Corrective and Preventive Actions

To correct a problem
And
Prevent it from ever happening again

Mission: To complete better CAPAs in shorter time, waste less time and effort, affording more time and effort improving our CAPA process / performance. Fewer loop-backs to previous stages.

Plantwide Vision: To be transformed into a highly productive, well disciplined, market leading, profit producing team of professionals who love what we do because we are winning!
Manufacturing is like an elephant.
A quality problem is like an elephant.
When something goes wrong – our product doesn’t get made the way it’s supposed to – we all want to know:

“Why did it happen and how can we stop it from ever happening again?”
There once was a football game where no one showed up except the quarterback. Would you want to play on that team?

“I don’t know all there is to know about this issue.”

.... Repeat issues ....
Qtech rec'vs issue, assigns a CAPA Lead.

CAPA Lead invites a team.

30 min

1 hr

The “shift hours clock”

The above times are in “shift hours”. For example, 3 hours after 2pm is 8:30am the next day, because 1st shift ends at 3:30pm.

For 2nd shift, 5 shift hours after 9pm is …. ?

Speed need: Without RC & CM we can’t report back to the customer.

Team

Gemba

Fish / 5Why

Person

Write-up Problem Descrip

Team

RootCause & CounterM Plan

Submit for Approval

5 hrs to finish (it may take a 2-hour meeting plus a 3-hour buffer to find an acceptable meeting time)

6 hrs to invite and present to Mgr
For every CAPA be sure to **see** the place under correction. That means we've got to do a Gemba for almost every CAPA. Gemba means 'go to shop floor'.

CAPAs can be ...

**Gembas made easy:**

*Use the Problem Discovery section of the 5P Sheet*
### 1A. Problem Definition / Discovery

**Consider:** Who, What, Where, Why, How and How Many

<table>
<thead>
<tr>
<th>Who</th>
<th>1. Who found the problem?</th>
</tr>
</thead>
<tbody>
<tr>
<td>What</td>
<td>2. What part has the problem? (Identify model, type)</td>
</tr>
<tr>
<td>Where</td>
<td>3. Where is it going with it? (Identify symptoms of problem)</td>
</tr>
<tr>
<td>When</td>
<td>4. Where was the part located when purchased the problem?</td>
</tr>
<tr>
<td>Why</td>
<td>5. Where on the part is the trouble located?</td>
</tr>
<tr>
<td>When</td>
<td>6. When was the problem first observed?</td>
</tr>
<tr>
<td>Why</td>
<td>7. When once does the problem occur? Is there a consistent trend?</td>
</tr>
<tr>
<td>How</td>
<td>8. What is the process's flow of the defect observed?</td>
</tr>
<tr>
<td>How Many</td>
<td>9. How many parts in each batch have the problem?</td>
</tr>
<tr>
<td>How Many</td>
<td>10. How many defects on each object? (Same defect)</td>
</tr>
<tr>
<td>How Many</td>
<td>11. Is the problem getting better, worse, or staying the same?</td>
</tr>
</tbody>
</table>

### 2C. Identify Root Cause(s)

<table>
<thead>
<tr>
<th>Why</th>
<th>1. Why defect?</th>
</tr>
</thead>
<tbody>
<tr>
<td>Who</td>
<td>2. Who detected the defect?</td>
</tr>
</tbody>
</table>

### 2D. Root Cause(s) Selection Justification

<table>
<thead>
<tr>
<th>&gt; QT</th>
<th>&gt; GHT</th>
<th>&gt; RP</th>
<th>&gt; DP</th>
</tr>
</thead>
</table>

### 3 Countermeasure(s)

<table>
<thead>
<tr>
<th>Countermeasure(s)</th>
<th>Responses</th>
<th>GHT</th>
<th>RP</th>
<th>DP</th>
</tr>
</thead>
</table>

### 4 Countermeasure Effectiveness

<table>
<thead>
<tr>
<th>Countermeasure(s)</th>
<th>Responses</th>
<th>GHT</th>
<th>RP</th>
<th>DP</th>
</tr>
</thead>
</table>

### 5 Feedback/Forward

<table>
<thead>
<tr>
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<th>Responses</th>
<th>GHT</th>
<th>RP</th>
<th>DP</th>
</tr>
</thead>
</table>
# 1-A Problem Definition / Discovery


<table>
<thead>
<tr>
<th>Who</th>
<th>1. Who found the problem?</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2. What part has the problem? (object) Model and type</td>
</tr>
<tr>
<td></td>
<td>3. What is wrong with it? (defect) Symptom of problem. Use illustrations to clarify</td>
</tr>
<tr>
<td>Where</td>
<td>4. Where was the part located when you found the problem?</td>
</tr>
<tr>
<td></td>
<td>5. Where on the part is the trouble located?</td>
</tr>
<tr>
<td>When</td>
<td>6. When was the problem first found? Date and Time.</td>
</tr>
<tr>
<td></td>
<td>7. When since then has the problem recurred? Is there a pattern forming?</td>
</tr>
<tr>
<td></td>
<td>8. When in the process was the defect first observed?</td>
</tr>
<tr>
<td>Why</td>
<td>9. Why is it a problem? Content of complaint</td>
</tr>
<tr>
<td>How</td>
<td>10. How was the problem found? Visual inspection or customer complaint?</td>
</tr>
<tr>
<td></td>
<td>11. How many parts or units have this problem?</td>
</tr>
<tr>
<td>How Many</td>
<td>12. How big is this defect? Size</td>
</tr>
<tr>
<td></td>
<td>13. How many defects on each object? (Same Defect)</td>
</tr>
<tr>
<td></td>
<td>14. Is the problem getting better, worse or staying the same?</td>
</tr>
</tbody>
</table>
Qtech receives issue, assigns a CAPA Lead.

CAPA Lead invites a team.

Team:
- Gemba
- Fish / 5Why

Person:
- Write-up Problem Descrip

Team:
- Root Cause & CounterM Plan

Submit for Approval
Your team’s goal for every potential escape point, every risk is to:

1. Describe it in the investigation
2. Identify it as a Root Cause
3. Create an effective Action in the CM Plan
The purpose of the Gemba is (choose best answer):

a. To find the Root Cause of the problem

b. So we can fully define or describe the problem

c. To contain the problem and prevent further escapes

d. To compare my opinion with other departments

e. To fulfill quality requirements
I couldn’t buy penny gum

Why occurred? Why escaped? Why occurred (2)? Why escaped (2)?

- No gum
- Bent penny
- Fishbone 5Why
- I couldn’t buy penny gum
- Wrong turn
- Counted wrong
- Lost penny
- Broken gum
- Counted wrong
- Wrong turn

Just list the 6 M’s
- Man
- Machine
- Method
- Measurement
- Material
- Environment

Then ….
Robust your root cause by flowing the process and the risk points. In this example, the process is in green marker, and the risks are in red.

Just list the 6 M’s
[ ] Man
[ ] Machine
[ ] Method
[ ] Measurement
[ ] Material
[ ] Environment
Dare to say, “This problem won’t happen again!”

The 5P

5P ↔ CAPA

A 5P summarizes the CAPA

Goal: A permanent fix
A robust tracking system is important. The best I’ve used, although not perfect, is called “EtQ Reliance”.

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Write-up Problem Descrip

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Benjamin Franklin's 7-Why Analysis:
For lack of a nail a shoe was lost,
for lack of a shoe a horse was lost,
for lack of a horse a rider was lost,
for lack of a rider an army was lost,
for lack of an army a battle was lost,
for lack of a battle the war was lost,
for lack of the war the kingdom was lost..

…and all because of the lack of a little horseshoe nail.
The more possible solutions you develop, the more likely you are to find a *good* one.

Qtech rec’vs issue, assigns a CAPA Lead.

CAPA Lead invites a team.

Brainstorm Logic
Team Communication Guidelines

- Listen to one another respectfully.
- Use a democratic process that enables everyone to speak.
- Take advantage of the skills and talents each person brings to the team.
- Express your own opinions and points of view.
- Encourage others to express different opinions and viewpoints.

- Raise the "tough" issues so they can be discussed.
- Avoid interrupting each other.
- Be just as careful how you say something as you are about what you say.
- Stay focused on goals—avoid personal attacks.
- Use constructive rather than destructive criticism.

Team Communication Guidelines
Nine Approaches for New Solutions
Guidelines for Giving and Receiving Feedback
Applying Emotional Intelligence in the Workplace Checklist
Approaches for New Solutions

- Change your thinking. See change as an opportunity rather than as a problem.
- Find out how others cope with a similar problem.
- Make small improvements in things you are doing already. For instance, if you already have a habit of daily planning at work, consider how you can use planning strategy in your personal life.
- Work cooperatively. When people work together to solve a problem, everyone is more likely to be satisfied and support the group solution. When groups agree on common goals, everyone becomes involved.
- Get someone on your team who disagrees with you.

While you are looking for options, stay open. Do not block out any feelings or ideas.

Take a break. Put your problem on the shelf and come back to it later. When you return, you may see new solutions that were not obvious when you were tired and discouraged.

Get someone on your team who disagrees with you.
### Guidelines for Giving and Receiving Feedback

<table>
<thead>
<tr>
<th>When receiving feedback...</th>
<th>When giving feedback...</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Assume a non-judgmental attitude.</td>
<td>1. Speak directly to the person.</td>
</tr>
<tr>
<td>2. Listen carefully for understanding.</td>
<td>2. Assume a non-judgmental attitude.</td>
</tr>
<tr>
<td>3. Ask for specific examples.</td>
<td>3. Make it timely.</td>
</tr>
<tr>
<td>4. Don't attempt to defend your behavior.</td>
<td>4. Give specific examples.</td>
</tr>
<tr>
<td>5. Clarify what you hear.</td>
<td>5. Maintain the person’s self-esteem.</td>
</tr>
<tr>
<td>6. Express appreciation for the effort.</td>
<td>6. Focus on <em>changeable</em> behavior.</td>
</tr>
<tr>
<td></td>
<td>7. Engage the person in developing solutions.</td>
</tr>
<tr>
<td></td>
<td>8. Express your confidence in the person.</td>
</tr>
</tbody>
</table>
THINK Intelligently About Emotions

- Distinguish between the person and his or her behavior.
- Ask questions to challenge your unrealistic negative thoughts.
- Notice which of your thoughts promote a pessimistic attitude, and change them so they encourage optimism.

FOSTER Emotional Intelligence in Others

- Model optimism for others, offering positive perspectives on issues.
- Foster a culture of civility and respect—say please, thank you, etc.
- Let others know that their work is meaningful and appreciated.

BEHAVE Wisely

- Practice active listening, and attend to nonverbal signals.
- Expand your emotional vocabulary in order to pinpoint exact feelings.
- Adapt your communication style to that of others.
- When you cannot change your circumstances, change yourself.
- Explore your problem-solving options creatively.
Qtech rec’vs issue, assigns a CAPA Lead.

CAPA Lead invites a team.

A quality problem is like an elephant.

Manufacturing is like an elephant.

Team
- Gemba
- Fish / 5Why

Person
- Write-up Problem Description

Team
- Root Cause & CounterM Plan

Submit for Approval
We create plans without problems. The other depts follow our plans.

We make tools and machines work. The other depts use our real-life genius applications to get good stuff to the customer.

We make these parts. Need I say more??

We keep customers happy. All the other depts follow our solutions to make customers happier and happier.

We produce the stuff. Engineers, Administration, technicians, shipping, etc., all support us.

We make the sale and run the business. Everyone else must line up with our world.
Working together, we can constantly surprise ourselves with strong ideas.

That’s the thing that makes our business strong.
A spreadsheet helps CAPA Teams spot **gaps** in their CAPA – to verify that:

1. The CAPA outlines the top RootCauses & potential RootCauses
2. All RootCauses have related observations in the Descript’n section
3. All RootCauses are appropriately addressed by Actions

### Some of the TTR 10457 corrective action efforts - for example only

<table>
<thead>
<tr>
<th>Investigation</th>
<th>Root Cause</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>A-011 rejected parts were witnessed outside the reject tote. The reject</td>
<td>Operator misrouted a part (likely). Raw part misrouted to next operation.</td>
<td>Cease rework. Don’t continue rework unless and until justification is made and approved by management.</td>
</tr>
<tr>
<td>tote was small and did not fit under the chute in a standard way.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There is currently no data collected on rejects from A-011 - no total</td>
<td>No continuous improvement effort has been ongoing -- the data that could establish WhyMade on rejects from A-011 is not available.</td>
<td>Start collecting data.</td>
</tr>
<tr>
<td>reject count, and no reject count broken down by station or code, to</td>
<td></td>
<td></td>
</tr>
<tr>
<td>facilitate the address over time of WhyMade root causes.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Part made it through the secondary sort inspection area. Secondary sort</td>
<td>Some Best Practice principles are not being implemented to their full extent.</td>
<td>?????.</td>
</tr>
<tr>
<td>inspector allowed part to escaped with missing bushing.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>There was a failure to apply the requirement that all repair and sort</td>
<td>Contributing: Rework is not a standardized, authorized process. No training or procedure for ongoing repairs to rework nonconforming height</td>
<td>Cease rework. Don’t continue rework unless and until there is a document and training, AND</td>
</tr>
<tr>
<td>activities must have a procedure -- rework was thought to be a temporary</td>
<td>adjuster link bushings.</td>
<td>justification is made and approved by management.</td>
</tr>
<tr>
<td>measure but now it’s been going on for (years?).</td>
<td></td>
<td></td>
</tr>
<tr>
<td>It’s not clear if rework is benefitting the plant: How was rework started?</td>
<td>The TriCon 13 policy of &quot;find one, fix one&quot; is interpreted at A-011 as &quot;one shift’s parts are removed from cell and fixed (reworked)&quot;. But while</td>
<td>Cease rework. Don’t continue rework unless and until justification is made and approved by management.</td>
</tr>
<tr>
<td>Was an assessment of risks and benefits ever done?</td>
<td>currently the totes are emptied at the end of each shift, in practice they are not always fixed immediately. Due to human resource constraints, the</td>
<td></td>
</tr>
<tr>
<td></td>
<td>rework generally builds up and is sorted as resources become available. Per Mike C there is currently allot of backup rework. Per Rand</td>
<td></td>
</tr>
<tr>
<td></td>
<td>10,000 parts (8500 in QA hold alone), mostly A and B links.</td>
<td></td>
</tr>
</tbody>
</table>
The four steps of a principled negotiation are:

1. Separate the people from the **problem**
2. Focus on **interests**, not positions
3. Invent **options** for mutual gain
4. Insist on using **objective criteria**
CAP-Doc – CAPA’s Continuous Improvement Cycle

Check, Act, Plan, Do … and Check Again

In CAPA: Plan the permanent CM (Countermeasure)

In CAPA: Implementing Countermeasures (Action Items)

Daily, hourly checks

In CAPA: Problem Description & Root Cause Analysis

START
1. What does CAPA stand for?  

Circle the best answer:
2. Successful CAPAs:
   a. Make our business stronger.
   b. Fix a problem permanently.
   c. Include a Gemba.
   d. All of the above.

3. The purpose of a Gemba is to:
   a. To find the Root Cause of the problem
   b. So we can fully define or describe the problem
   c. To contain the problem and prevent further escapes
   d. To compare my opinion with other departments
   e. To fulfill quality requirements

4. A Countermeasure Plan has Actions that must address:
   a. A Root Cause of the quality problem.
   b. All the Root Causes of the quality problem.
   c. The Description of the Problem.
   d. The Gemba.

5. Team success depends on:
   a. Good communication
   b. Creative approaches
   c. Open feedback
   d. Civility, respect, and optimism
   e. Negotiation
   f. All the above

6. True or False:  5Whys are fairly easy.

7. True or False:  Completing a 5P sheet is equal to announcing, “This problem won’t happen again.”
QUESTIONS?

1. What does CAPA stand for? ______________________________________________________________

Circle the best answer:

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Please take the Quiz and sign the Training Acknowledgement Report