Sources of Root Cause Analysis Failures

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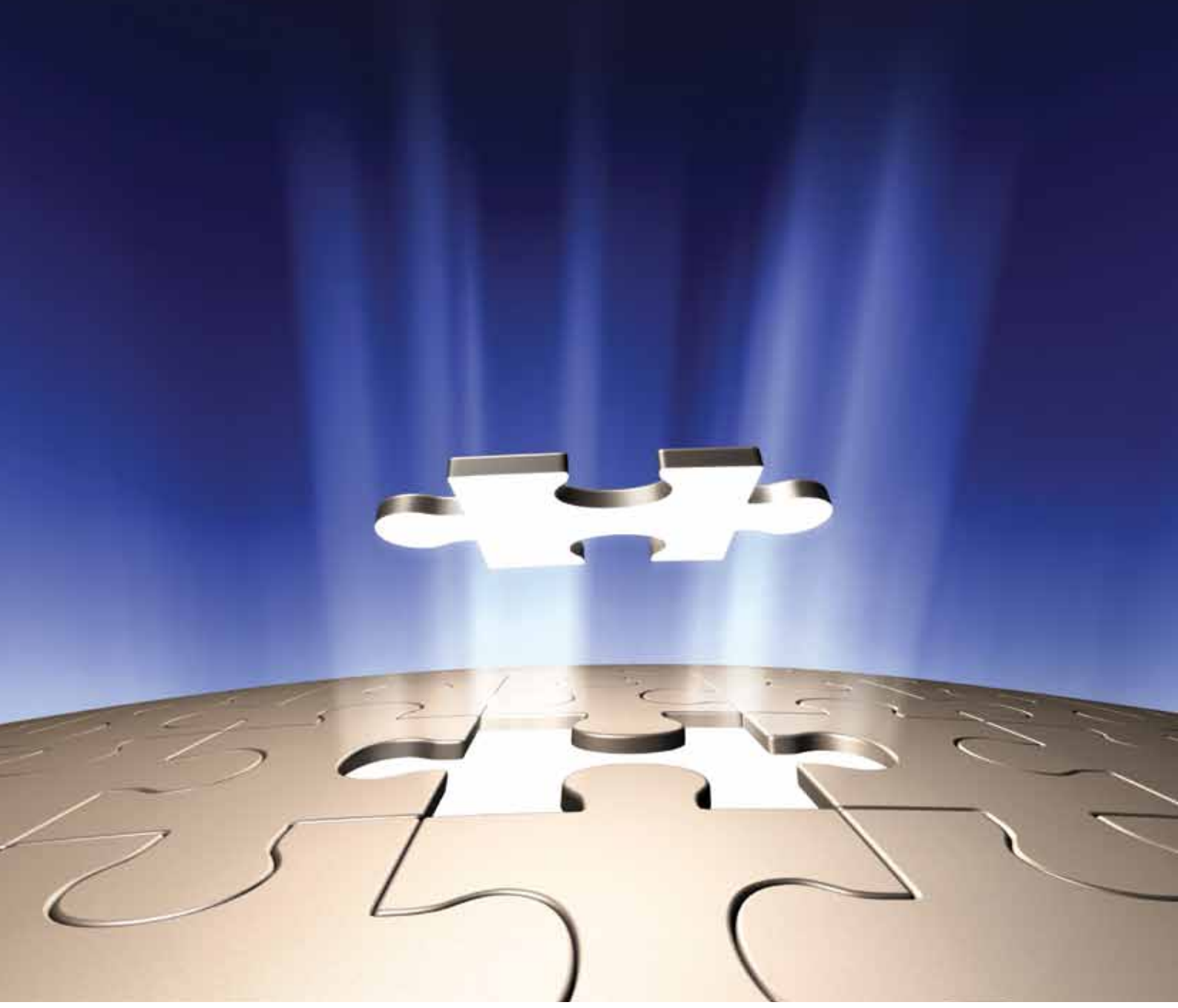
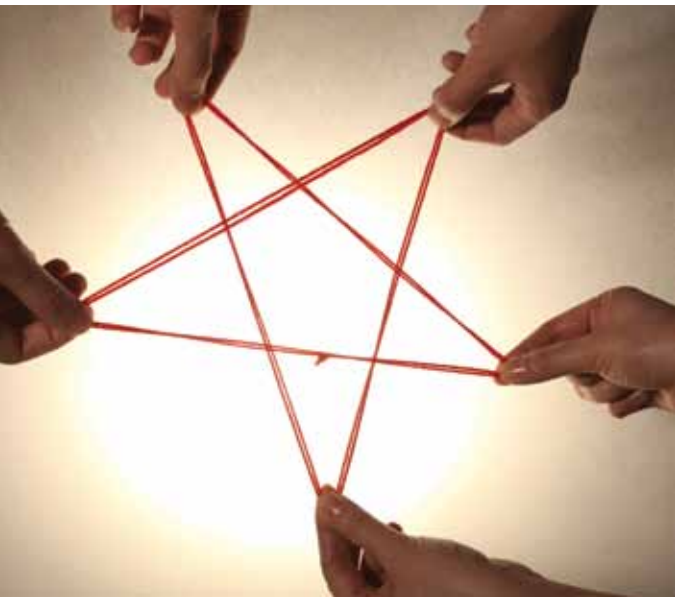
By now, all pharmaceutical quality problems should be solved. After all, regulators have long required companies to solve problems. But warning letters from the US Food and Drug Administration (FDA) prove that companies still have root cause analysis failures. When root cause analysis fails, companies fail to solve problems (prevent the problem's recurrence) and, thereby fail to ensure the safety and effectiveness of the drugs.





Why do pharmaceutical companies and companies involved in pharmaceutical testing have problems with root cause analysis? This article discusses four sources of root cause analysis failures:

1. We don't do root cause analysis...we just solve problems
2. We ask 'Why' five times
3. We gave management what they wanted
4. The problems were too small for root cause analysis

The article also provides ideas to avoid these failures in the future with suggestions for senior managers.

Introduction

A warning letter from the US FDA is big trouble. It can mean product recalls, additional inspections, third party audits, rejection of data in applications or removal by the FDA of the rights to distribute pharmaceuticals in the United States. Here are four excerpts from FDA letters indicating that a regulated facility is in trouble because they did not perform adequate root causes analysis and then fix the sources of the problems:

'In your response, your firm states that you plan to evaluate all critical process parameters and that those results will be reviewed to determine final operating ranges. Your response, however, is inadequate in that it does not address: 1) specific details about your re-validation plans and in particular, whether you will determine the root cause to clearly demonstrate a full understanding of your products and processes before initiating the re-validations,...'[1]

'...your approach to investigating sources of contamination in bioequivalence studies is inadequate and has resulted in the submission of invalid data to the agency. You should have conducted a systematic and thorough evaluation to identify and correct the source of contamination when it was first observed.'[2]

'Investigations related to Field Alert Reports (FARs) submitted to the agency during 2009 and 2010, regarding your packaging and labeling system are found to be inadequate. Your inability to implement appropriate corrections to prevent future significant problems raises concerns regarding the robustness of your quality system...

Your investigation into the April 12, 2010 event attributed the root cause to a human error. ... Your investigation regarding the March 24, 2011 event also attributed human error as the root cause of the problem. ... We are concerned with your inability to conduct a thorough evaluation of your packaging and labeling systems and identify problems that may lead to subsequent or new incidents of product/labeling mix-ups. It is your responsibility to determine the appropriate corrective actions that will reduce the possibility of future product/labeling mix-up problems.'[3]

'...Your firm's OOS investigation relating to impurity levels for (b)(4), lot (b)(4), concluded that the root cause was a laboratory error, but the investigation did not identify what specific laboratory error occurred. ... Your response indicates that you will revise your procedure for conducting OOS investigations, YIS-HIN-0003, 'SOP on OOS Investigation.' Please note, that it is critical that your firm thoroughly investigate all OOSs to determine the root cause.'[4]

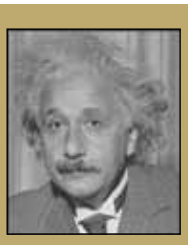
These are just four sample letters. Many more are produced each year and are available at the FDA website: www.fda.gov. FDA letters identify failures to perform root cause analysis, failures to document the scientific basis of the problem investigation and inadequate root cause analysis with the root causes listed as human error, bad handwriting and failure to follow a procedure.

These failures are not limited to US pharmaceutical manufacturers – they happen around the world. Root cause analysis failures are an international phenomenon.

To prevent these common root cause analysis failures, one must understand them and what needs to be done to prevent them. Understanding four common failure sources and the actions a regulated facility should take to make sure their root cause analysis doesn't fail is a start to the improvement of root cause analysis in any industry.

Failure Source 1: We don't do root cause analysis...we just solve problems

A common mistake made by problem solvers around the world (not just those in the pharmaceutical industry) is that they skip the whole root cause analysis process. When they see a problem, they jump to conclusions and implement a fix. This reminds me of a quote commonly attributed to Albert Einstein:



"We can't solve problems by using the same kind of thinking we used when we created them."

ALBERT EINSTEIN

Problem solvers often see 'human error' as the cause. They then jump to common conclusions – the three standard corrective actions. What are the three standard corrective actions? They are listed in the book, *TapRooT® - Changing the Way the World Solves Problems*[5]*:*

1. **Counselling/Discipline** – Which often starts with, 'Counsel the employee to be more careful when.'
2. **Training** – As in 'conduct more training' or 'retrain'.
3. **Procedures** – Write one if you don't already have one or make the one you have longer.

Using this 'same kind of thinking' doesn't get us beyond our current knowledge and doesn't solve the problems we face. This is why the FDA sees problems happening over and over again. It's why the FDA becomes concerned that a company's corrective actions are not going to prevent future recurrence of a quality issue.

And by the way... anytime one sees a 're' anything as a corrective action – retrain, reemphasise or review – an action that didn't work the first time to stop a problem is being re-used. What will make it work this time?

The obvious fix to this failure source is to perform a detailed, systematic, root cause analysis. But, as the following sections will show, this may not be as easy as it seems.

Failure Source 2: We ask "Why" five times

The most common root cause analysis technique written about in quality journals is '5-Whys.' This technique is simple and easy to understand. In theory all one has to do is to ask and answer the question "why" five times and the root cause of a problem will be found.

Examples of this technique are often given to prove how easy and effective the technique is. Taiichi Ohno, the creator of the '5-Whys' technique, is often quoted[6] as using this example to teach his students the way to ask why five times:

1. "Why did the robot stop?"
The circuit has overloaded, causing a fuse to blow.

2. "Why is the circuit overloaded?"

There was insufficient lubrication on the bearings, so they locked up.

3. "Why was there insufficient lubrication on the bearings?"

The oil pump on the robot is not circulating sufficient oil.

4. "Why is the pump not circulating sufficient oil?"

The pump intake is clogged with metal shavings.

5. "Why is the intake clogged with metal shavings?"

Because there is no filter on the pump.

To me, this as an example of troubleshooting, not root cause analysis.

Troubleshooting determines the part that failed and the reason that the part failed, not the root cause of the problem. Root cause analysis digs further into the human performance, management system and organisational causes of a problem.

First, let's start where the example ended and ask: "Why was there no filter on the pump?" Did the designer neglect to include it? Or was it removed and never replaced during maintenance? Surely if the filter wasn't replaced during maintenance, then this is a human error! Now all we have to do is to pick one or more of the standard corrective actions, for example, counsel the mechanic to be more careful when replacing filters, and then we have reached a common conclusion to a '5-Whys' analysis (in this case with only six whys).
Therefore, even in a '6-Whys' analysis, the root causes of failed human performance aren't reached. It is unlikely they will be reached with more "why" questions because most people asking the "why" questions don't have training in the causes of human error. Why people make mistakes is beyond their current knowledge.

Second, even if the pump needs a filter, where did the metal shavings come from? Was the system contaminated during assembly? Is a part wearing inappropriately? The world's foremost expert in '5-Whys' root cause analysis (Taiichi Ohno) has missed a whole line of inquiry. This isn't just a problem for Taiichi Ohno. Addressing a single causal factor when there are several is a common mistake made by those using '5-Whys'.

This single, well-known example shows two of the built-in problems with asking why five times. But one may need more evidence to be convinced to abandon a common root cause analysis tool. Thus, I refer readers to a detailed discussion of five reasons '5-Whys' fails to produce acceptable results in the article 'Under Scrutiny'[7] in 'Quality Progress'.

If one is using the '5-Whys' technique and experiencing the same inadequate results that others frequently experience, what can one do? Adopt a more advanced root cause analysis system based on the proven human factors and equipment troubleshooting techniques.

Developing a system that uses advanced human factors and equipment troubleshooting techniques to guide investigators to the real root causes of quality issues isn't easy. One needs to build the right guidance without creating too much complexity. As W. Edwards Deming said:

"Lack of knowledge…that is the problem. You should not ask questions without knowledge. If you do not know how to ask the right questions, you discover nothing." W. EDWARDS DEMING

Building a system with the right questions – the right knowledge – has been the pursuit of my professional life. That's why I would caution those looking for an advanced system to beware of those that haven't done their homework. Seemingly insignificant errors in the way the root cause analysis is performed, the way the information is organised and the way the questions are defined and categorised can lead to missed opportunities to solve problems (and, therefore, regulatory issues). Thus, I can't help but recommend that readers review the basis of TapRooT®[8] to understand how an advanced root cause analysis system should function.

Failure Source 3: We gave management what they wanted

Management really wants the problem to go away. But they also want a simple, no cost answer they can quickly implement and forget.

Sometimes these are opposing goals – effective solutions vs. simple, easy corrective actions. The easiest answers to present to management may be the ones they are most familiar with – the standard three corrective actions.

Unfortunately, most real problems aren't solved with simple, no-cost solutions. Sometimes the effective solutions require capital projects, changes in work processes, management attention or, even worse, management change. Finding the right answer (or answers) requires thorough root cause analysis.

But even with root cause analysis, problem solvers and management may have a hard time developing an effective corrective action. They can't see 'outside the box' – beyond their current experience. Management needs problem elimination. That's why an effective root cause analysis system needs to go beyond asking effective questions to find root causes. An effective system needs to help problem solvers and management consider potential solutions that they might not think of on their own.

The job of a problem solver is to provide a thorough analysis based on evidence and then develop effective actions to prevent recurrence. The problem solver, with the help of the root cause analysis system, must confront the real issues effectively.
To stop investigators from just telling management what they think management wants to hear (simple corrective actions from the standard three), management asks for better solutions. Thus, management needs advanced root cause analysis training so they know what to ask for.

Also, the root cause system used should help the problem solvers see outside the box. It should get them beyond their current knowledge and help them develop fixes based on the latest human factors and equipment reliability technology.

Thus, an advanced root cause analysis system has to provide expert systems for root cause analysis and guidance for the development of effective corrective actions.

Failure Source 4: The problems were too small for root cause analysis

Many times I've heard:

"We simply don't have time to do analysis of all the small problems that we have. We must use simple analyses for smaller problems."
And then thought...bad analysis of small problems allows bigger problems to happen.

Most would agree that solving big problems by never letting them occur in the first place is probably the best medicine. After all, would the CEO of a major oil company prefer to wait for an accident like the Deepwater Horizon to learn to improve your drilling operations or would they rather heed the warnings of smaller incidents and, thereby, prevent the major accident from happening?

I've never seen a major accident that didn't have precursors. Sometimes these are called 'weak signals' but for people experienced in achieving operational excellence, they are warning sirens that should not be ignored.

Why then do many companies miss the signals in incidents and near-misses? Besides failure to perform adequate root cause analysis (mentioned previously), there are several reasons. They include:

1. Complacency
2. False sense of economy
3. Short-term focus
4. Failure to understand how to achieve operational excellence

Missing the opportunity to avoid major accidents by learning from smaller problems is even more of a tragedy when one considers the financial and personal losses that occur in a major accident or quality issue and how much easier it is to learn from a small problem.

Why is it easier to effectively learn from a small problem? Because small problems are easier to analyse. There is less blame to get in the way of the investigation. All the witnesses are alive and willing to cooperate. Live witnesses aren't 'lawyered up'. Management is much less defensive and the company isn't lawyered up. Usually there isn't perceived pressure from regulators.

Then why don't companies learn from small problems?

First, companies need an effective screening process to pick which small problems could become big problems. Management can then direct problem-solving resources to the problems with the largest possible risk-based return on the investigative effort.

Second, management has to avoid complacency, a false sense of economy and a short-term focus and then concentrate on achieving operational excellence. The need for this can be less than intuitive when only small things are going wrong.

Management can use the 'fact' that nothing big has happened as proof that things are safe and quality is acceptable. Unfortunately, this is exactly what management thought before every major accident or quality fiasco on record.

To avoid this failure, management must be concerned with small failures and make sure the ones that could result in major problems are thoroughly investigated using advanced root cause analysis and, once investigated, that the corrective actions are implemented. Constant vigilance is the price of operational excellence.

Conclusion

Senior managers: don't fall victim to the common problems that produce root cause analysis failures. Avoid major quality issues and FDA warning letters by effectively using advanced root cause analysis. To improve your root cause analysis processes, start with these four action items:

1. Make sure that your facility performs advanced root cause analysis to develop effective corrective actions, and that your problem solvers aren't jumping to conclusions.
2. Don't allow the use of '5-Whys' and don't accept substandard root cause analysis. Remember, human error is NOT a root cause.
3. Get training for your management team on advanced root cause analysis and demand more than 'simple' answers. Ask for thorough root cause analysis that uses advanced human factors and equipment troubleshooting techniques that develop effective fixes beyond the 'standard three'. And never accept an answer that starts with 're'.
4. Develop a screening process to catch important smaller incidents (near-misses) and ensure that these smaller incidents get advanced root cause analysis and effective corrective actions. Then insist resources are applied so that learning from these small problems prevents major accidents and quality issues.

Once your reactive learning processes are optimised, you will be ready for the next step in operational excellence – developing proactive processes using the same advanced root cause analysis tools to get an additional step ahead of trouble and become a true learning organisation.

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