Form by Design

Using flowcharting techniques for robust form design

FILLING OUT simple forms should be easy, right? Yet, how many of us have had the experience in which a simple and easy-to-follow form took more than one time to fill out 100% correctly?

Now, let's make the forms more complicated and the stakes higher. For example, when you're documenting records for the medical device industry, there is huge potential for costly mistakes. End users could be harmed because of errors associated with poor documentation.

Even in instances such as this, form design is an often underappreciated skill. With forms and their associated instructions, there is a balance to maintain: too little information and the instructions aren't useful, and too much detail and users will skim over them, possibly missing important information.

Using process mapping to help create a clear and concise form with a logical flow is one way of addressing this concern. The first step in this evolution is to ask yourself: What is the form designed to do? A truly robust form should not only be clear and concise, but should also provide needed information in fields that are easily searchable if the form were to be converted into an electronic format.

While recently seeking to improve how we process and document corrective action and preventive action (CAPA) requests, my manager and I were struggling to come up with a system that was robust, yet still streamlined and easy to use. This was challenging due to the nature of most CAPAs, which require input from multiple users and disciplines and must have the potential for multiple feedback loops due to some steps occasionally needing to be repeated.

As we struggled with format, we decided to step back, map the entire process and begin again. Because of how our system worked, we decided to depict how it functions using a swim lane diagram, also known as a cross-functional flowchart, shown in Online Figure 1 on this article's webpage at www.qualityprogress.com.

Going through the mapping process and asking the questions that we had to ask to properly map our process made us think hard about how it should work and allowed us to identify several opportunities to improve how we do things that had been previously overlooked. Per our procedures, we had eight individual roles and two group/department roles to consider, shown in Table 1.

We also had to consider that individuals could play more than one role in the process. The corrective action team that was to determine root cause, corrective action and effectiveness verification had to consist of, at a minimum, the process owner and a member of the quality assurance department. Additionally, a subject matter expert was required if neither the process owner nor the quality assurance representative was an expert on the issue under review.

Roles and tasks in the CAPA process / TABLE 1

Role	Task
1. Corrective action and preventive action (CAPA) initiator	Identifies issue and initiates CAPA.
2. Process owner	Area manager where issue identified.
3. Subject matter expert	Expert with knowledge of subject issue.
4. Quality assurance (QA) reviewer	Reviews each phase of CAPA for appropriateness.
5. QA corrective action team (CAT) member	QA personnel who is part of CAT.
6. CAPA coordinator	Assigns CAPA numbers, maintains log and tracks CAPA progress.
7. QA manager	Reviews CAPA for appropriateness before closure.
8. Engineering manager	Reviews CAPA for appropriateness before closure.
9. CAT	Determines root cause, corrective action and effectiveness check.
10. Document control	Receives and files closed records; maintains files.

Strategy that works

After we had completed the process mapping, designing the form was easy. We wound up with a four-page form, one page for each phase of the process.

1. Initiation.
2. Investigation.
3. Corrective action/effectiveness verification.
4. Closure.

Having one page of the CAPA form for each phase of the process allowed us to save the form on a shared drive, type in information for greater legibility and print it out for signatures after completion of that phase. An email alert was sent to all CAPA participants as each phase of the CAPA process was completed.

We were able to design a form that was user friendly, flowed logically, reflected our process and provided needed information. It wasn't master control, but it was the next best thing, and it worked great for us. QP

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