



The Economics of Quality

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What is Quality?

"Conformance to specifications"

What is **NOT** Quality?

"Apple pie and Chevrolet"

FDA Definition in 21 CFR 820.3

"The totality of features and characteristics that bear on the ability of a device to satisfy fitness-for-use, including safety and performance." ⁽²⁾

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Elements of a Quality System

Quality Assurance

"...part of quality management focused on providing confidence that quality requirements will be fulfilled." ⁽⁵⁾

Quality Control

"...part of quality management focused on fulfilling quality requirements." ⁽⁵⁾



Keys to a good Quality System

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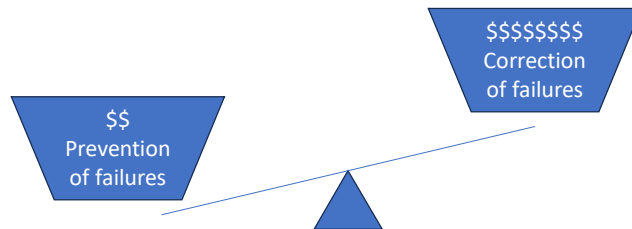
Fun Facts ⁽⁴⁾

- 62% of employers do not calculate the “cost of quality”.
- \$10,000 = estimate of a **simple** failure investigation costs.
- \$100,000 = estimate of a **complex** failure investigation costs.
- Over \$1 Million = costs associated with regulatory sanctions.
 - Recalls, import bans, fines, lawsuits, etc.

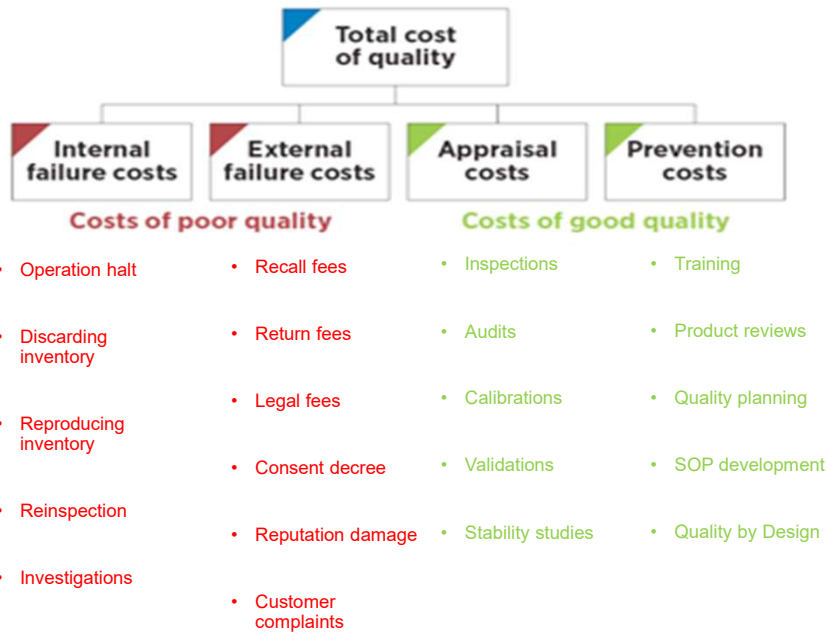
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What is the “Cost of Quality” ?

“A methodology that allows an organization to determine the extent to which its resources are used for activities that prevent poor quality, that appraise the quality of the organization’s products or services, and that result from internal and external failures.” (7)



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Prevention Costs

Costs incurred to prevent or avoid quality problems. They are planned and incurred before actual operation.

- Training
- Product Reviews
- Quality planning
- Improvement projects
- Quality by design
- Implementing AI
- Process optimization



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Appraisal Costs

Costs incurred to determine the degree of conformance to quality requirements.

- External inspection
- In-process and final inspection
- Internal and external audits
- Stability studies
- Batch release testing
- Validation studies
- Calibrations



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Internal Failures

Costs associated with defects found before the customer receives the product or service.

- Failed product scrapping
- Rework of failed batches
- Investigations

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External Failures

Costs associated with defects found after the customer receives the product or service.

- Recall
- Processing returns
- Customer complaints
- Reputation stain
- Lawsuits
- Adverse events

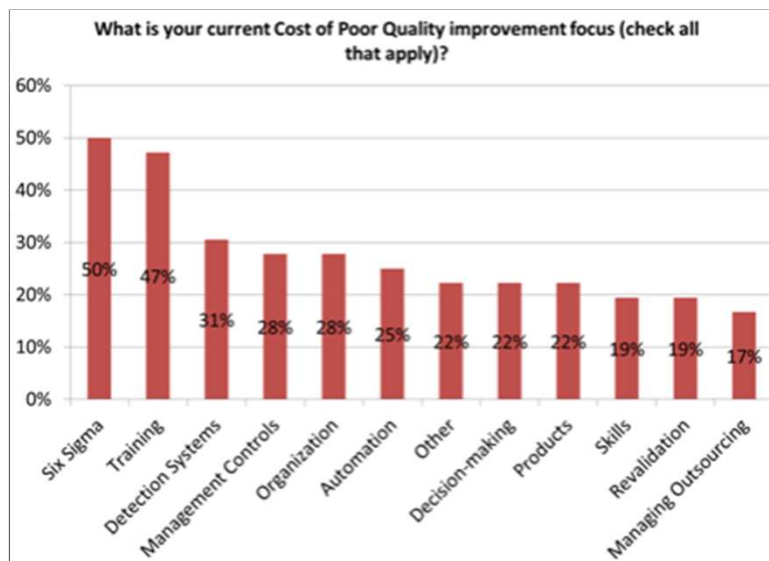
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Investigations. When and Why ?

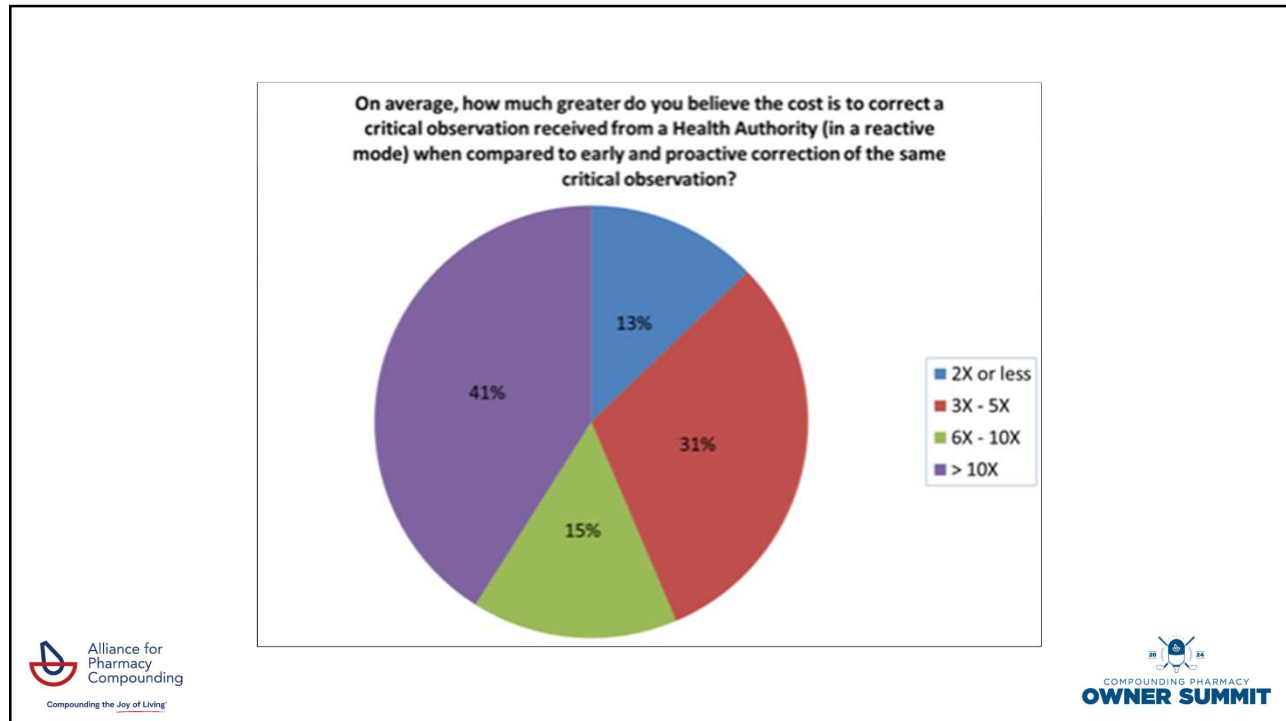
- Reactive Investigations
 - More common
 - Bad practice
 - Expensive business implications (Recalls, reworks, scraping product...)

- Proactive investigations
 - Best practice
 - Tracking and trending data
 - Noticing inefficiencies and addressing them before they turn to business concerns

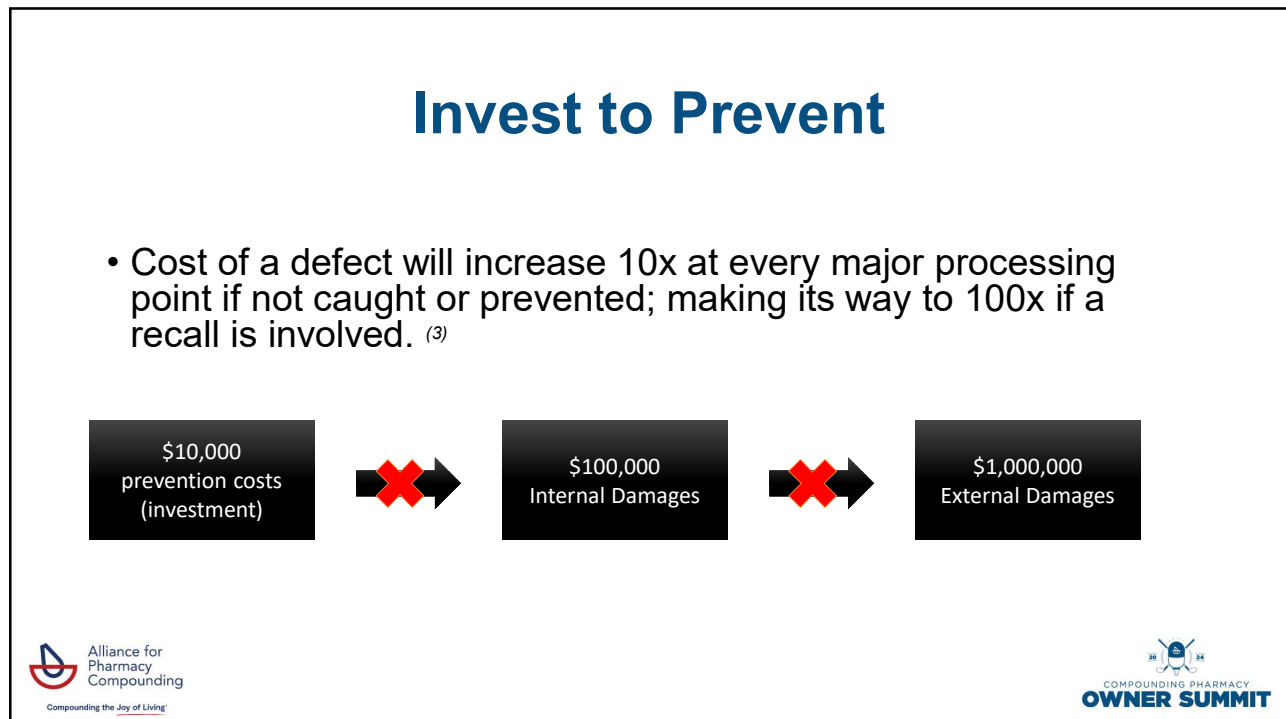
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Common Misconception

 Finished product testing is sufficient to demonstrate quality.

 Building and maintaining a quality system.

Management Responsibilities

- Review SOPs and processes annually.
- Continuous training of employees.
- Continuous process validations.
- Continuous personnel qualifications.
- Continuous calibration of equipment.
- Internal audits.
- External audits.
- GAP analysis.
- Inspections.
- Stability studies.

Recommended Cost of Quality

- Small to medium size compounding facilities = 7-10% of their annual revenue
- Medium to large size compounding facilities = 1-3% of their annual revenue. ⁽⁶⁾

Large Operation 1-3%	Small Operation 7-10%
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Pharmaceutical Quality System

Elements

Quality Manual

- Describes the quality system.
 - Scope
 - Quality policy
 - Describes intentions related to quality
 - Regulatory compliance
 - Continual improvement
 - Developed by senior management
 - Reviewed periodically
 - Processes
 - Materials, personnel, documents, quality management, etc.
 - Management responsibilities



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Cost of Poor Quality

Regulatory Risk

- FDA 483 Observations and/or State Board of Pharmacy violations or deficiencies
- Fines
- Warning letters
- Consent decree or Agreed Board Order (ABO)

Business Risk

- Costs associated with:
 - Batch rejection
 - Waste
 - Recall
 - Remediation
 - Labor
 - Liability insurance
- Trust and reputation



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Case Study

Ross' Rx is a pharmacy with annual revenue averaging \$2.5 Million. They invite a consulting service to perform a Gap Analysis and the results from the audit suggest adjustments which will cost nearly \$200,000. The investment is not something Ross' Rx is able to make immediately. The adjustments are postponed for the following year depending on sales.

Annual Revenue	\$2.5 M
Current Investment in Quality	\$60 K
Recommended Annual Investment	\$175K to \$250K (7% - 10%) + \$200K Additional Findings

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Case Study (Continued)

- The pharmacy receives an unexpected knock at the door from the FDA. The citations are nearly identical to those from the previous Gap Analysis. Ross' Rx is requested to:

1. Recall product.
2. Cease production until the adjustments are made.

Refund for 10,500 Prescriptions	\$1.5 M
Recall Costs	\$11,500
Consulting/Remediation Expenses	\$300 K
Legal/Attorney Fees	\$350 K
TOTAL	\$2,161,500

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