

SELF-ASSESSMENT FOR INVESTIGATION HANDLING IN PHARMA OPERATIONS



Use the following questions to assess your Investigation and CAPA program.

Part 1

1

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

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

2

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

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

3

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

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

4

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

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

5

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

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

Part 2

AND move low risk investigations to closure in 5 days?

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

AND are human performance tools embedded in your process?

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

AND investigation report "tell the story"

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

AND do you employ the CAPA hierarchy? (Google CAPA hierarchy)

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

AND are you tracking deviation reoccurrence?

- ☐ ALWAYS
- ☐ SOMETIMES
- ☐ HARDLY EVER

Each of the above questions points to an essential characteristic of an investigation and CAPA program.

If under **Part 1** of this survey you scored **HARDLY EVER** with any question we recommend you act with urgency to address the gap(s) in your investigation system.

If under **Part 2** you scored **HARDLY EVER** with any question you have an excellent opportunity to improve your system and take it to the next level.

SELF-ASSESSMENT FOR INVESTIGATION HANDLING IN PHARMA OPERATIONS



System Health Check ▼

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

.....

.....

.....

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

.....

.....

.....

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

.....

.....

.....

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

.....

.....

.....

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

.....

.....

.....

If you are NOT making progress or need additional support in this area please contact us at **HealthSciences@nsf.org**.