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One Edwards Lifesciences Site Chopped Its Open CAPAs By Half. Here's How Your Firm Can Too

The heart device giant is using a new Case for Quality framework to fast-track CAPAs

by Shawn M. Schmitt

Two Edwards quality experts explain to *Medtech Insight* how the firm is benefiting by using a new CAPA framework that shifts corrective and preventive action from a one-size-fits-all method to a more nuanced approach that separates higher-risk events from others that don't need to be elevated to the level of a traditional CAPA.

Several years ago, heart device giant *Edwards Lifesciences Corp.* realized it needed to give its corrective and preventive action (CAPA) system a makeover.

Through internal audits the manufacturer had discovered that it was "taking corrective actions what weren't being classified as corrective actions, and therefore weren't being appropriately followed for effectiveness," explained Dan Buehner, the company's director of quality engineering. He said the firm also avoided taking some corrective actions "because it was going to require the full execution of a traditional CAPA."

So Edwards tweaked its decision-making process around CAPA in an effort to stay compliant with US Food and Drug Administration requirements. But not long after, the company was swimming in a sea of open CAPAs.

The manufacturer's CAPA overhaul "basically created a situation where any and all corrective action, regardless of what size it was, regardless of how complex the issue was, or how complex the solution was going to be, was going to require a formal CAPA," Buehner told *Medtech Insight*.

"That was basically what we had to do to demonstrate compliance" with the FDA's Quality System Regulation under *21 CFR, Part 820.100*.

Buehner and others at the company knew further changes needed to be made to the CAPA system, so last year Edwards put together an internal team to study the issue and propose a different methodology for deciding when to open a CAPA. But the output of that team didn't get the green light from top leaders.

"We already had what we called 'Level One' and 'Level Two' CAPAs within our quality system, but there really wasn't much of a difference between the two. So this team was proposing to create more of a difference between those levels of CAPA," Buehner said. "But our executive quality leadership team flatly refused that, with the primary concern that we would be found noncompliant [by the FDA] and that we would incur problems."

> ***"We've reduced the number of open CAPAs that we have by more than 50%, and the things we are opening traditional CAPAs for now are really the things that make sense to." – Dan Buehner***

It wasn't long after that rejection by quality leaders, however, that Edwards found a promising potential solution to its CAPA woes: a new corrective and preventive action framework that helps firms distinguish a minor issue that shouldn't be converted into a traditional CAPA, from a higher-risk event that necessitates the opening of one.

Since piloting the framework earlier this year, Edwards has slashed the number of open CAPAs at its Draper, UT, manufacturing site by more than half. Buehner works out of the Draper plant, which makes devices like the SAPIEN 3 and PASCAL systems for transcatheter aortic valve replacement (TAVR), among other products.

"We've reduced the number of open CAPAs that we have by more than 50%, and the things we are opening traditional CAPAs for now are really the things that make sense to, that we should do a deeper dive into," he said.

Buehner added that using the novel CAPA framework also helped the Draper facility reduce its time to implement corrective actions by roughly 75%.

He said the framework "allows you to put your focus where it's needed the most, and it allows

you a means to take the simple and straightforward corrective actions in a manner that is compliant with regulations, but also matches the level of concern or scrutiny that's necessary for those actions."

CAPA Reimagined

The framework used by Edwards is the centerpiece of the ongoing *CAPA Process Improvement Pilot* from the Medical Device Innovation Consortium, under the umbrella of the joint FDA/MDIC *Case for Quality Collaborative Community*.

> Edwards Lifesciences is not alone in confronting issues with CAPA systems. Corrective and preventive action has long been a sore spot for device makers, and CAPA violations routinely turn up on FDA-483 inspectional observation forms and agency warning letters.

Edwards has two of its sites – Draper and Irvine, CA – enrolled in the pilot, and industry heavy-hitters *Medtronic PLC*, *Johnson & Johnson*, *Boston Scientific Corp.*, *Siemens AG*, *Stryker Corp.* and *BD* are also taking part.

The pilot's goal is to help manufacturers focus on the most important events that could impact product quality and patient experience, rather than dumping every event – regardless of risk or significance – into their CAPA system. (Also see "*Not Your Grandfather's CAPA: Case For Quality Pilot Gives Corrective And Preventive Action A Facelift*" - Medtech Insight, 28 May, 2020.)

The framework splits CAPAs into two lanes:

- External: Outside issues and high-risk trends are addressed with this more traditional CAPA approach.
- Fast-track: Internal events and low-risk trends can be addressed using this type of CAPA, which allows for reduced root-cause documentation and simplified effectiveness checks.

"Fast-track CAPAs – they're the simple ones that, right off the bat, you know what happened. You know an easy way to take care of it. And, so, now we can do that. We can do that, and we can still be compliant," Buehner said.

He reiterated that opening old-school CAPAs for "really simple things to fix" can gum up a CAPA system. That's because those CAPAs call for time-consuming activities such as root cause analysis, and require multiple layers of review and approval, among other things.

Using the framework, Edwards' Draper site was able to implement more than 30 fast-track CAPA solutions over a four-month time frame – "all of which would have been traditional CAPAs before" the pilot program, Buehner said. (He stressed that Edwards isn't converting CAPAs

opened before the pilot into fast-track CAPAs: "Once the traditional CAPA has been opened, we've got to see it through.")

Using the fast-track process "frees up people to continue working on old CAPAs in our system, to just keep whittling them down, instead of having new ones keep popping up," Buehner said.

So how does a device maker decide whether a particular event should be placed in the fast-track bucket or the more traditional one? "Well, that's up to each organization, to determine what their threshold is for when to apply the fast-track CAPA process," Buehner explained.

At Edwards, "we've chosen a point where it's pretty much anything that has stayed within control of the company – we didn't have a major product escape, and it's not something that has the potential to create a critical level of risk to the patient," he said. "If we've been able to identify something in that state, then we're allowing ourselves to use the fast-track CAPA process to address that issue."

And this is where risk management comes into play. "You have to know what your risk levels are," Buehner said. "You have to have a mature risk assessment process in order to apply this CAPA framework consistently."

Progress Checks With FDA

As pilot participants, Edwards' Draper and Irvine facilities must take part in progress checks every three months with FDA officials.

During a May progress check at the Irvine site – held virtually because of the pandemic – Edwards officials met with Bleta Vuniqi, an FDA biomedical engineer who works on the agency's Case for Quality team, and Marc-Henri Winter, an engineer in the FDA's device center.

Kristy Reade, the Irvine plant's quality engineering manager, described in an interview with *Medtech Insight* how that meeting – which was the facility's first – unfolded.

Device Week, 29 May 2020 – CAPA Gets A Nip And Tuck

By Shawn M. Schmitt and Elizabeth Orr

29 May 2020
In 2018 the US FDA and the Medical Device Innovation Consortium (MDIC) embarked on a mission to recast corrective and preventive action – CAPA – as a continuous learning tool, rather than a place where problems often go to linger, be ignored and never die. On this week's podcast we talk about the latest in those efforts, including a pilot...

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"We reviewed our procedures, our process to implement this framework. And then we provided

them a list of records, and they chose from that list, and then we sent them the files for review," Reade said. "So, it was good to be able to partner with [the FDA] on this and get feedback outside of an inspection environment, to understand from their perspective how we were executing the framework and the expectations."

Feedback that Reade received from the FDA during and after the meeting tracked closely with findings made by an external auditor hired by the company, boosting her confidence in what she was being told by the agency. The hourlong meeting was "very informative and useful," she said.

> ***"After Dan and the Draper site had their progress check, we all met again and talked about the observations from the reviews." – Kristy Reade***

A week after Irvine's check-in, the company's Draper site underwent the same type of meeting, also with the FDA's Vuniqi and Winter.

Buehner explained how it went: "We walked through how we had implemented the framework. We showed them how our procedures tied into existing quality systems. And then they asked us for some records. We supplied them with some samples: 'Here are some instances where we used a fast-track CAPA; here are instances where the framework told us we didn't need to; here are some instances where the framework pointed toward a traditional CAPA,' and things like that."

He said the information exchange with Vuniqi and Winter was similar to what the company would expect during a facility inspection – except it was much more collaborative.

"The feedback was delivered in a coaching style, as opposed to a compliance-check style," Buehner said.

Then, "after Dan and the Draper site had their progress check, we all met again and talked about the observations from the reviews," Reade added.

Interestingly, Buehner said he didn't feel uncomfortable forking over information to Vuniqi and Winter, despite their working for the FDA.

That's because "Edwards was the first company to get on board with the Case for Quality Voluntary Improvement Program," or *CfQ VIP*, he said. "So, *we've had a couple of years of*

experience with that, and we've really gotten to see that the FDA is putting its money where its mouth is on that, that it has been highly collaborative, that there is no attempt at enforcement or punitive discussions, or anything like that."

CfQ VIP – another joint FDA/MDIC initiative – aims to boost product, manufacturing and process quality at device firms by appraising the companies against an industry-modified version of the *Capability Maturity Model Integration* (CMMI) framework. (Also see "*Chasing Quality Isn't Easy. But An FDA Pilot Aims To Boost Quality By Appraising The Capability Of Manufacturing Sites*" - Medtech Insight, 7 May, 2018.)

Biweekly Collaborative Meetings

The CAPA Process Improvement Pilot was developed by a Case for Quality team called "*#makeCAPAcool*." Manufacturers that enroll in the pilot must appoint people to join that group.

Being part of #makeCAPAcool takes commitment. The team meets on a biweekly basis to review data from "report-out forms" submitted by participating firms and update the framework with any lessons learned.

Both Reade and Buehner are members of #makeCAPAcool, and they religiously attend the meetings.

"That experience has been refreshing. It's nice to know that we're not alone in the kind of struggles we've had with CAPA in the past," Buehner said. "It's nice to know that there are other people from other companies in the industry that are passionate and engaged about trying to address this problem and to make an improvement for the entire industry, and move us in a direction that's meaningful, that sets us up to be able to be more focused on continuous improvement, more focused on the patient, more focused on what we can do to help people who need these products, as opposed to so much of that effort having to go into just demonstrating compliance."

He went on: "The conversations are sincere. There are a lot of people who have lived through a lot of [CAPA issues] and have a lot of different, unique perspectives. We can learn from each other, and some of the little nuances or tricks that we've been able to figure out to make our quality systems move more smoothly, and things like that. So, it's been a really open, collaborative kind of environment."

What's Next For Edwards?

As for the future, Buehner said Edwards is moving ahead cautiously – but optimistically – when it comes to one day rolling the CAPA framework out to all of its facilities.

"The intention, for now, is that we keep the CAPA pilot just to [the Draper and Irvine] sites, work

through the pilot phase with the MDIC team, see that through, and then based on those results, which we anticipate will be favorable, then we move to implement it for the whole organization," Buehner said.

[Editor's note: *To learn more about the CAPA pilot and the #makeCAPAcool framework, email Kathryn Merrill at Kathryn.Merrill@medtronic.com*.]