**The Voluntary Improvement Program: How to Enroll, Opportunities, and Best Practices**
**October 8, 2024**

**Moderator: CDR Kim Piermatteo**

**CDR Kim Piermatteo:** Hello everyone and welcome to today's CDRH webinar. Thanks for joining us. This is Commander Kim Piermatteo of the United States Public Health Service, and I serve as the Education Program Administrator in the Division of Industry and Consumer Education within CDRH. I'll be the moderator for today's webinar.

Today, we would like to discuss with you the Voluntary Improvement Program, including enrollment and participation criteria, the value expectations and regulatory opportunities for participants, best practices for submitting a 30-day notice, and address your questions about this program.

I'd now like to introduce our presenter for today's webinar. Erin Keith, Senior Advisor on the Compliance and Quality Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ. We'll begin with a presentation from Erin and then field your questions about our topic.

Before I turn it over to Erin, I'd like to provide a few reminders. First, please make sure you've joined us through the Zoom app and not through a web browser to avoid technical issues. Second, the intended audience for this webinar is industry. Trade Press reporters are encouraged to consult with the CDRH trade press team at cdrhtradepress@fda.hhs.gov. And members of national media may consult with FDA's Office of Media Affairs at fdaoma@fda.hhs.gov. And, lastly, we look forward to interacting with you during our live question-and-answer segment of today's webinar. So, if you have a question, please wait, and raise your hand at the end of today's presentation to get into the queue.

Thank you all again for joining us. I'll now turn it over to Erin to start today's presentation.

**Erin Keith:** Thank you, Kim. Our learning objectives for today's webinar are provide background information on the Voluntary Improvement Program, describe the value of the program for participants, describe enrollment and expectations for participation in the program, and describe the regulatory opportunities for program participants, as well as describe ways sponsors can support the program's 30-Day Notice review goal.

We're going to discuss a little bit of background on the program next.

This program employs the use of a third-party quality maturity appraisal model based on the Capability Maturity Model Integration, or CMMI, approach. CMMI is owned by the Information Systems Audit and Control Association, ISACA. The voluntary improvement appraisal process used in the program was collaboratively developed, and it is implemented by ISACA. The collaborators included the Medical Device Innovation Consortium, or MDIC, Case for Quality members, the Case for Quality Collaborative Community members, ISACA, and FDA. A primary goal of the program is to move industry practices and behaviors to have them focus on continuous improvement and away from meeting the bare minimum for regulatory compliance.

High-level results of the program can include improved product quality and availability, increased manufacturing performance and value, best practices, and investment in improvement. And it has also helped to identify broad industry-wide areas of improvement. The implementing guidance is fostering

medical device improvement. It was issued in September 15, 2023. Next, we'll take a dive into the logistics and implementation of the program.

The organizational model for the Voluntary Improvement Program is atypical, and it can be a little hard to get your head around how the overall program works. There is an external element to the program that is outside of FDA's and industry's manufacturing sites' interactions over any given regulatory issue. The external element helps to both develop and maintain the appraisal regulatory tool as well as implement the appraisal process.

ISACA, the Case for Quality Collaborative Community, and the appraisal team are all part of developing and maintaining the regulatory tool. ISACA, the appraisal team, and the industry site implement the appraisal process at that given site. The industry site can then interact with FDA and use some of the appraisal outcomes or information in support of certain regulatory submissions with FDA.

Next, let's talk about the typical quality journey a site goes through when they join the program.

The typical journey starts with convincing the senior leadership of the site to spend the money to cover the cost of the appraisal. After that, the site contacts ISACA to begin the process of enrollment. FDA confirms for ISACA a site's eligibility. Once the contract between the site and ISACA is signed, the planning for the first appraisal begins.

Through the conduction of that appraisal, the first appraisal, the site identifies its strengths and opportunities for improvement. The site takes the information and develops an improvement plan with the help of their lead appraiser. FDA is not involved in this. Quarterly meetings between the site and the lead appraiser occur to provide coaching and to keep the momentum of continuous improvement moving forward.

Quarterly submissions of performance metrics that support the improvement plan are provided to ISACA, and FDA sees these metrics. Implementation of the improvement plan is how the site obtains the benefits of continuous improvement. The appraisal, the improvement plan development, and the plan implementation happen yearly.

Next, I'd like to share some of the value of participating in the program that has been reported to FDA by the participants. FDA did an assessment recently of the participants through interviewing participating sites.

At the time of this assessment, there were approximately 120 sites that were enrolled. These sites represent companies that enrolled between one to 25 sites, employed between 25 to over 500 employees at a given site. Manufacturers make the full range of Class I, Class II, and Class III devices. They participate in the manufacture of PMA, 510(k), and 510(k)-exempt devices. Some of the sites include only 510(k) devices. And the sites consist of both original equipment and contract manufacturers.

These sites identified the value of participating in the program as the predominant value being the culture change they experience, which created a trusted environment to discuss quality problems, improved internal communication across various aspects of the company, and the change in looking forward for improvement versus looking backwards to confirm compliance. They valued the best

practices and coaching from the lead appraisers, as well as the savings from continuous improvement projects. Many sites also valued the better communications with FDA that developed as a result of participation. And they valued the opportunities to save review time and inspection time.

FDA also looked at internal data, and the next set of slides show the program's potential for impacting patient safety. This slide shows the cumulative number of recalls at all enrolled sites over time. Keep in mind that in 2017 is when the first activities in the VIP pilot began.

This slide shows sustained enrollment in VIP's impact on the patient safety. This is a slide of cumulative recalls for enrolled VIP sites, emphasizing the time period where there was sustained enrollment of sites. The preliminary assessment suggests a faster rate of decline in recalls among enrolled sites compared to non-enrolled sites. FDA looks at a decrease in recall rates as resulting in fewer patients exposed to the risks associated with the hazards inherent in the cause of any recall.

This slide is showing that the Class I recalls for VIP-enrolled sites versus non-VIP-enrolled sites over time. This, too, suggests that with sustained enrollment in the Voluntary Improvement Program, there is a drop in the recalls for the sites enrolled in the program compared to those sites not enrolled.

And, finally, this last slide is to give you a flavor of the variety of products that are made at the sites that are enrolled in the Voluntary Improvement Program. Across the various product areas, the product panels shown here are preliminary assessments suggest that sustained enrollment in the program shows a similar effect on decreasing recall events for enrolled sites versus non-enrolled sites.

This slide is just a summary of the value of the program as seen by industry and FDA's public health goals. The apparent systemic downward trend in recalls we just discussed, but it is a sign of VIP improving patient safety, culture changes that lead to better communications over quality concerns, continuous improvement savings for the sites, patient access is improved by the reduced time to implement manufacturing changes and increase production yields. And patient safety can also be impacted as there have been projects that have reported a decrease in manufacturing defects leaving the facility as a result of the continuous improvement projects they conducted. And the sites also value the coaching that they obtained from lead appraisers and information about best practices that they receive from the lead appraisers.

Next, let's look at enrollment and expectations for participating sites.

Our guidance Fostering Medical Device Improvement explains the actions FDA takes implementing the program. It also explains how all the stakeholders engage with the program. First, let's talk about the enrollment criteria for the program that includes any medical device manufacturer that is part of the life cycle of any device distributed in the United States. The site has to have a positive compliance history that is an inspection with an NAI or VAI inspectional finding or an MDSAP audit with an NAI or VAI classification. There can be no open OAI inspections, and it cannot be the subject of a judicial action.

For industry to remain enrolled in the program, they commit to annual appraisals, engagement with the appraiser, commitment to the agreed upon appraisal process, quarterly check-ins with the lead appraiser, providing performance metrics to ISACA, and proactively notifying FDA regarding product safety issues and recalls.

For those enrolled in the program, FDA commits to confirming site eligibility for enrollment, engaging proactively with participating manufacturing sites to resolve any safety issues, contact and engage with the participating manufacturing sites to discuss and resolve any issues brought to FDA's attention during an appraisal that jeopardized their participation in the program. Please note that this has not occurred to date in the eight years of the operation of the pilot and now the formal program.

FDA and VIP participants have a shared goal and responsibility to proactively and quickly address quality issues or safety risks that arise during program participation through collaboration and communication.

This is a resource slide for you. It provides more information about the Voluntary Improvement Program. There is a link to the guidance document. There is a link to the MDIC site, with information on the program and ISACA site where the enrollment process begins.

Now, we'll talk a little bit about the potential regulatory opportunities for qualifying participants.

Enrolled sites can take advantage of certain regulatory opportunities, modified formats for PMA and HDE, 30-day notice, site change, or original manufacturing section submissions. There is a reduced review time goal for the 30-day notice and site change submissions, which is subject to available resources. The goals are 10 days and 25 days respectively.

Newly enrolled sites are afforded a two-year reprieve from a typical surveillance inspection to provide the space to focus on implementing their continuous improvement program and developing a continuous improvement culture at the site.

In assessing the program, the Voluntary Improvement Program, we had conversations with FDA staff that review these 30-Day Notices and what we'd like to do now is share some information that we obtained through that process with you to help improve the odds of us collectively meeting that reduced review time frame goal.

So some of those additional things that we learned from staff were that reviewers valued the least burdensome approach to the review memo and the streamlined review. Those things could save them time. And when the submission content is in the sweet spot, it takes less of their resources to confidently review a Voluntary Improvement Program 30-Day Notice. However, as the volume of the program's 30-Day Notices has grown, the annual average review time has grown as well. And we are not making the 30-day goal as often as we would like. The Voluntary Improvement Program submissions have grown from less than 1% to approximately 38% of all 30-Day Notice submissions, with the cardiovascular office receiving most of these Voluntary Improvement Program submissions, making it an even larger percentage of their 30-Day Notice workload.

Through the evaluation, we noticed that there were some submission attributes that seem to correlate with increased review time. Interactions with the sponsor to clarify or request additional information, insufficient detail in change descriptions or summary of evidence to support changes, submissions with incorrectly applied 30-Day Notice policy, and submitting extraneous information in your 30-Day Notice were things that could increase the review time.

Some practices to avoid when submitting 30-Day Notices in this program include annual reportable changes, submitting promises for future testing instead of the testing, submitting for complex changes

that are not well suited for summary or 30-Day Notice review, and deviating from general 30-Day Notice review policy or program policy.

There are some best practices to consider. So when describing the change, use pictures, diagrams, or videos to help FDA understand the change. Include context in the reason for the change and avoid using in-house terminology that FDA staff may not be aware of. When providing summary-level information for testing or of testing, provide sufficient detail such that FDA can assess the test article, the test method, the sample size, the acceptance criteria, results, and the relevance of the test to supporting the change. Include the patient contacting status for material supplier changes. Identify when using identical testing for changes implemented for another device and include the prior submission notice, the prior submission number. Learn from prior successes and failures to improve your submissions and in advance of a VIP submission, consider aligning submission strategy with the review team, such as the submission timing and the content.

In summary, the Voluntary Improvement Program provides value to the enrolled sites, leads to safer product, and increased availability of product, is open to any site with a positive inspection history, that is manufacturing a device marketed in the United States. And the program offers regulatory opportunities to those participants who qualify.

Thank you for listening. This concludes my prepared remarks, and we can go back to you now, Kim.

**CDR Kim Piermatteo:** Thanks, Erin, for providing lots of great information about the Voluntary Improvement Program. We are now going to transition to our interactive question-and-answer segment of today's webinar, but, first, I'd like to introduce two additional panelists who will be joining Erin for this segment.

That is Keisha Thomas, Associate Director of the Compliance and Quality Staff within CDRH's Office of Product Evaluation and Quality, or OPEQ, and Dr. Sara Royce, Assistant Director for the Implantable Electrophysiology Devices Team within the Office of Health Technology number 2A in OPEQ as well.

Welcome to you both, and thanks for joining us.

Before we get started, I'd like to go over how we will manage this segment and a few reminders. To ask a question, please select the Raise Hand icon, which should appear on the bottom of your Zoom screen. I'll announce your name and give you permission to talk. When prompted, please select the blue button to unmute your line and then ask your question.

When asking your question, please remember to limit yourself to asking one question only and try to keep it as short as possible. After you ask your question, excuse me, after you ask your question, please lower your hand in Zoom. And then if you have another question, please feel free to raise your hand again in Zoom to get back into the queue, and I will call on you as time permits.

So as you think about and prepare your questions for our panelists, I'd like to ask our additional panelists a few questions that we've previously received regarding this program. And the first one I will come to Keisha. So, Keisha, I want to ask you the following question. The question is, is there a limit to the number of companies that can enroll in the Voluntary Improvement Program or a limit to the number of facilities a company can enroll in the program?

**Keisha Thomas:** Hi. Thanks, Kim. I'll gladly answer this question. There is no limit on the number of companies CDRH will accept into VIP, and there is no limit in the number of sites or facilities a company enrolls as long as they meet the eligibility criteria for the program.

**CDR Kim Piermatteo:** Thanks, Keisha. So for our next question, I am going to come to Sara. Sara, the question I have for you is my company submits 30-Day Notices through this program using the recommended template and containing content as recommended in the Fostering Medical Device improvement FDA Activities and Engagement with the Voluntary Improvement Program guidance. However, we regularly receive interactive requests for additional information, including test reports or supportive test sample sizes. Isn't this information supported by the VIP appraisal?

**Sara Royce:** Thanks for the question, Kim. The FDA review team uses the modified submission format to review these 30-Day Notices. While the modified format does allow for reduced information regarding the description of the device and summary-level information regarding the support of test results, the agency needs to be able to clearly understand the proposed manufacturing change. They also need to understand how the performed testing ensures device safety and effectiveness.

Interactive requests like the ones you are receiving for additional details are often the result of submissions where sufficient details are not provided to the agency regarding the change or the testing protocol. In an effort to meet time to decision goals, test reports can efficiently provide the details regarding specific changes, test protocols, and results such as mean, maximum, and minimum reported values or sample sizes. However, providing clear summaries of this information in the original submission is really the recommended way to improve review efficiency.

**CDR Kim Piermatteo:** Thank you, Sara. Okay, so, again, I want to remind our attendees, if you have a question for a panelist, please raise your hand in Zoom. In the meantime, I'm going to come back to Erin for another question that we have previously received about the program. And, Erin, that question is what kinds of information is shared with FDA if I participate in the Voluntary Improvement Program?

**Erin Keith:** Thanks, Kim, for that question. So, FDA sees some of the information that is developed as a result of an appraisal, but we don't see all of it. We have access to summary information related to the appraisal that shows us, it gives us an idea of the relative maturity of the company, but it doesn't include the details that the company has, nor does it help identify, nor do we see the plan where you are identifying what you want to improve on during the year as a result of the appraisal feedback.

The other piece of information that we do see are the metrics. The metrics and that summary information is important to us because we believe that it will help us in making other types of decisions related to your site that can occur through the course of a given year. The sort of benefit-risk decisions we make related to inspections and/or how we would communicate with you during a recall. Back to you, Kim.

**CDR Kim Piermatteo:** Thanks, Erin. Again, I encourage you if you have a question to ask our panelists. Sara, though, I'm going to come back to you with another question. And this question is can we use the Voluntary Improvement Program to submit minor design changes that are resulting from a change in manufacturing?

**Sara Royce:** Thanks, Kim. Minor design changes to the device design, software changes, labeling, and/or sterilization and packaging changes, these should be submitted as real-time supplements. For additional information, I recommend referencing the FDA guidance Modifications to Devices Subject to Premarket Approval: The PMA Supplement Decision-Making Process.

**CDR Kim Piermatteo:** Great. Thanks, Sara. okay, Keisha, I'm going to come to you with another question. Keisha, that question is, how can data from the Volunteer Improvement Program be used in regulatory applications, and how does this impact sponsors?

**Keisha Thomas:** Sure. So, as a part of the Volunteer Improvement Program, FDA is given access to information about the quality and maturity of the site, which includes the level of maturity changes over time that are being made at the site that identifies its strengths and its opportunities for improvement each year. And that gives us insight into what's happening inside of a facility.

We only get this information in summary format. We don't see the detail that the company receives from the appraisal itself, but we do get the summary breakdown and it gives us some idea of what's happening. We have access to the metrics data that the site submits associated with the appraisal, which confirms that the site is implementing the improvement plan that they developed and designed with the appraiser.

The appraisal maturity information and the metrics provide a window into the site's ability to promptly and adequately address quality and safety challenges when they arise. We then use this information at FDA to inform benefit-risk decision-making used in implementing regulatory programs such as the need for surveillance inspection, the need for pre-approval inspection associated with a submission, or how we interact with the company over a recalled product or post-market safety signals.

Participants in VIP are also able to submit a streamlined 30-Day Notice, site change supplemental original PMA manufacturing section, with the goal here is to reduce the review days associated with a 30-Day notice to 10 days and 25 days for a site change supplement. So those streamlined submissions and reduced review time frames can lead to changes making the devices available to the marketplace faster and improving availability to the devices for patients.

**CDR Kim Piermatteo:** Thank you, Keisha. That was a lot of good information. Again, I encourage our attendees to ask questions to our panelists. They are here, available to you to ask, there we go, to ask your questions. So the first question is coming live from Alex. Alex, I have unmuted your line. Please unmute yourself and ask your question.

**Alex Zoellick:** Hey, guys, thanks very much for all the helpful info. Can you hear me alright?

**CDR Kim Piermatteo:** Yes, we can.

**Alex Zoellick:** Awesome. Guess my question is, is the program intended to be on a project-by-project basis, or are you guys kind of looking for an annual enrollment or a multi-annual enrollment if that makes sense?

**CDR Kim Piermatteo:** Thank you, Alex, for your question. I'm going to open it up to any of the panelists. So, Erin, Keisha, Sara, please feel free to chime in.

**Erin Keith:** So, I'll start off, Kim, and then if anybody wants to chime in, feel free to do so. So the program is an annual commitment that can be renewed. So, to participate and receive the benefits, you need to be continuously enrolled through that program. It is an assessment that is made annually, a plan that is developed and implemented over that course of the year, and then the following year, there is another appraisal and another plan developed. The idea is for continuous improvement and for it to be a long-term event that you will continue to find benefit in long-term participation.

**Alex Zoellick:** Awesome. That's really helpful. Thank you very much.

**CDR Kim Piermatteo:** Thank you, Alex, for your question. And thank you, Erin, for your response. Okay, again, feel free to raise your hand in Zoom to ask our panelists your questions. I'm going to come back to you, Erin, actually, for another question. And that question is, what does an appraisal cost?

**Erin Keith:** Thanks, Kim. The cost of the appraisal is impacted by the scope of that appraisal and ISACA is the best source of information on the actual cost of the appraisal. Companies have reported to us in conversation ranges in the cost for the appraisal, but that's based on the size of their site, whether they're conducting a single or a multi-site appraisal at that given point in time. And ISACA does have a reduced fee program for companies that meet the definition of small company per the definition that FDA uses for our other programs.

**CDR Kim Piermatteo:** Thanks, Erin. Okay, I am going to, I think for the team, we're going to go through maybe a couple more questions that we've received for the good of the whole. I'm going to come to Keisha next. Keisha, the question is the Case for Quality Collaborative Community was mentioned in the presentation. What is that, and how can people get involved?

**Keisha Thomas:** Sure. So, the Collaborative Community, the Case for Quality Collaborative Community is the collaborative community that focuses on the developing of tools that support improvements in quality excellence inside of organizations. It's just one of several collaborative communities in which FDA participates. The Collaborative Community is facilitated by the Medical Device Innovation Consortium, or MDIC. And if you're interested in your organization participating in the Case for Quality Collaborative Community, you can contact MDIC to learn how to get involved at the MDIC website.

**CDR Kim Piermatteo:** Thanks, Keisha. Again, please raise your hand, engage, interact with our panelists today. That's what we are here for. I'm going to come to Sara next for another question. And, Sara, that question is, we have noticed that while some 30-Day Notice submissions are reviewed in a shortened time frame, many take the full 30-day review clock. What is the reason for this delay, and how can it be improved?

**Sara Royce:** Thanks, Kim. The review goal is based on available resources. So, while we always try to meet the review goal time of 10 days, some reviews will take longer and this can depend on the availability of experts in the review area, the need for additional information that might need to be obtained interactively, or just the overall number of submissions at the time when you submit. All these factors will likely increase the time to decision.

**CDR Kim Piermatteo:** Thanks, Sara. Alright, it looks like I'm going to come back to Alex. Alex, you have another question. I've unmuted your line. Please ask your question.

**Alex Zoellick:** Thank you for taking me again. My question is, how much input do, or will the companies have in the appraisal plan? Are the goals for the plan kind of collaborative with the company, or is that kind of coming from what the appraiser sees as maybe shortcomings or improvement areas?

**Erin Keith:** So, the plan is based upon the feedback that the company gets in the appraisal, where it identifies for the company what its strengths are and its areas for, the opportunity for improvement. It is up to the company to decide what their priorities are. So the company makes that decision on what they're going to focus on for that year. It is not FDA's decision, and it is not the appraiser's decision.

**Alex Zoellick:** OK, thank you.

**CDR Kim Piermatteo:** Thanks, again, Alex. And thank you, Erin, for your response. We have another question, and that question is coming from V Madikonda. I have unmuted your line. Please unmute yourself and ask your question.

**V Madikonda:** Okay, thank you for giving me a chance to ask a question. My question is, if an organization has a site which performs research, like R&D site, and then other sites conduct the manufacturing, do we have to register both the sites, or just registering the R&D site is, yeah?

**CDR Kim Piermatteo:** Thanks for that question. Erin, I think, I mean, if you would like for him to rephrase that question, let me know. But I think he's asking about which site.

**Erin Keith:** Right. So, all sites that participate in the life cycle of the development, manufacturing, what FDA calls manufacturers, all those types of sites that can register and list with FDA are all eligible for participation.

And if I have not fully answered your question, if I have not fully answered that question, I am open to rephrasing it, so I get to your other points, other concerns as well.

**V Madikonda:** No, no, I think, my question was framed at a headquarter site performs the research and regulatory activities, submissions, and everything. So then there could be sites which does purely the manufacturing. So to get the full benefits of this program, do we have to register both the sites or registering the headquarters site, which does the research, and regulatory submissions, and all that is adequate? That was basically my question.

**Erin Keith:** So all sites are eligible. All of those sites are eligible. But how you choose to enroll and what you start with is up to the company and what is their priority for themselves and which sites they might feel would benefit the most from the program to begin with. We've had lots of sites that have started with one facility and/or companies that start with one facility and then move on too many sites that are enrolled in the program that cover a variety of activities that go on, including regulatory. And we even have some sites that have non-regulatory elements to them that are involved. And they've chosen to enroll them because the appraisal model looks at all of the company's processes, not just what's regulated by FDA.

**V Madikonda:** Okay, thank you.

**CDR Kim Piermatteo:** Thank you for that question. And thank you, Erin, for your response. Our next question is coming from Chaz. Chaz, I have unmuted your line. Please unmute yourself and ask your question.

**Chaz Weyer:** Yeah, hi. Just a simple question. How can get a copy of the slides you just presented here?

**CDR Kim Piermatteo:** Hi, Chaz. This is Kim. So right now, we have the printable slides. They are available on the webinar event page. And then they are also posted to CDRH Learn. As I'll mention later, we will post the recording of today's webinar within the next week or two, and that will also include a transcript. But right now, the slides are available if you just go to www.fda.gov and then you can search for CDRH events, and you will find them listed in chronological order. So for today's date, 10/8, you will see today's slides.

Okay. Alright, again, we're going to go through maybe one or two more questions. But if anyone has any questions, please feel free to raise your hand.

I'm going to come back to Erin again for another question. I think this is a good question to sort of reiterate some of the, I guess, what are the benefits to enrolling in the program. So, from the initial implementation of the program, what are some of the biggest lessons learned, and how is the program continuing to grow and evolve? And I am going to direct that to Erin.

**Erin Keith:** Sorry.

**CDR Kim Piermatteo:** Sorry. I'm going to direct that to Erin.

**Erin Keith:** I'm sorry. I thought I had come off mute, but I hadn't. My apologies.

So, some of the biggest lessons learned from this program, from pilot to present, is the importance of building trust with the community in order to have the program be developed and be successful. We also learn that not everything was going to work perfectly the first time and that keeping, we just needed to keep trying and improving. Collaboration is key to building the program and maintaining the program. A lot of our participants have noted that quality is the journey, it's not the destination.

And, also, voluntary is the key from FDA's perspective for this to be successful in having industry adopt a quality culture. If we make this a new requirement, then it becomes the same thing that we have now. And we get a segment of our industry that will try to just meet that bare minimum and treat it as checking a box and we're not really getting to the heart of what we want to do, which is have that continuous quality culture at your sites. So you find your problems faster. We know you're going to fix them, and we all have more confidence in the products that are in the marketplace.

**CDR Kim Piermatteo:** Great.

**Erin Keith:** And I think that's all I've got right now, trying to think of other things, but that's it.

**CDR Kim Piermatteo:** Thanks, Erin. Okay, Renee, I'm going to come to you next. I have unmuted your line. Please unmute yourself and ask your question.

**Renee Cveykus:** Yeah, I want to, thank you, everyone, for doing this program. I really appreciate it. I wanted to ask a very simple question. Why did the FDA start the VIP program?

**Erin Keith:** So, this goes back a ways and Keisha, feel free to chime in because I know you were parts of it in the beginning when I was not. But back in like 2010, 2012, the Agency looked at what were barriers to the adoption of continuous quality approaches and continuous improvement approaches within industry and they identified many things. And one of them was a lack of trust, concerns, and barriers to change. And we have implemented this program to try to adjust some of those barriers to have companies implementing continuous improvement and taking the longer look at quality than they had been at the time. Keisha, would you like to add anything?

**Keisha Thomas:** Sure. Erin, I think you were, you're spot on with how we got here. What we've learned over time with the entire Case for Quality initiative as a whole, with VIP as one of the programs under that umbrella, is that compliance is just one part, right, of what companies are responsible for. But trying to find ways where we can get companies to be focused on enhancing and improving a culture of quality inside of their organization in many ways staves off us having to get to a place where there are compliance issues, or we have to utilize enforcement tools in order to encourage organizations to shift gears and remediate. And so having a program where companies can raise their hand and self-identify and say, we want to be above and beyond just meeting the basic compliance requirements, this program was born out of that concept, where organizations get to own being proactive, having a third-party appraiser come in, assess their organization as a whole.

It's a variety of practice areas. Those practice areas are not just associated with manufacturing, but they also cover business processes and practices and to work internally to change the culture of quality inside. And so, this program allows for that, even though you're not directly dealing with FDA with the appraisal, what you are doing is sending a message to FDA that you want to go above and beyond the standard expectations and improve. And as an agency, we wanted to find ways to incentivize and support companies doing that.

**Renee Cveykus:** Excellent. Thank you.

**CDR Kim Piermatteo:** Thanks, Renee, for that question. And thank you, Erin, and Keisha, for your response. Okay, I'm going to make one last call out. If anyone has any questions, please raise your hand in Zoom.

Okay, seeing none, we are going to go ahead and move to close today's webinar. So, thank you all again for your participation during our question-and-answer segment and thank you to our panelists for your participation as well. I'm going to go ahead and turn it back over to Erin to provide her final thoughts for today. Erin.

**Erin Keith:** So thank you all for coming and joining us today to learn more about the Voluntary Improvement Program. Thank you for your questions. FDA would like to encourage all of you to consider enrolling your sites in the Voluntary Improvement Program as a mechanism for, a mechanism of improving patient safety and device quality. And Kim, back to you to close us out.

**CDR Kim Piermatteo:** Great. Thanks, Erin, for those final thoughts. As I mentioned earlier, a recording of today's webinar and a transcript will be posted in the next few weeks to the webinar event page, as well

as to CDRH Learn under the section titled Postmarket Activities and the subsection titled General Policy. I've provided a screenshot of where you can find these materials in CDRH Learn on this slide.

If you have any additional questions about today's webinar, feel free to reach out to us in DICE at DICE@fda.hhs.gov.

And, lastly, we hope you're able to join us for a future CDRH webinar. You can find a listing of all of our upcoming CDRH events, including upcoming webinars via the link provided on the bottom of this slide at www.fda.gov/cdrhevents.

Thank you all again for joining us. This concludes today's CDRH webinar. Have a great day.

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