

# Managing Supplier Corrective Action



Presented to the  
National Association of Purchasing  
Managers  
and the  
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November 8<sup>th</sup>, 2006  
by  
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## Managing Supplier Corrective Action




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**What  
you  
will  
take  
away:**


### Managing Supplier Corrective Action

- Why an Effective Supplier Corrective Action Program Matters
- Corrective Action Terms and Definitions
- Corrective Action in Standards and Regulations
- Classic Corrective Action Approaches
- Recommended Supplier Corrective Action Program Elements
- Tips, Tricks and Techniques for Effective Supplier Corrective Action Programs
- Possible Supplier Corrective Action Program Metrics
- Why Supplier Corrective Action Programs Fail
- Assuring Long Term Supplier Corrective Action Program Effectiveness
- Corrective Action References and Some Web Links to Nifty Corrective Action Tools
- Some Tools You can start Using Today

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**Why an  
Effective  
Supplier  
Corrective  
Action  
Program  
Matters:**


### Managing Supplier Corrective Action

- It Makes **Good Business Sense** to:
  - correct supplier-related problems that cause waste
  - make sure wasteful supplier-related problems don't happen again
  - prevent certain potential supplier-related problems from ever happening
  - have an effective program to assure this

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**Why an Effective Supplier Corrective Action Program Matters (continued):**

### Managing Supplier Corrective Action

- Many of your organization's Customers Require or Prefer Quality Management System Registration
  - *Most current Quality Management System Standards Require Corrective Action and Recurrence Control or Preventive Action*
  - *Most current Quality Management System Standards Imply that Supplier Quality Must Be Similarly Managed*

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**Why an Effective Supplier Corrective Action Program Matters (continued):**

### Managing Supplier Corrective Action

- From ISO 9001 and ISO 13485:
  - *7.4.2 Purchasing information*  
*In the Purchasing document, clearly describe the requirements for the purchased product [or service].*  
*When applicable, include in the purchase order*
    - c) *quality management system requirements.*

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Terms and Definitions:

### Managing Supplier Corrective Action

- ***The most comprehensive acronym for Corrective Action and Preventive Action is “CAPA”:***
  - Corrective Action & Preventive Action
  - OR
  - Corrective And Preventive Action

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Terms and Definitions  
(continued):

### Managing Supplier Corrective Action

- ***The most frequently used acronym for Supplier Corrective Action Acronym is “SCAR”:***
  - Supplier Corrective Action Request
  - OR
  - Supplier Corrective Action Response
  - OR
  - Supplier Corrective Action Report

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## Managing Supplier Corrective Action




- **From ISO 9000:**
  - *Nonconformity, Discrepancy, Deficiency or Finding:*
    - *Failure to meet or fulfill a specified requirement*
    - *A **process** that does not conform to a system requirement*

Terms and Definitions (continued):

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## Managing Supplier Corrective Action


- **From ISO 9000:**
  - *Nonconformance or Defect:*
    - *A character (characteristic) or dimension of a **product or material** that does not conform to or fulfill a specified requirement*

Terms and Definitions (continued):

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Terms and Definitions (continued):


## Managing Supplier Corrective Action

- **From ISO 9000:**
  - *Nonconforming or Defective Product or Material, a Defective:*
    - *A product or material that has one or more Nonconformances or Defects associated with it*

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Terms and Definitions (continued):




## Effective Corrective and Preventive Action (Corrective Action) Systems

- **From ISO 9000:**
  - *Correction or Remedial Action:*
    - *Disposition to Perform Rework or an Adjustment to deal with an existing nonconforming condition or nonconformity*

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Terms and Definitions (continued):




### Effective Corrective and Preventive Action (Corrective Action) Systems

- **From ISO 9000:**
  - *Corrective Action or Recurrence Control:*
    - *Action taken or plan implemented to eliminate the cause of an existing nonconformity so as to prevent recurrence*

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Terms and Definitions (continued):




### Managing Supplier Corrective Action

- **From ISO 9000:**
  - *Preventive (adjective) Action or Preventative (noun)*
    - *Action taken or plan implemented to eliminate the cause of a potential nonconformity, defect or other undesirable situation so as to prevent occurrence*

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**Corrective  
Action in  
Standards  
and  
Regulations**




## Managing Supplier Corrective Action

- ISO 9001:2000 – General
- AS 9100 or AS-EN-JIQS 9100 and FAA FAR Title 14 Part 21 – Aerospace
- ISO 13485, GMP/HACCP, cGMP, 21 CFR 211, 21 CFR 820 – Foods, Drugs, Medical Devices
- QS 9000, ISO TS2 (TS 16949:2002) and TE 9000 – Automotive
- TL 9000 - Telecommunications

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**Corrective  
Action in  
Standards  
and  
Regulations:**  
  
ISO  
9001:2000  
  
General




## Managing Supplier Corrective Action

- 5.6.2 Management Review Inputs:
  - "Management review inputs shall include:
    - Preventive Action Status
    - Corrective Action Status"
- 8.2.2 Internal Audits:
  - "When deficiencies arise, the responsible management shall take timely corrective action.
  - Audit follow-up activities include:
    - The verification of corrective actions taken."
- 8.2.3 Process Measuring and Monitoring:
  - "As appropriate, take corrective action to ensure product conformity."

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**Corrective  
Action in  
Standards  
and  
Regulations:**  
ISO  
9001:2000  
General  
(continued)

## Managing Supplier Corrective Action

- **8.3 Nonconforming Product Control:**
  - “If the nonconformity is discovered after the product has been delivered or put into use, the organization shall take appropriate corrective steps.”
- **8.4 Data Analysis:**
  - “Additionally, data analysis reveals information about:
    - Preventive action opportunities.”
- **8.5.1 Continuous Improvement:**
  - “Continually improve the Quality Management System by utilizing:
    - Corrective Actions
    - Preventive Actions”

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**Corrective  
Action in  
Standards  
and  
Regulations:**  
ISO  
9001:2000  
General  
(continued)

## Effective Corrective and Preventive Action (Corrective Action) Systems

- **8.5.2 Corrective Action:**
  - “Take Corrective Action to stop the recurrence of the nonconformities.
  - Take Corrective Actions that are appropriate to the nonconformity.
  - The corrective action procedure includes:
    - Reviewing nonconformities and customer complaints
    - Determining the causes for nonconformities
    - Determining the need for corrective actions
    - Identifying the appropriate corrective action
    - Implementing the corrective action
    - Keeping records of corrective action results
    - Reviewing corrective action taken.”

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**Corrective Action in Standards and Regulations:**  
ISO 9001:2000  
General (continued)




## Effective Corrective and Preventive Action (Corrective Action) Systems

- 8.5.3 Preventive Action:
  - “Take Preventive Actions to address potential nonconformities. Actions are appropriate to the size of the potential problem.
  - Have a preventive action procedure that includes:
    - Identifying potential nonconformities
    - Evaluating the need for preventive actions
    - Determining preventive actions
    - Implementing preventive actions
    - Keeping records of preventive action results
    - Reviewing preventive actions taken.”

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**Corrective Action in Standards and Regulations:**  
AS9100  
Aerospace




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- 8.5.2 g & h Corrective Action
  - “A documented procedure shall be established to define requirements for:
    - flow down of the corrective action requirement to a supplier, when it is determined that the supplier is responsible for the root cause, and
    - specific actions where timely and/or effective corrective actions are not achieved.

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Corrective Action in Standards and Regulations:  
**ISO 13485**  
QMS for Medical Devices

## Managing Supplier Corrective Action




### ■ 8.1 Remedial Requirements

- **Perform remedial processes**
  - Plan remedial processes.
  - Plan how remedial processes will be used to assure conformity.
  - Plan how remedial processes will be used to maintain system.
- **Implement remedial processes.**
  - Use remedial processes to demonstrate conformance.
  - Use remedial processes to maintain your quality system.

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Corrective Action in Standards and Regulations:  
**ISO 13485**  
QMS for Medical Devices  
(continued)

## Managing Supplier Corrective Action




### ■ 8.5 Take required remedial actions

- 8.5.1 Maintain your quality management system.
  - Use audits to help maintain the effectiveness of system.
  - Use quality data to help maintain system effectiveness.
  - Use quality policy to help maintain system effectiveness.
  - Use quality objectives to help maintain system effectiveness.
  - Use management reviews to help maintain system effectiveness.
  - Use **corrective actions** to help maintain system effectiveness.
  - Use **preventive actions** to help maintain system effectiveness.

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## Managing Supplier Corrective Action

■ **Sec. 211.192 Production record review.**




- All drug product production and control records, including those for packaging and labeling, shall be reviewed and approved by the quality control unit to **determine compliance** with all established, approved written procedures before a batch is released or distributed.
- Any **unexplained discrepancy** (including a percentage of theoretical yield exceeding the maximum or minimum percentages established in master production and control records) or the failure of a batch or any of its components to meet any of its specifications **shall be thoroughly investigated**, whether or not the batch has already been distributed.
- The **investigation shall extend to other batches** of the same drug product and other drug products that may have been associated with the specific failure or discrepancy.
- A **written record of the investigation** shall be made and shall include the **conclusions and followup**.

**Standards and Regulations:**  
**21 CFR 211**  
**Pharmaceuticals (cGMP)**

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## Managing Supplier Corrective Action

■ **Sec. 211.198 Complaint files.**




- (2) Where an investigation under 211.192 is conducted, the written record shall include the findings of the investigation and followup. The record or copy of the record of the investigation shall be maintained at the establishment where the investigation occurred in accordance with 211.180(c).
- (3) Where an investigation under 211.192 is not conducted, the written record shall include the reason that an investigation was found not to be necessary and the name of the responsible person making such a determination.

**Standards and Regulations:**  
**21 CFR 211**  
**Pharmaceuticals (cGMP)**

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**Standards and Regulations:**  
**21 CFR 820**  
**Medical Devices (GMP)**




## Managing Supplier Corrective Action

- **PART 820 -- QUALITY SYSTEM REGULATION**
  - Subpart J--Corrective and Preventive Action
  - Sec. 820.100 Corrective and preventive action.
    - (a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements [noted on the next slide]
    - (b) All activities required under this section, and their results, shall be documented.

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**Standards and Regulations:**  
**21 CFR 820**  
**Medical Devices (GMP)**




## Managing Supplier Corrective Action

- Sec. 820.100 (a) Corrective and preventive action.  
The procedures shall include requirements for:
  - (1) **Analyzing** processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;
  - (2) **Investigating the cause** of nonconformities relating to product, processes, and the quality system;
  - (3) **Identifying the action(s) needed to correct and prevent recurrence** of nonconforming product and other quality problems;
  - (4) Verifying or validating the corrective and preventive action to **ensure that such action is effective** and does not adversely affect the finished device;
  - (5) Implementing and **recording changes** in methods and procedures needed to correct and prevent identified quality problems;
  - (6) Ensuring that **information** related to quality problems or nonconforming product **is disseminated** to those directly responsible for assuring the quality of such product or the prevention of such problems; and
  - (7) Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for **management review**.

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## Managing Supplier Corrective Action

- **QS 9000 Corrective Action Requirements:**
  - Identical to ISO 9001:2000
- **TL 9000 Corrective Action Requirements:**
  - Identical to ISO 9001:2000 PLUS
  - Includes additional Industry Standard Measurement Reporting Requirements through the QuEST Forum at University of Texas at Dallas

**Standards and Regulations:**




**QS 9000**

**Automotive And**

**TL 9000**

**Telecommunications**

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## Managing Supplier Corrective Action

### 5 WHY Approach

- **Root Cause Analysis Method**
- **Popularized in association with the Toyota Production System (1970's)**
  - **Why did THIS happen?**
    - **Why did THAT happen?**
      - **Why did THAT happen?**
        - **Why did THAT happen?**
        - **And.... Why did THAT happen?**

**Classic Corrective Action Approaches:**

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**Classic Supplier Corrective Action Program Approaches:**

## Managing Supplier Corrective Action




### 8-D (8 Disciplines) Approach

- **Ford Motor Company “TOPS” initiative (Team Oriented Problem Solving)**
- **D-1: Use a Team Approach**
- **D-2: Describe the Problem**
- **D-3: Implement and Verify Interim Containment Measures**
- **D-4: Define and Verify Root Causes**
- **D-5: Verify the Corrective Action(s)**
- **D-6: Implement Permanent Corrective Actions**
- **D-7: Prevent Problem Recurrence**
- **D-8: Congratulate the Team**

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**Recommended Supplier Corrective Action Program Elements:**

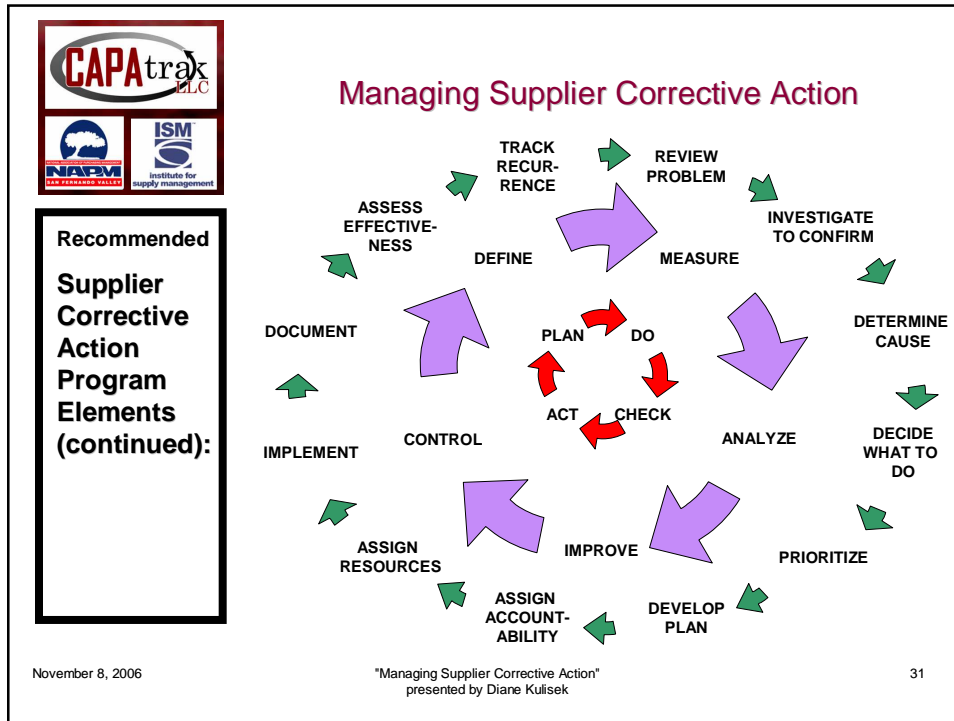
## Managing Supplier Corrective Action

1. **REVIEW nonconformities and concerns about potential nonconformities**
2. **INVESTIGATE / EVALUATE to confirm**
3. **DETERMINE CAUSES**
4. **DECIDE whether or not to take further action**
5. **SET PRIORITY and timeline for taking action**
6. **Identify the appropriate action and DEVELOP A PLAN**
7. **ASSIGN ACCOUNTABILITY and PROVIDE RESOURCES for plan implementation**
8. **IMPLEMENT the plan**
9. **DOCUMENT the results**
10. **Review results to ASSESS EFFECTIVENESS**
11. **TRACK results to ASSESS RECURRENCE**


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- 
- Managing Supplier Corrective Action**
- Tips, Tricks and Techniques for Effective Supplier Corrective Action Programs:
- **Make sure the people with the authority to establish priority, assign accountability and allocate resources participate in a Supplier Corrective Action review meeting**
  - **Involve the top/senior management, at first.**
    - As significance of issues declines or workforce empowerment increases, reduce organizational levels of participants.
  - **Meet weekly, at first.**
    - As number of problems to review declines reduce meeting frequency.
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**Tips, Tricks and Techniques for Effective Supplier Corrective Action Programs:**

### Managing Supplier Corrective Action

- Start with a review of the problems with the greatest financial impact on the organization and the greatest potential for success in resolving, usually in this order:
  - Supplier Service or Material Issues
  - Supplier Audit Findings and Observations
  - Supplier Process Capability Issues
  - Purchased Product Design/Specification Issues
- Obtain financial information about each problem from the Accounting Department, whenever possible.
- Group problems whenever possible (i.e. identify “generic” problems)

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**Tips, Tricks and Techniques for Effective Supplier Corrective Action Programs:**

### Managing Supplier Corrective Action

- If there is an unmanageable backlog, close out as many as can be justified due to “cold trails” (passage of time)
  - Rule of thumb: six months after problem detection or report is usually too long to wait before starting a Corrective Action effort
  - NOTE: this does NOT apply to regulatory violations
- Utilize an automated tracking system
  - Be sure that the system has been validated for 21 CFR Part 11 compliance, if necessary
  - Enable Suppliers and/or Buyers to enter the first data about the problem into the tracking system
  - Tap supplier audit observations and trend analyses for preventive actions.
- TRAIN TRAIN TRAIN TRAIN TRAIN

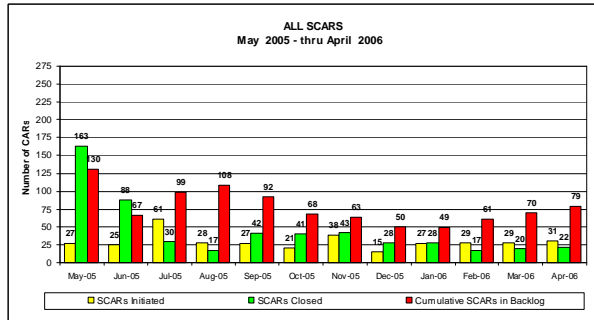
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Examples of Supplier Corrective Action Program Metrics:

## Managing Supplier Corrective Action

### Supplier Corrective Action Requests Initiated, Closed and in Backlog over Time – 12 Months Rolling



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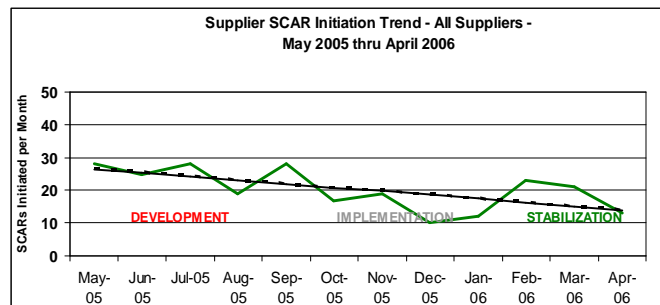
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Examples of Supplier Corrective Action Program Metrics (continued):

## Managing Supplier Corrective Action

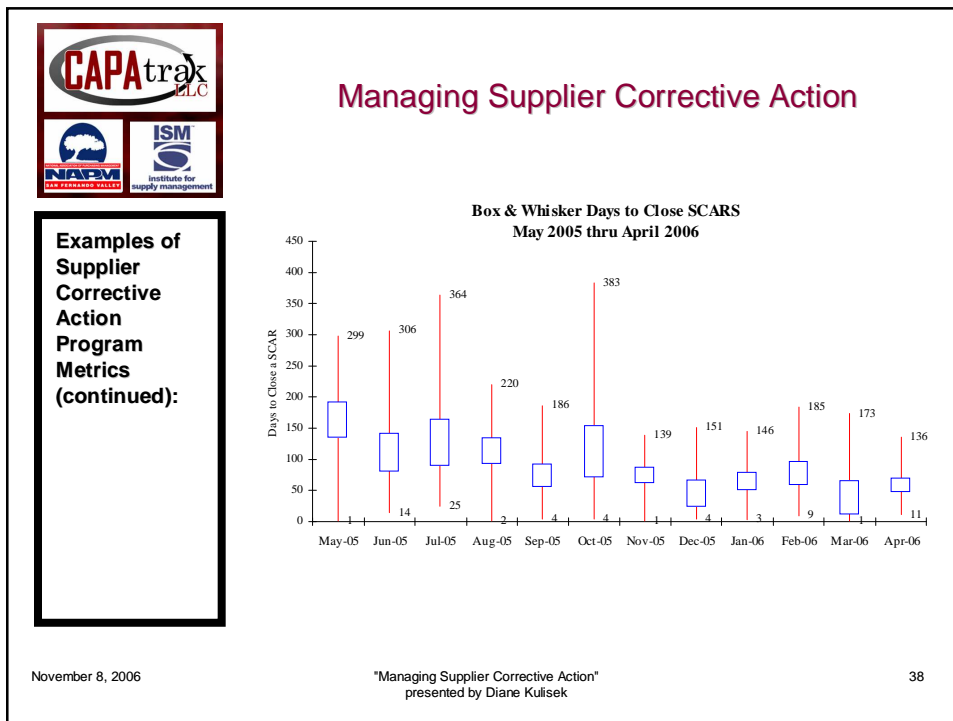
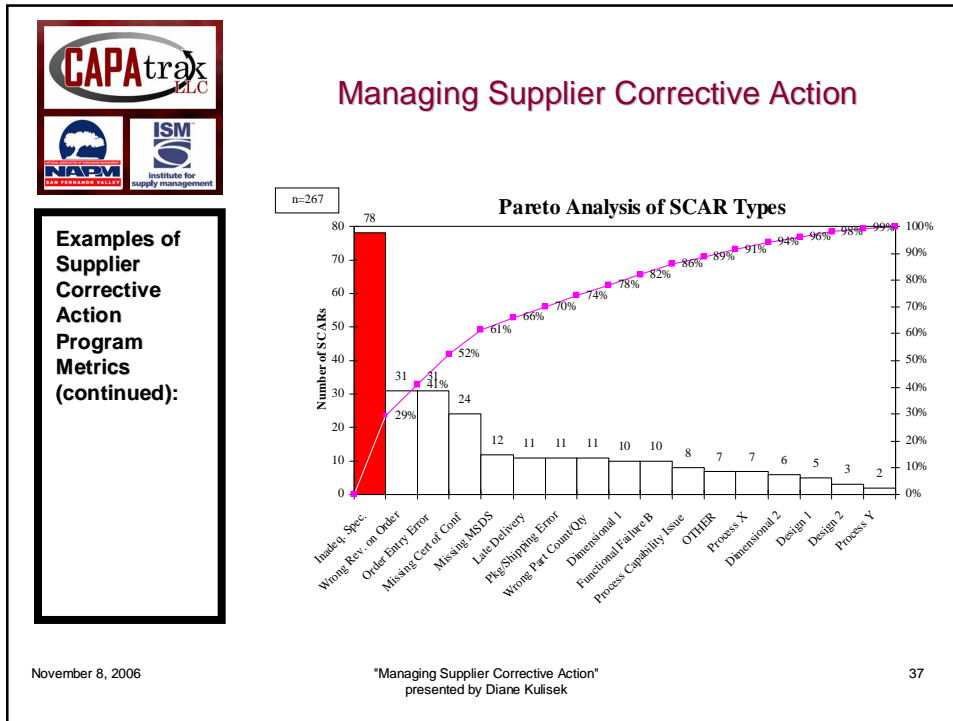
### Supplier Corrective Action Requests Initiated Over Time 12 Month Trend Analysis






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## Managing Supplier Corrective Action

1. Absence of Management Support/Commitment
2. No or poor Role Definition
3. No criteria established for when and when not to pursue Supplier Corrective Action
4. Failure to include specific requirements for timely and effective Supplier Corrective Action in contracts or purchase orders
5. Failure to quantify significance, especially in terms of \$\$\$ and/or inadequate leverage (\$\$\$) with Suppliers
6. Lack of consequences for poor Supplier Performance
7. Deviating from the agreed upon PROCESS
8. No or poor TRAINING
9. No Tracking or Reporting

**Why Supplier Corrective Action Programs Fail:**

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## Managing Supplier Corrective Action




1. Make sure Supplier Corrective Action is understood by Top Management at the **BOTTOM LINE (\$\$\$)**
2. Engage Top Management in Supplier Corrective Action Reviews
3. Include Supplier Corrective Action Metrics in regular Operations Reviews
4. Make sure that, as Supplier SCARs **Decrease** (due to effective Supplier Corrective Action), other metrics for Supplier Performance **Increase/Improve**
  - If not.... figure out WHY
  - Engage front line Buyers and your Suppliers' representatives
5. Communicate Results with the rest of the company (Lessons Learned)
6. Recognize and Reward Achievements
7. TRAIN TRAIN TRAIN TRAIN TRAIN

**Assuring Long Term Supplier Corrective Action Program Effectiveness:**

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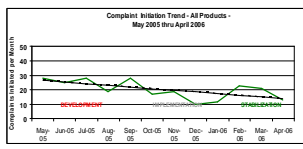
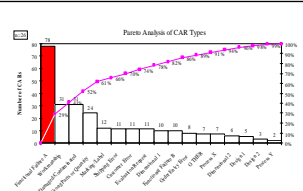
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## Managing Supplier Corrective Action

**Assuring Long Term Supplier Corrective Action Program Effectiveness (continued):**

### SUPPLIER CORRECTIVE ACTION SYSTEM IMPROVEMENT DASHBOARD

**Plan:**

1. Address top three drivers with Weekly Action Teams
2. Establish Root Causes and Develop Supplier Corrective Action Plans with Due Dates and Actionees
3. Monitor Progress at Executive Quarterly Reviews and Baseline Key Performance Indicators
4. Establish Annual Improvement Goals for KPM's
5. Achieve a 50% Overall Improvement by End of FY




**Progress: Status = GREEN**

1. Functional Problem is driver.
2. Buyer for Supplier "X" assigned as Improvement Champion
3. Action Plan is in development; results will be presented with milestones and due dates next week.

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**References and Web Links to Some Nifty Tools:**

- Links to Information about some of the better known automated Corrective Action tracking Systems:
  - AssurX CATSWeb - <http://www.assurx.com/solutions.html>
  - ETQ – [www.etq.com/quality](http://www.etq.com/quality)
  - InfinityQS – [www.infinityqs.com](http://www.infinityqs.com)
  - MasterControl - [www.mastercontrol.com](http://www.mastercontrol.com)
  - ProQuis – [www.proquis.com](http://www.proquis.com)
  - Pilgrim WebCAR – [www.pilgrimsoftware.com](http://www.pilgrimsoftware.com)
  - QualTrax – [www.qualtrax.com](http://www.qualtrax.com)
  - TrackWise - <http://www.sparta-systems.com/solutions/qms/CorrectiveAction/index.shtml>

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**References and Web Links to Some Nifty Tools (continued):**

■ **Recommended References**

- Nice article on "Selecting a Web-based Corrective and Preventive Action System" in Quality Digest Magazine (note: it was written by an AssurX Representative, so there is some bias)  
[http://www.qualitydigest.com/april02/html/Corrective\\_Action.html](http://www.qualitydigest.com/april02/html/Corrective_Action.html)
- U.S. Department of Energy Web-based CAMP (Corrective Action Management Program); includes 72-page CATS (Corrective Action Tracking System) User Guide  
<http://www.eh.doe.gov/camp/trackingsys.html>
- Relex FRACAS (Failure Reporting, Analysis and Corrective Action System) Product information  
<http://www.relexsoftware.com/products/fracas.asp>  
Case Studies and Related Articles  
<http://www.relex.com/products/literature.asp>
- Relatively inexpensive Web-based Corrective Action tracking system for small to medium companies from Soule Quality Systems; "caTracker"; live demo available on line; white paper on "Optimizing the Value Stream" downloadable  
<http://www.soulequalitysystems.com/index.htm>

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**References and Web Links to Some Nifty Tools (continued):**

■ **Web Links to Some Nifty Tools**

- Electronic Root Cause Analysis Training (eRCA) at \$140. per license; also check out the "RealityCharting" software for problem analysis  
[www.apollorca.com](http://www.apollorca.com)
- Inexpensive CD & DVD training on Problem Prevention Techniques, Cause & Effect Demonstration and Process Cause & Effect Analysis (currently buy 2 get 1 free; \$99. each)  
[www.qci-intl.com](http://www.qci-intl.com)

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	<h3>Managing Supplier Corrective Action</h3>	
<p><b>References and Web Links to Some Nifty Tools (continued):</b></p>	<ul style="list-style-type: none"><li>■ <b>Web Links to Some FREE Nifty Tools</b><ul style="list-style-type: none"><li>● Free Corrective Action Request and Response Forms to Download from CAPAtrak: <a href="http://www.capatrak.com/freestuff.asp">http://www.capatrak.com/freestuff.asp</a></li><li>● Free Corrective Action Procedure template and other ISO-related downloads from Clinivation: <a href="http://www.clinivation.com">http://www.clinivation.com</a></li></ul></li></ul>	
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