Using the Cost of Poor Quality to Drive Process Improvement

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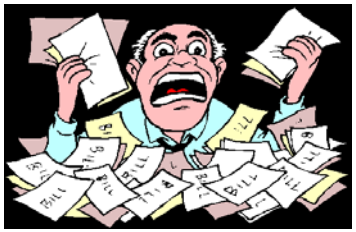
Objectives: To Understand COPQ

1. What is COPQ
2. Elements of the model
3. Calculating COPQ
3. Real World Applications
4. Implementing Improvement actions

1. COPQ Introduction

The Cost of Poor Quality (COPQ)

- Represents the <u>difference</u> between
  - The **actual cost** of production or service



  - What the **cost would be** if the process were effective in manufacturing products that
    - met customer needs and
    - were defect free.

COPQ Equation

COPQ = Costs (external failures + internal failures + appraisal + preventive action)

Many times white collar poor quality costs are not included in COPQ calculations (out of conformance purchases, excess inventory, ...) (Atkinson)

Why Cost of Poor Quality?

- Speaks in the language of management, $$$
- Shows how profit is affected by quality
- Can prioritize quality improvement actions
- Serves as the impetus for actions

In the US about a third of what we do consists of redoing work previously "done". (Juran)

Related Quality Initiatives

- Six Sigma uses defect costs to quantify savings
- Lean Manufacturing focuses on reducing appraisal costs
- Design Controls focuses on early review and test activities to find defects early

Defects are not free. Somebody makes them and gets paid for making them. (Deming)

2. Elements of the Model

¤	¶ Personnel¤	Rework/· Retest¤	Supplier· Defects¤	Document·· Review¤	R&D· Test· Defects¤	R&D·or·Mfg·· Validation·Test· Defects¤
¤	**R&D·or·Mfg.·Engineers¤**	¤	¤	¤	¤	¤
1.→¤	Failure·Investigation·¤	¤	¤	¤	¤	¤
2.→¤	Identify·Root·Cause·¤	¤	¤	¤	¤	¤
3.→¤	Define·Corrective·Action¤	¤	¤	¤	¤	¤
4.→¤	Coordinate·with·Supplier·¤	¤	¤	¤	¤	¤
5.→¤	Implement·Corrective·Action·¤	¤	¤	¤	¤	¤
6.→¤	Verify/Validate·Effectiveness·¤	¤	¤	¤	¤	¤
7.→¤	Update·R&D·Documents·¤	¤	¤	¤	¤	¤
8.→¤	Update·Manufacturing· Documents·¤	¤	¤	¤	¤	¤
9.→¤	Perform·Regression·Testing·¤	¤	¤	¤	¤	¤
10.→¤	Perform·Validation·¤	¤	¤	¤	¤	¤
¤	**Total·Hours·R&D·or·Mfg· Engineers·Personnel¤**	¤	¤	¤	¤	¤
¤	**Manufacturing·Personnel·¤**	¤	¤	¤	¤	¤
11.→¤	Rework·¤	¤	¤	¤	¤	¤
12.→¤	Reprocess·¤	¤	¤	¤	¤	¤
¤	**Total·Hours·Manufacturing· Personnel·¤**	¤	¤	¤	¤	¤

Cost of External Failures

- Costs for defects found by the customer:
  - MDRs,
  - Reports of corrections and removals,
  - Field service corrections,
  - Field service bulletins, and
  - Software patches.

Cost for Internal Failures

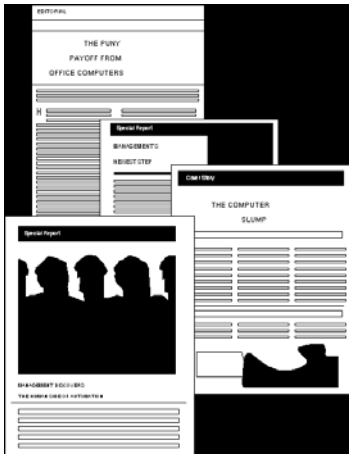
Cost for defects found by R&D or Mfg

- Unclear requirements
- Improper design and implementation
- Improper design and implementation
- Incorrect test documentation
- Incoming inspection defects
- In-process testing defects
- Final acceptance testing defects
- Rework

Cost for Appraisal

Costs for checking defects including:

- Review of system specifications (R&D),
- Review & inspection during manufacturing processes,
- Review of quality records, and
- Audits

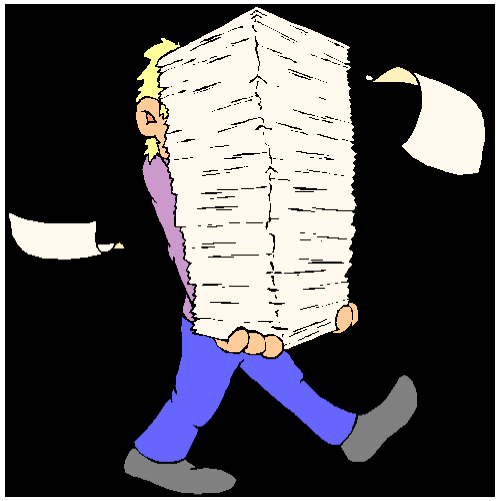


Cost for Preventive Action

Cost for initiatives to improve processes:

- Use techniques to better understand requirements
- Employ programs to reduce design defects
- Implement tools to reduce manufacturing defects
- Institute quality improvement programs

3. Calculating COPQ



Estimating the Numbers

Calculate full time personnel

- $200,000/year for full time personnel
- Assume 2000 hours per year
  - 50 weeks x 40 hours
  - $100/hour

Sample Spreadsheet Worksheets

Labor Rates

Defect Costs (External and Internal)

1. Estimate the number of defects
2. Estimate the hours to address each defect
3. Estimate the cost per defect including various labor rates
4. Estimate any additional costs that may be incurred for defects
5. Estimate the total cost per defect category
6. Estimate the total cost for all defects for a year period

Appraisal Costs

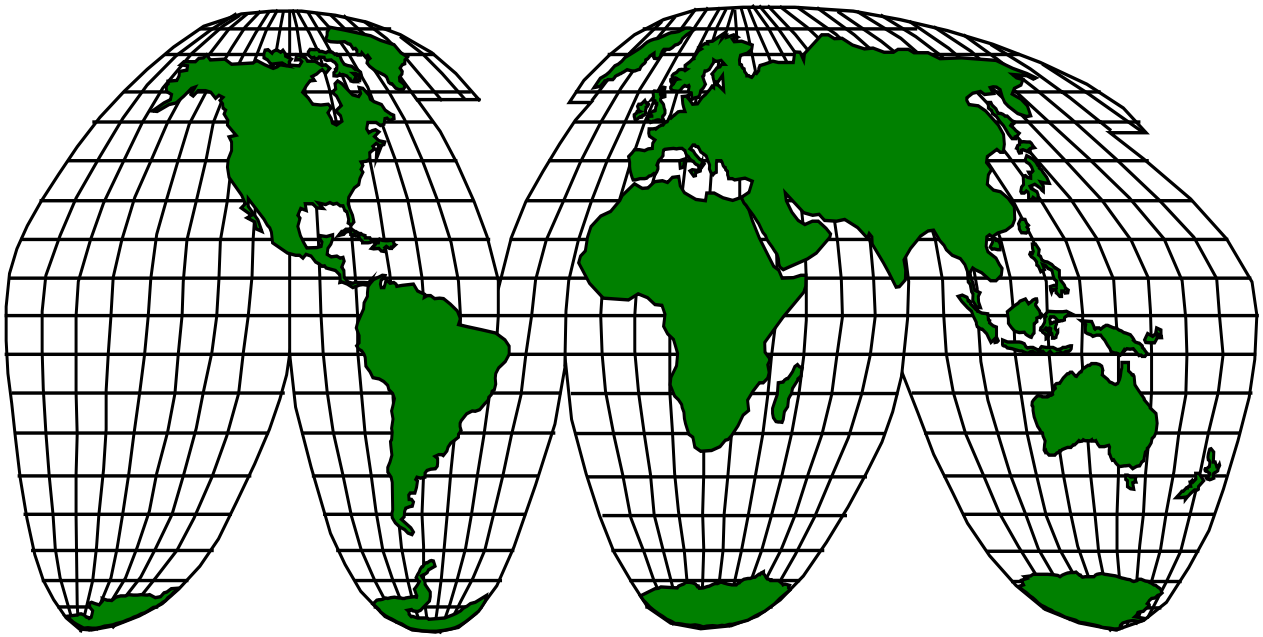
1. Estimate appraisal labor costs
2. Estimate appraisal capital costs
3. Estimate appraisal total costs

Preventive Action Costs

1. Estimate total preventive action costs

Total COPQ

4. Real World Applications



Implementing COPQ

- With little or no financial system changes Medical Device Manufacturers can
  - Identify their external failure costs
  - break these costs out by product, complaint symptom, part usage, serial number, customer and region
  - Pareto these costs and prioritize corrective actions
- Through appropriate statistical analysis we can;
  - Identify any changes in rate for a particular issue and tie down the timeline.
  - Determine if differences exist in either serial numbers / lot numbers or regions
- This additional information can dramatically reduce the time spent investigating the root cause.

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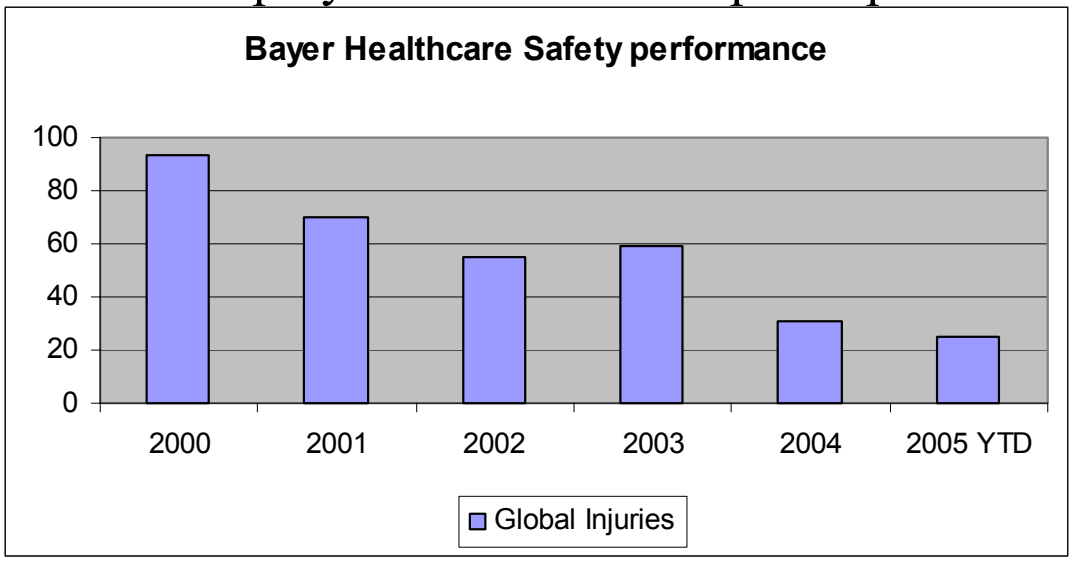
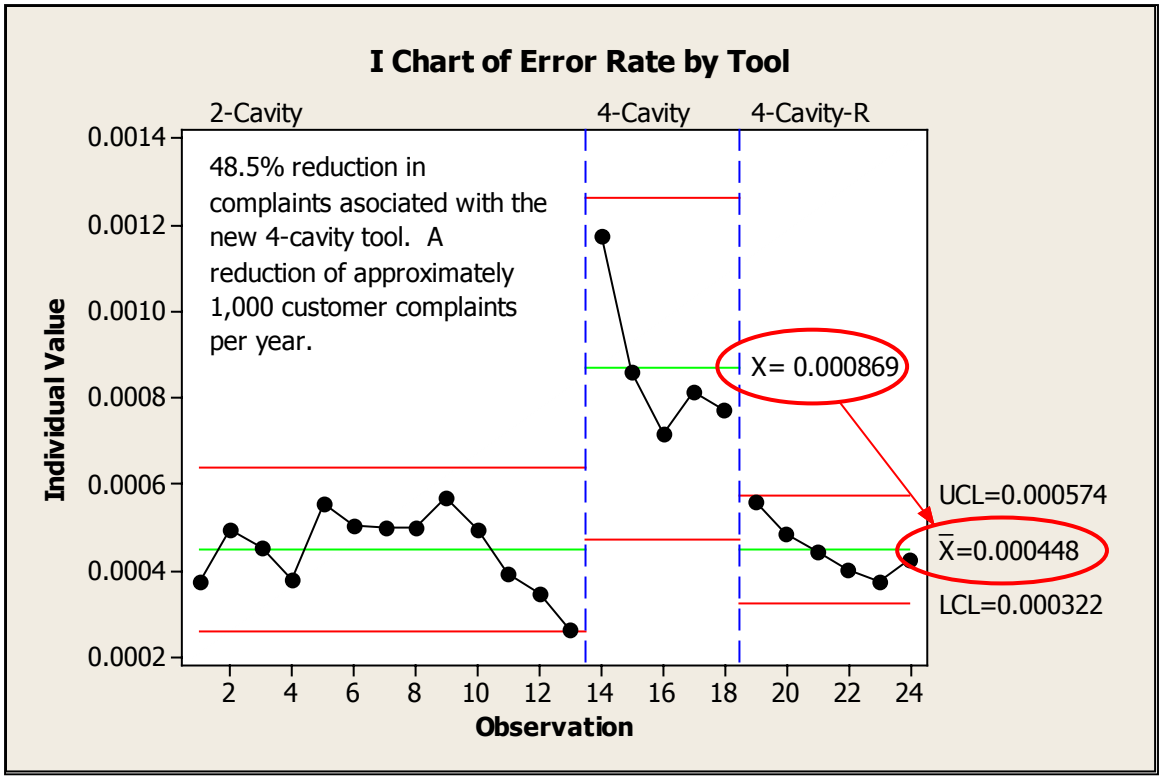
Internal Failure: Safety Accidents

- Bayer considers the costs of work related accidents to be a cost of poor quality.
- Bayer has estimated that indirect costs are 6-8 times direct costs (replacement workers, missed shipments/sales/development schedules, administrative costs, OT).
- To improve in this area we initiated the Bayer Structured Safety & Health program (BSSHP).
- One of the key elements within this program is a employee close call system which encourages the identification and correction of potential hazards and raises employee awareness and participation in safety.



Performance in 2005 represents a 73% reduction over year 2000 performance with estimated savings of over $2 Million.

Customer Complaint Reduction



In this case Bayer has reduced customer complaints associated with this issue by over 48%. This correction also had hard cost savings in excess of $275,000.00

By utilizing our external failure data Bayer has been able to identify high impact (cost and customer) issues and drive improvements in these areas.

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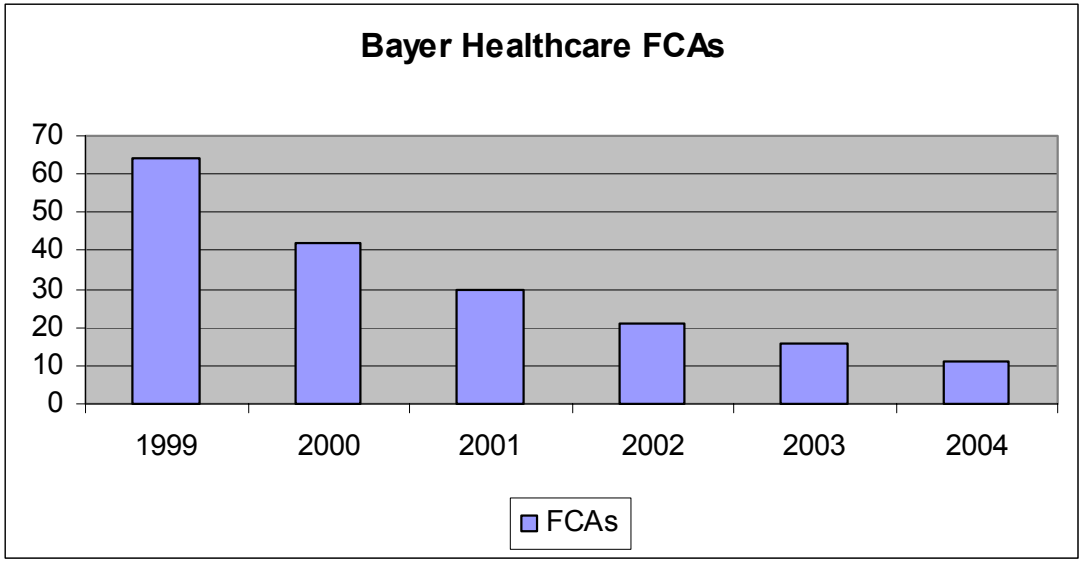
Field Corrective Actions

- **F**ield **C**orrective **A**ction: A correction or removal for product no longer under Bayer's control.
- The costs associated with an individual FCA can range from $20K to up to $30 Million for a full product recall.
- We have consistently reduced the number of FCAs every year since 1999, and 2004 represented an 83% reduction in FCAs



With an average cost of $250,000 this equates to over $13,000,000 in savings through FCA prevention.

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COPQ: Data

- By analyzing the data already collected through our quality system we have been able to determine that
  - Worldwide part replacement costs = 3.4% of sales
  - Worldwide complaint handling costs = 0.8% of sales
  - Worldwide field service visit costs = 4.8% of sales
- Direct External failure costs total = 9% of sales.
- We have used this information to begin the process of addressing our COPQ.

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Industry Example

COPQ as a percent of total costs	**Before**	**After**
• Failure cost	6.3%	4.0%
• Appraisal cost	2.8%	2.2%
• Preventive action cost	0.2%	0.6%
• Total	9.3%	6.8%

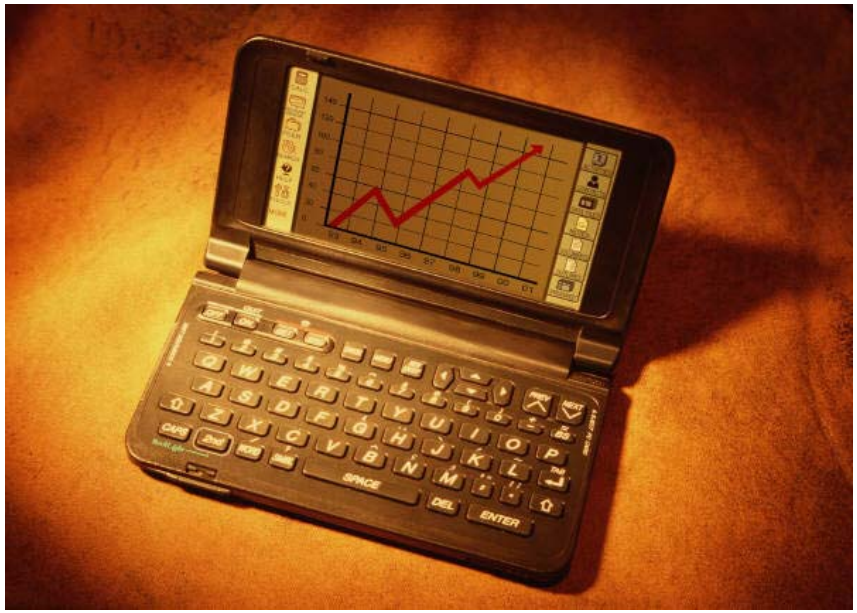
Savings

• Appraisal costs reduced	$430,000
• Scrap and rework reduced	$2,068,000
• Complaint costs reduced	$536,000

Reference: Total Quality Control, Armand V. Feigenbaum, p.131

For many companies quality costs are 20% of sales (Juran)

5. Driving Process Improvement

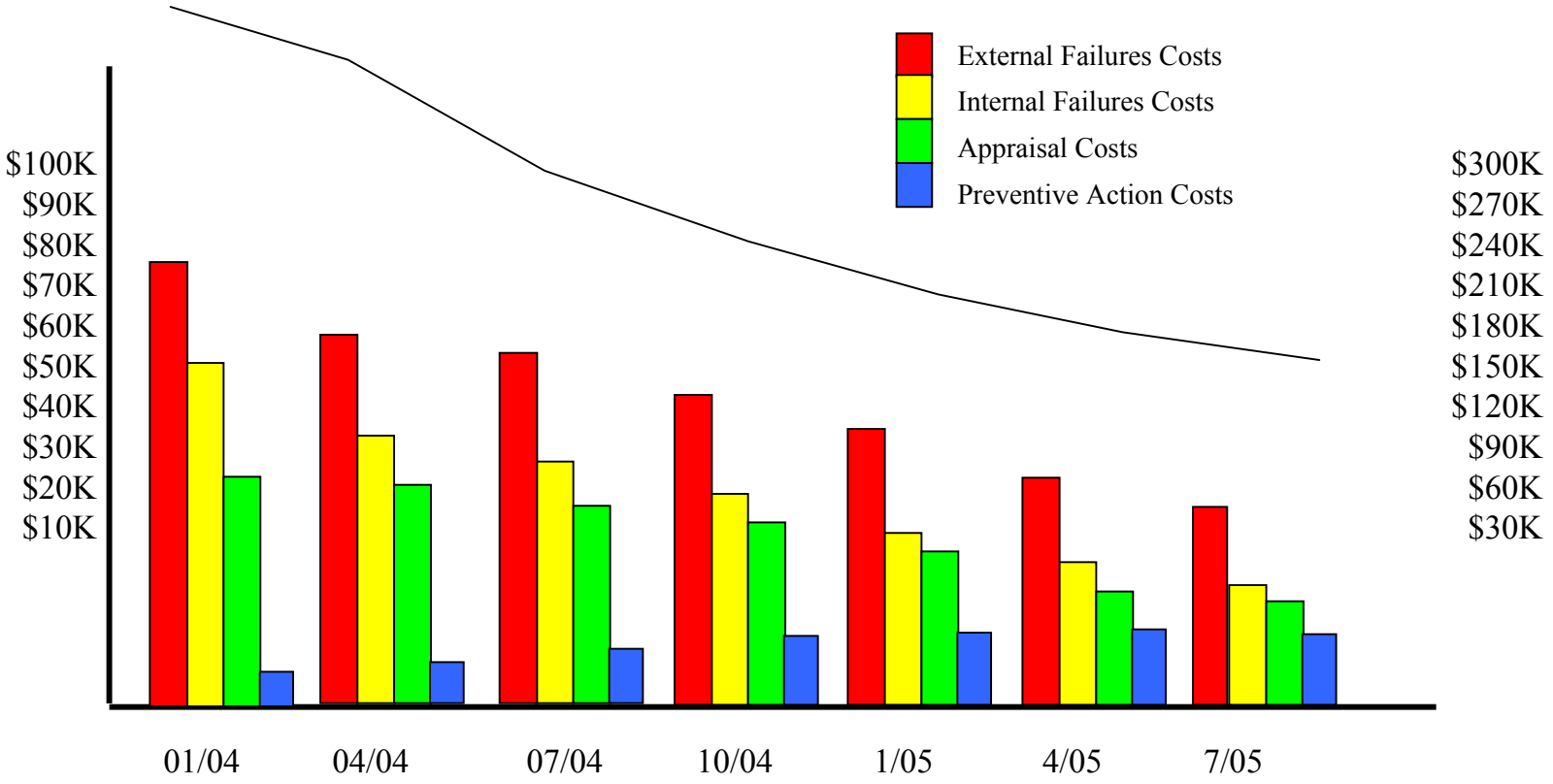


Four Assumptions in the Model

1. There is a root cause for each defect
2. Defects are preventable
3. It is better to prevent than correct defects
4. Inspection/testing can be reduced for capable processes

Investment in Preventive Actions can yield significant savings!

Trend Chart using COPQ Model



Cost Of Poor Quality = (cost of external failures) + (cost of internal failures) + (cost of appraisal) + (cost of preventive actions)

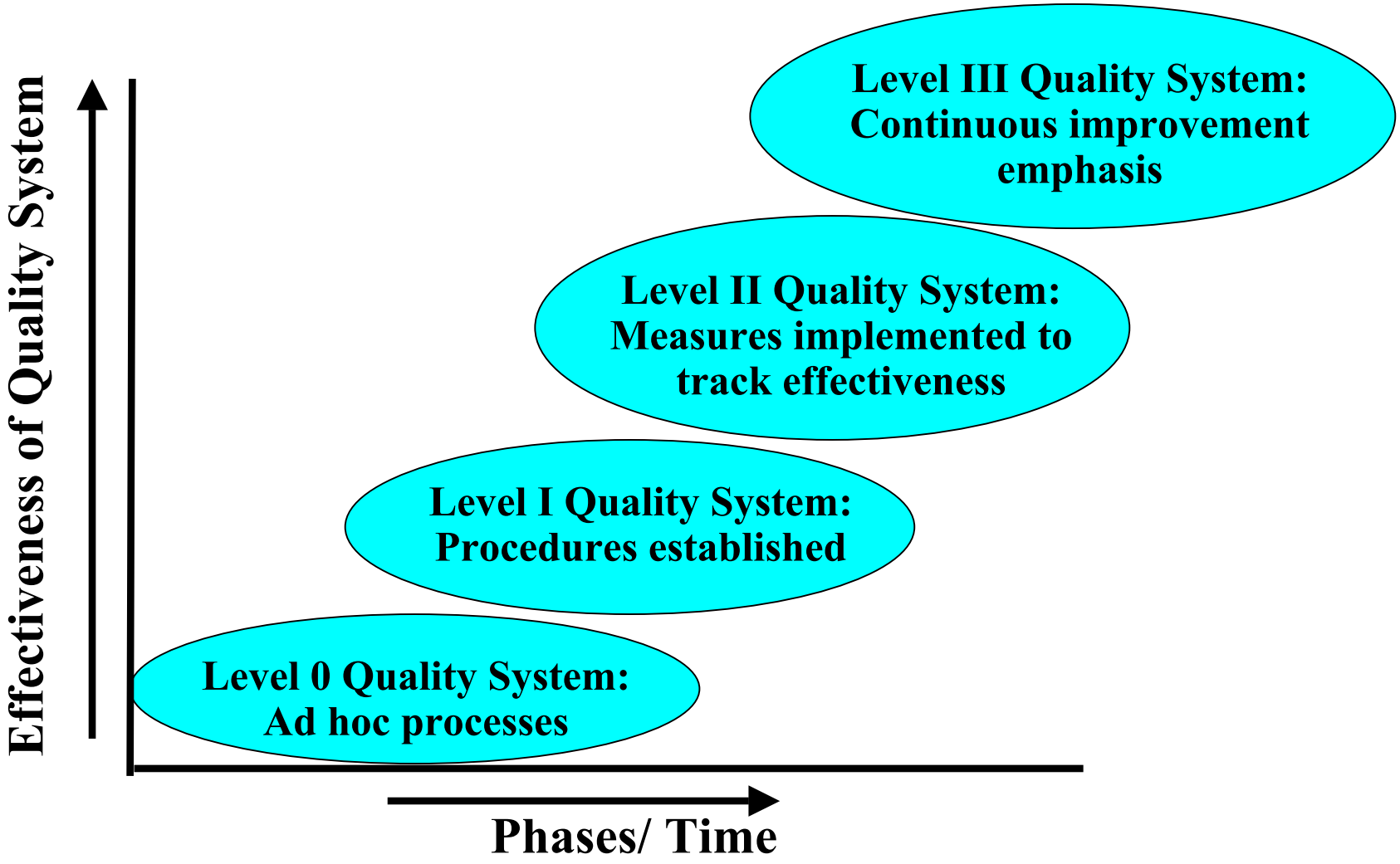
Improvement Activities: Manufacturing

- Reduce errors with process design changes (poka-yoke)
- Addition of test fixtures to simplify manual processes
- Capability studies to define optimum parameter settings
- Enhance supplier controls to refine part specifications
- Redesign of device for improved manufacturability
- Addition of automated manufacturing equipment
- Enhanced automated test equipment
- Refinement of acceptance test criteria
- Real time automated test data trending
- Refinement of work instructions/formulations

Improvement Activities: Research and Development

- Redesign to reduce parts to improve reliability
- More system integration testing for design changes
- Closer participation of R&D in definition of manufacturing processes
- Conduct early parallel design and test activities
- Use focused checklists to enhance review effectiveness
- Employ focus groups to better understand customer needs
- Use project post-mortems to identify root cause for historical failures
- Redesign to facilitate future changes
- Implement a culture of defect prevention

Quality Improvement Evolution



Summary: Why COPQ

- Add to the “toolbox” of the quality professional
- Shows that investment in quality yields dividends
- Defines priorities for improvement actions
- Facilitates a culture of continuous improvement

For Further Information

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CSS specializes in providing quality system and validation services for medical device and pharmaceutical manufacturers.