U.S. FOOD & DRUG ADMINISTRATION

Welcome To Today's Webinar

Thanks for joining us!
We'll get started in a few minutes

Today's Topic:
The Voluntary Improvement Program: How to Enroll, Opportunities, and Best Practices

October 8, 2024

The Voluntary Improvement Program: How to Enroll, Opportunities, and Best Practices

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Learning Objectives

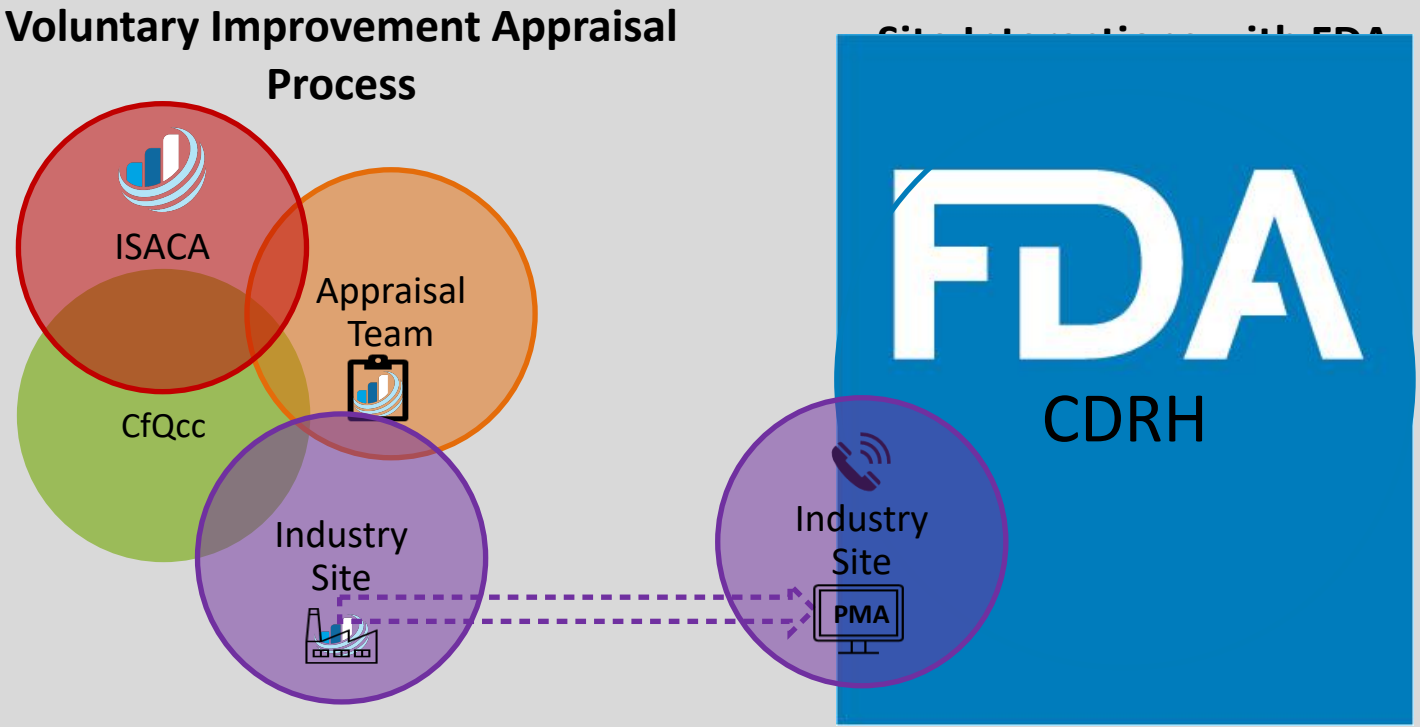
- Provide background information on the Voluntary Improvement Program (VIP)
- Describe the value of VIP for participants
- Describe enrollment and expectations for participation in VIP
- Describe the regulatory opportunities for VIP participants
- Describe ways sponsors can support the VIP 30-Day Notice review goal

Background

Overview of VIP

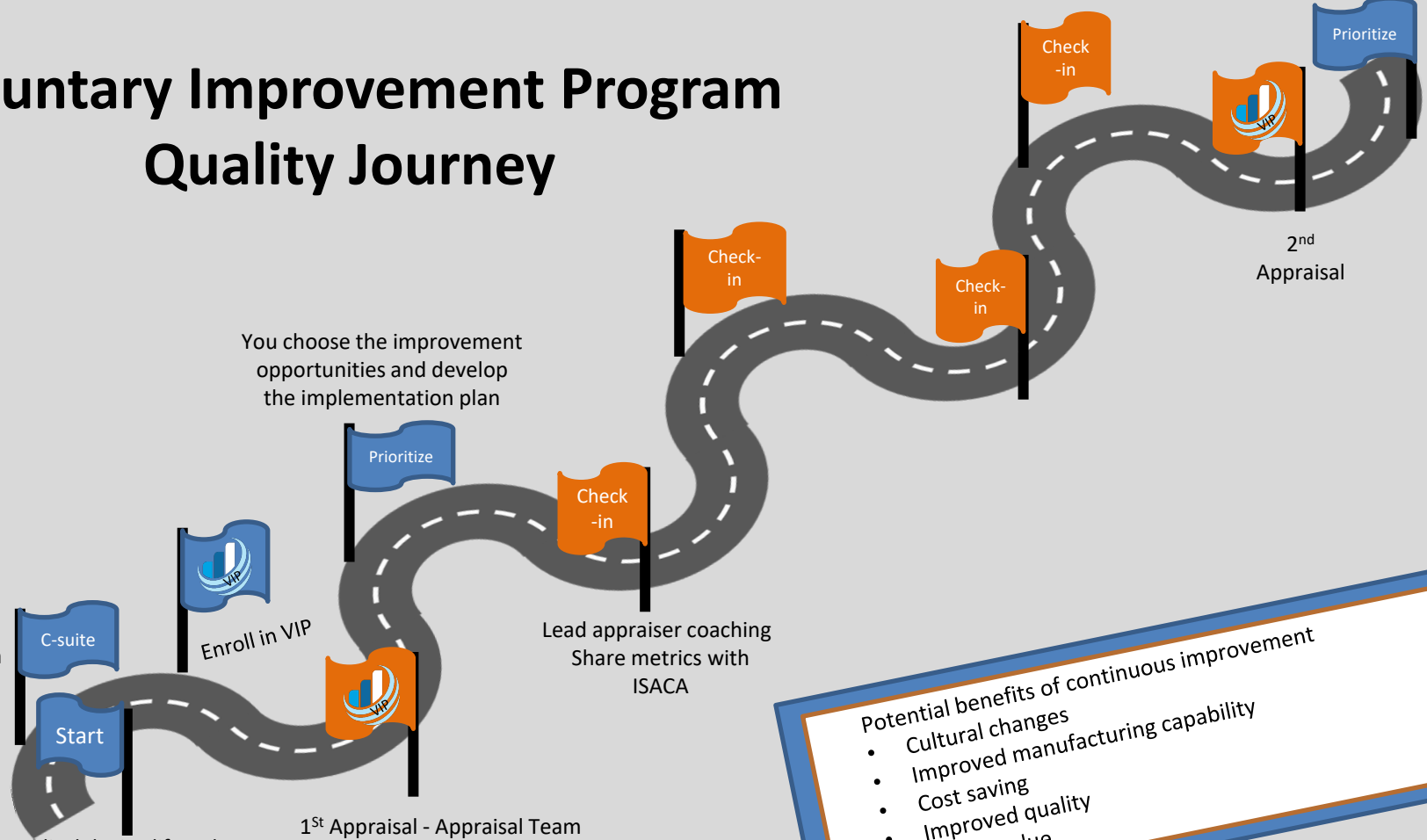
What	Model collaboratively developed Voluntary quality maturity appraisal program assessed by third-party
Why	Intend to improve product quality, safety and availability through a focus on continuous improvement
Intended Results	Improved product quality and availability Increased manufacturing performance and value Best practice sharing and investment in improvement Identified broad improvement opportunities
Status	Final guidance: *Fostering Medical Device Improvement: FDA Activities and Engagement with the Voluntary Improvement Program* *issued September 15, 2023*

Collaborations within the Voluntary Improvement Program



ISACA: Information Systems Audit and Control Association
CfQcc: Case for Quality Collaborative Community
PMA: Premarket Approval Application

Voluntary Improvement Program Quality Journey



Manufacture in medical device lifecycle
Positive compliance profile
No official action indicated (OAI) status or judicial action

1St Appraisal - Appraisal Team
- Identifying strengths and opportunities
- Sharing best practices

Potential benefits of continuous improvement
- Cultural changes
- Improved manufacturing capability
- Cost saving
- Improved quality
- Added value

Value for Participants

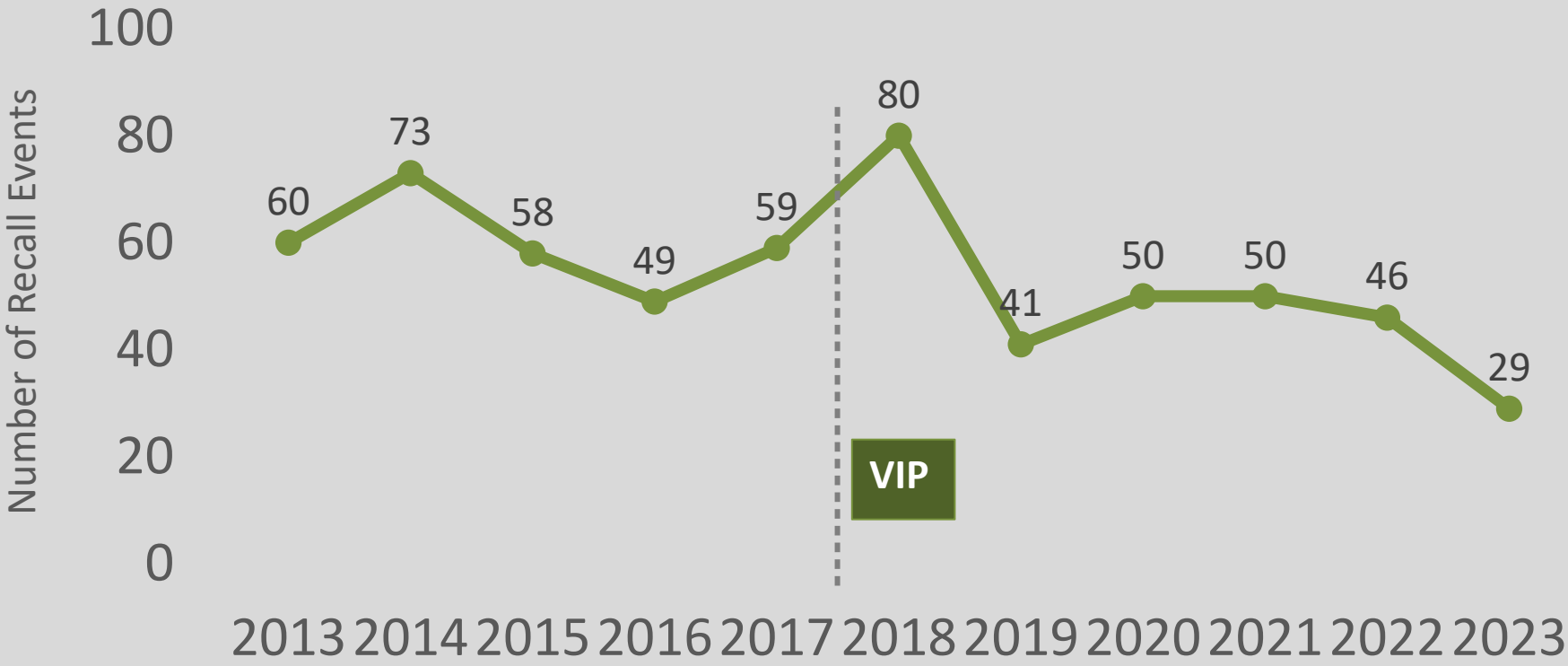
Demographics of Enrolled Sites

120 Sites	Companies enrolled 1 to 25 sites
Class III/II/I sites	25 to 500+ employees
Some 510(k) only sites	Original equipment and contract manufacturers

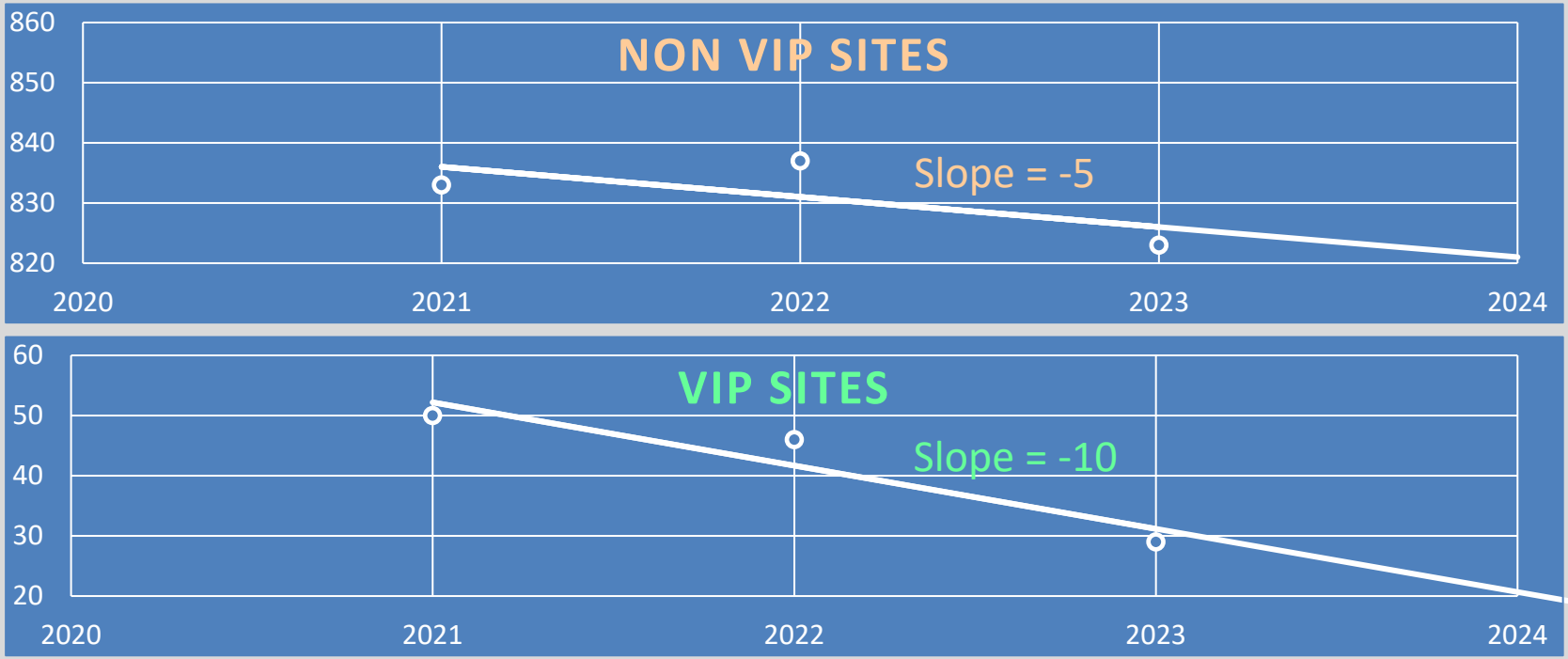
Value Reported By Enrolled Sites

Quality culture	Continuous improvement savings
Trusted environment	Coaching from appraisal team
Improved communication	Forward looking/improvement
	FDA PMA program opportunities

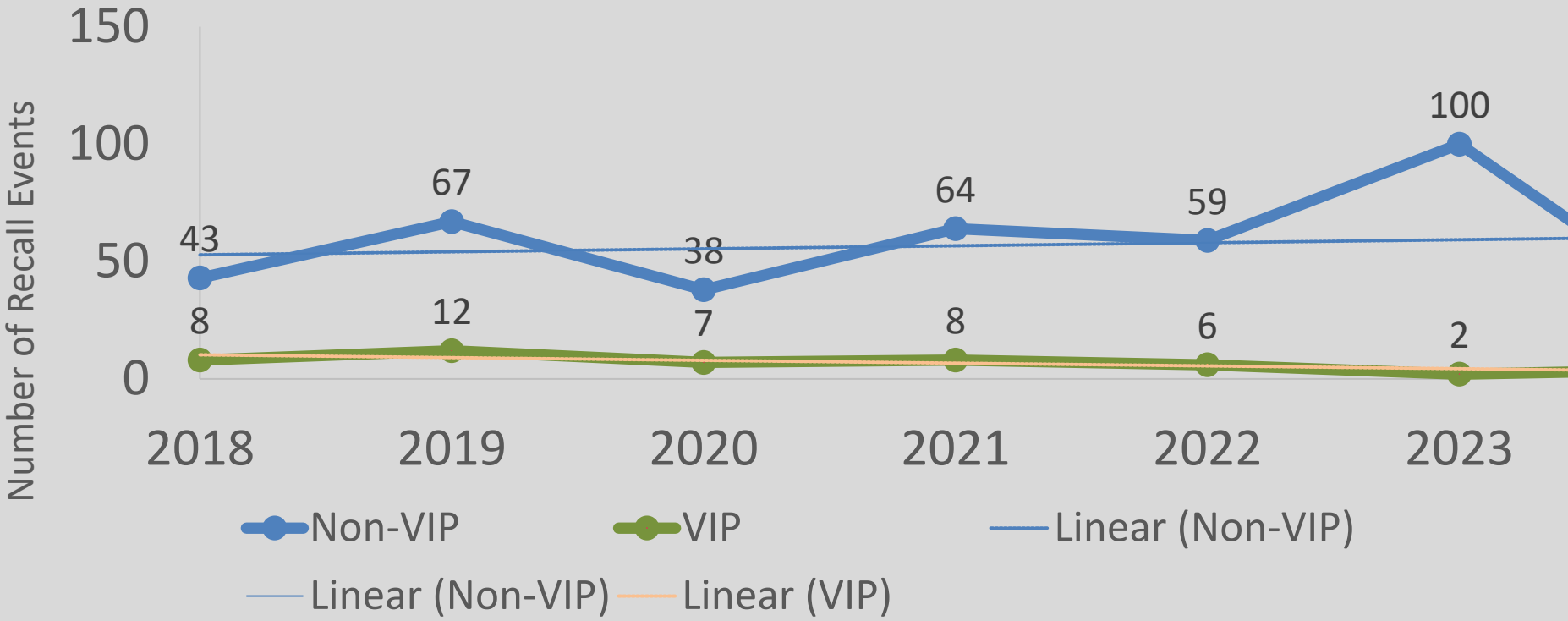
VIP Recall Trending



Sustained VIP Enrollment Impact on Patient Safety

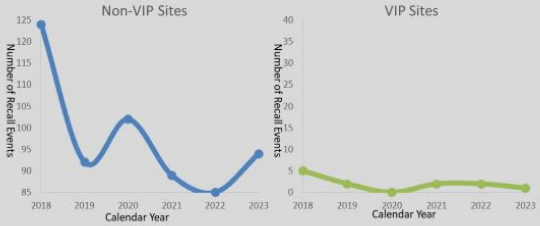


VIP Recall Trending – Class I Recalls



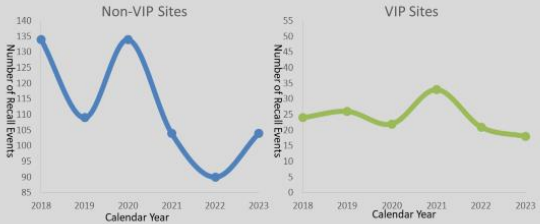
Recall Event Trends

General Hospital Panel

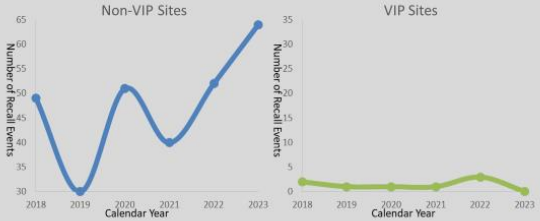


Clinical Chemistry Panel

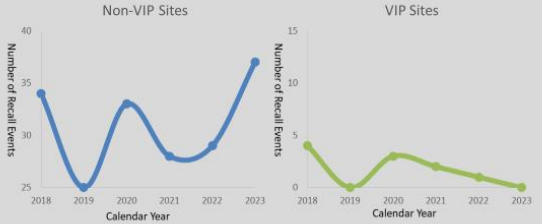
Cardiovascular Panel



Anesthesiology Panel



Neurology Panel



Reported Value from Sustained VIP Enrollment

Systemic downward recall trend

Patient access

Culture changes

Patient safety

Continuous improvement savings

Coaching to improve

Enrollment and Expectations for Participation

VIP Participation

Fostering Medical Device Improvement

VIP site enrollment criteria:

- Part of lifecycle for any medical device distributed in the U.S.
- Positive inspection history
- No current OAI status or subject to a judicial action

VIP Participation

Fostering Medical Device Improvement

Site Commitments:

- Annual appraisal
- Engage with appraiser
- Commit to the agreed upon appraisal process
  - Quarterly check in with lead appraiser
  - Provide performance metrics to ISACA
- Proactively notify FDA regarding product safety issues and recalls

VIP Participation

Fostering Medical Device Improvement

FDA Commitments:

- Confirm site eligibility for enrollment
- Engage proactively with participating manufacturing sites to resolve any issues such as signals, potential safety issues, or recalls
- Contact and engage with participating manufacturing site to discuss and resolve any issues brought to FDA's attention during an appraisal that jeopardize its participation in VIP

Voluntary Improvement Program Resources

Resource	Link
Fostering Medical Device Improvement Guidance	www.fda.gov/regulatory-information/search-fda-guidance-documents/fostering-medical-device-improvement-fda-activities-and-engagement-voluntary-improvement-program
Medical Device Innovation Consortium (MDIC) / Voluntary Improvement Program	https://mdic.org/project/voluntary-improvement-program/
Information Systems Audit and Control Association (ISACA) / Voluntary Improvement	www.isaca.org/enterprise/voluntary-improvement-program

Potential Regulatory Opportunities for Qualifying Participants

FDA Regulatory Opportunities

Fostering Medical Device Improvement

- FDA Consideration in Risk-Based Inspection Planning
- Opportunity to utilize a Modified Submission Format
  - Premarket Approval Application (PMA) and Humanitarian Device Exemption (HDE) 30-Day Change Notices for Modifications to Manufacturing Procedures or Methods of Manufacture
  - PMA and HDE Manufacturing Site Change Supplements
  - PMA or HDE Manufacturing Modules

Supporting the FDA's VIP 30-Day Notice Review Goal

VIP Assessment: FDA and Patients

- Benefits for FDA Staff
  - Least burdensome and streamlined review
  - Time savings vs traditional 30-Day Notice
  - Program participation bolsters confidence in 30-day submissions
- Benefits for Patients
  - Reported improved product access
  - Reported safer product
- 30 Day Notice Review Challenges
  - 10 Day review goal is dependent on resources
  - Grown to 38% of 30-Day Notice Submissions

Submission Attributes that Increase Review Time

- Interactions with the sponsor to clarify or request information
- Insufficient detail in change descriptions or summary of evidence to support changes
- Submissions with incorrectly applied 30 Day-Notice policy
- Submitting extraneous information

Practices to Avoid

- Including annual reportable changes
- Submitting promises for future testing
- Submitting VIP 30-Day Notices for complex changes not suited for summary or 30-day review
- Deviating from general 30-Day Notice program policy

30-Day Notice Best Practices

- When describing the change:
  - Use pictures, diagrams, videos to help FDA understand the change
  - Include context in the reason for the change (avoid in-house terminology)
- When providing summary-level information of testing:
  - Provide sufficient detail such that FDA can assess test article, test method, sample size, acceptance criteria, results (such as descriptive statistics instead of "PASS"), and relevance of test to supporting the change
  - Include patient contacting status (for material/supplier change)
  - Identify when using identical testing for changes implemented for another device, and prior submission number
- Learn from prior successes and failures to improve submissions
- Consider aligning with the review team in advance on VIP 30-day notice strategy (submission timing and content)

Summary

The Voluntary Improvement Program:

- Provides value to enrolled sites
- Leads to safer products and increased availability
- Open to any site
  - positive history
  - manufacturing of a device marketed in the U.S.
- Offers regulatory opportunities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Additional Panelists

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Office of Health Technology 2A

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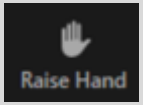
Let's Take Your Questions

- **To Ask a Question:**
  1. Raise your hand in Zoom 

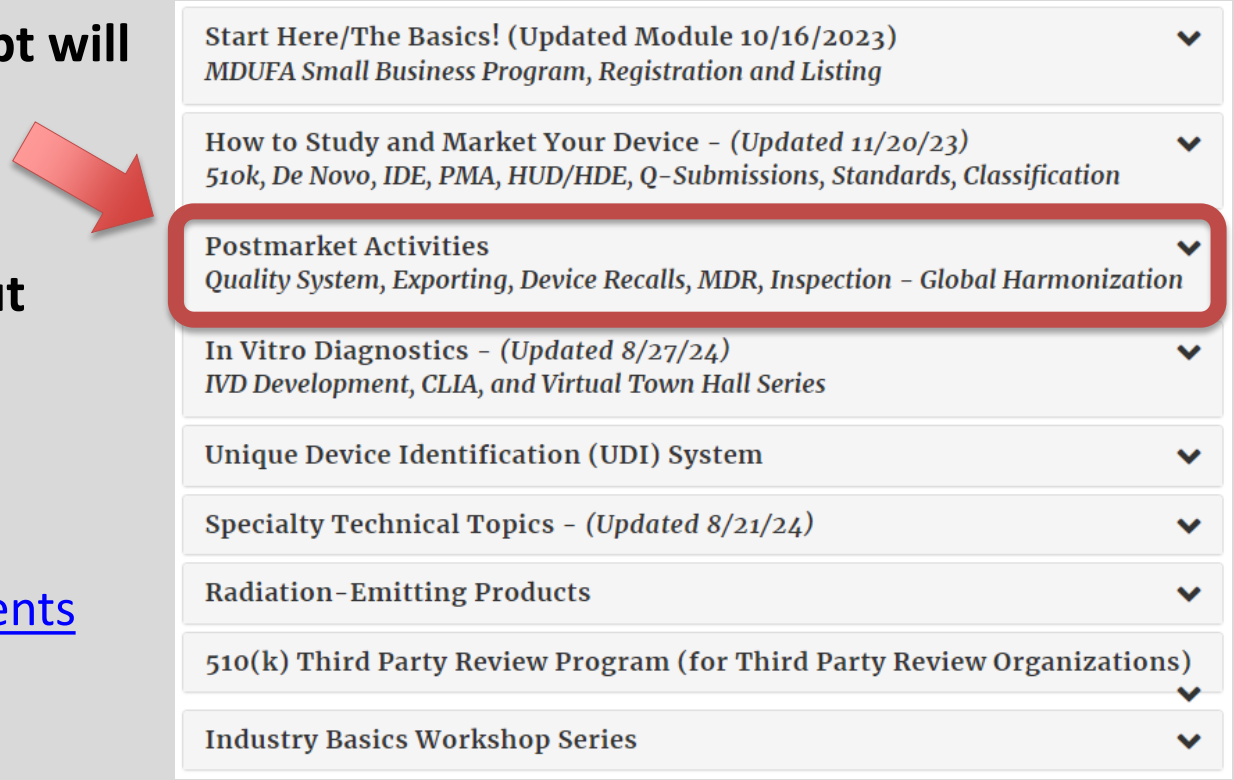
  2. Moderator will announce your name and invite you to ask your question
  3. Unmute yourself when prompted in Zoom to ask your question

- **When Asking a Question:**
  - Ask one question only
  - Keep question short
  - No questions about specific submissions

- **After Question is Answered:**
  - Mute yourself and lower your hand
  - If you have more questions - raise your hand again

Thanks for Joining Today!

- **Presentation and Transcript will be available at:**
  - CDRH Learn
- **Additional questions about today's webinar**
  - Email: DICE@fda.hhs.gov
- **Upcoming Webinars**
  - www.fda.gov/CDRHevents

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