Frequently Asked Questions

Webinar Title: Conducting Quality Investigations
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Question: Do you have any recommendations/guidance when it comes to IT-related investigations (data center power outages, servers crashing, network equipment failures, change control gone awry, etc., incidents beyond quality data lost)?
Answer: IT-related investigations apply the same principles as any deficiency or failure investigation. The difference would be in selecting the right investigative tool to drive to root cause.

Question: What are the "8Ds"?
Answer: The 8Ds stand for the Eight Disciplines of Problem Solving. It is a team-based process developed by the Ford Motor Company and is used to solve complex problems. There are 8 steps in the process. These steps include many of the elements recommended in our webinar including the writing of an investigation plan, forming a team, defining the problem and documenting the investigation and its conclusions. There are many processes and tools available for performing investigations. Regardless of which process/tools you use, the important points to remember are to have a robust investigation plan and thoroughly document your investigation results and conclusions.

Question: You didn't mention CAPA in the webinar. How does CAPA relate to investigations?
Answer: It is important to understand that not all investigations result in a CAPA. CAPA is a specific discipline within the umbrella of investigations and stands for Corrective Action/Preventive Action. CAPAs are viewed as improvements to a process implemented to eliminate undesirable situations or product non-conformities. After implementation CAPAs require an Effectiveness Check to confirm that the preventive action alleviated the situation repeating itself. There are many steps to CAPA and the information presented in our webinar is the basis for performing an effective CAPA investigation.

Question: Is it ok if I am not able to find the actual root cause, but instead I have several contributing factors and define corrective actions for all of those factors?
Answer: Some investigations will uncover a number of issues that might contribute to the problem being investigated. These would be considered probable root causes. When this happens you are probably dealing with an issue that should be captured in your CAPA program. In the CAPA program you would put in the corrective action for each of the identified potential root causes and then monitor the process to make sure that the issue does not repeat itself. You might also try and rank the contributing factors and try to determine the issue that you consider the most probable root cause. Bottom line, if you have identified more than one factor that contributed to the issue you should remediate them all, monitor your process to be sure the problem does not recur and document your investigation results and conclusions so your rationale is clearly understood.

Question: While I understand the concern with Human Error as a root cause, I would like to know your thoughts on if a robust investigation was performed there certainly might be cases where Human Error is an appropriate root cause. I think the important piece is to ask "why" the Human made the error and it may end up being more appropriate to further define Human error as a root cause a bit more (e.g., lapse of memory, slips of action, violation, etc.)
Answer: It is important to keep in mind that human error is rarely a true root cause. That doesn't mean it can't be the root cause, it just means that it is rare that unforced human error is the root cause (i.e., there is usually something in the process that causes that human error). Asking the "why" was the human error made may lead you to uncover a process issue that led to the human error which could be categorized further as described (e.g., lapse of memory, slips of action, violation, etc.). However, if the human error keeps recurring, even after retraining, then your initial investigation was probably not in-depth enough and you should consider performing another investigation into the issue. You will need to remove the "Human element" if all your investigation still end up with "Human error". You will need some type of automation. If automation is not possible, you will need to add a secondary inspection to reduce the chance of reoccurrence of the error.

Question: If after the root cause analysis is performed and the cause due to human error, what would be your recommendation to correct and prevent recurrence?
Answer: The best way to prevent human errors is to make sure people are appropriately trained and understand their roles and responsibilities. When a root cause is determined to be human error you need to monitor that process closely for recurrence of the human error. If you have a recurrence then your initial categorization of the root cause as human error was probably incorrect and you should revisit your earlier conclusion. You will need to remove the "Human element" if all your investigation still end up with "Human error". You will need some type of automation. If automation is not possible, you will need to add a secondary inspection to reduce the chance of reoccurrence of the error.

Question: How do you know if your root cause is accurate?
Answer: Once you have identified your root cause and put in steps to remediate it you would monitor the process change for recurrence of the issue over time. If the original deviation does not recur then you probably identified the correct root cause.

Question: How deep would be the investigation? Is there any guidance to help us to identify which cases really need to be investigated and then when a CAPA would need to be developed?
Answer: Any deviation needs to be investigated. The depth of the investigation will depend on the complexity of the issue/deviation. There are many tools available to help with your investigation but there is no official regulatory guidance document covering this subject. As a rule of thumb the corrective action in CAPA addresses an existing product or quality problem. Once the correction is made then the preventive measures are put in place to prevent the recurrence of the problem. After the preventive measures are put in place the company needs to monitor the process and determine if the preventive action did indeed prevent recurrence of the problem. This is known as effectiveness checks and once the effectiveness checks are determined to be successful the CAPA can be closed.