

Introductions and Premarket Overview

**FDA Small Business
Regulatory Education for Industry (REdI)**
Silver Spring, MD
September 27, 2016

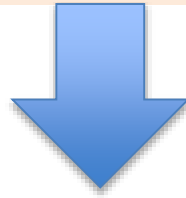
Elias Mallis

Director

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



1000 establishments/square mile



New FY 16 Establishments

3,151

9 new establishments EACH day!
365 days/year

22,000

Premarket Submissions/Year

➤ 60 per day (365 days/year)

➤ almost 8 per hour!

25

guidances issued in 2016

almost 3 /month

Learning Objectives

- Introduce the Program Agenda and Today's Speakers
- Review the FDA and CDRH Regulatory Groups at a glance
- Discuss the Overall Premarket Submission Approach

Agenda – Day 1

Device Track



Time	Topic	Speaker
9:30 – 10:00:	Intros; Submission Process	Elias Mallis
10:00 – 10:30:	Resources	Diane Nell
10:30 – 11:15:	Design Controls	Stanley Liu
11:15 – 12:15:	IDE Program	Soma Kalb
12:15 – 1:30:	Lunch	
1:30 – 2:30:	510(k) Program	Kim Piermatteo
2:30 – 2:45:	Break	
2:45 – 3:30:	<i>de novo</i> Program	Sergio de del Castillo
3:30 – 4:15:	PMA Program	Donna Headlee
4:15 – 4:45:	Wrap-Up: Question and Answer	All

Poll Question

D1S1-1

View Votes

Edit

End Poll

D1S1-1: How do you rate your knowledge of FDA Medical Device Regulations, Policies?

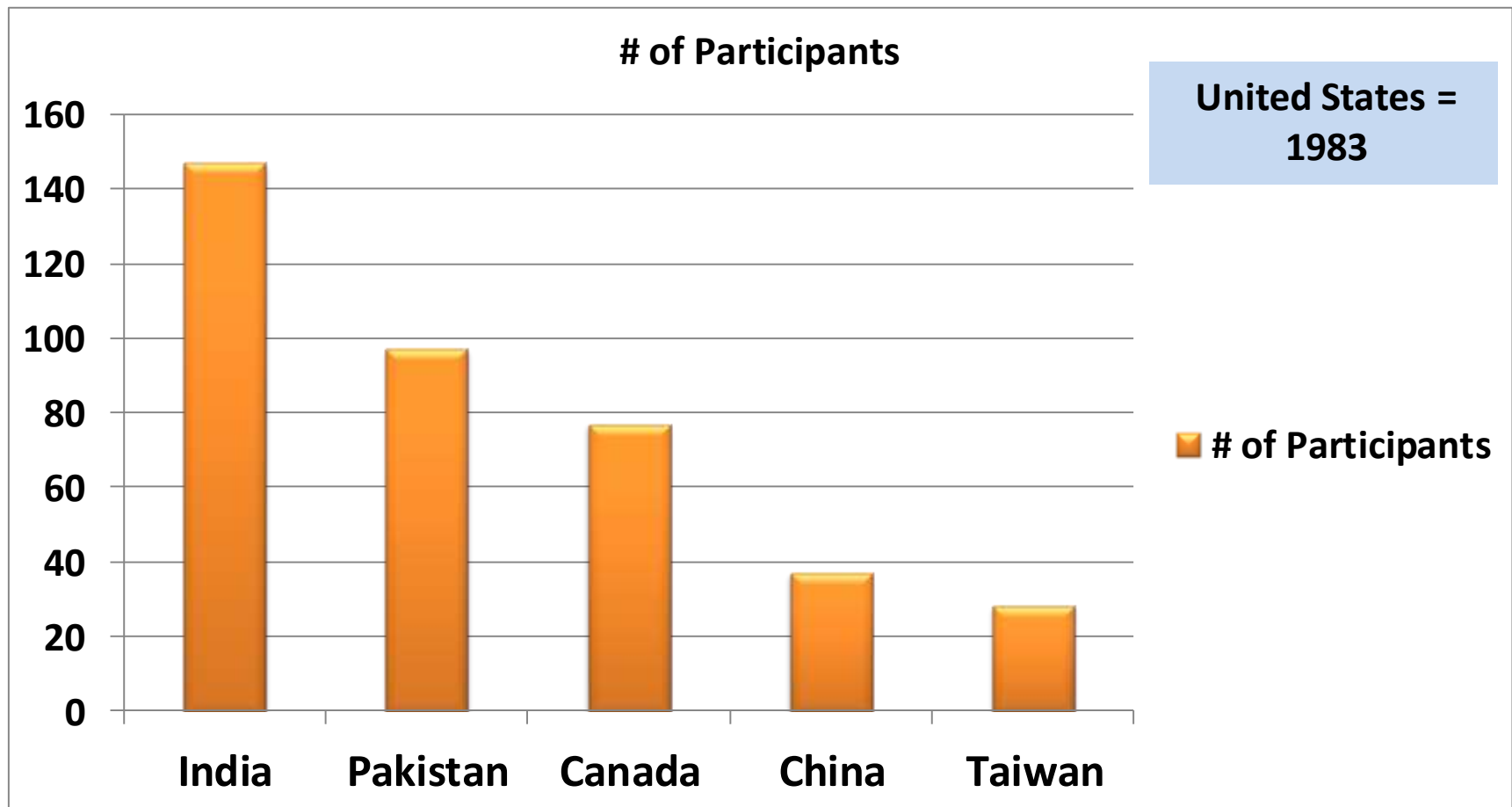
<input type="radio"/> Beginner/New to Field	<div></div>	0%	(0)
<input type="radio"/> Basic	<div></div>	0%	(0)
<input type="radio"/> Moderate	<div></div>	0%	(0)
<input type="radio"/> Advanced	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☒ Broadcast Results

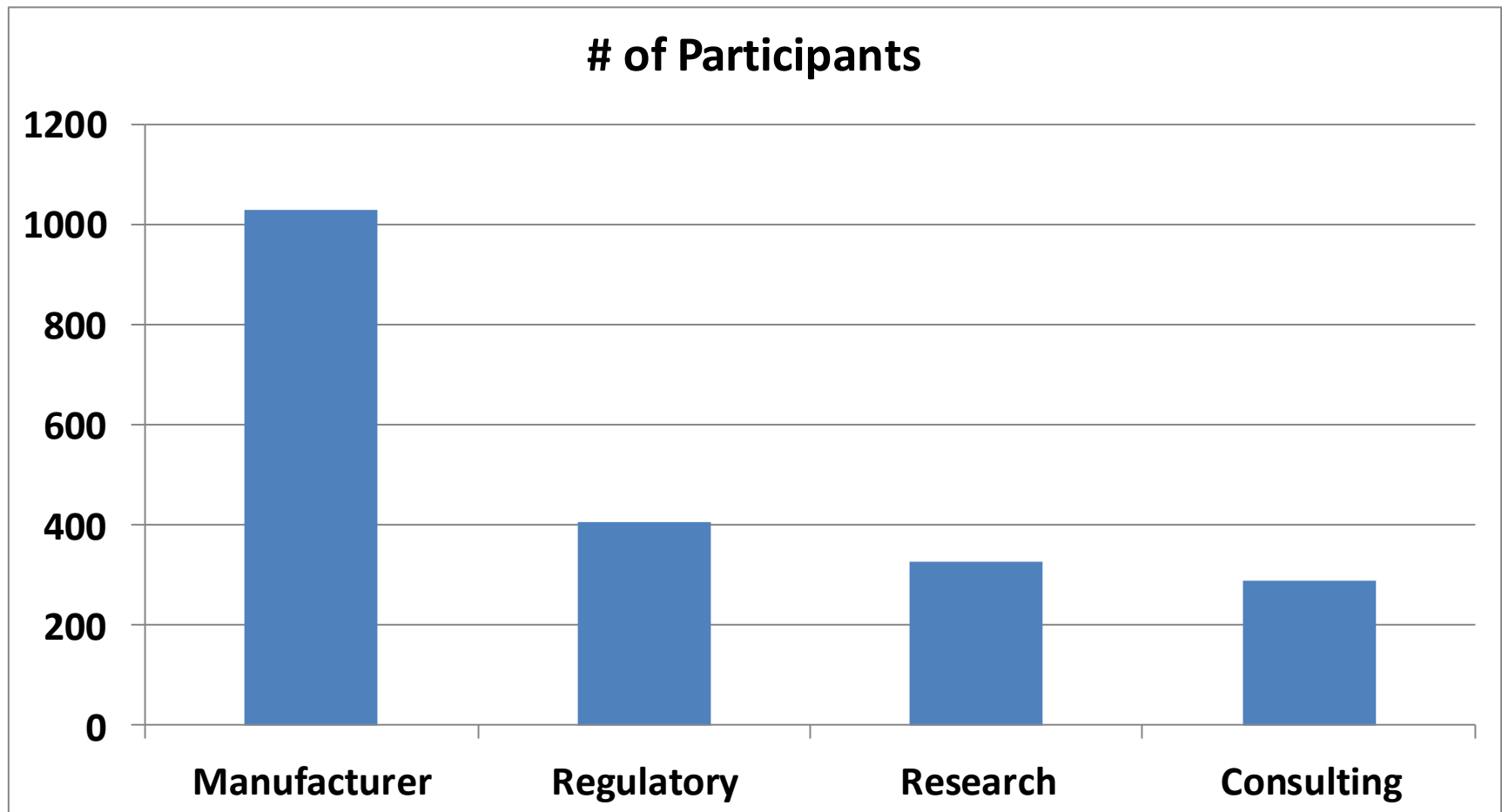
REdI Audience Demographics

total: 2590

Where You are Located



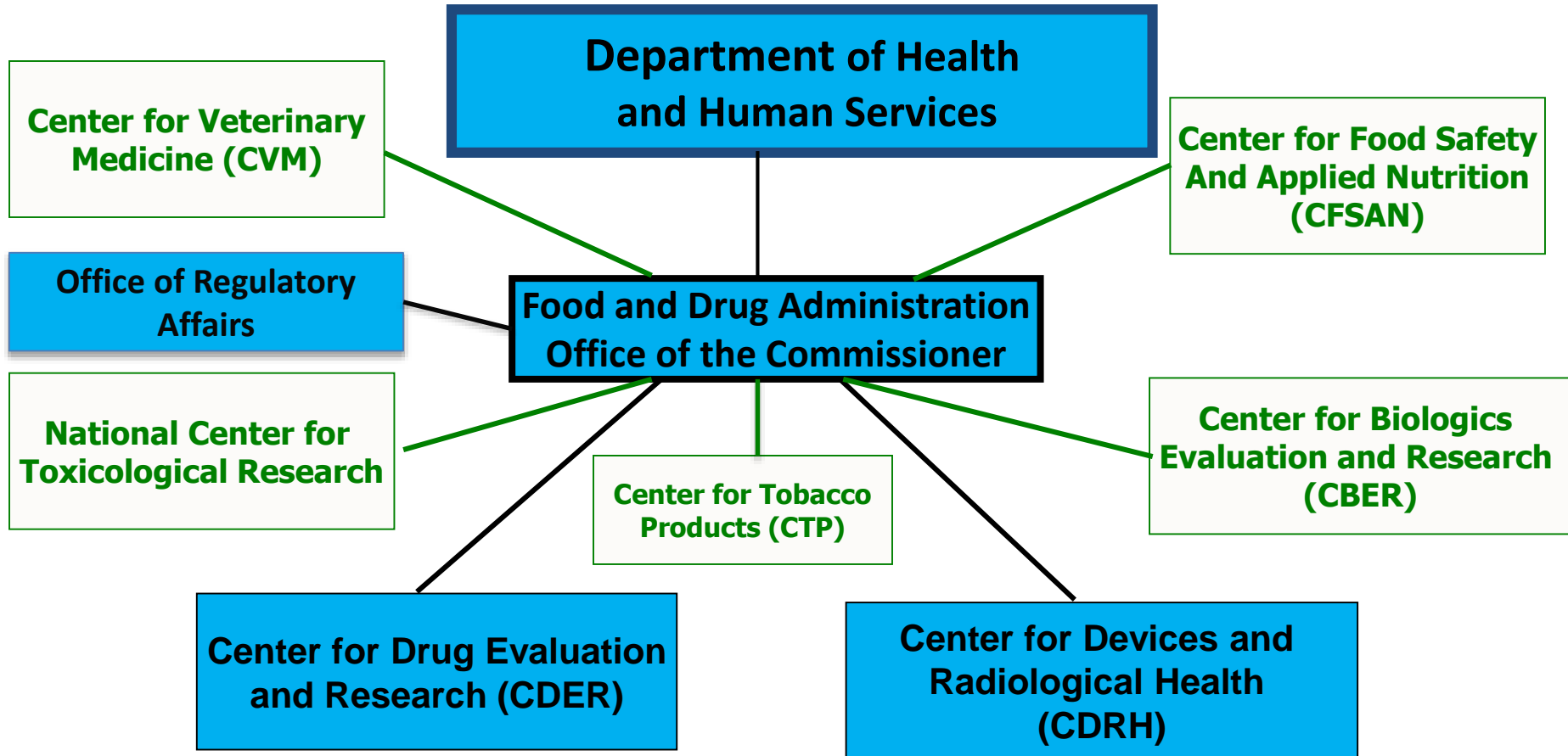
Business Type



FDA and CDRH

Regulatory Groups – at a glance

FDA Organizational Chart



Center for Devices and Radiological Health

Office of the Center Director

CDRH Ombudsman

Office of
Compliance

Office of Device
Evaluation

Office of
Management

Office of
Surveillance and
Biometrics

Office of
Communication
and
Education

Office of *In Vitro*
Diagnostics and
Radiological
Health

Office of Science and
Engineering Laboratories

Office of the Center Director (OCD)

- provides CDRH's overall direction and Strategic Plan
- sets cross-cutting regulatory policy for CDRH
- facilitates external relations and partnerships
- oversees device innovation for unmet public health needs
- coordinates medical device international efforts
- manages complaints about Center (Ombudsman)

REdI Rep: Vasum Peiris (Chief Pediatric Medical Officer)

Office of Device Evaluation (ODE)

- **evaluates premarket submissions for all device types**
 - IDE, 510(k), *de novo*, PMA, HDE, pre-Submission
 - except *in vitro* diagnostics (IVDs) and radiology products
- **structured with 7 Review Divisions and Front Office**
 - based on product disciplines (e.g., cardiology, surgery)
- **conducts reviews with teams, within set timeframes**

REdI Reps: Sergio de del Castillo and Soma Kalb (ODE Front Office)

Office of Compliance (OC)

- **evaluates, enhances and ensures compliance with medical device laws** [except *in vitro* diagnostics (IVDs) and radiology products]
 - leads domestic enforcement activities/recalls for devices
 - supports foreign device manufacturer/importer compliance for products coming into the United States
 - enforces labeling, promotion and advertising
 - conducts bioresearch monitoring of ongoing clinical studies (including IVDs and rad products)

Office of Surveillance and Biometrics (OSB)

- **leads statistical and epidemiology analyses**
 - premarket clinical studies
 - post-approval studies, registries
- **conducts global postmarket surveillance of medical devices**
 - adverse events, medical device reporting, signals/trends
- **collaborates with hospitals through Medical Product Safety Network (MedSun)**

Office of *In Vitro* Diagnostics and Radiological Health (OIR)

- **manages all premarket and postmarket activities for IVDs and radiological medical devices**
 - “total product life cycle”
 - premarket: IDE, 510(k), *de novo*, PMA, HDE, pre-Submission
 - postmarket: quality systems, medical device reporting
- **administers Federal Law to support clinical laboratory community (CLIA)**

Office of Science and Engineering Laboratories (OSEL)

- **conducts lab-based regulatory research**
- **provides scientific/engineering expertise, data and analyses**
 - to support regulatory processes (premarket and postmarket)
- **collaborates with colleagues to develop, translate, and disseminate science/engineering information**

Office of Management (OM)

- **manages Center's Budget**
 - develop/implement long-range operational plans/budgets
- **provides administrative/human resource support to Center**

Office of Communication and Education (OCE)

- manages risk communications
- manages communication with CDRH
- manages FDA Device Websites
- manages Device Freedom-of-Information (FOI) program
- leads internal education for Center Staff
- **leads external education for stakeholders**

Your DICE REdI Reps!

- Aileen Velez Cabassa
- **Anike Freeman**
- Donna Headlee
- **Elias Mallis**
- Kim Piermatteo
- **Joseph Tartal**
- Stanley Liu
- **Tonya Wilbon**

Question

D1S1-2

View Votes

Edit


End Poll

D1S1-2: Which Office will review an application to study a new knee implant?

<input type="radio"/> OC (Compliance)	<div></div>	0%	(0)
<input type="radio"/> ODE (Device Evaluation)	<div></div>	0%	(0)
<input type="radio"/> OIR (In Vitro Diagnostics)	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

Question

D1S1-3 

D1S1-3: Which Office will investigate a failure with pregnancy test kit?

<input type="radio"/> OC (Compliance)	<div></div>	0%	(0)
<input type="radio"/> ODE (Device Evaluation)	<div></div>	0%	(0)
<input type="radio"/> OIR (In Vitro Diagnostics)	<div></div>	0%	(0)
<input checked="" type="radio"/> No Vote			

☐ Broadcast Results

Overview of Premarket Submission Process

Submission Process: in 5 Steps

- 1. Establish Your Product**
- 2. Verify that Product is a medical device**
- 3. Identify Regulatory Pathway**
- 4. Develop Valid Scientific Evidence**
- 5. Submit Premarket Application**

1. Establish Your Product

- ✓ **Identify product (device) description**
- ✓ **Identify purpose**
 - Intended use
 - Indications for use
 - Duration of use
 - Target patient population (age range; disease)

2. Verify that Product is a Medical Device

A medical device defined

“... an instrument, apparatus, implement, machine, contrivance, implant, *in vitro* reagent, or other similar or related article, including any component, part, or accessory, which is:

Section 201, Food Drug and Cosmetic Act (FD&C Act)

A medical device defined

- intended for use in the **diagnosis** of disease or other conditions, or in the **cure, mitigation, treatment, or prevention of disease** in man, or
- intended to **affect the structure or any function** of the body,
- and which does not achieve its primary intended purposes through **chemical action** within or on the body of man and which is not dependent upon being **metabolized** for the achievement of its primary intended purposes.” **(in other words, not a drug)**

Medical Devices are Diverse

- **Complexity of design**
 - Bandage vs. a dual-chamber pacemaker
- **Purpose**
 - Hospital bed vs. ventilator
- **Impact on care of patient**
 - Urinary catheter vs. hemodialysis system

Is my Product a Medical Device?

- **Stay tuned for next presentation!**
- **General tip: look for established precedent**
 - Prior FDA decisions for similar device + intended use
 - especially recent decisions
 - Review FDA Classification Regulations

3. Identify Regulatory Pathway

- Identify regulatory classification
- Classification will generally indicate regulatory pathway (market submission type) for that device type

Regulatory Classification

Based on Device Description **and** Intended Use:

- Classification Exists or
- Classification Does not Exist

Regulatory Classification

- Determines extent of regulatory control (risk-based)
- Regulatory Control increases from Class I to III
- Product Codes
 - Three-letter “tagging” for unique device + intended use)
 - Identical device with different intended uses may have different classifications/product codes

Same Device + Different Intended Use = **Different** Regulatory Classification

Radio-Frequency (RF) Energy-Based Surgical Clamp

➤ **ablate general soft tissue**

- Class II, 510(k)
- preclinical testing

➤ **treat paroxysmal atrial fibrillation**

- Class III, PMA
- animal testing; prospective clinical study

What are “Regulatory Controls”

- Requirements that apply to a product area
- Provide consistent requirements
- With appropriate level of regulatory oversight
- Generally broad, but may be specific

Classes of Medical Devices

Class	Risk	Controls	Submission
I	lowest	general	<ul style="list-style-type: none">• exempt• 510(k)
II	moderate	general and special (if available)	<ul style="list-style-type: none">• 510(k)• exempt
III	highest	general and PMA	<ul style="list-style-type: none">• PMA• HDE

Happy 40th Birthday!

- CDRH established on May 28, 1976
- enactment of Medical Device Amendments
- FDA classified all known devices in use at that time by Class and Product Code



What if Classification Doesn't Exist?

- Requires PMA by default
- May be eligible for *de novo* if specific criteria are met
- ✓ FDA Final Decision of New Device Submissions trigger creation of new Classification

4. Develop Valid Scientific Evidence

21 CFR 860.7(c)(1)

- Requires valid scientific evidence for safety and effectiveness

21 CFR 860.7(c)(2)

- Defines valid scientific evidence

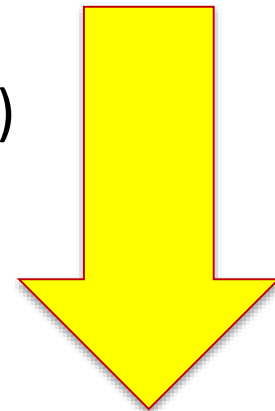
CFR = Code of Federal Regulations

Valid Scientific Evidence

- **Precedent for device type**
 - **Special controls**
 - **Guidances**
- ✓ **to establish safety and effectiveness profile for device**

Progressive Evidence Rigor

- Based on inability to sufficiently address safety and/or efficacy questions/issues with lower degree of “rigor”
- **Progressive Paradigm:**
 1. Descriptive information (no new testing)
 2. Bench (engineering) testing
 3. Animal (*in vivo*) testing
 4. clinical studies



5. Submit Premarket Application

- Each submission type has own sets of processes, regulations (except *de novo*), review times, evidence burden
- **Review Times:**
 - FDA uses calendar days, not business days
 - Based on MDUFA = Medical Device User Fees of 2012
- **After Legally Marketed:**
 - Complete Registration and Listing

Summary

- CDRH is divided into distinct offices with dedicated roles:
 - Premarket Review Offices: ODE and OIR
 - Postmarket Review Offices: OC, OSB, and OIR
- Planning your Regulatory Strategy Upfront involves (1) deciding your product and intended use and (2) understand its regulatory classification

Industry Education Resources

Three Resources

1. CDRH Learn – Multi-Media Industry Education

- over 115 modules
- videos, audio recordings, power point presentations, software-based “how to” modules
- mobile-friendly: access CDRH Learn on your portable devices

www.fda.gov/Training/CDRHLearn

2. Device Advice – Text-Based Education

- comprehensive regulatory information on premarket and postmarket topics

www.fda.gov/MedicalDevices/DeviceAdvice

3. Division of Industry and Consumer Education (DICE)

- Contact DICE if you have a question
- Email: DICE@fda.hhs.gov
- Phone: 1(800) 638-2041 or (301) 796-7100 (Hours: 9 am-12:30 pm; 1 pm-4:30pm EST)
- Web: www.fda.gov/DICE

Remember!

**We're just a
phone call or
email away!**



