

CORRECTIVE AND PREVENTIVE ACTIONS – CAPA



**Orange Empire Section 0701
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February 12, 2002

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PROGRAM

WHY DO IT?

DEFINITIONS

RELATIONSHIPS

TYPICAL SOURCES

TYPICAL PROBLEMS

TYPICAL REASONS

SOLUTIONS

TAKE HOME IDEAS

WHY DO IT?

- FDA Regulatory requirement - § 820.100
- Current FDA inspections give priority to CAPA
- ISO 9001 Standards (1994) – § 4.14
- Makes business sense, but do it smart
- **DO IT FOR EXCELLENCE**

DEFINITIONS

RELATIONSHIPS

TYPICAL SOURCES

- Process analysis, scrap and yield report, etc.
- Inspection data: incoming, in-process, finished product
- Complaints: customer, employees, Med Watch, field reports, etc.
- Audits: internal, third-party
- FDA 483s, if any
- Other reports about non-conformance

TYPICAL PROBLEMS

- Warning letter summary:
 - Procedure missing/inadequate
 - Lack of investigative procedure/documentation
 - Preventive actions not taken
- Procedure not followed
- Too many “open” files
- No real progress
- No prioritization
- Inadequate/nonexistent root cause analysis
- Sometimes, the assigned cause has little to do with the nonconformance, hence ineffective solution
- Trend analysis not done
- Verification/validation is not done, or is weak
- CAPA coordinator not supported

TYPICAL REASONS

- Lack of support from the top
- Lack of “shared ownership” of CAPA
- Risk analysis missing or inadequate – another “denial”
- Lack of prioritization
- Unimportant stuff ties up resources and dilutes effort
- No real trending
- Denial, unwillingness to look at product and quality issues
- Preventive actions missing: identify and eliminate causes of *potential* nonconformance or quality problem
- There is usually no pay-off for the employee working on CAPA.
- Sometimes used to ‘beat-up’ employees. Discourages cooperation between employees and groups
- Reason for too many “open” files: combination of too many files (lack of priority), lack of commitment, hence lack of participation. CAPA coordinator gets “stuck” with the problem

SOLUTIONS

- Management commitment from the top
- Leadership: “shared ownership” of CAPA
- Leadership: Willingness to look at product and quality issues
- Perform risk analysis and prioritize
- Work on MDR, if any, and other higher risk items first
- Trending
- Preventive actions: identify and eliminate causes of *potential* nonconformance or quality problem. Apply risk analysis techniques
- Recognize employees working on CAPA.
- Encourage cooperation between employees and groups
- Track CAPA items and review them often (every two weeks)
- Provide reasonable goals such as close 75% of files within 90 days and others within 180 days
- Give plenty of “atta-boys”
- Reward good behavior and results