICE Educational Resources

- **CDRH Learn**
  - Consists of multi-media industry educational information
  - Contains 260 modules
  - Includes videos, audio recordings, power point presentations, software-based “how to” modules
  - Modules are mobile-friendly
    - **www.fda.gov/CDRHLearn**

CDRH Learn - www.fda.gov/CDRHLearn

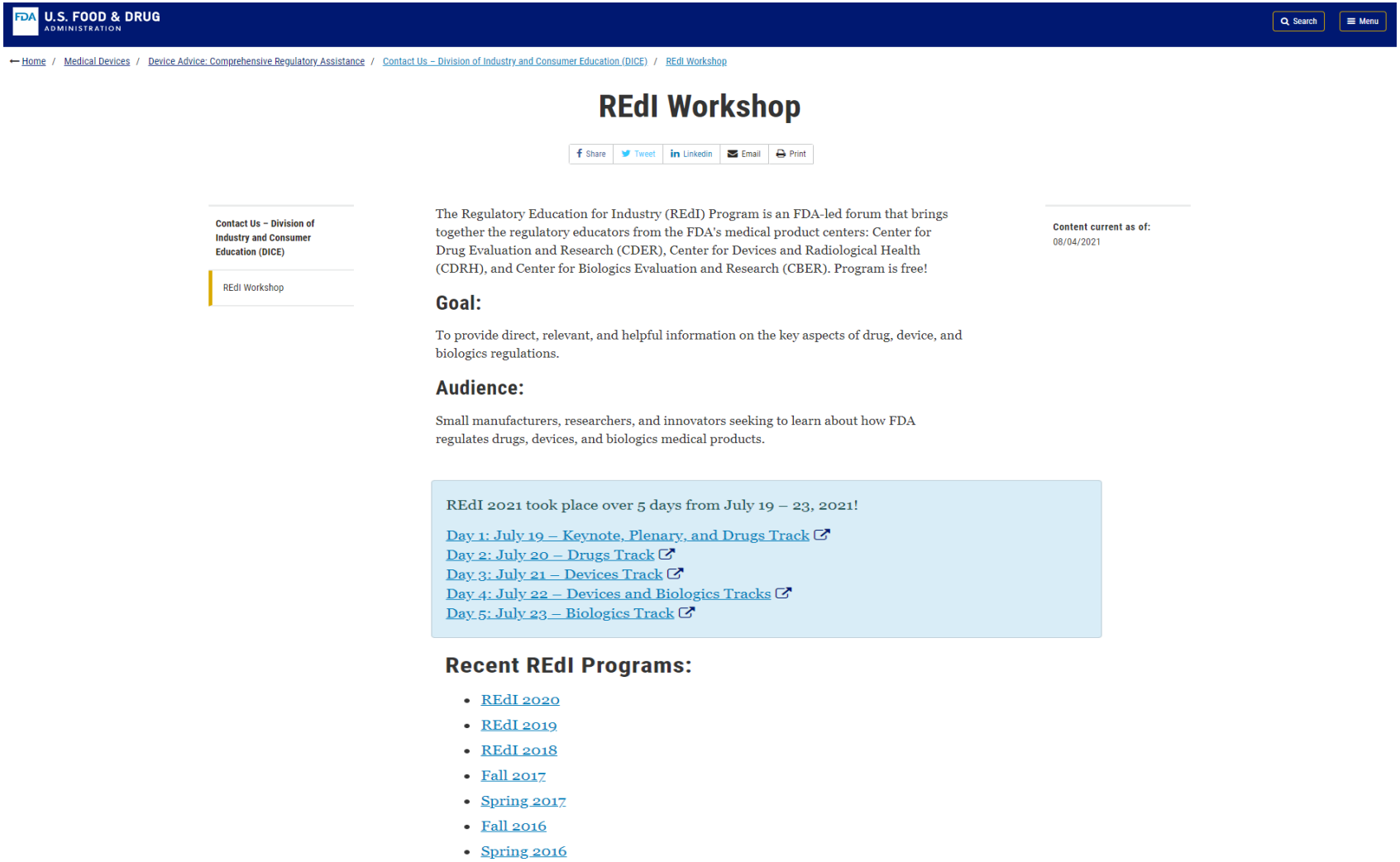


DICE Educational Resources

- **Regulatory Education for Industry (REdI)**
  - Free annual conference
  - Collaboration with the Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER)

- **Industry Basics**
  - Consists of a webinar
    - (virtual presentation)
  - Includes live question and answer session

REdI Workshop – Link



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REdI Workshop

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Contact Us – Division of Industry and Consumer Education (DICE)

REdI Workshop

The Regulatory Education for Industry (REdI) Program is an FDA-led forum that brings together the regulatory educators from the FDA's medical product centers: Center for Drug Evaluation and Research (CDER), Center for Devices and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER). Program is free!

Content current as of: 08/04/2021

Goal:

To provide direct, relevant, and helpful information on the key aspects of drug, device, and biologics regulations.

Audience:

Small manufacturers, researchers, and innovators seeking to learn about how FDA regulates drugs, devices, and biologics medical products.

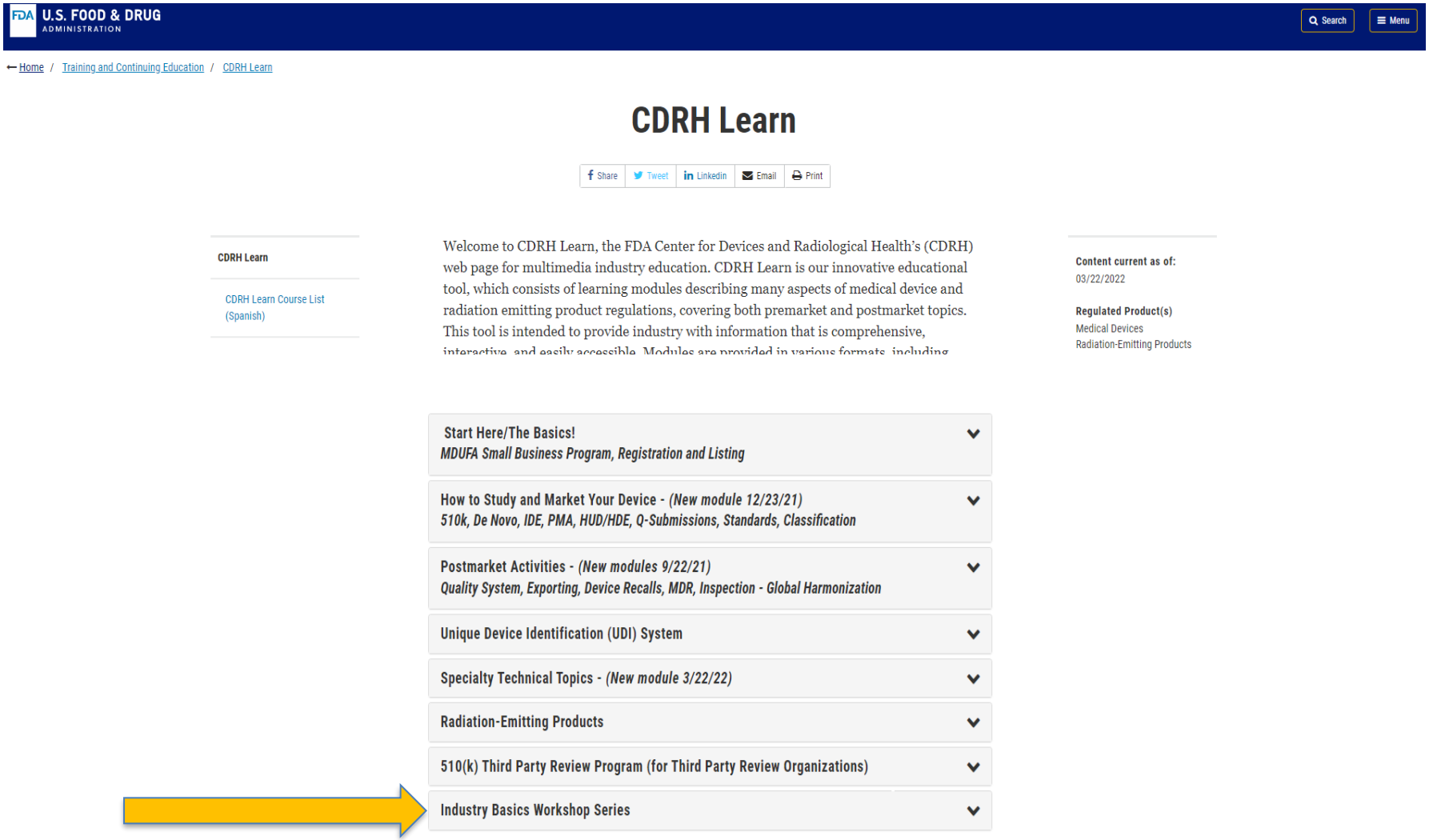
REdI 2021 took place over 5 days from July 19 – 23, 2021!

Day 1: July 19 – Keynote, Plenary, and Drugs Track
Day 2: July 20 – Drugs Track
Day 3: July 21 – Devices Track
Day 4: July 22 – Devices and Biologics Tracks
Day 5: July 23 – Biologics Track

Recent REdI Programs:

- REdI 2020
- REdI 2019
- REdI 2018
- Fall 2017
- Spring 2017
- Fall 2016
- Spring 2016

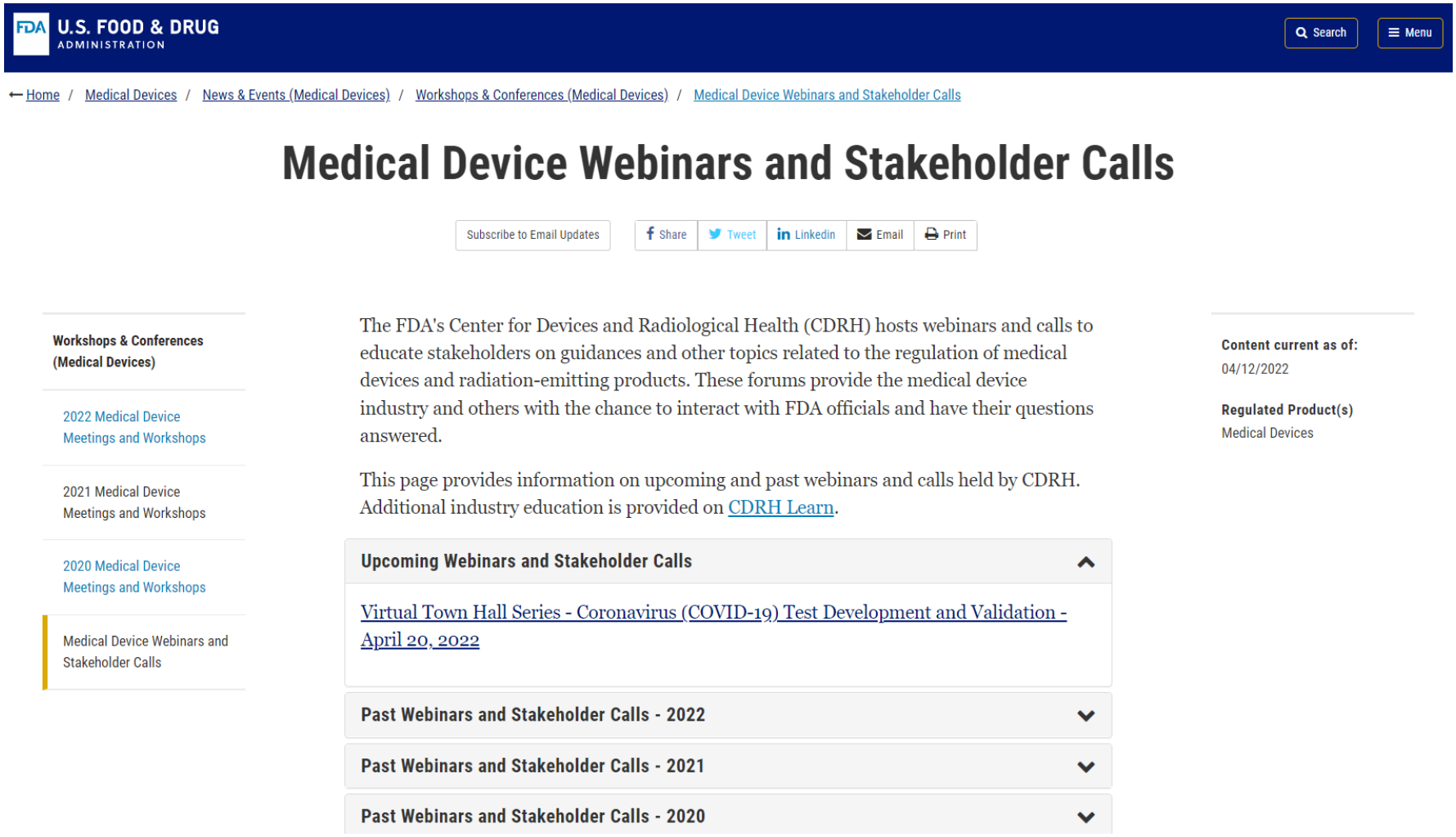
Industry Basics - www.fda.gov/CDRHLearn



DICE Educational Resources

- **Medical Device Webinars and Stakeholder Calls**
  - Webinar with live question and answer session
    - For example:
      - Draft guidance: Transition Plan for Medical Devices Issued EUAs
      - Draft guidance: Content of Premarket Submissions for Device Software Functions
  - Stakeholder calls (Virtual town hall) series
    - IVD's for COVID-19

Medical Device Webinars and Stakeholder Calls – Link



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Medical Device Webinars and Stakeholder Calls

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Workshops & Conferences (Medical Devices)

- 2022 Medical Device Meetings and Workshops
- 2021 Medical Device Meetings and Workshops
- 2020 Medical Device Meetings and Workshops
- Medical Device Webinars and Stakeholder Calls

The FDA's Center for Devices and Radiological Health (CDRH) hosts webinars and calls to educate stakeholders on guidances and other topics related to the regulation of medical devices and radiation-emitting products. These forums provide the medical device industry and others with the chance to interact with FDA officials and have their questions answered.

This page provides information on upcoming and past webinars and calls held by CDRH. Additional industry education is provided on CDRH Learn.

Upcoming Webinars and Stakeholder Calls

Virtual Town Hall Series - Coronavirus (COVID-19) Test Development and Validation - April 20, 2022

Past Webinars and Stakeholder Calls - 2022

Past Webinars and Stakeholder Calls - 2021

Past Webinars and Stakeholder Calls - 2020

Content current as of:
04/12/2022

Regulated Product(s)
Medical Devices

Contact Information

Contact DICE

- **Phone: (301) 796-7100 Eastern Time**

  We are available: M-F

  9:00 AM - 12:30 PM

  1:00 PM - 4:30 PM

- **Email: DICE@fda.hhs.gov**

  Typically Respond within 2 business days

We are here to help YOU!

Call to Action

- Use DICE's educational resources
  - Attend REdI and Industry Basics
  - Register for 2022 REdI Conference
- Contact DICE with general device regulatory questions
- Subscribe to CDRH Email Lists
  - CDRH Industry and CDRH New


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