Navigating the Medical Device Regulatory Framework Utilizing CDRH Resources

FDA Small Business Regulatory Education for Industry (REdI)

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CDR Kimberly Piermatteo

Education Program Administrator
Division of Industry and Consumer Education
Office of Communication and Education
Center for Devices and Radiological Health
U.S. Food and Drug Administration

Learning Objectives

- Discuss medical device legislation and CDRH's organization
- Define medical device and radiation emitting product
- Identify the steps to market a new medical device
- Discuss additional need to know resources

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Key Medical Device Legislation

- 1938 Federal Food, Drug, and Cosmetic Act (FD&C Act)
- 1976 Medical Device Amendments of 1976
- 2002 Medical Device User Fee and Modernization Act
- **2023 Medical Device User Fee Amendments (MDUFA V) (effective Oct. 1, 2022)**

***Coming Soon**

NEED TO KNOW

- MDUFA Reports

U.S.C. vs. FD&C Act vs. Regulations

- United States Code (U.S. Code)
- FD&C Act
- Code of Federal Regulations (CFR)
- Federal Register

NEED TO KNOW

- U.S. Code
- CFR Search (CFR Title 21)
- Electronic Code of Federal Regulations (eCFR)
- Regulations.gov

CDRH's Mission

- Assure access to **safe**, **effective**, and **high-quality** products
- Provide **understandable** and accessible **science-based information**
- Facilitate **innovation** and assure consumer **confidence**


CDRH
Office of the Center Director
Office of Communication and Education
Office of Management
Office of Policy
Office of Product Evaluation and Quality
Office of Science and Engineering Laboratories
Office of Strategic Partnerships and Technology Innovation

Office of Health Technology (OHT)

Office Title	Product Area
OHT1	Ophthalmic, Anesthesia, Respiratory, Ear, Nose and Throat (ENT), Dental
OHT2	Cardiovascular
OHT3	Gastro-renal, Obstetrics and Gynecology, General Hospital, Urology
OHT4	Surgical, Infection Control
OHT5	Neurological, Physical Medicine
OHT6	Orthopedic
OHT7	In Vitro Diagnostics
OHT8	Radiological Health

*Recent Change

NEED TO KNOW

- CDRH Management Directory

Want Updates?

NEED TO KNOW

- FDA.gov/Medical Devices
- [FDA] Get Email Updates
- Subscribe to CDRH Email Lists
- **CDRHNew – News and Updates**

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Medical Device Definition

- Intended for:
  - **diagnosis** of disease or other conditions
  - or **cure, mitigation, treatment, or prevention** of disease
  - or to affect the **structure** or any **function** of the body

Medical Device Definition (continued)

- Does **NOT achieve** its primary intended purposes **through chemical action** or dependent on being **metabolized**

- Does **NOT** include **certain software functions** excluded pursuant to section 520(o).

Medical Device Definition

NEED TO KNOW

- 21 U.S.C. 321(h)
- How to Determine if Your Product is a Medical Device
- CDRH Learn Module: Is My Product a Medical Device?

In Vitro Diagnostics (IVDs)

- **Reagents, instruments, and systems** intended for use in the diagnosis of disease or other conditions.

- Examples: Home Pregnancy Test, Glucose Test Strip

NEED TO KNOW

- In Vitro Diagnostics [Homepage]

Radiation Emitting Products

- When in operation (i) contains or acts as part of an **electronic circuit** and (ii) **emits electronic product radiation**
- Examples: Diagnostic Ultrasound, X-Rays, Medical Lasers

NEED TO KNOW

- Radiation-Emitting Products Industry Assistance: Walk-through
- Getting a Radiation Emitting Product to Market: FAQs

Knowledge Check

A radiation emitting product must only comply with the radiation safety regulations.

1. True
2. False
3. It Depends

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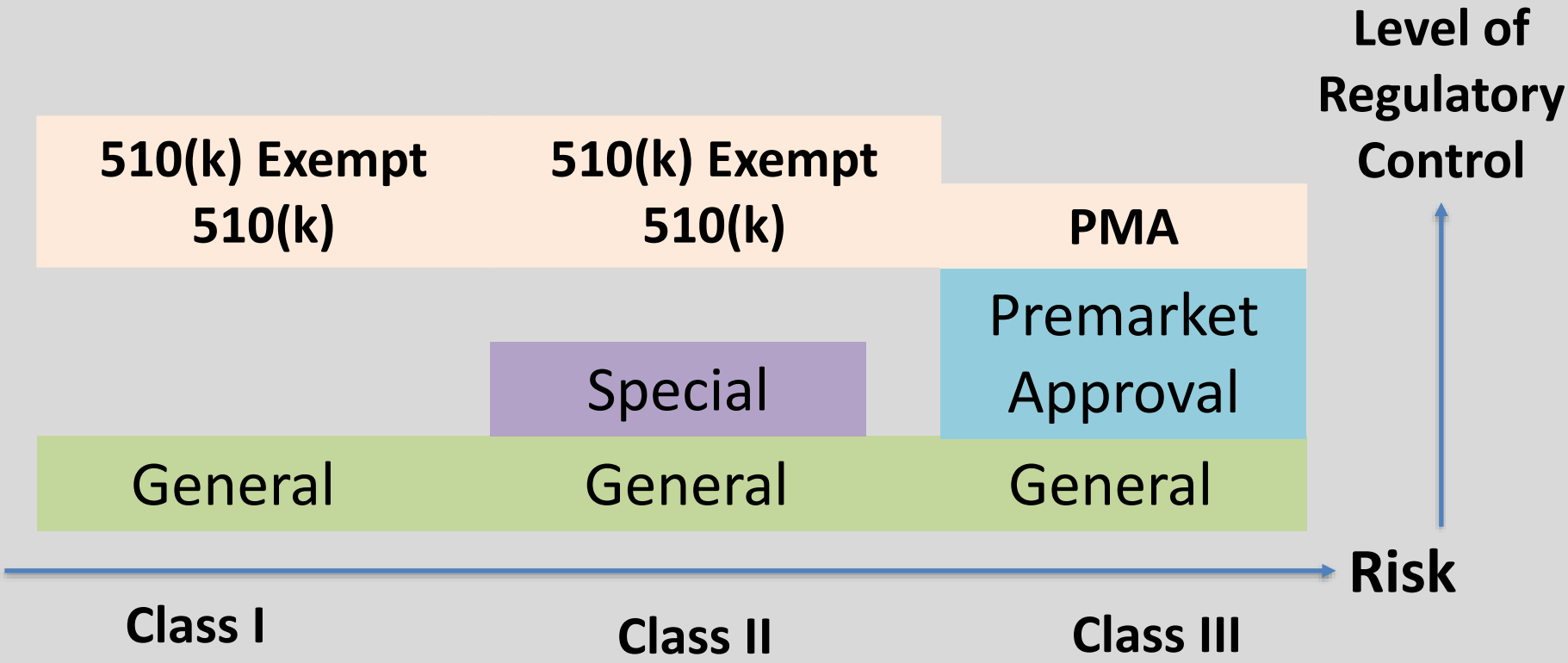
NEED TO KNOW

- **How to Study and Market Your Device**

1. Classify Your Device and Understand Applicable Regulatory Controls
2. Select and Prepare the Correct Premarket Submission
3. Send your Premarket Submission to the FDA
4. Comply with Applicable Regulatory Controls Including Establishment Registration and Device Listing

Classification & Regulatory Controls



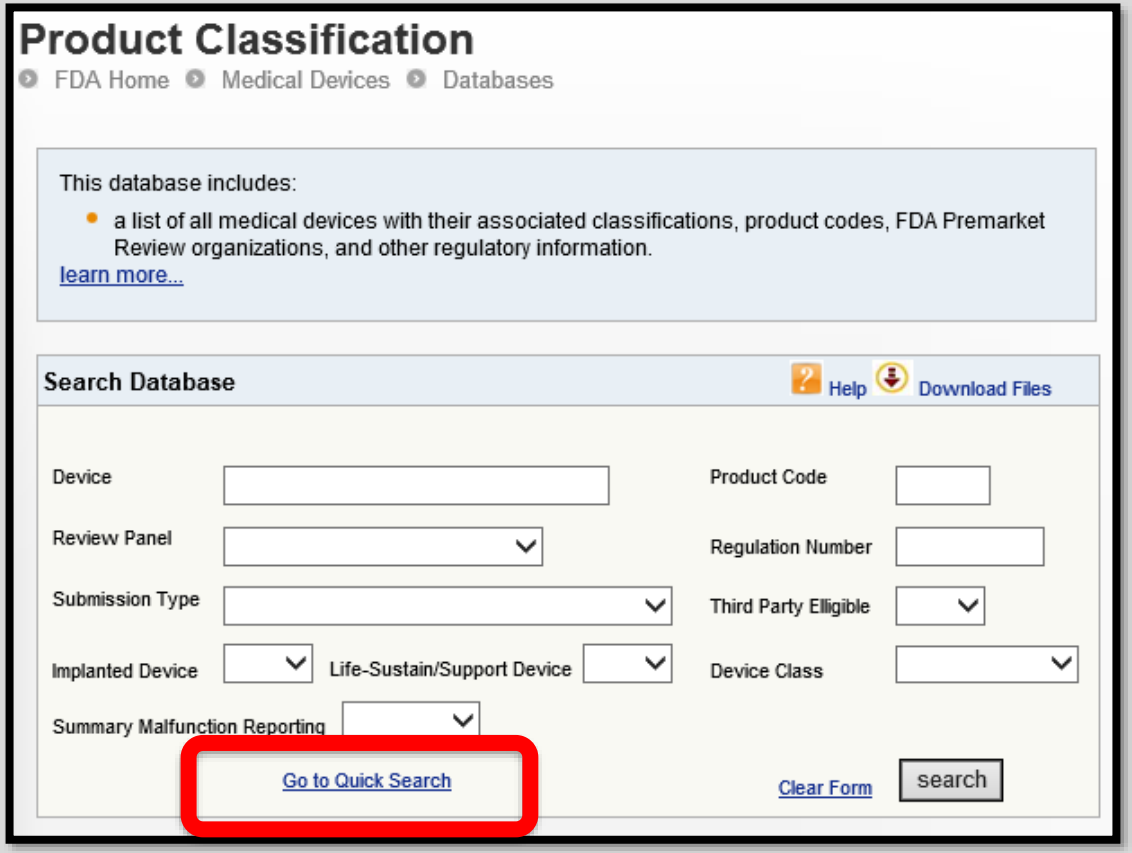
Classification & Regulatory Controls

NEED TO KNOW

- Classify Your Medical Device
- Class I and Class II Device Exemptions
- Regulatory Controls
- CDRH Learn – How is My Medical Device Classified?
- Product Classification Database

NEED TO KNOW

- Product Classification



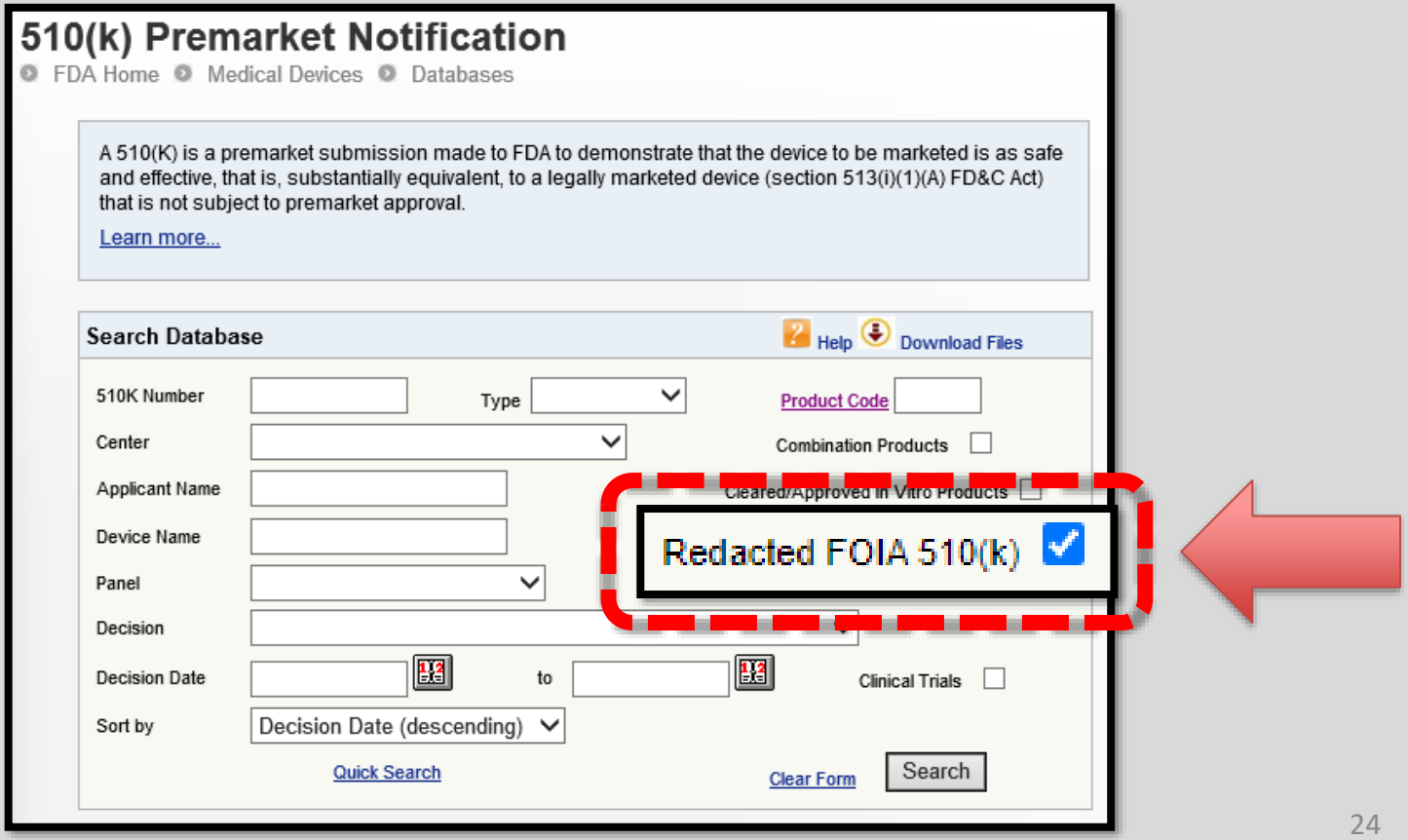
Premarket Submissions

NEED TO KNOW

- Premarket Submissions: Selecting and Preparing the Correct Submission
- Guidance Documents
  - The Q-Submission Program Guidance
- Class II Special Controls Documents
- Recognized Consensus Standards
- CDRH FOIA

NEED TO KNOW

- 510(k) Premarket Notification Database



Premarket Submissions (cont.)

NEED TO KNOW

- FDA Forms
- eCopy Program
- eSTAR Program
- Medical Device User Fees
- Reduced Medical Device User Fees: Small Business Determination (SBD) Program
- Progress Tracker

Continued Compliance

NEED TO KNOW

- Postmarket Requirements (Devices)
- Establishment Registration and Device Listing
- Quality System Regulation
- Medical Device Reporting/eMDR
- Medical Device Tracking

Knowledge Check

Should I register my device when I submit my 510(k)?

1. Yes
2. No
3. It depends

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NEED TO KNOW

- **Device Advice**

- Written content
- Over 300 pages of total product life cycle regulatory information
- Over 30 regulatory categories

NEED TO KNOW

- **CDRH Learn**

- Multi-media video training modules
- Presentations, computer-based training, webinars
- Approximately 200 modules (most ~ 20 min)
- Mobile-friendly

NEED TO KNOW

- **Division of Industry and Consumer Education**

Phone: (800) 638-2041

- Hours of Operation: 9 AM – 12:30 PM; 1 – 4:30 PM ET

Email: dice@fda.hhs.gov

- DICE will respond within 2 business days

Resources

Slide Number	Cited Resource	URL
5	Federal Food, Drug, and Cosmetic Act (FD&C Act)	www.fda.gov/regulatory-information/laws-enforced-fda/federal-food-drug-and-cosmetic-act-fdc-act
5	Medical Device Amendment of 1976	www.govinfo.gov/content/pkg/STATUTE-90/pdf/STATUTE-90-Pg539.pdf
5	Medical Device User Fee and Modernization Act	www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-and-modernization-act-2002-mdufma
5	Medical Device User Fee Amendments	www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/medical-device-user-fee-amendments-2023-mdufa-v

Resources

Slide Number	Cited Resource	URL
5	MDUFA Reports	www.fda.gov/industry/medical-device-user-fee-amendments-mdufa/mdufa-reports
6	U.S. Code	uscode.house.gov/browse.xhtml
6	CFR Search (CFR Title 21)	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
6	Electronic Code of Federal Regulations (eCFR)	www.ecfr.gov/current/title-21
6	Regulations.gov	www.regulations.gov/

Resources

Slide Number	Cited Resource	URL
7	CDRH Management Directory	www.fda.gov/about-fda/cdrh-offices/cdrh-management-directory-organization
10	FDA.gov/Medical Devices	www.fda.gov/Medical-Devices
10	[FDA] Get Email Updates	www.fda.gov/about-fda/contact-fda/get-email-updates
10	Subscribe to CDRH Email Lists	www.fda.gov/about-fda/center-devices-and-radiological-health/subscribe-cdrh-email-lists
10	CDRHNew – News and Updates	www.fda.gov/medical-devices/news-events-medical-devices/cdrhnew-news-and-updates

Resources

Slide Number	Cited Resource	URL
14	21 U.S.C. 321(h)	uscode.house.gov/view.xhtml?req=(title:21%20section:321%20edition:prelim)%20OR%20(granuleid:USC-prelim-title21-section321)&f=treesort&edition=prelim&num=0&jumpTo=true
14	How to Determine if Your Product is a Medical Device	www.fda.gov/medical-devices/classify-your-medical-device/how-determine-if-your-product-medical-device
14	CDRH Learn Module: Is My Product a Medical Device?	fda.yorkcast.com/webcast/Play/e0eec5f6ee3d4947a70fcedef32993f71d
15	In Vitro Diagnostics [Homepage]	www.fda.gov/medical-devices/products-and-medical-procedures/in-vitro-diagnostics

Resources

Slide Number	Cited Resource	URL
16	Radiation-Emitting Products Industry Assistance: Walk-through	www.fda.gov/radiation-emitting-products/getting-radiation-emitting-product-market-frequently-asked-questions/radiation-emitting-products-industry-assistance-walk-through
16	Getting a Radiation Emitting Product to Market: FAQs	www.fda.gov/radiation-emitting-products/electronic-product-radiation-control-program/getting-radiation-emitting-product-market-frequently-asked-questions
20	How to Study and Market Your Device	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/how-study-and-market-your-device

Resources

Slide Number	Cited Resource	URL
22	Classify Your Medical Device	www.fda.gov/medical-devices/overview-device-regulation/classify-your-medical-device
22	Class I and Class II Device Exemptions	www.fda.gov/medical-devices/classify-your-medical-device/class-i-and-class-ii-device-exemptions
22	Regulatory Controls	www.fda.gov/medical-devices/overview-device-regulation/regulatory-controls
22	CDRH Learn – How is My Medical Device Classified?	fda.yorkcast.com/webcast/Play/17792840509f49f0875806b6e9a1be471d

Resources

Slide Number	Cited Resource	URL
22, 23	Product Classification Database	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
24	Premarket Submissions: Selecting and Preparing the Correct Submission	www.fda.gov/medical-devices/how-study-and-market-your-device/premarket-submissions
24	Guidance Documents	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products
24	The Q-Submission Program Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/requests-feedback-and-meetings-medical-device-submissions-q-submission-program

Resources

Slide Number	Cited Resource	URL
24	Class II Special Controls Documents	www.fda.gov/medical-devices/guidance-documents-medical-devices-and-radiation-emitting-products/class-ii-special-controls-documents
24	Recognized Consensus Standards	www.fda.gov/medical-devices/premarket-submissions-selecting-and-preparing-correct-submission/standards-and-conformity-assessment-program
24	CDRH FOIA	www.fda.gov/about-fda/center-devices-and-radiological-health/cdrh-foia-how-get-records-cdrh
25	510(k) Premarket Notification	www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMN/pmn.cfm

Resources

Slide Number	Cited Resource	URL
26	FDA Forms	www.fda.gov/about-fda/reports-manuals-forms/forms
26	eCopy Program	www.fda.gov/medical-devices/how-study-and-market-your-device/ecopy-program-medical-device-submissions
26	eSTAR Program	www.fda.gov/medical-devices/how-study-and-market-your-device/voluntary-estar-program
26	Medical Device User Fees	www.fda.gov/medical-devices/premarket-submissions/medical-device-user-fees
26	Reduced Medical Device User Fees: Small Business Determination (SBD) Program	www.fda.gov/medical-devices/premarket-submissions/reduced-medical-device-user-fees-small-business-determination-sbd-program

Resources

Slide Number	Cited Resource	URL
26	Progress Tracker	www.fda.gov/medical-devices/industry-medical-devices/tracking-your-premarket-submissions-progress-progress-tracker
27	Postmarket Requirements (Devices)	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/postmarket-requirements-devices
27	Establishment Registration and Device Listing	www.fda.gov/medical-devices/how-study-and-market-your-device/device-registration-and-listing
27	Quality System Regulation	www.fda.gov/medical-devices/postmarket-requirements-devices/quality-system-qs-regulationmedical-device-good-manufacturing-practices

Resources

Slide Number	Cited Resource	URL
27	Medical Device Reporting/eMDR	www.fda.gov/medical-devices/postmarket-requirements-devices/mandatory-reporting-requirements-manufacturers-importers-and-device-user-facilities
27	Medical Device Tracking	www.fda.gov/medical-devices/postmarket-requirements-devices/medical-device-tracking
31	Device Advice	www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance
32	CDRH Learn	www.fda.gov/training-and-continuing-education/cdrh-learn
33	DICE	www.fda.gov/DICE

Summary

- Key legislation ensures access to **safe**, **effective**, and **high-quality** products
- The **risk** of a device determines the extent of **regulatory controls**
- There are **four main steps** to bring a new device to market
- Available **resources** can help you navigate the regulatory framework

Questions