

SELF-ASSESSMENT FOR INVESTIGATION HANDLING IN PHARMA OPERATIONS



Use the following questions to assess your Investigation and CAPA program. Use the flip side of this sheet to highlight the strengths and weaknesses of your investigation system.

Q Do you triage your investigations to ensure that you spend the sufficient time of those investigations which present the greatest risk?

Q Do you apply root cause analysis tools to investigate issues thoroughly, especially when an event presents a high level of patient risk?

Q Do you ensure your actions (CAPAs) are clearly linked to root cause?

Q Do you prioritize CAPAs to ensure you select the most robust actions?

Q Are you checking for CAPA effectiveness and looking out for possible unintended consequences?

Each of the above questions points to an essential characteristic of a investigation and CAPA program. If you answered NO to any of the above questions it is an indication that you see room for improvement.

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Insert your answers to each question below. Note the strengths and highlight any weaknesses of your company's Investigation and CAPA program.

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RECOMMENDATION: Act now and address the system weaknesses you are seeing. Ensure investigators and approvers are well trained and certified.

If you are NOT making progress or need additional support in this area please contact Jim Morris at jmorris@nsf.org