

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

Taking Preventive Action *How Asking Good Questions Leads to the Root Cause of Problems*

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One of the most frequent citations in FDA 483 Observation Reports and Warning Letters is lack of or inadequate Corrective and Preventive Action taken when problems occur. An integral part of any Quality System and GXP system is getting to the root cause(s) and taking appropriate preventive action.

The pathway to take when launching an investigation into a problem or issue starts with asking questions. This column will look at how asking good questions can lead us to the root cause(s) and the implementation of effective solutions.

Questions are the key to discovery

A typical question asked by managers when they enter the production areas is "How's it going?" And typical responses include "Fine," "Great," or "OK." So what did the manager learn through this exchange? Nothing. Worse yet, if monthly reports indicate things are not fine or

great, or even just OK, then the manager may conclude that asking workers questions doesn't work in trying to improve the operation.

Who knows the process better than those actually doing it? Of course the workers have a lot of knowledge about how the system works and where problems exist.

The key to discovery is in asking better questions. Rather than "How's it going?" it's better to ask "What's getting in your way today or this week?" or "What's causing you frustration or driving you nuts this week?"

Note that these questions cannot be answered by a simple "Yes" or "No" or "Fine." They are open-ended questions, and require a response that involves some thinking and analysis.

Whether you are a manager, supervisor, or professional being asked to troubleshoot a system or process or fix a problem, the place to start is in asking good

questions of the right people – those closest to the process being examined.

Once you get a response to your open-ended question, the follow up question should be “Why?” “Why do you suppose that’s happening?” is a good follow-up question.

Getting to the root cause of the problem may require a series of follow-up Why questions. Here’s an example.

The Situation

There have been a higher than usual number of accidents in a specific area of the production floor. Most of these involve people slipping and falling. Most are minor accidents but some required medical treatment. Production output in this area is also down from the usual rates.

A meeting takes place with the people working in the area where the accidents have been occurring.

Two questions come to mind to start the discussion. “Why have there been more accidents lately?” and “What are some reasons that production output is lower than in the past?”

The people in the area reveal that one piece of equipment is dripping oil onto the floor. Workers are frustrated by having to stop the process and

clean up the oil periodically, and sometimes it goes unnoticed until someone slips and falls.

Follow-up question - “Why is the oil leaking from the machine?”

The workers explain that the gaskets don’t last very long – they seem to deteriorate quickly. The process must be stopped to change gaskets.

Follow-up question - “Why are these gaskets going bad so frequently?”

An investigation discovers that we recently changed suppliers for the gaskets we use on that machine.

Follow-up question - “Why did we change suppliers for the gaskets?”

Answer - We got a lower price and thus saved the company money. The new supplier was the low bidder for the gasket contract.

Follow-up question - “Why did we go with the low bidder?”

The investigation reveals three reasons.

1. The emphasis from Management in this bad economy has been to be as cost conscious as possible.

2. The people in Purchasing get evaluated on the basis of cost savings.
3. A company policy requires us to buy from the lowest bidder.

The Solution

The example above is a very simple one. The obvious solution is to buy better gaskets. The root cause however lies in the evaluation process of the people in Purchasing, the low bid purchasing policy, and how management explains what being cost conscious means.

Without the series of Why questions in the above example, one may stop at the first explanation and issue more rags to clean up the leaking oil. Or replace the gaskets more frequently, before they start leaking. Both these actions are Corrective Action and raise our costs. Buying more rags and more gaskets which in turn adds even more downtime and further reduces output.

Even worse, without asking any questions at all, managers might conclude that the solution is to conduct safety training for everyone in Production. (Don't laugh – think of how often these types of across-the-board knee-jerk solutions are proposed and/or implemented.)

Preventive action would entail changing the job evaluation process for the people in Purchasing, revising the low bid purchasing policy, and/or having management be more careful in explaining company-wide initiatives.

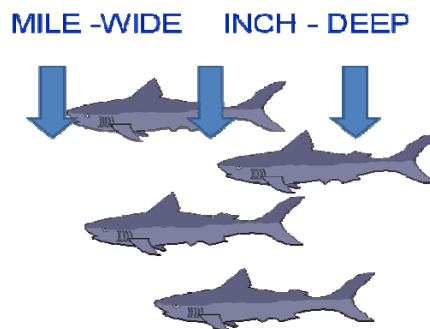
Real world problems

The problems encountered in the workplace can be complex. Getting to the root cause or causes can require intense investigations and time, sometimes weeks or even months.

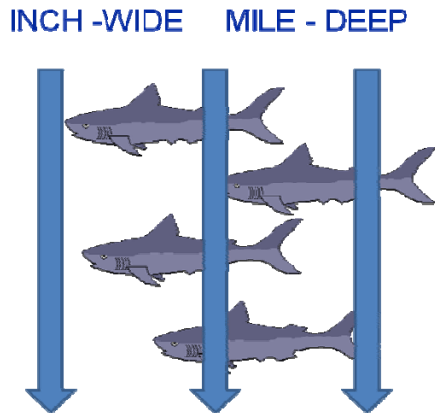
Effective Root Cause Analysis also requires the discipline and diligence to stick with it.

Defining the Issue or Problem

The better one defines the issue or problem the easier it is to investigate. Too often the problem or issue is defined in broad terms. The investigation then stretches over a broad scope and digging deep can be very time consuming. This is known as going a "Mile wide and an inch deep."



It is far better to define the issue or problem sharply or crisply. Then drill down deep – go an “Inch wide and a mile deep.” The use of tools like flow charts and process maps can help define the issue and frame the investigation.



Implementing the Solution

Once you’ve drilled deep enough to get beyond the “Presenting problem(s)” to the root cause “Real problem(s)” it’s time to ask some additional questions before proceeding with implementation of a solution.

The late Dr W. Edwards Deming often said during his famed Four-day seminars, *“The questions are more important than the answers.”* So in Deming’s spirit, here are some additional questions to ask before the implementation begins.

“What is the purpose of this solution?” Make sure everyone involved in the implementation

effort knows why we are doing this.

“How will we know when it is successful?” What will finished look like?

“What will it take to accomplish this?” How will we go about making this happen? By what method?

Will the customers care about this? Consider both your internal and external customers. If it has no impact on the customer, does it make sense to proceed?

“What data do we have?” We shouldn’t move ahead unless we have solid data to confirm our findings and theories.

“Where did the data come from?” Was the data gathered properly? Is the data valid? Based upon the answers to the questions posed above, now is the time for implementation of the proper solution.

Summary

The questions are indeed more important than the answers. The right questions lead you to discover the best answers. Optimization of our systems and processes should be an ongoing part of your Quality and GXP system.

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