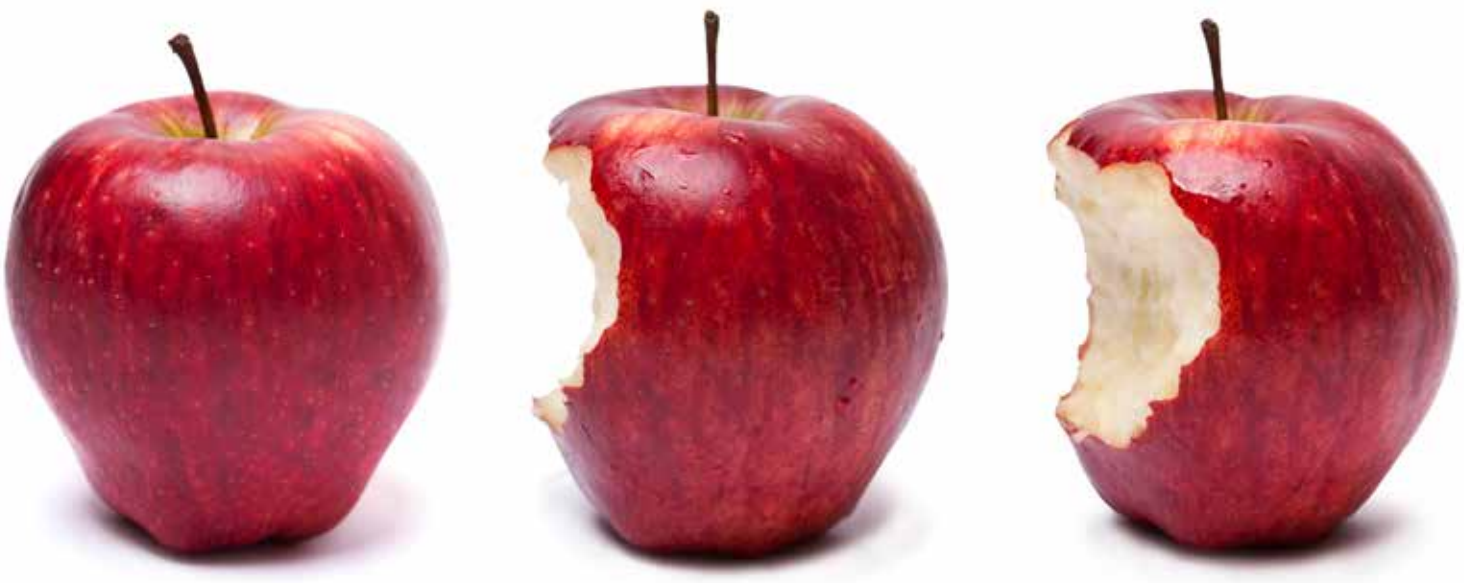
Get at the Core

Dig deeper to find the real root cause of a defect

by Devin I. McElroy



In manufacturing defect investigations, human error often can be incorrectly identified as the root cause of the defect. As a result, a common corrective action is retraining employees. The problem is that the actual root cause of the manufacturing defect is not identified and remediated. Thus, recurrent defects occur.

As a 25-year veteran quality practitioner in the medical device manufacturing and pharmaceutical industries, I have seen numerous organizations appropriately implement root cause analysis (RCA) investigations as a result of product defects, process gaps or customer complaints. Repeatedly, I have witnessed the RCA outcome, or root cause, incorrectly identified as human error (or some variant) with retraining used as an inadequate corrective action, resulting in a false remediation of identified defects.[1]

To prevent this, there are additional methods organizations can use—including in-depth investigation tools and questions—to determine more robust root causes and remediation efforts.

Just the Facts

Human error is an insufficient root cause because it doesn't identify the real problem causing the defect.

Employee retraining often is implemented as a corrective action, but because human error isn't the true root cause, retraining doesn't prevent the defect from recurring.

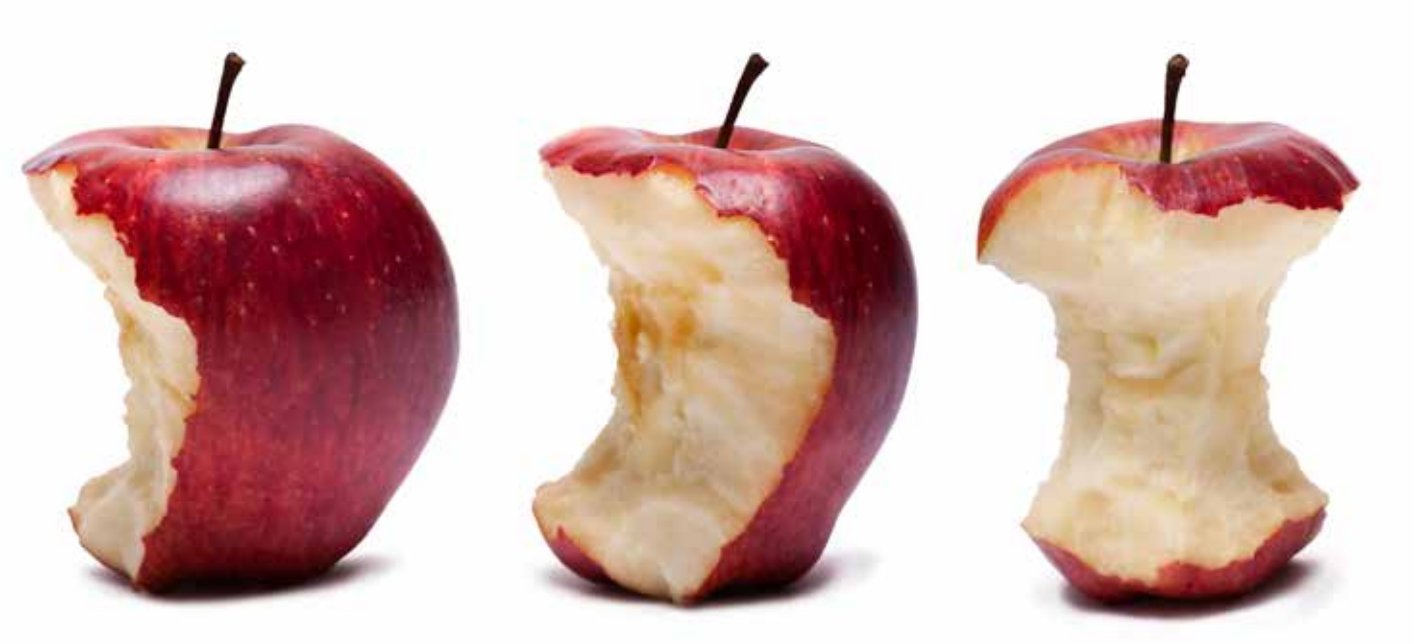
Asking "Why did the human err?" will help you identify the true root cause of a problem.

Root cause analysis

Professionals working in the medical device industry are familiar with RCA because it is at the heart of all investigations into nonconformances and defects found in a manufacturing facility.

Title 21 of the U.S. Code of Federal Regulations, part 820, subpart J, section 820.100 is corrective and preventive action.[2] The regulation states that identifying product defects and the cause of the defects, and implementing actions to correct the problem are required as part of a robust quality management system (QMS). All registered product design owners and manufacturing facilities must meet the requirements of this regulation. The regulation does not, however, state how to do this. It also does not identify good or bad corrective and preventive action programs, systems or steps.[3, 4]

The goal of any RCA investigation is to identify one or two elements that, if corrected, will reduce the recurrence rate of an error to acceptable levels, or even to zero.[5] Therefore, a robust investigation must be performed. If there are three or more root causes identified



for a defect, it can generally be assumed the root cause has not yet been found and additional investigation is required.

The analysis must consider all the preliminary causes or symptoms,[6] and determine whether there is a more basic cause that addresses all the symptoms identified. Human error is one symptom that requires additional investigation.

Root cause: human error

Many times in my experience as a quality professional, I have seen organizations erroneously identify human error as the resultant root cause of failure analysis efforts. Human error is an inadequate root cause because it does not address the true reason the failure occurred and, therefore, a remediation cannot be implemented to prevent future defects. Humans will always err—no one is perfect—so manufacturing systems must be robust enough to ensure product defects will not be introduced despite human error. Human error must be an expected variable, and a robust manufacturing process will keep human error to a minimum.

Visual inspection is a perfect example. The literature shows visual inspection performed by humans is rife with error. For instance, depending on what a human expects to see,[7] expects not to see, and environmental or internal distractions, the rate of reliability of human visual inspection for true rejects is about 85%[8] (which falls to 65% for false rejects).

According to a study performed by systems analyst Judi See, the acceptable level of true rejection should be 90% or higher.[9] Therefore, in many cases, the level of error for human visual inspections is unacceptable. Many organizations have gone to computerized visual inspection systems to reduce the error to acceptable levels.

A manufacturing example

This example involves a human performing a step in a manufacturing process. Except for fully automated systems, almost all manufacturers have some level of human performance in their manufacturing processes.

An assembler is working on the line of a medical device manufacturer that makes complex electromechanical treatment machines. The assembler's job consists of attaching a metal tip to the end of a transparent tube, inserting the tube into a plate through a specific hole and gluing the tube in place using a fixative. The assembler inspects her work through a visual enhancement tool (magnifying light) to ensure the tip is seated fully on the tube, there is no adhesive overflow into the tube and the base of the tip is 2.00 mm (± 5 microns) from the surface of the plate. The assembler uses a calibrated scale (ruler) to ensure the proper distance. The assembler sets the assembly horizontally on a drying fixture. Typically, the assembler creates about 240 subassemblies per eight-hour shift.

One day, the assembler comes to work after a huge fight with her spouse. On this day, the assembler creates only 180 subassemblies during her eight-hour shift because, understandably, her mind is not completely on her work.

At the end of the manufacturing line, a quality engineer reviews all subassemblies to ensure they meet requirements before passing them to the next phase of the manufacturing process. Normally, the assembler has no more than two or three rejects per day. But today, she has 17 rejects—a considerable increase. As a result, an RCA investigation is conducted and the root cause is erroneously identified as human error. The proposed corrective action is retraining.

There are two problems with this scenario. On a normal day with few internal (or personal) distractions, the assembler does a great job and her work is well over the acceptable quality limit (AQL) of 98%. Today, her AQL is under 91%. A corrective action report is implemented as a result of this lower-than-acceptable AQL and human error is identified as the root cause. In this case, the RCA investigator failed to ask one more question in the five whys analysis: "Why did the human err?"

The assembler's work normally has about a 99% AQL, so will retraining help? The short answer is no. She knows how to do her job, and she does it well. In addition, retraining will not change her acceptance rates because, although human error may have contributed to the cause of the defects, retraining will not prevent the same situation from recurring.

Likely, the assembler will go back to doing a great job and effectiveness checking will show the AQL return to acceptable levels. Everyone will declare the retraining was effective, and no further actions will be proposed. In addition, because the assembler has proven repeatedly that she knows how to perform her job adequately, retraining will not teach her anything new and actually wastes her time.

Two weeks later, the assembler has another argument with her spouse. Has the retraining prevented a recurrence of this defect? Of course not, because the defect wasn't caused by her lack of training. A more effective RCA would have identified the appropriate root cause—the dependence on visual

inspection and hand placement of a part in a subassembly. This cause might be remediated appropriately by using a fixture to ensure appropriate placement.

In addition, using a metered adhesive dispenser also might prevent the addition of too much adhesive. The use of these tools would ensure that, despite human error, the defect rate of the work would remain consistent.

Due to personal distractions, the assembler still might create fewer subassemblies than usual, but if her defect rate remains consistent, the rate of quality defects for the subassembly will not be affected.

In addition to adding tools or fixtures to remove or alleviate the potential for human error, retraining the assembler—who already knows how to do her job well—will not present her with any new information with which to perform her work more effectively. This presumes there has been no change in the process between the day before when the assembler was doing her job well and the next day when her quality rate dropped so precipitously.

Akin to retraining, threatening to put the assembler on a performance improvement plan or applying sanctions against her perks also is not effective. These actions will not correct the problem's real cause.

The scenario presented here has several problems: human error, personal distractions and a manufacturing process 100% reliant on human processes.

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A more robust root cause of the high defect rate is the lack of a tool or fixture to ensure the location of the base of the metal tip falls within acceptable ranges. A better corrective action might be to introduce a fixture to ensure the appropriate dimensional tolerances are attained despite the presence of human error.

This is just one example. However, there are numerous scenarios to which this example can be applied.[10]

Finding a better root cause

In an RCA investigation, when human error is found to be the cause of a product or process defect or problem, a thorough investigator using the five whys method[11, 12] will ask one more question: "Why did the human err?" Answering this question can result in a better root cause for which a solution may reduce recurrence of the event if the same human error should repeat. Here are some examples of why a human might err:

1. **Confusing procedure**—Poorly written; vague or superfluous instructions; hard to follow.
2. **Internal (personal) distractions**—Personal life; illness; injury; disability.
3. **External distractions**—Noisy environment; frequent interruptions; poor layout or workflow.
4. **Unaware the procedure existed**—Inaccessible to employee; inadequate communication of procedural changes.
5. **Procedural updates**—Updates occur too often; too many revisions; employee can't keep up with procedural changes; procedures released inconsistently.
6. **Intentional misuse or willful misconduct**—Employee is disgruntled or dissatisfied.
7. **Inadequate electronic clearance on automated systems**—Another employee's ID or login is used; unauthorized workarounds; unable to access automated systems.
8. **Missed a step in the procedure or work instruction**—Instructions are unclear or illegible.
9. **Inadequate paper-based systems**—Printer errors; misnumbered or missing pages.

10. **Inadequate software-based systems**—Software glitch.
11. **Employee apathy**—Lack of motivation; bored with the job; unaware of the effect on quality.
12. **Employee unable to perform certain steps**—Inaccessible or inappropriate fixtures, tools or equipment.

Many other issues could cause a human to err. A competent process for corrective actions looks beyond the human error to determine whether there is something affecting the employee and whether there is a corrective action that will eliminate the cause of the human error, thus preventing the human from erring in the first place. This is the definition of a truly robust manufacturing system—one that will produce quality products despite the constant potential for human error.

Corrective action: retraining

As mentioned, the corrective action must consider factors beyond this particular instance. There are two things the investigator can ask: Is the defect of such an impact that it must be corrected? Is this an isolated incident?

If defective assemblies are discovered early in the manufacturing process and can be disassembled and reassembled at a low cost, some organizations might choose to disassemble and reassemble the defective product. If the organization elects to do so, however, robust corrective actions should be established to prevent rework.

If this is an isolated incident in an otherwise acceptable level of work by an employee, you could argue that any time spent implementing another corrective action would be an inefficient use of resources. The lower quality level produced on a given day does not reflect the overall level of quality to be expected from the assembler. Therefore, retraining the assembler likely will not improve his or her overall quality of work. Therefore, other causes and corrective actions should be considered.

In and of itself, retraining does not correct any of the potential human errors identified above. For instance, no amount of retraining will improve a disgruntled or dissatisfied employee's performance. Retraining with an instructor may help initially if the employee doesn't understand the procedure, for example, but the employee's quality level may again decrease if the procedure is revised.

Identifying the true cause of the defect (inadequate facilities, numerous interruptions, noisy environment, inability to access electronic systems, lack of proper fixtures or tools, for example) can go much further in preventing future incidents of any identified defects in that the corrective action will help prevent the human from erring in the first place. A robust corrective action also ensures consistency across processes when multiple individuals are performing the same tasks, which reduces or even eliminates human variation.

Ultimately, identifying the cause of the human error, or the causes contributing to human error—along with a corresponding corrective action for the real root cause—will have a greater effect on reducing or eliminating future defects.

Whenever human variation can be removed from a manufacturing process through the implementation of fixtures, tools, equipment or automated processes, the manufacturing process itself will result in reduced overall variation and fewer manufacturing defects. QP

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