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

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Score</th>
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<tbody>
<tr>
<td>1</td>
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If you are NOT making progress or need additional support in this area please contact us at HealthSciences@nsf.org.