

How Can DICE Help You?

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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?

A man in a dark suit is shown from the chest up, sitting at a laptop. He has a distressed expression, with his hands pressed against his temples and forehead. The background is a solid blue color.

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?



- Division 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



- Written web content
- Regulatory information across the total product lifecycle.
- Over 300 pages to reference.
- Organized into ~30 categories.

Device Advice: Comprehensive Regulatory Assistance

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Device Advice:
Comprehensive
Regulatory Assistance

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

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](#)





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Resource: CDRH Learn



- 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



- 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

Resource: Guidance Documents



- 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

OCTOBER 2023

[Download the Final Guidance Document](#)

Final

Cross-cutting

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

[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



- 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



- **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.

