Corrective Action
Preventative Action

Defining Alternatives to Training
As a Root Cause

Presentation Sponsors
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Background

- BA in Business from Baker College (Flint, MI)
- Significant Training in Lean, Six Sigma, Employee Development, Strategic Planning and Auditing
- Over 20 years in Quality
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  - Microelectronics for Medical and Health industry
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Successful implementation of CAPA is highly dependent upon understanding performance indicators and effectively using them to identify performance deficiencies.

When “training” is used as a default response in corrective actions, preventative actions and system audit responses, the opportunity to leverage CAPA for continuous improvement and strategic advantage is lost.
Today’s Focus

- We will review the many forms of Corrective and Preventative actions.
- We will then turn our attention to Root Cause Analysis with a focus on understanding the 6 phases of Performance.
- Taking away recognition that “training” is only one seventh of the performance indicator elements.
Agenda

- Corrective & Preventative Action Review
- Defining Performance Indicators
- Organizational Culture Impact
- Philosophy to Application
References

- “The New Economics” – Dr. Edward Deming
- “Let’s Talk Quality” – Phillip Crosby
- “Quality Planning and Analysis”, “Quality Control Handbook–6th Addition” – Juran
- “Implementing Six Sigma–2nd Addition” – Forrest Breyfogle
- “The Oz Principle”, “Journey to the Emerald City”– Craig Hickman, Tom Smith, Roger Connors
Respect to the pioneers....

- Crosby Stills & Nash
Respect to the pioneers....

- Crosby, Juran, Harrington, Deming.
Corrective & Preventative Actions

Review of methodologies
**CAPA Definition**

- *Improvement to an organization's processes taken to eliminate causes of non-conformities or other undesirable situations.*
  - Reactive – Corrective
  - Preemptive – Preventative
Over View of Types

- 4 Step– PDCA– *Deming–Shewart*
- 5 Step– DMAIC–
- 6 Step– Six Step –Several Versions.
- 8 Step– 8D – Eight Disciplines
PDCA
4 Step Process
Plan

- Establish the objectives and processes necessary to deliver results in accordance with the expected output (the target or goals).
- By establishing output expectations, the completeness and accuracy of the specification is also a part of the targeted improvement. When possible start on a small scale to test possible effects.
Do

- Implement the plan, execute the process, make the product. Collect data for charting and analysis in the following "CHECK" and "ACT" steps.
Check

- Study the actual results (measured and collected in "DO" above) and compare against the expected results (targets or goals from the "PLAN") to ascertain any differences.
- Charting data can make this much easier to see trends over several PDCA cycles and in order to convert the collected data into information. Information is what you need for the next step "ACT".
Act

- Request corrective actions on significant differences between actual and planned results. Analyze the differences to determine their root causes. Determine where to apply changes that will include improvement of the process or product.

- When a pass through these four steps does not result in the need to improve, the scope to which PDCA is applied may be refined to plan and improve with more detail in the next iteration of the cycle, or attention needs to be placed in a different stage of the process.
DMAIC

5 Step Process
Define

- Define the problem, the voice of the customer, and the project goals, specifically.
Measure

- Measure the key aspects of the current process and collect relevant data.
Analyze

- Analyze the data to investigate and verify cause-and-effect relationships. Determine what the relationships are, and attempt to ensure that all factors have been considered. Seek out root cause of the defect under investigation.
Improve

- Improve or optimize the current process based upon data analysis using techniques such as design of experiments, poka yoke or mistake proofing, and standard work to create a new, future state process. Set up pilot runs to establish process capability.
Control

- Control the future state process to ensure that any deviations from target are corrected before they result in defects. Implement control systems such as statistical process control, production boards, visual workplaces, and continuously monitor the process.
6 Step Process
Define

- Define the problem, non-conformance or potential issue.
Define and implement temporary countermeasures to contain the problem.
Root Cause

- Conduct analysis to determine the root cause of the problem.
Define and implement permanent countermeasure that will prevent re-occurrence.
Verify

- Analyze data to determine the effectiveness of the actions implemented.
Update

- Determine and update all procedures/processes and documentation to the improved method.
Eight Disciplines
8 Step Process
8D

1. Form Team
2. Define Problem
3. Implement Containment
4. Conduct Root Cause Analysis
5. Determine Countermeasures
6. Implement Countermeasure
7. Measure Effectiveness of Counter Measure
8. Implement New Control
1. Form Team

- D1: Use a Team: Establish a team of people with product/process knowledge.
2. Define Problem

- **D2: Define and describe the Problem:** Specify the problem by identifying in quantifiable terms the who, what, where, when, why, how, and how many (5W2H) for the problem.
- Of the team. The team needs to be formally thanked by the organization.
3. Implement Containment

- D3: Developing Interim Containment Plan
  Implement and verify Interim Actions: Define and implement containment actions to isolate the problem from any customer.
4. Conduct Root Cause Analysis

D4: Determine and Identify and Verify Root Causes and escape points: Identify all applicable causes that could explain why the problem has occurred. Also identify why the problem has not been noticed at the time it occurred. All causes shall be verified or proved, not determined by fuzzy brainstorming. One can use 5Whys or Ishikawa Diagram to map causes against effect/Problem identified.
5. Determine Countermeasures

- D5: Choose and verify Permanent Corrections (PCs) for Problem/Non Conformity: Through pre-production programs quantitatively confirm that the selected correction will resolve the problem for the customer.
6. Implement Countermeasures

- D6: Implement and validate PCAs: Define and Implement the best corrective actions.
7. Verify Effectiveness

- D7: Prevent recurrence/Corrective Actions: Modify the management systems, operation systems, practices, and procedures to prevent recurrence of this and all similar problems.
8. Congratulate Team

D8: Congratulate your Team: Recognize the collective efforts of the team. The team needs to be formally thanked by the organization.
Common Themes
Corrective And Preventative Action
Common

- **Planning Stage**
  - Teams, Problem Definition, Containment Activities

- **Root Cause Stage**
  - Arguably the single most important element of the problem solving process. Finding the root cause and directly applying actions to remedy.

- **Verification Stage**
  - Did we accomplish what we intended? Was the problem eliminated and prevented from reoccurring.
Common

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Root Cause Analysis

- Fault Tree
- Ishikawa
- 5 Why’s
- Variance Analysis
- Pareto Analysis
- FMEA
- M⁴E
Cause as a Human Element

- Human Error: “To err is Human”
- An inappropriate or undesirable human decision or behavior that reduces, or has the potential for reducing, effectiveness, safety, or system performance.
  - Studies on Human Error have concluded four main categories.
    - Omission – Didn’t do it, on purpose or accident.
    - Commission – Did it incorrectly
    - Sequence – Did it in the wrong order
    - Timing/Rate – Did it at the wrong time or wrong speed
Performance Indicators
Performance

Desired Performance – Actual Performance = Need

Let’s Define The “Need”
TRAINING

EDUCATION

DEVELOPMENT
TRAINING
Today

EDUCATION
Future

DEVELOPMENT
Tomorrow
Job Performance

- Incentives
- Capacity
- Feedback
- Measurement
- Knowledge and Skills
- Standards
- Conditions
Job Performance

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- Capacity
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- Measurement
- Knowledge and Skills
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- Conditions

Only one of these 7 is effected by Training
The individuals Knowledge and Skills are provided by training.
Incentives

**Definition**
- any factor (financial or non-financial) that enables or motivates a particular course of action, or counts as a reason for preferring one choice to the alternatives

**Key Questions:**
- Is there incentive for Performing well?
- Is “punishment for good performance” prevented?
- Are all available incentives being used?
Capacity

- **Definition**: an individual's mental or physical ability: aptitude, skill
- the faculty or potential for treating, experiencing, or appreciating

- **Key Questions**:
  - Does the employee have the mental capacity for the position?
  - Does the employee have the physical capacity for the position?
  - Do they have the prerequisites for training?
Feedback

- **Definition**
  - the information about the initial event that is the basis for subsequent modification of the event

- **Key Questions:**
  - Are the employees informed about how they are doing?
  - Is feedback tied to performance and not personality?
  - Is feedback given by someone who matters?
Measurement

- **Definition**
  - is the process or the result of determining the ratio of a physical quantity, such as a length, time, temperature etc., to a unit of measurement, such as the meter, second or degree Celsius.

- **Key Questions:**
  - Is Performance Measured?
  - Are Measurement based on Task Performance?
  - Are Measurements Objective?
Knowledge and Skills

- **Definition**
  - A skill, knowledge or ability is something a worker knows or can do that enables the worker to successfully perform the duties of the job.

- **Key Questions:**
  - Did they ever perform the task property?
  - Is Training Provided?
  - Could they perform the task correctly if their life depended on it?
Standards

- **Definition**
  - Any norm, convention or requirement

- **Key Questions:**
  - Do they know what to do?
  - Do they know when to do it?
  - Do their supervisors agree on what and when?
Definition
- a particular mode of being of a person or thing; existing state; situation with respect to circumstances

Key Questions:
- Is enough time available?
- Are proper tools and equipment available?
- Are the procedures clear and workable?
What are your Job Performance Indicators?
“NEED” is defined as Actual Performance minus Desired Performance.
Performance is impacted by several variables.
Training specifically targets the Knowledge & Skills of the learners.
It is easy to go below the line and “Blame” training for poor performance until you know and understand the elements of performance.
Organizational Culture
How the culture impacts the Performance
Culture

- Intentional or not, there is a culture in your organization.
- If you are not “Actively” & “Knowingly” driving a specific culture, the culture will drive your organization and business.
- A “results” oriented organization with an emphasis on Personal Accountability as a positive cultural aspect will be able to apply and benefit from the Human Performance indicators we described.
When working on continuous improvement and performance improvements through problem solving activities, understanding and addressing ALL the elements of human performance will drive more effective and efficient problem solving activities.

“...most troubles and most possibilities for improvement add up to proportions something like this:

* – 94% belong to the system (the responsibility of management)

* – 6% are attributable to special causes.

Deming
The MME Culture

- 2 year Journey
- “Journey to the Emerald City”
- The “Results Pyramid”
- Above and Below the line.
- Culture of Accountability
From philosophy to application
Can I Still use Training??

- When Knowledge and Skills are absent, training is still an appropriate response.
- Many Organizational Standards (ISO, GMP, TS, etc) require Competency and Training as part of the Quality Management System.
  - Often also require verification that training is effective.
You can.....

- Use your current systems and methodologies, but when a root cause of “training” comes across your desk, What can you do?
  - Make a Check List as part of your Root Cause Analysis System.
  - Challenge yourselves and others to truly find the Cause, without the true root cause, all actions are simple busy work or guesses.
  - Continuously learn and use your “experiences” to create new beliefs in others.
  - Find one thing, work on, make it better, do not allow the “February Fall” to happen.
Questions?

Follow up through my contact information
A special thanks to....

Twin Cities Medical Valley

Minnesota

Section 1203

MME

BE THE MATCH

YOU!