

Frequently Asked Questions

Webinar Title: Conducting CAPA Investigations

Date of Webinar: September 21, 2016

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Question: When should you close a CAPA?

Answer: Close a CAPA once you followed your documented process for closing a CAPA, all the documentation is completed and attached and the CAPA was approved for closure. Ideally the CAPA is closed when the effectiveness check has passed, however in some cases we know that an effectiveness check may take a long time, for example, when the product is only produced once every couple of years. Think creatively and explore other ways to prove effectiveness and sustainability of your corrective action. If you need to close a CAPA before the effectiveness check is completed, write a thorough and solid justification and ensure that you have mechanisms in place to ensure that there continues to be progress in completing the effectiveness checks.

Question: When do you get Management involved?

Answer: Keep management involved by having monthly update meetings. It is often difficult to get time with management, but having regular planned meetings will allow management to schedule their time. Review your key CAPA system metrics at these meetings. The usual reason why a CAPA system is not working is the lack of resources. Ask for more people to work on CAPAs if you have CAPA that are not being worked on. Ask for people to have more time to work on CAPAs if their CAPAs are not progressing. Ask for money to be spent on training if people do not have the skills to work on CAPAs. The key at this meeting is to present the problems and ask for what is needed to solve the problems.

Question: What do you do if a CAPA fails an effectiveness check?

Answer: Reassess the effectiveness check plan. Were the right criteria selected to determine reoccurrence of the failure? Are you checking for red when you should be checking blue? If the correct success criteria were selected, and the corrective action failed, then both the investigation and corrective action need to be redone. When you see a

trend of CAPAs failing effectiveness check, you will need to do an investigation to see the cause of the trend.

Question: What are the thoughts about extensions to timeliness? Should there be a limit to the number of timeline extensions (vs. having the item go overdue)?

Answer: The need for an extension to a CAPA for timeliness should be established as part of your firm's Investigations/CAPA procedure. From an audit perspective, it is usually better to follow your internal procedures and request the extension rather than letting the CAPA go overdue. Whether you follow the procedure and request the extension or let the CAPA go overdue, you should always document the reason for the delay in completing the CAPA.