OMDRHO | Office of Medical Device and Radiological Health Operations

Program Keynote

Anne Reid, Program Director

OMDRHO 4th Conference 07/13/2022

Program Updates

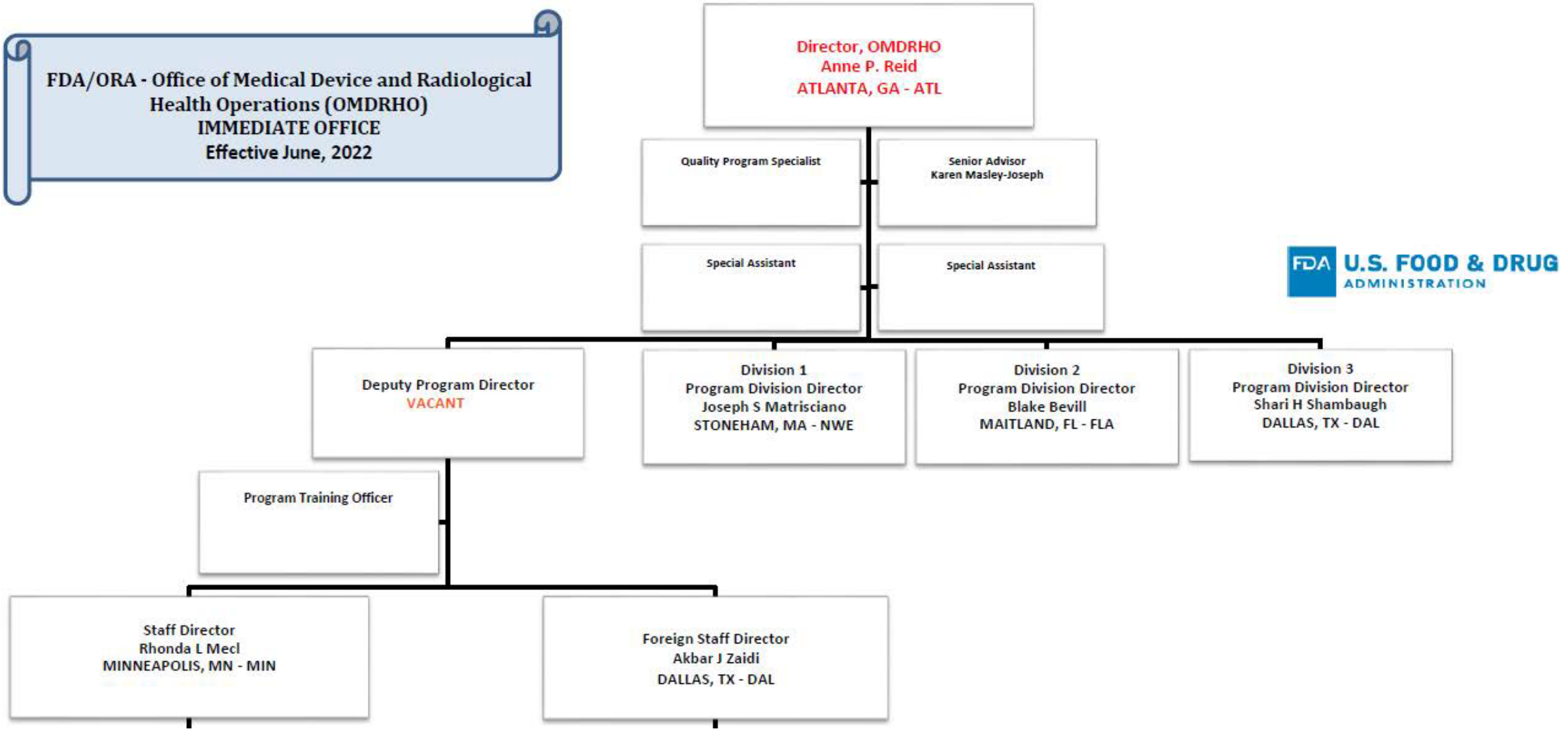
Operational Status

Key Initiatives

OMDRHO

PROGRAM UPDATES

OMDRHO Program



OMDRHO webpage on fda.gov

www.fda.gov/ORADevices

FDA U.S. FOOD & DRUG ADMINISTRATION

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Office of Medical Device and Radiological Health Operations (OMDRHO)

A Day in the Life - Medical Device Program

Frequently Asked Questions About FDA Inspections of Combination Products

OMDRHO 2022 Annual Virtual Conference - 07/13/2022

Working Together - Keeping Informed: FDA Medical Device Virtual Conference 2021 -

What We Do

- Inspections
- Remote Regulatory Assessments (RRA)
- Recalls
- Compliance
- Medical Device Databases
- CDRH Related Links
- Additional Information

Content current as of:
02/22/2022

Regulated Product(s)
Medical Devices
Radiation-Emitting Products

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A Day in the Life - Medical Device Program

Frequently Asked Questions About FDA Inspections of Combination Products

Working Together - Keeping Informed: FDA Medical Device Virtual Conference 2021 - 06/23/2021 - 06/23/2021

46th International Good Manufacturing Practices Conference - 03/07/2022

What We Do

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Regulated Product(s)
Medical Devices
Radiation-Emitting Products

About the Office

The Office of Medical Device and Radiological Health Operations (OMDRHO) is a program office within the Office of Medical Products and Tobacco Operations (), a part the Office of Regulatory Affairs (ORA).

...irects the Office of Medical Devices and ...lth Operations. The office structure ... the foreign and domestic medical device and radiological health inspection and operations staff including three divisions with responsibility for oversight of staff conducting inspections, managing compliance activities, recalls, and partnerships.

Pending Update!

Vision

All patients, providers, and consumers are informed, protected, and have access to safe, reliable medical devices and radiological health products

Mission

Protect and enhance public health by minimizing risk and by supporting access to safe, effective and quality medical devices and radiological health products.

Key Contacts

Hot Topics

- Federal Register :: Public Inspection: Medical Devices; Quality System Regulation
- Philips Respironics Recall FAQ
- Office of Medical Devices and Radiological Health Operations Divisions Boundary Map
- Work with Us - Visit Jobs at the Office of Regulatory Affairs
- OMDRHO CSO Recruitment Flyer

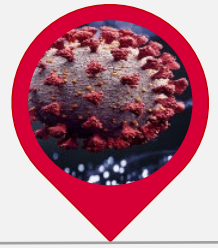
Links to Inspectional handouts!

Inspections

- What should I expect during an inspection?
- FAQS about combination product inspections
- Divisional & Foreign Inspectional Handouts
  - Inspectional Handout - OMDRHO Division 3 West
  - Inspectional Handout - OMDRHO Division 2 Central
  - Inspectional Handout - OMDRHO Division 1 East
  - Inspection Handout - OMDHRO FDA 483 Responses to Foreign Inspections
- Resources used by FDA investigators and inspectors in their daily activities

Links to Hot Topics!

COVID Timeline



MARCH
Suspend Surveillance Inspections

2020

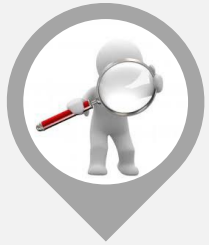
MAY
Resiliency Roadmap & MedCon 2021

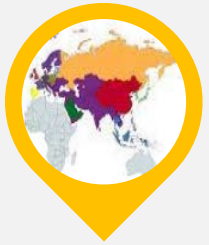
JUNE
Begin RRAs

JULY
Return to Baseline Inspections

NOV
Updated Resiliency Roadmap

2021





JAN
Pause

FEB
Resume Inspections

APRIL
Resume Foreign Inspections

2022

Inspection Types

COMMODITY	TIER 1: MISSION CRITICAL	TIER 2: HIGHER PRIORITY	TIER 3: LOWER PRIORITY
Medical Devices and Radiological Health	Essential product assignment	Application-approval inspection not considered mission critical	Post-approval inspection
	Agency crisis or emergency response For-cause work	For-cause but not considered mission critical	
	Application-approval for high-priority product	Overdue MQSA inspection*	Routine-surveillance, including inspection and sampling assignment
	Mission-critical violation follow-up	High-risk assignment based on Risk Based Work Plan	

Inspectional Coverage 2020 - present

	2020 April – Sept	2020 – 2021 Oct – March	2021 April – Sept	2021 – 2022 Oct – March	2022 April – June
Mission Critical	X	X	X	X	X
Prioritized Domestic	X	X	X	X	X
Foreign			X	X	X
All Types, All Geography				X	X
RRA	X	X	X	X	X

RRAs

REMOTE REGULATORY ASSESSMENTS

continue to be available

enterprise-wide

- Multi-Commodity- will continue to see use of this regulatory tool
- For Devices, RRAs are voluntary; No Form 482 Notice of Inspection
- Remote, interactive engagement to review records firms are required to maintain
- No Form 483 Inspectional Observations - findings verbally discussed with firm

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CURRENT OPERATIONAL STATUS

FY22 - Current Operational Status

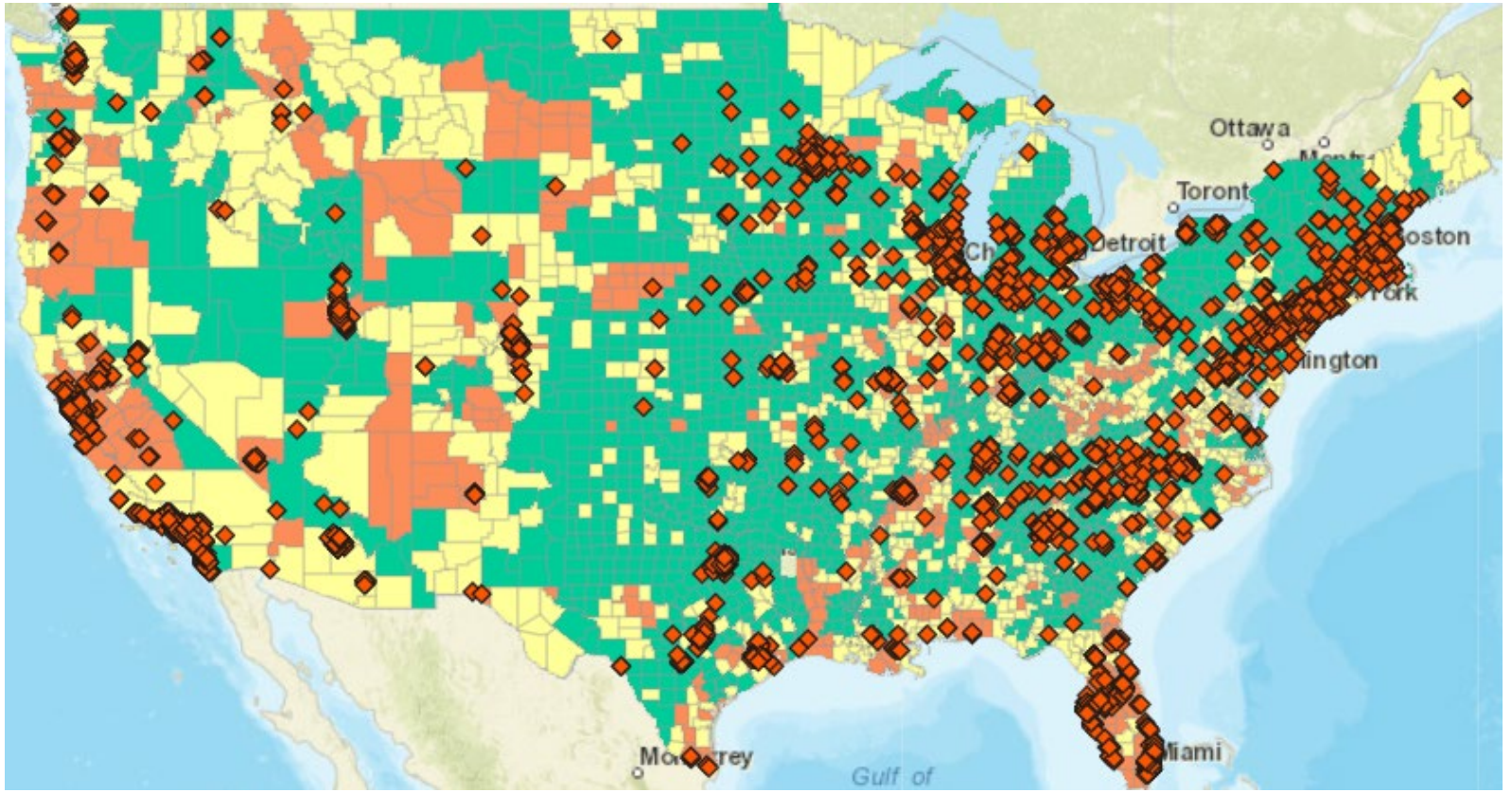
Operating Status

CURRENT STATUS

Nationwide

Applies to: **Wednesday, June 29, 2022**

STATUS: OPEN WITH MAXIMUM TELEWORK FLEXIBILITIES TO ALL CURRENT TELEWORK ELIGIBLE EMPLOYEES, PURSUANT TO DIRECTION FROM AGENCY HEADS



Continue to prioritize:

- PMA
- Compliance Follow-up
- For Cause: Complaint, Class1 Recalls
- Risk Based
- Surveillance

FY22 Current Operational Status

Resumed travel mid-April:

- Mission Critical
- Priority
- Performed by Cadre to start

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FY22 INITIATIVES

FY22 OMDRHO Key Initiatives

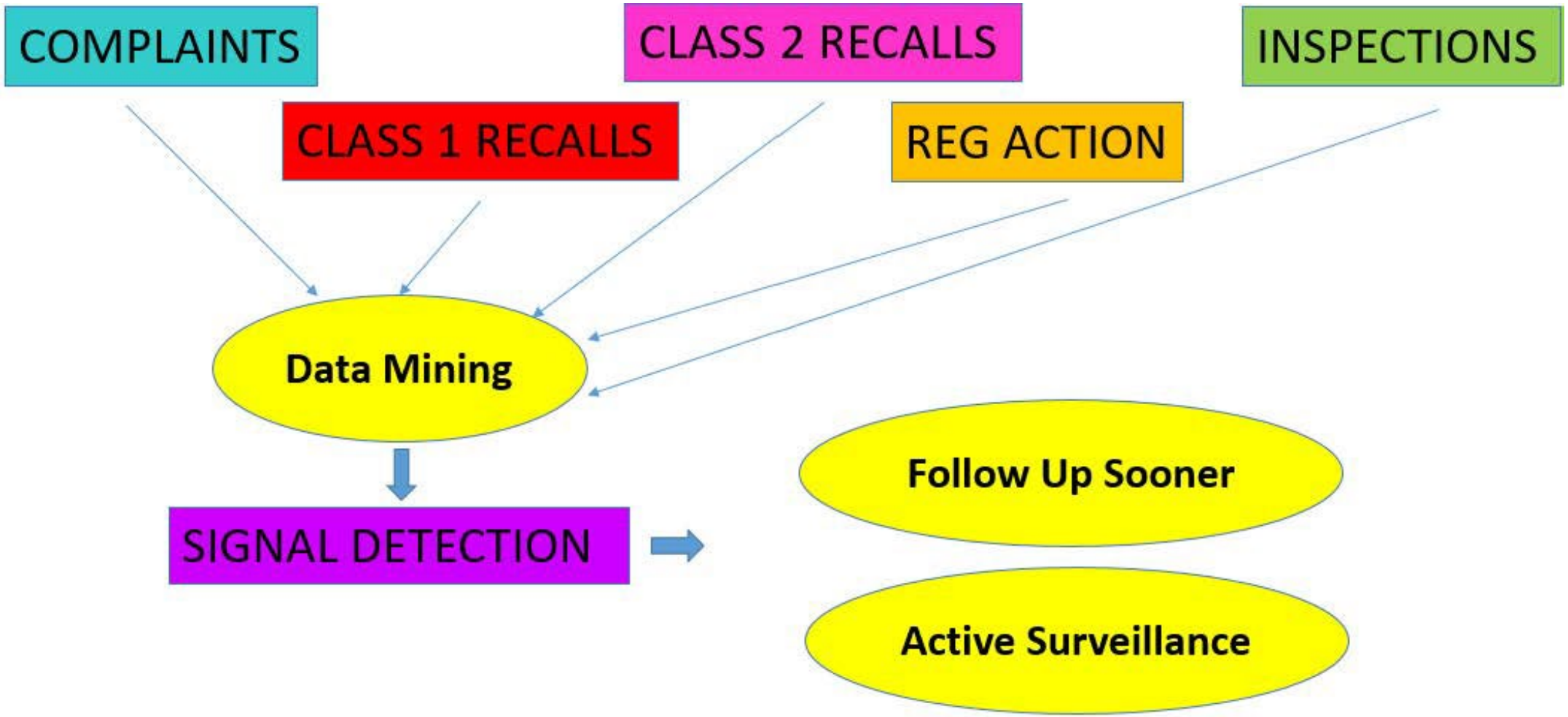
WORKFORCE	- Inspectional guidance when encounter 510k concerns - EUA resource summary for investigators
RISK MANAGEMENT	- Review post market signals by firm for follow-up needs - RRA Process Improvements
PARTNERSHIPS	- PEAC - MedCon - OMDHRO Conference
STRATEGIC DIRECTION	- One Medical Device and Radiological Health Program - 820 Transition

FY22 Risk Management Initiative

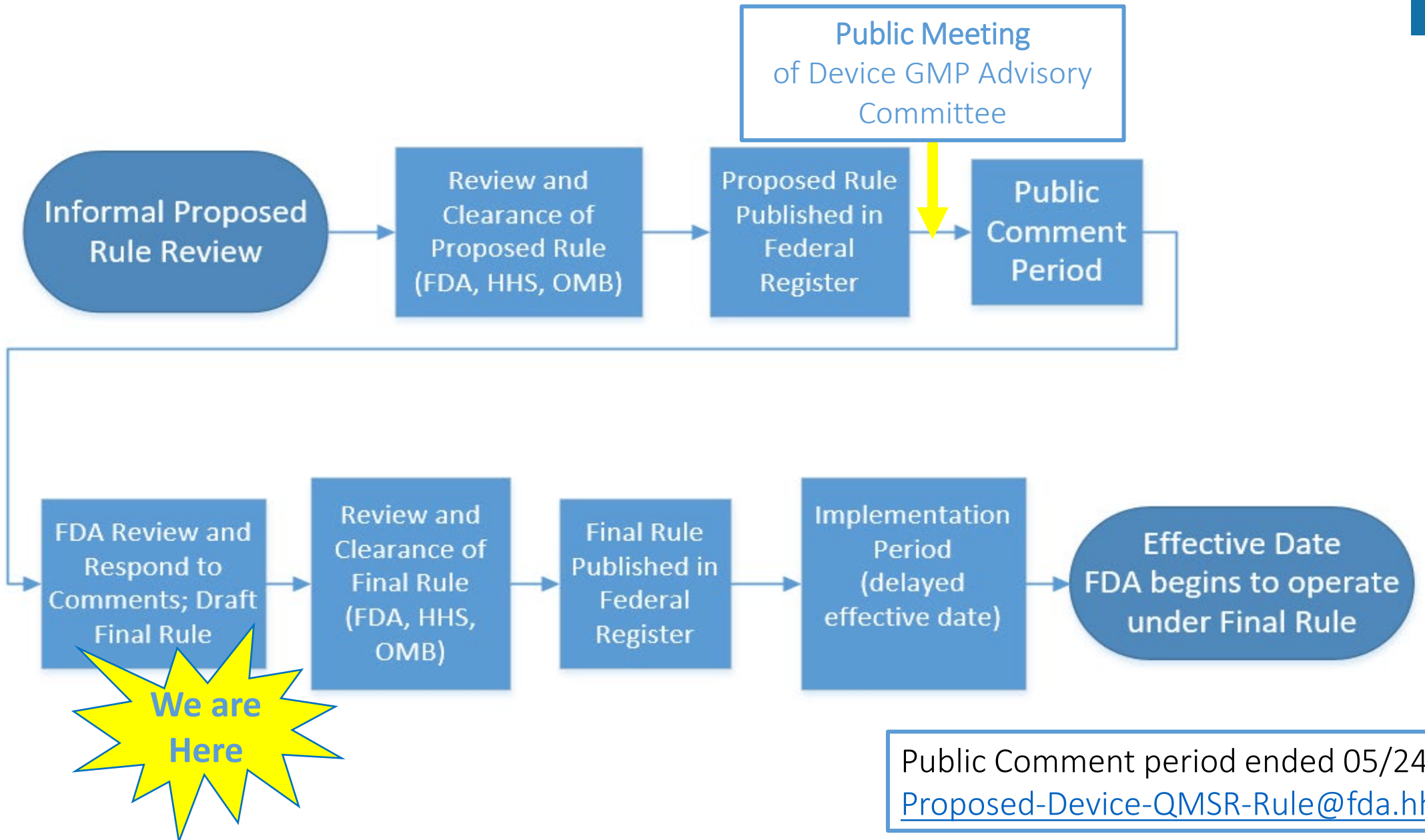
Signals Concept

- Review Individual data sources
- Combine to FEI view
- Publish visual report @ frequency

Data Driven Risk-Based Approach



820 Transition



Public Comment period ended 05/24/2022:
Proposed-Device-QMSR-Rule@fda.hhs.gov

Questions?

Disclaimer

Thank You!