How Can DICE Help You?

Giselle Blanco, M.S.
Consumer Safety Officer
Division of Industry and Consumer Education (DICE),
Office of Communication, Information Disclosure, Training and Education (OCITE)
CDRH | US FDA

FDA | NIH: Regulatory Do's and Don'ts: Tips from FDA – September 4, 2024

- **Confused?**
- **Overwhelmed?**
- **Don't know where to look?**
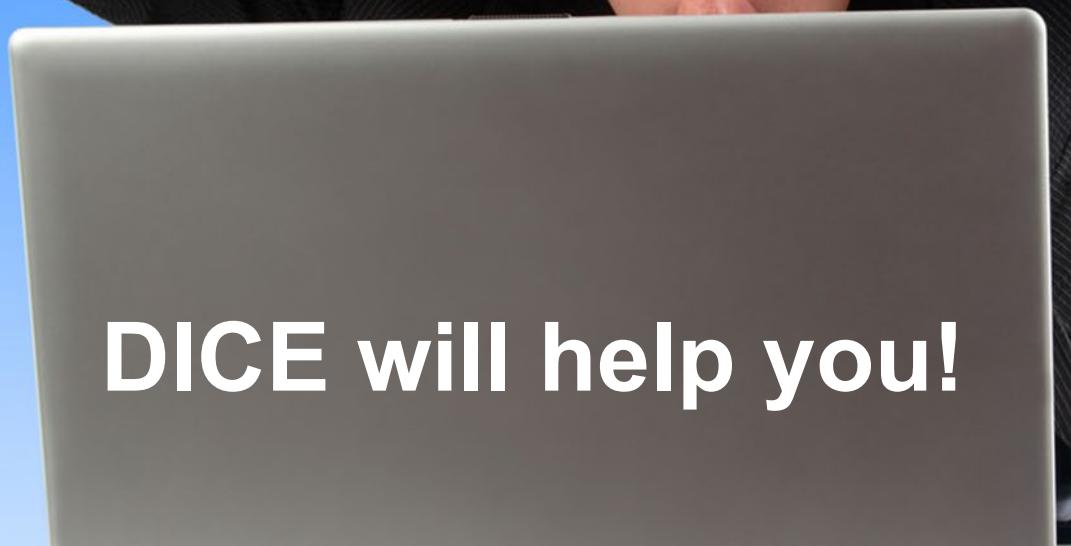
DICE will help you!
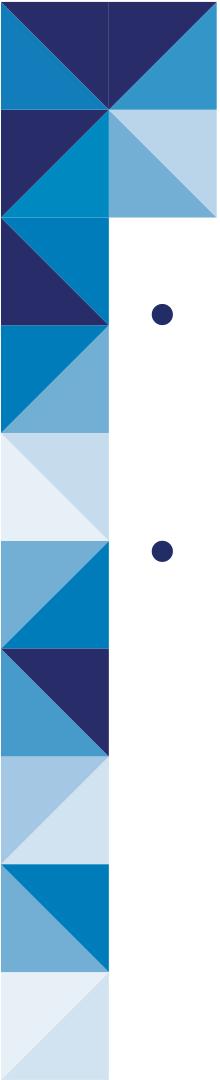
Learning Objectives

- Explain who **DICE** is and what we do.

- Identify and describe the various **educational resources** about medical device regulation.

Intro to DICE

Who is DICE?

- **D**ivision of **I**ndustry and **C**onsumer **E**ducation

- Vision statement:
  - Our stakeholders have educational information that is always
    - ✓ Accurate
    - ✓ Timely
    - ✓ Targeted
    - ✓ Useful

Who is DICE?

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

DICE: Who We Are

- Various professional backgrounds
  - Biology, chemistry, engineering, non-clinical, clinical, regulatory.

- Advanced degrees
  - PhD, Masters, PharmD, MD.

- Industry and FDA experience
  - CDRH, CDER, CVM, ORA

- Experience in DICE
  - Ranging from over 1 year to 30 years.

Educational Resources
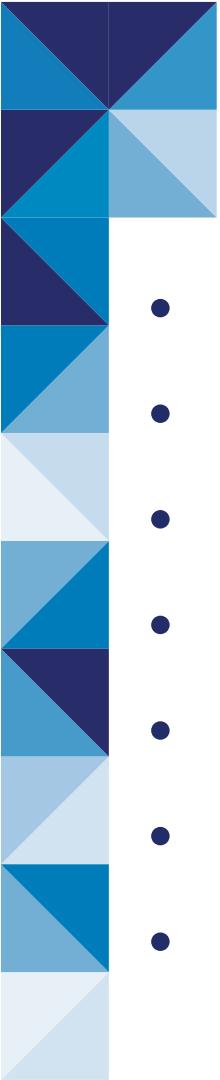
Educational Resources

- Contact DICE!
- Device Advice
- CDRH Learn
- CDRH Events
- Guidance documents
- CDRH Email Lists
- Q-Submission Program

Resource: DICE

- **Phone: (800) 638-2041**
  - Hours: 9 am–12:30 pm; 1-4:30 pm, ET.

- **Email: dice@fda.hhs.gov**
  - Response within 2 business days.

Resource: DICE

- DICE's inquiries (2023)
  - Phone: 10,365
  - Emails: 27,307

  - Total 37,672

Resource: DICE

- Top 5 industry question categories asked (2023):
    1. Premarket Notification (510(k))
    2. Classification / Device Determination
    3. Establishment Registration and Device Listing
    4. Importing / Exporting
    5. Labeling
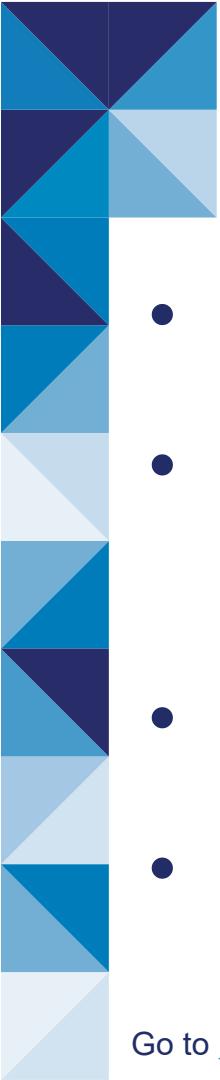
Resource: Device Advice

FDA

- Written web content

- Regulatory information across the total product lifecycle.

- Over 300 pages to reference.

- Organized into ~30 categories.

Device Advice: Comprehensive Regulatory Assistance

f Share   **X Post**   **in Linkedin**   **✉ Email**   **🖶 Print**

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains medical device laws, regulations, guidances, and policies, across the entire product lifecycle.

Content current as of:
06/27/2024

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

BRINGING A DEVICE TO MARKET

Is it a Medical Device?

Medical Device User Fees

How to Study and Market Your Device

Device Registration and Listing

Device Advice: Comprehensive Regulatory Assistance

f Share   X Post   in Linkedin   ✉ Email   🖶 Print

Welcome to Device Advice, the Food and Drug Administration's (FDA's) Center for Devices and Radiological Health (CDRH) web page for comprehensive regulatory education. Device Advice is CDRH's premier text-based resource that explains medical device laws, regulations, guidances, and policies, across the entire product lifecycle.

Content current as of:
06/27/2024

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

BRINGING A DEVICE TO MARKET

Is it a Medical Device?

Medical Device User Fees

How to Study and Market Your Device

Device Registration and Listing

Resource: CDRH Learn

FDA

- Multimedia, video-based modules

- Formats: presentations, "how-to" guides, webinars.

- 333 modules to reference (April, 2024)

Start Here/The Basics! (Updated Module 10/16/2023)
MDUFA Small Business Program, Registration and Listing

How to Study and Market Your Device - *(Updated 11/20/23)*
510k, De Novo, IDE, PMA, HUD/HDE, Q-Submissions, Standards, Classification

Postmarket Activities
Quality System, Exporting, Device Recalls, MDR, Inspection - Global Harmonization

In Vitro Diagnostics - *(Updated 7/18/24)*
IVD Development, CLIA, and Virtual Town Hall Series

Unique Device Identification (UDI) System

Specialty Technical Topics - *(Updated 7/23/24)*

Radiation-Emitting Products

Start Here/The Basics! (Updated Module 10/16/2023)
MDUFA Small Business Program, Registration and Listing

An Introduction to FDA's Regulation of Medical Devices

Presentation 🔗   Printable Slides   Transcript

How is CDRH Structured?

Presentation 🔗   Printable Slides   Transcript

Is My Product a Medical Device?

Presentation 🔗   Printable Slides   Transcript

An Introduction to the Medical Device User Fee Program: MDUFA V *(New 7/19/23)*

Presentation 🔗   Printable Slides Transcript

MDUFA Small Business Program

Resource: CDRH Events

FDA

- List of sponsored and co-sponsored
  - webinars,
  - town halls,
  - meetings,
  - workshops.

Search:

Date	Event Type	Event
11/06/2024	Workshop	Accreditation Scheme for Conformity Assessment and Use of Chemical Analysis to Support Biocompatibility of Medical Devices
09/19/2024	Workshop	Public Workshop - Food and Drug Administration/National Institutes of Health Joint Workshop: Developing Implanted Brain-Computer Interface Clinical Outcome Assessments to Demonstrate Benefit, September 19 and 20, 2024
08/22/2024	Webinar	Webinar - In Vitro Diagnostic Products (IVDs) - MDR Requirements, Correction and Removal Reporting Requirements, and Quality System Complaint Requirements
08/21/2024	Conference	UGA/FDA 11th Annual Medical Device Regulations Conference
08/07/2024	Town Hall	Medical Device Sterilization Town Hall: Sterilization Short Topics and Open Q&A
07/25/2024	Meeting	Virtual Public Meeting - Home as a Health Care Hub - Stakeholder Listening Session
07/16/2024	Webinar	Webinar - In Vitro Diagnostic Product (IVD): Classification

Go to CDRH Events

Resource: Guidance Documents

FDA

- Describe the Agency's current thinking on a topic.

- Informative and answers most questions on a topic.

- May be device-specific or cross-cutting.

Resource: Guidance Documents

- Guidance document topics
  - Premarket Submissions
  - Design, production, labeling, manufacturing, and testing of devices
  - Clinical Studies
  - Inspections
  - Enforcement policies

GUIDANCE DOCUMENT

Electronic Submission Template for Medical Device 510(k) Submissions

Guidance for Industry and Food and Drug Administration Staff

Cross-cutting

OCTOBER 2023

Download the Final Guidance Document

Final

GUIDANCE DOCUMENT

Soft (Hydrophilic) Daily Wear Contact Lenses – Performance Criteria for Safety and Performance Based Pathway

Guidance ~~for Industry~~ and Food and Drug Administration Staff

MARCH 2023

Device-specific

Download the Final Guidance Document

Read the Federal Register Notice

Final

Guidance Document Search

Search

Showing 1 to 10 of 604 entries (filtered from 2,748 total entries)

Filters   ^

Product

FDA Organization

Center for Devices and Radiological ...   ▼

Topic

Issue Date

Draft or Final

Open for Comment

Resource:
CDRH Email Lists

FDA

- Subscribe to receive the latest regulatory updates and upcoming events.

  – CDRH Industry,

  – CDRH New,

  – And many more.
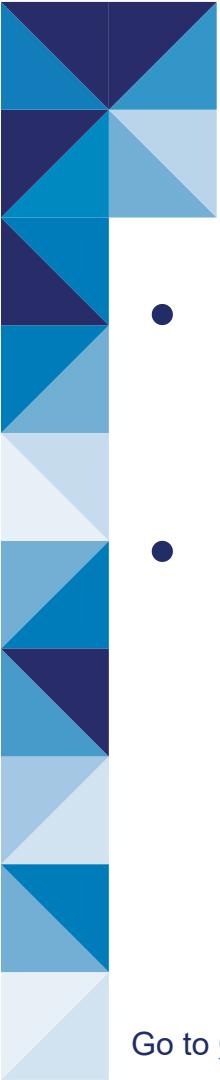
Resource: Q-Submission Program

- Q = "Question"

- 9 types of Q-Submissions
  - **Pre-Submission** is applicable for most questions.

Resource: Q-Submission Program

- Pre-Submission
  - Interact with FDA **early** & **throughout development**.
  - **Free** & voluntary.
  - Feedback comes from FDA's **review experts**.
  - Written feedback and an optional in-person or teleconference meeting.
  - Timeframe:
    - Written feedback by Day 70
    - Meeting by Day 75.

Resource: Q-Submission Program

- Examples of appropriate questions for a Pre-Submission:
  - *Based on our regulatory strategy and discussion of the pre-clinical testing provided, does FDA concur that clinical data is likely not needed to support a future 510(k)?*
  - *Are the proposed trial design and selected control group appropriate?*
  - *Is our justification for not conducting carcinogenicity studies adequate?*

Resource: Q-Submission Program

- Pre-Submissions are **NOT** for:
  - Medical device determinations or classifications.
  - Obtaining regulatory requirements for a medical device.
  - Pre-review of data.

Summary and Resources

- [Contact DICE](#)!
- [Device Advice](#)
- [CDRH Learn](#)
- [CDRH Events](#)
- [Guidance documents](#)
- [CDRH Email Lists](#)
- [Q-Submission Program](#)

Your Call to Action

FDA

- **DON'T**:
  - Leave regulatory education for last!
  - Believe that regulatory compliance is the "last step" in your device's lifecycle.

- **DO**:
  - Use educational resources as **early** as possible.
  - Contact DICE.

U.S. FOOD & DRUG ADMINISTRATION