February 20, 1962 - Friendship 7 – Hooray John Glenn!

Atlas 6 – Project Mercury

USA First Manned Orbital Mission

Grand Central Station NYC

New Rules of CAPA

ASQ North Jersey General Meeting

February 16, 2011

The New Rules of CAPA (Corrective Action/Preventive Action)

Carl Perini MS, ASQ CPGP CQA CSSBB
International Specialty Products, Wayne NJ
ASQ North Jersey Education Committee

The New Rules of CAPA

Distinction:

- Corrective actions are the actions that are to be taken to address the root cause of a detected nonconformance and prevent the detected nonconformance from recurring.

- Preventive actions are the actions that are to be taken to address the root cause of a potential nonconformance and prevent the potential nonconformance from occurring.

The New Rules of CAPA

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The New Rules of CAPA

Distinction:

- Corrective actions are the actions that are to be taken to address the root cause of a detected nonconformance and prevent the detected nonconformance from recurring – i.e. permanent corrective action

- Preventive actions are the actions that are to be taken to address the root cause of a potential nonconformance and prevent the potential nonconformance from occurring – i.e. permanent preventive action

The New Rules of CAPA
QMS Requirements

ISO 9001:2000

- 8.5.2.f Corrective action

  A documented procedure shall be established to define requirements for reviewing the corrective action taken.

The New Rules of CAPA QMS Requirements

ISO 9001:2000

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ISO 9001:2008

- 8.5.2.f Corrective action

  A documented procedure shall be established to define requirements for reviewing the effectiveness of the corrective action taken.

The New Rules of CAPA QMS Requirements

ISO 9001:2000

- 8.5.3.e Preventive action

  A documented procedure shall be established to define requirements for reviewing the preventive action taken.

ISO 9001:2008

- 8.5.3.e Preventive action

  A documented procedure shall be established to define requirements for reviewing the effectiveness of the preventive action taken.

The New Rules of CAPA

- ISO/TS 16949:2009 - QMS - automotive organizations
  8.5.2 Corrective Action & 8.5.3 Preventive Action per ISO 9001:2008

- RC 14001:2008 (ISO 14001) Environmental Mgmt Systems & Responsible Care
  4.5.3.e Review the effectiveness of corrective actions & preventive actions taken.

- ISO/IEC 17025:2005 Testing and Calibration Laboratories
  4.11.4 Ensure that the corrective actions taken have been effective.
  4.12.2 Preventive actions - include controls to ensure that they are effective.

- HACCP CODEX - General Principles of Food Hygiene
  5.6 Management should take appropriate preventive & corrective action.
  10. Corrective actions must be developed for each CCP.

The New Rules of CAPA

- ICH Q10 2008 – Pharmaceutical Quality Systems –
3.2.2 The pharmaceutical company should have a system for implementing corrective actions and preventive actions.

- IPEC – PQG GMP Guide 2006 - 8.5.2 Corrective Action / 8.5.3 Preventive Action

The excipient manufacturer should establish, document and maintain procedures for: ensuring that corrective actions / preventive are implemented and effective.

- 21 CFR Part 820 – Sec 100.a.4 - Corrective and preventive action
Verifying or validating the corrective action to ensure that such action is effective and does not adversely effect the finished product.

Nonconformance structure
Potential Nonconformance structure

Suggested four part structure :

1. ***Nonconforming Condition/Potential Nonconforming Condition:***

   What's wrong? - Details the operation or part of the system that has failed or has potential to fail

2. ***Requirement:***

   Why is it wrong? - Statement of the requirement that was not satisfied or has potential not to be satisfied (i.e. internal, standard, customer, legal)

3. ***Objective Evidence:***

   Proof of what's wrong - Identifies in a traceable manner the specific observed instance(s) (record, documents, equipment) of nonconformance or potential nonconformance

Nonconformance structure
Potential Nonconformance structure

Suggested fourth part:

4. ***Objective statement:***

   So what? – Provides reason nonconformity or potential nonconformity is of concern to help understand its importance.

   Also explains the value of the requested action:
   NC/potential-NC can lead to unhappy customer or product return – gets management attention.

Example - four part nonconformance

1. ***Nonconforming condition requiring corrective action:***

   New QC staff member issued test results without required proof of training effectiveness.

2. ***Requirement:***

   Section 3.6 of ‘Training’ Procedure states that training effectiveness for new hires is confirmed by having their results signed by the supervisor who did the training when the test is carried out for the first time.

3. ***Objective Evidence:***

   Certificate of analysis no. 072-2011 was first time new QC staff member performed GC test. These results were issued by the new QC staff member but were not signed by the supervisor who performed the training.

Nonconformance example – part four

4. ***Objective statement:***

   This could lead to customers receiving nonconforming product due to erroneous results reported on the COA due to incomplete training of the QC analyst.

   Customer receipt and/or use of nonconforming product could lead to complaint, loss of future sales and/or potential litigation.

Example - four part potential NC

1. ***Potential nonconforming condition requiring preventive action:***

   A new device has two push-buttons where a spring must be put under each button. If assembler were to forget to put the spring under the button, then a defect would occur.

2. ***Requirement:***

   Engineering drawing R1-104264 and accompanying BOM show that finished assembly contains a spring (P/N 992-8) under each of two buttons (P/N 112-1). Unit function requires actuation of both buttons. Buttons will not actuate if spring is missing.

3. ***Objective Evidence:***

   There is no mistake-proof mechanism in place that will ensure operators will assemble all units so that there is always a spring under each button.

Potential NC example – part four

4. ***Objective statement:***

   This could lead to customers receiving nonconforming assemblies containing buttons that will not actuate.

   Customer receipt and/or attempted use of nonconforming assemblies could lead to complaint, loss of future sales and/or potential litigation.

CAPA response steps

There should be four basic steps in your CAPA response process:

1. Planning
   - Performed by the area where nonconformance or potential nonconformance exists
   - The output is a plan of action that is submitted to issuer for review and approval
2. Implementation
   - Performed by the area where NC/potential-NC exists
   - The output is evidence of implementation
3. Verification
   - Performed by the area and then by issuer
4. Closure
   - Ensures continual improvement of the effectiveness the QMS

Step 1. CAPA planning

- Plan should include the following:
  1. Traceability to the relevant NC/potential-NC
  2. Identification of the CAPA owner
  3. Target completion dates
  4. A description of containment action taken
  5. A **detailed** root cause analysis using 5 why or other problem solving methodology
  6. A description of the actions that are to be taken to permanently remove the root cause

Step 1. CAPA planning

- You should ensure that the CAPA plan include:
  - Clear reference to the systems/processes/activities being changed
  - A description of verification methods that you are going to use
  - Metrics by which effectiveness will be gauged upon completion
  - Details of the investigation that you have conducted to ensure that the same issues do not exist in other areas of the organization
  - Approval (at each required level of management/ownership)

Step 1. CAPA planning

- Containment and CAPA are different steps
  - they should not be confused in your plan

- Containment actions:
  -short term steps taken to control and mitigate the impact of NC/potential-NC
  -stop the problem from getting worse
  -protect your internal/external customer's operation

- Containment actions include:
  -correction
  -immediate corrective/preventive action
  -immediate communication
  - verification that the NC/potential-NC situation does not further degrade

Step 1. CAPA planning

- Observation: water spreading on floor (NC)
- Containment / quick response:

Step 1. CAPA planning

- Observation: water spreading on floor (NC)
- Containment / quick response: close valve

Step 1. CAPA planning

- Observation: water spreading on floor (NC)
- Containment / quick response: close valve
- Investigate direct cause: damaged hose
- Temporary correction:

Step 1. CAPA planning

- Observation: water spreading on floor (NC)
- Containment / quick response: close valve
- Investigate direct cause: damaged hose
- Temporary correction: tape hose

Step 1. CAPA planning

- Initial corrective action: install flex SS hose
- Confirm root cause:

Step 1. CAPA planning

- Initial corrective action: install flex SS hose
- Confirm root cause: lack of inspection

Step 1. CAPA planning

- Initial corrective action: install flex SS hose
- Confirm root cause: lack of inspection
- Permanent corrective action: add recurring inspection
  revise preventive maintenance program
  QMS upgrade

Step 1. CAPA planning

Dandelion

Taraxacum officinale

Step 1. CAPA planning

- Many direct causes – too superficial
- Common tool to reach root cause: 5 Why’s

Five Whys Example

Question	Answer
1. Why did the machine stop?	It blew a fuse.
2. Why did the fuse blow?	The fuse was the wrong size.
3. Why was the wrong size in the fuse box?	The engineer put it there.
4. Why did the engineer do that?	The supply room issued the wrong size fuse.
5. Why?	The stock bin was mislabeled.

Step 2. CAPA implementation

- Implement the plan and develop records that demonstrate that:
  - Described actions have been taken (i.e. records, charts, diagrams)
  - Defined time scales have been met
  - Verification of Effectiveness has been completed
  - Required approvals have been obtained
  - The corrective action/preventive action is efficient in meeting your overall quality objectives and targets.

Step 3. Verification of CAPA

The area and then the issuer should:

- Review the root cause analysis
- Review the effectiveness of changes made to the organization's system, processes and activities
- Evaluate objective evidence to support implementation
- Sample the subject and other areas to ensure effectiveness of changes
- Perform any identified follow-up
- Document the above verification and provide conclusion

Step 4. CAPA Closure

Ensure continual improvement of the effectiveness the QMS

Results become input to:

- management review
- benchmarking
- improvement teams (MRB, six sigma, Quality Circle…)
- risk management (FMEA)
- lean initiatives

Helpful Hints

- Most people weren't hired to do CAPA
- Not part of typical job description
- Takes time away from core responsibilities

- Therefore use request sheet (CAR / PAR)
- Provides simple organization
- Prompts response
- Enables tracking
- Includes milestones, dates, and approvals

Helpful Hints

- Objective evidence : don’t place blame & don’t use names

- Effectiveness checks: keep site of original finding confidential

- Entire process: quality staff on-going support & clarification
  teamwork versus over-the-wall

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New York Yankees Active Roster

#	Pitchers	B/T	Ht	Wt	DOB
	Dellin Betances	R-R	6'8"	245	Mar 23, 1988
66	Andrew Brackman	R-R	6'10"	240	Dec 4, 1985
34	A.J. Burnett	R-R	6'4"	230	Jan 3, 1977
62	Joba Chamberlain	R-R	6'2"	230	Sep 23, 1985
	Pedro Feliciano	L-L	5'10"	190	Aug 25, 1976
	Robert Fish	L-L	6'3"	225	Jan 19, 1988
	Steve Garrison	S-L	6'1"	185	Sep 12, 1986
65	Phil Hughes	R-R	6'5"	240	Jun 24, 1986
48	Boone Logan	R-L	6'5"	215	Aug 13, 1984
43	Damaso Marte	L-L	6'2"	215	Feb 14, 1975
45	Sergio Mitre	R-R	6'3"	225	Feb 16, 1981
74	Hector Noesi	R-R	6'2"	175	Jan 26, 1987
47	Ivan Nova	R-R	6'4"	210	Jan 12, 1987
	Ryan Pope	R-R	6'3"	190	May 21, 1986
42	Mariano Rivera	R-R	6'2"	185	Nov 29, 1969
30	David Robertson	R-R	5'11"	190	Apr 9, 1985
52	CC Sabathia	L-L	6'7"	290	Jul 21, 1980
64	Romulo Sanchez	R-R	6'5"	260	Apr 28, 1984
	Brian Schlitter	R-R	6'5"	235	Dec 21, 1985
	Rafael Soriano	R-R	6'1"	220	Dec 19, 1979
	Daniel Turpen	R-R	6'4"	230	Aug 17, 1986
#	Catchers	B/T	Ht	Wt	DOB
29	Francisco Cervelli	R-R	6'1"	210	Mar 6, 1986
	Russell Martin	R-R	5'10"	230	Feb 15, 1983
20	Jorge Posada	S-R	6'2"	215	Aug 17, 1971

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#	Catchers	B/T	Ht	Wt	DOB
29	Francisco Cervelli	R-R	6'1"	210	Mar 6, 1986
	Russell Martin	R-R	5'10"	230	Feb 15, 1983
20	Jorge Posada	S-R	6'2"	215	Aug 17, 1971
#	Infielders	B/T	Ht	Wt	DOB
24	Robinson Cano	L-R	6'0"	205	Oct 22, 1982
76	Reegie Corona	S-R	5'11"	160	Nov 7, 1986
2	Derek Jeter	R-R	6'3"	195	Jun 26, 1974
	Brandon Laird	R-R	6'1"	215	Sep 11, 1987
12	Eduardo Nunez	R-R	6'0"	155	Jun 15, 1987
19	Ramiro Pena	S-R	5'11"	165	Jul 18, 1985
13	Alex Rodriguez	R-R	6'3"	230	Jul 27, 1975
25	Mark Teixeira	S-R	6'3"	220	Apr 11, 1980
#	Outfielders	B/T	Ht	Wt	DOB
22	Colin Curtis	L-L	6'1"	200	Feb 1, 1985
11	Brett Gardner	L-L	5'10"	185	Aug 24, 1983
27	Greg Golson	R-R	6'0"	190	Sep 17, 1985
14	Curtis Granderson	L-R	6'1"	185	Mar 16, 1981
	Melky Mesa	R-R	6'1"	165	Jan 31, 1987
	Jordan Parraz	R-R	6'3"	215	Oct 8, 1984
60	Kevin Russo	R-R	5'11"	190	Jul 8, 1984
33	Nick Swisher	S-L	5'11"	210	Nov 25, 1980


pepsi
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at&t
DELTA
CASIO
HESS
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Canon

Summary

- State the NC/potential-NC clearly
- Investigation to identify root cause
- Develop an action plan (Plan)
- Implement plan (Do)
- Verify implementation (Check)
- Verify effectiveness (Check)
- Perform any required follow-up (Act)
- Closure - QMS effectiveness

Further reading

- *The Corrective Action Handbook*
- *The Preventive Action Handbook*

by Denise Robitaille

The New Rules of CAPA (Corrective Action/Preventive Action)

Q & A