

What's Your Cost of Poor Quality? Calculating an ROI for Your Lab's Quality Program

Presented by Jennifer Dawson
MHA, LSSBB, CPHQ, DLM(ASCP)SLS, QLC, QIHC, Senior
Director, Quality for Human Longevity, Inc.

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CardinalHealth
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Logistics
Product
Business
Patient

Learning Objectives



- Discuss the concept of Cost of Quality and its components.

- Differentiate between hard and soft costs

- Review methodologies to capture and track Cost of Poor Quality (CoPQ).

- Analyze how labs can use CoPQ data to demonstrate a return on investment for their quality efforts.

Challenge: Quality is Nebulous

qual·i·ty

/ˈkwælədē/ 

noun

1. the standard of something as measured against other things of a similar kind; the degree of excellence of something.
"an improvement in product quality"
synonyms: [standard](#), [grade](#), [class](#), [caliber](#), [condition](#), [character](#), [nature](#), [form](#), [rank](#), [value](#), [level](#);
[More](#)

Everyone agrees that quality is important but...

- How do you define quality?
- How do you measure quality?
- What is the return on investment?
- How do you justify additional investment in quality?

Non-Conforming Events

- Failure to meet a requirement
- Something doesn't go as planned in the lab
- Also called: Accident, adverse event, error, event, incident, non-conformity, and occurrence
- Regulatory requirement to track (CLIA § 493.1239, general laboratory systems quality assessment)



Non-Conforming Event Management

Purpose: Identify and characterize problems so investigations can be carried out, root causes identified, and improvement projects initiated, thus eliminating reoccurrence.

- Risk Management
- Can be done: manually or electronically



The struggle is real

Many labs struggle with:

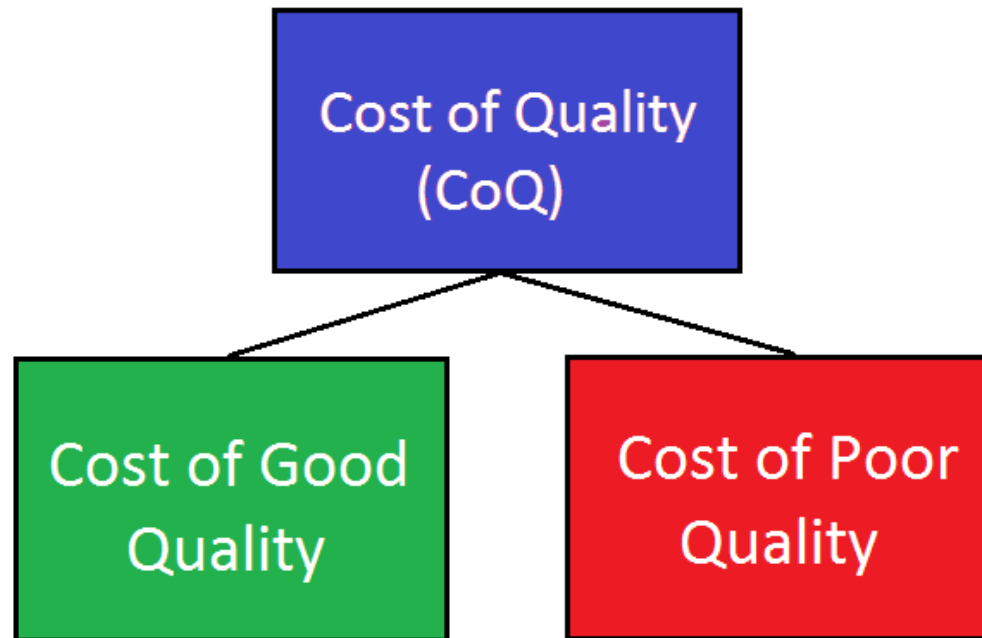
- ✓ Reporting
- ✓ Keeping up with events
- ✓ Justifying expending resources for FTEs and software



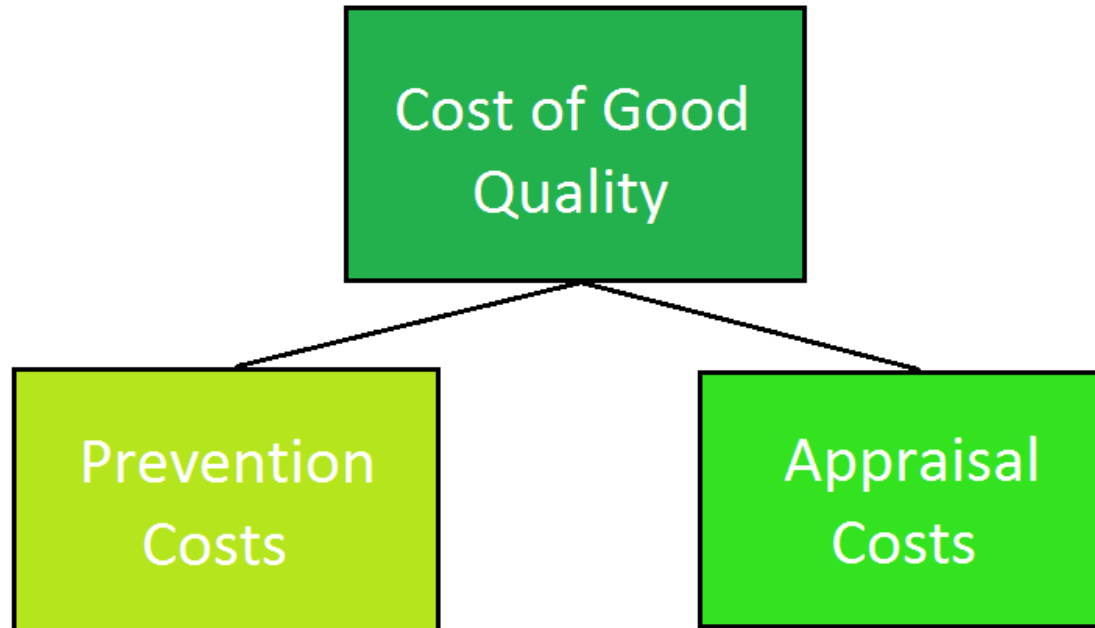
Cost of Quality



Cost of Quality = Cost of Good Quality + Cost of Poor Quality



Cost of Good Quality



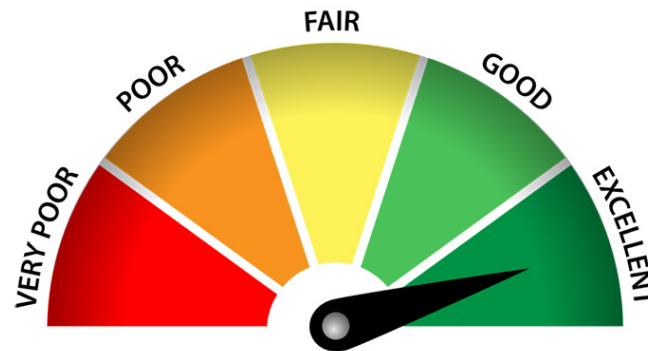
Cost of Good Quality

PREVENTION COSTS

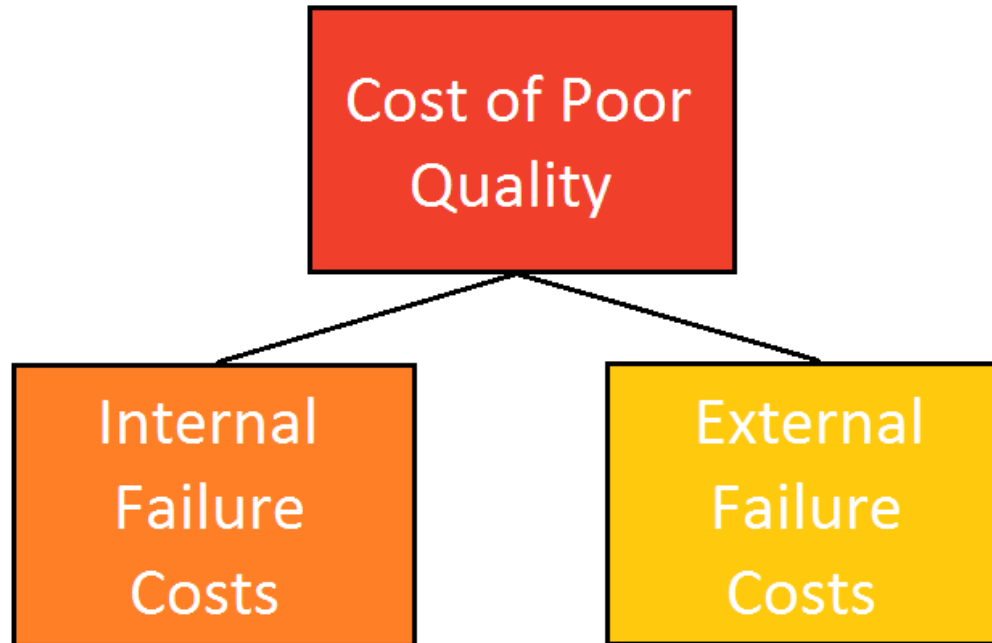
- Quality Planning
- Training
- Product or service requirements
- Preventive maintenance
- Quality Management System
- Quality Improvement activities

APPRAISAL COSTS

- Competency Assessments
- Calibration/Quality Control
- Proficiency Testing
- Alternative Assessment
- Internal Audits
- Inspections (CLIA, CAP, TJC, etc.)



Cost of Poor Quality



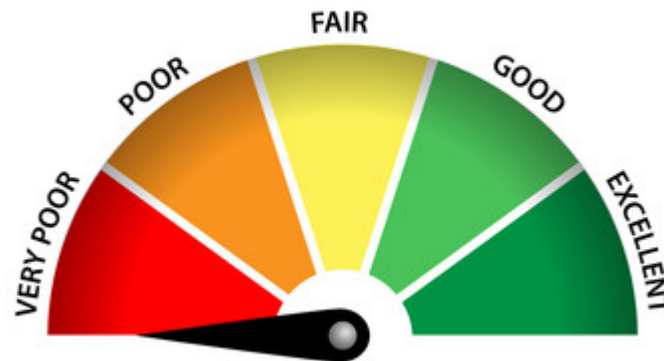
Cost of Poor Quality

INTERNAL FAILURE COSTS

- Downtime
- Inefficiencies
- Data entry errors
- Missing specimens
- Retesting
- Repair
- Recollected samples (if internal)
- Failure Analysis

EXTERNAL FAILURE COSTS

- Customer complaints
- Attrition
- Misdiagnoses
- Harm to patients
- Corrected reports
- Lawsuits

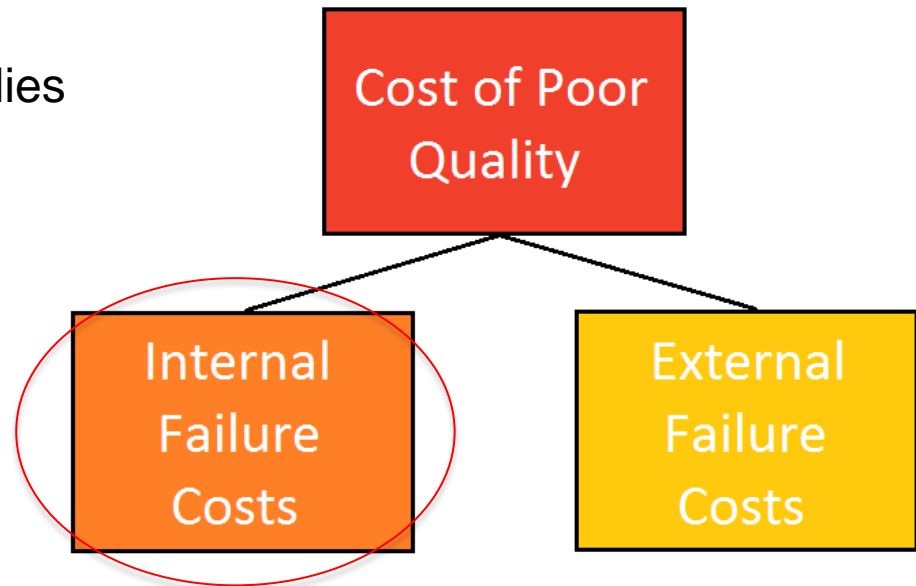


CoPQ: Not Always Obvious



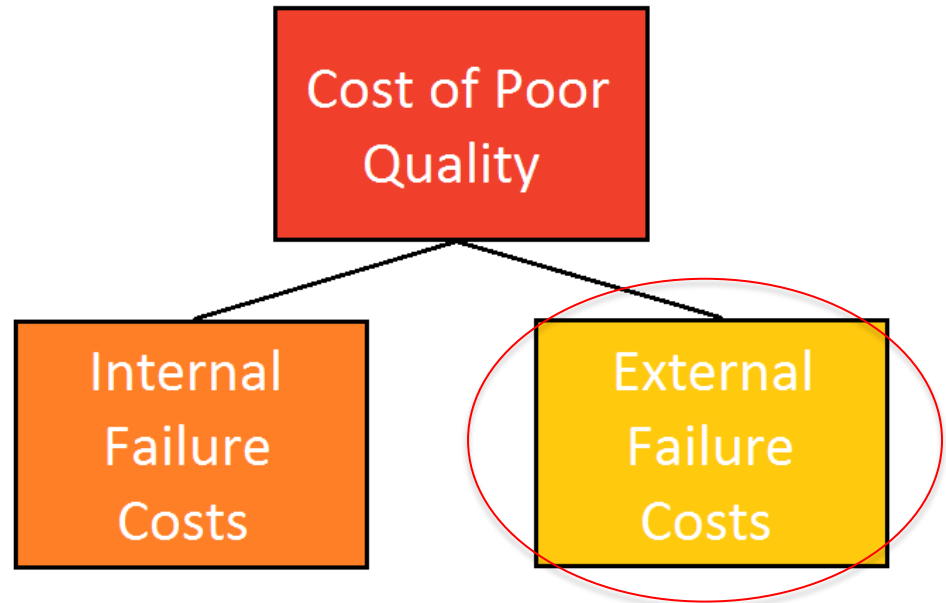
Cost of Poor Quality – Soft vs Hard Costs

- Cost of Poor Quality
 - Internal Failure
 - Hard – Start here
 - Rework
 - » Reagents/Supplies
 - » Labor
 - Investigations
 - Management Time
 - Soft
 - Low Morale
 - Delays



Cost of Poor Quality

- External Failure
 - Soft or Hard
 - Complaints
 - Reputational Damage
 - Patient Harm
 - Litigation
 - Client Attrition



Calculating “Soft” Failure Costs

- ***Much harder to do but something can be done***
 - Example:
 - 10 incorrect INR results in last year due to analytical error
 - 1 resulting lawsuit
 - Law suit cost the organization \$100,000

$$\frac{\$100,000}{10} = \$10,000 = \text{Failure cost per instance}$$

Tracking CoPQ

Internal Failures – Hard Costs

Internal Failures – Hard Costs				
Considerations	#	Units	Cost/Unit	Total
Wasted Tech Time	2	Hours	\$15.00	\$30.00
Wasted Reagents	10	mL	\$20.00	\$200.00
Process Redesign	3	Hours	\$70.00	\$210.00
Occupational Health Visit	1	Visit	\$1500	\$1500.00
Management Time	2	Hours	\$80.00	\$160.00
Investigation	2	Hours	\$50.00	\$100.00
Overtime	3	Hours	\$15.00	\$45.00
Client Education	2	Hours	\$15.00	\$30.00
Rework -Failed Run	2	Runs	\$100.00	\$200.00
Complaint Handling	.25	Hours	\$15.00	\$3.75
Total				\$2478.75

Tracking CoPQ - Soft Costs



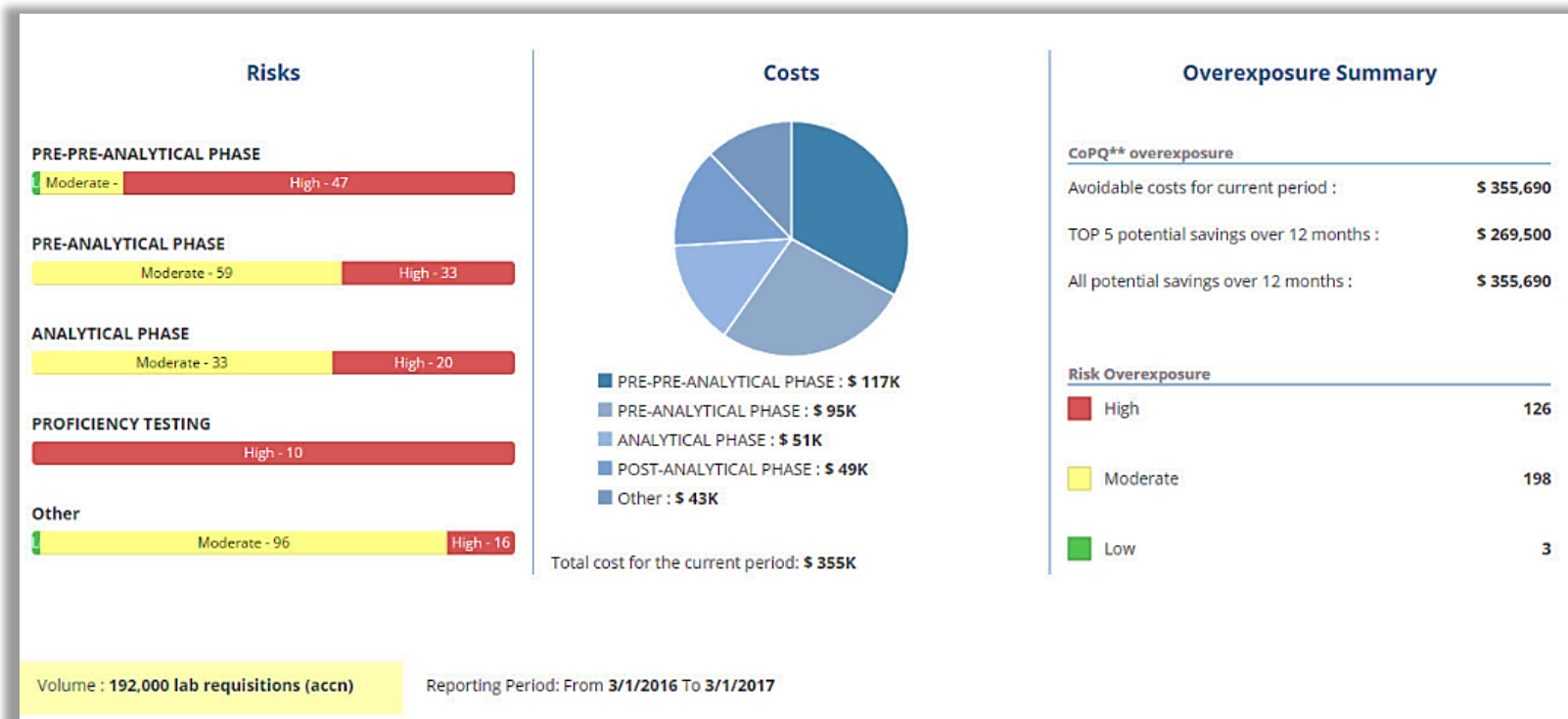
Internal Failure – Soft Costs

Considerations	\$ Estimate
Low Morale	\$0.00
Lost Sales	\$2500.00
Equipment Downtime	\$0.00
Harm to Employees	\$0.00
Total	\$2500.00

External Failure – Soft Costs

Considerations	\$ Estimate
Reputational Damage	\$250.00
Litigation/Malpractice	\$2500.00
Corrected Reports	\$0.00
Harm to Patients	\$0.00
Total	\$2750.00

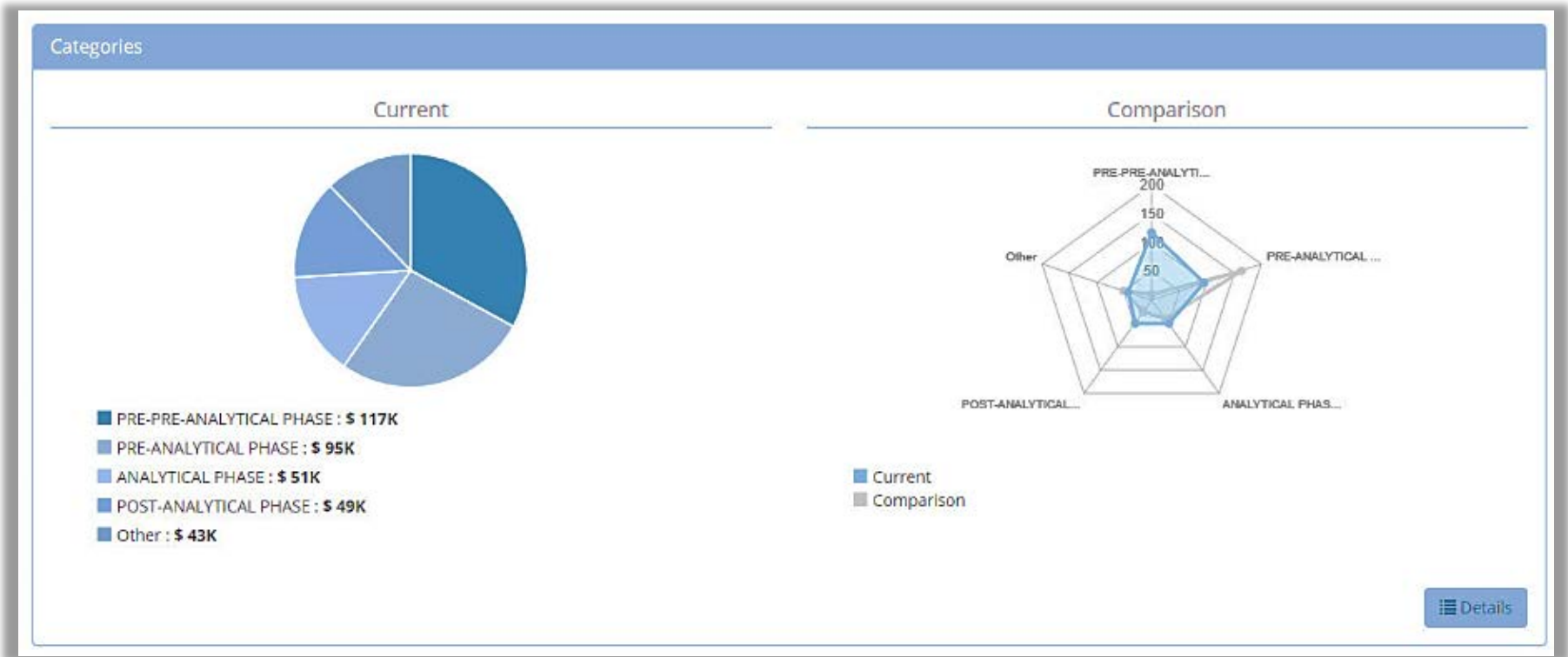
Tracking CoPQ using Software (Omni-Assistant)



Tracking CoPQ Using Software (Omni-Assistant)

Event / Category	Current period			Tolerance	CoPQ				
	Nb of events	Ratio*	Trend	Ratio*	Cost per event	Total cost	Avoidable costs	Potential savings over 12 months	Risk
Identification Error - Mislabeled Specimen(s) Pre-Pre-Analytical Phase: From the time the physician orders to the time the lab receives (Outside the organization)	46 3 Ticket(s)	0.2396	↑	0	\$2,500	\$115,000	\$115,000	\$115,000	■
Identification Defect (Internal) - Mislabeled Specimen(s) Pre-Analytical Phase: From the time the lab receives the specimen to the time the testing is performed (Inside the organization)	32 10 Ticket(s)	0.1667	↓	0	\$2,500	\$80,000	\$80,000	\$80,000	■
Turn Around Time Post-Analytical Phase: From the completion of testing to transmission of result (Inside the organization)	42 3 Ticket(s)	0.2188	—	0	\$1,000	\$42,000	\$42,000	\$42,000	■
Specimen Lost (Internal) - Irreplaceable Specimen(s) Analytical Phase: From the time testing begins to when it ends	7 2 Ticket(s)	0.0365	↑	0	\$2,500	\$17,500	\$17,500	\$17,500	■
Switched Specimens Analytical Phase: From the time testing begins to when it ends	3 3 Ticket(s)	0.0156	↑	0	\$5,000	\$15,000	\$15,000	\$15,000	■
Test Report/Results Post-Post-Analytical Phase: From receipt of results to decisions regarding treatment of patient (Outside the organization)	6 6 Ticket(s)	0.0313	—	0	\$2,500	\$15,000	\$15,000	\$15,000	■

Tracking CoPQ Using Software (Omni-Assistant)



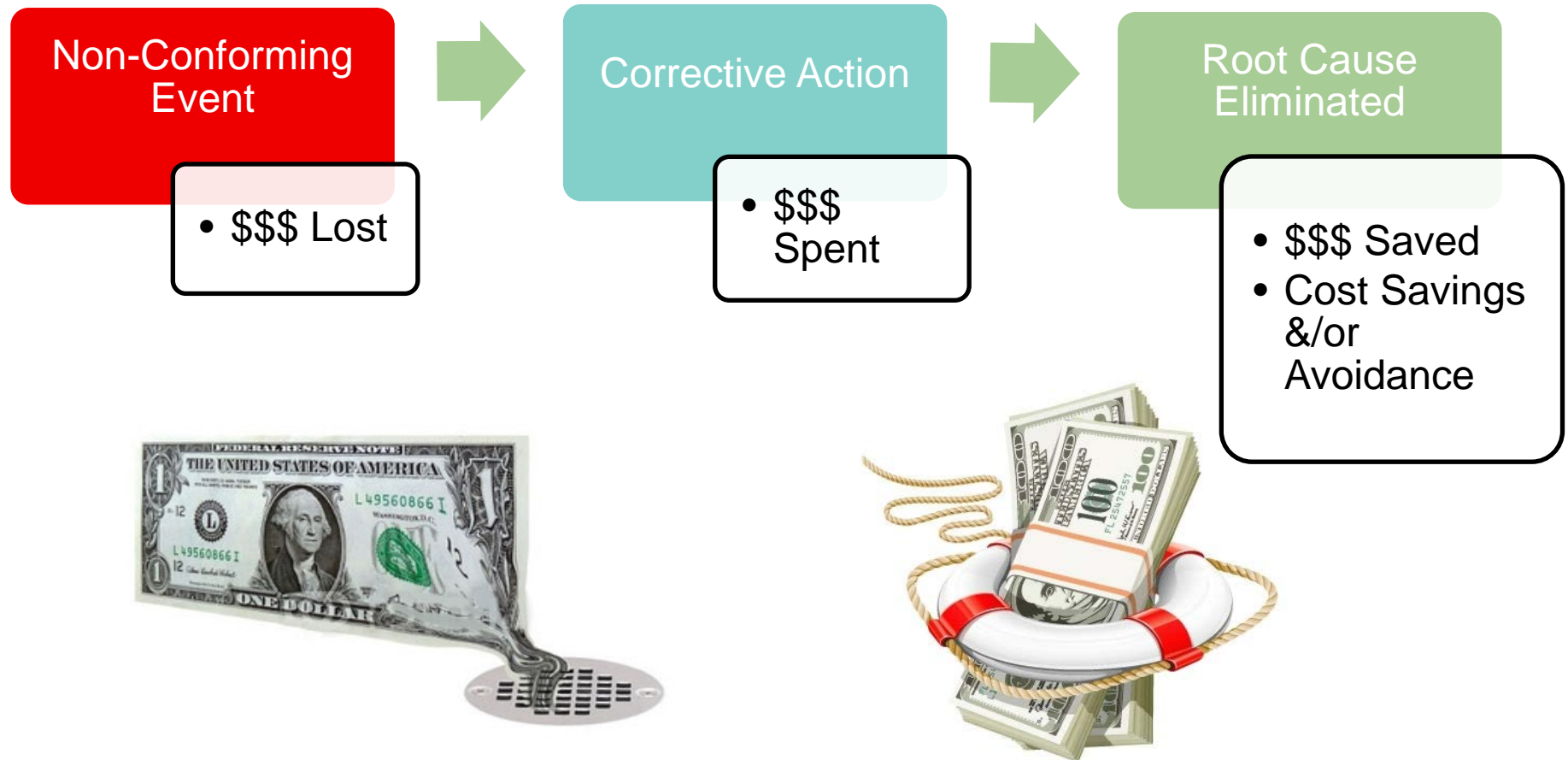
Definitions

- **Return on Investment (ROI):** the benefit (or return) of an investment is divided by the cost of the investment, and the result is expressed as a percentage or a ratio (Investopedia)

$$ROI = \frac{(\text{Gain from Investment} - \text{Cost of Investment})}{\text{Cost of Investment}}$$

- **Cost Savings:** Actions that lower current spending, investment or debt levels. They result in a tangible financial benefit.
- **Cost Avoidance:** Any action that avoids costs in the future. They represent potential increases in costs that are averted through specific preemptive actions.

Why does CoPQ matter?



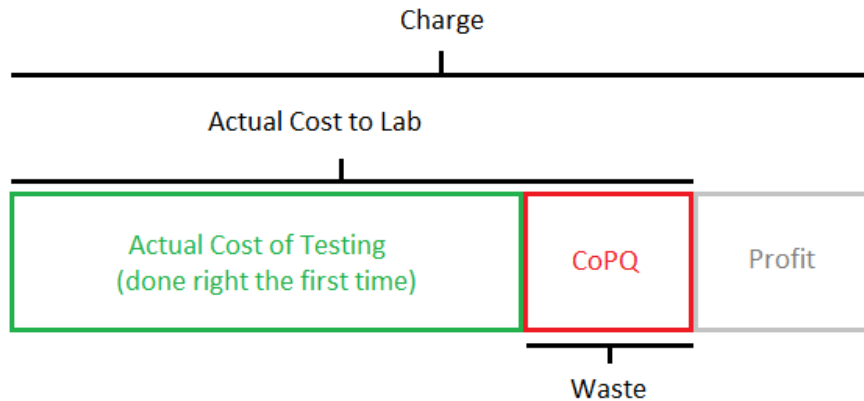
In the Words of Lucia Berte:

- For each failure there is a root cause.
- Causes are preventable.
- Prevention is always cheaper.

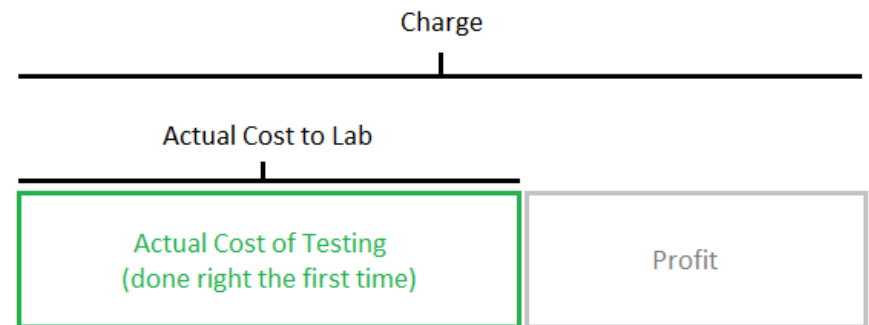
SAVE \$\$\$ BY FOCUSING ON PREVENTION!



Reduce CoPQ = Maximize Profits



CoPQ negatively impacts your bottom line and drives down profits!



Adapted from the Cost of Quality. Lucia Berte. 2013

Review - Cost of Poor Quality (CoPQ)

The Cost of Poor Quality in the Lab

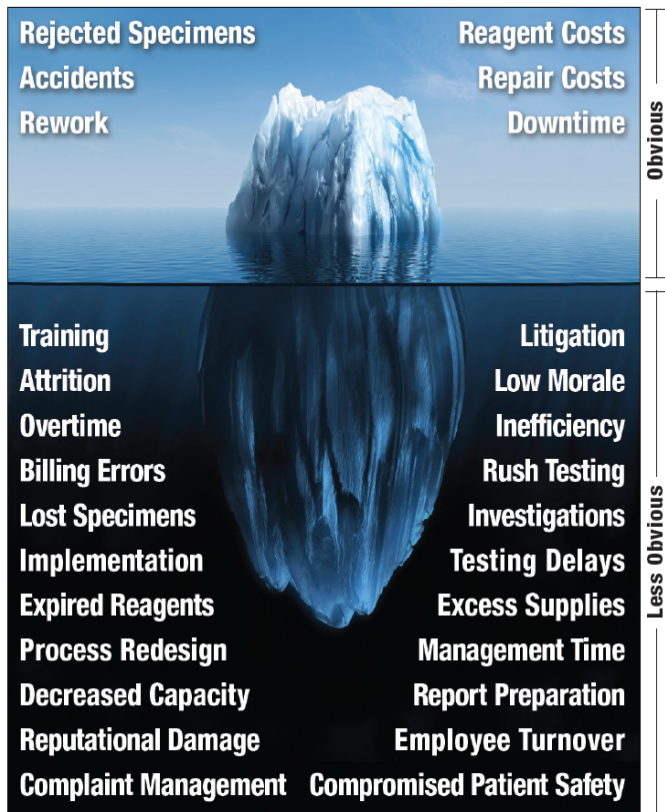
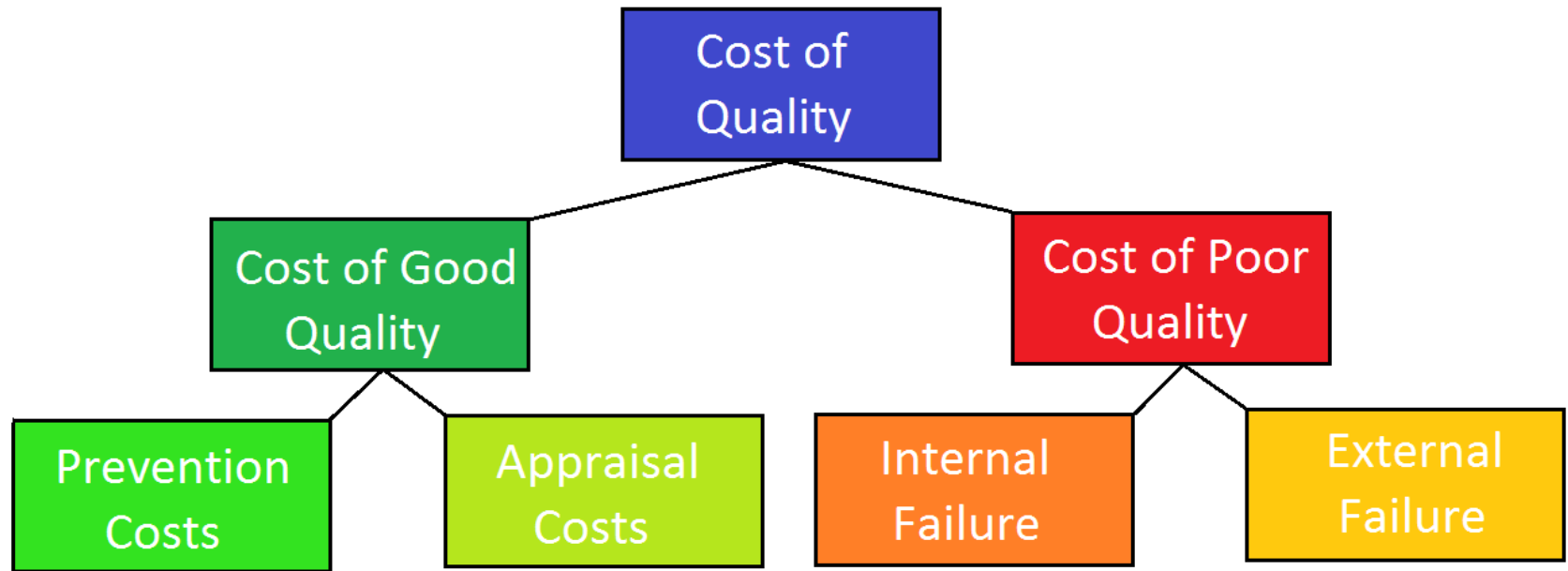


Image courtesy of *Medical Lab Management*, Vol 2(5):8.

- The cost associated with providing poor quality products or services
- The cost of not doing it right the first time
- Allows us to quantitate financial benefit of our quality program
 - Allows us to speak the language of the “C suite”
- Quality = Cost Savings and Cost Avoidance
- Internal vs. External Failure Costs
- Resources:
 - CLSI. QMS-20-R Understanding the Cost of Quality in the Laboratory. 2014.
 - American Society for Quality, www.asq.org

Summary: Cost of Quality Breakdown






Cost of Good Quality vs Cost of Poor Quality

Finding the “Sweet Spot”

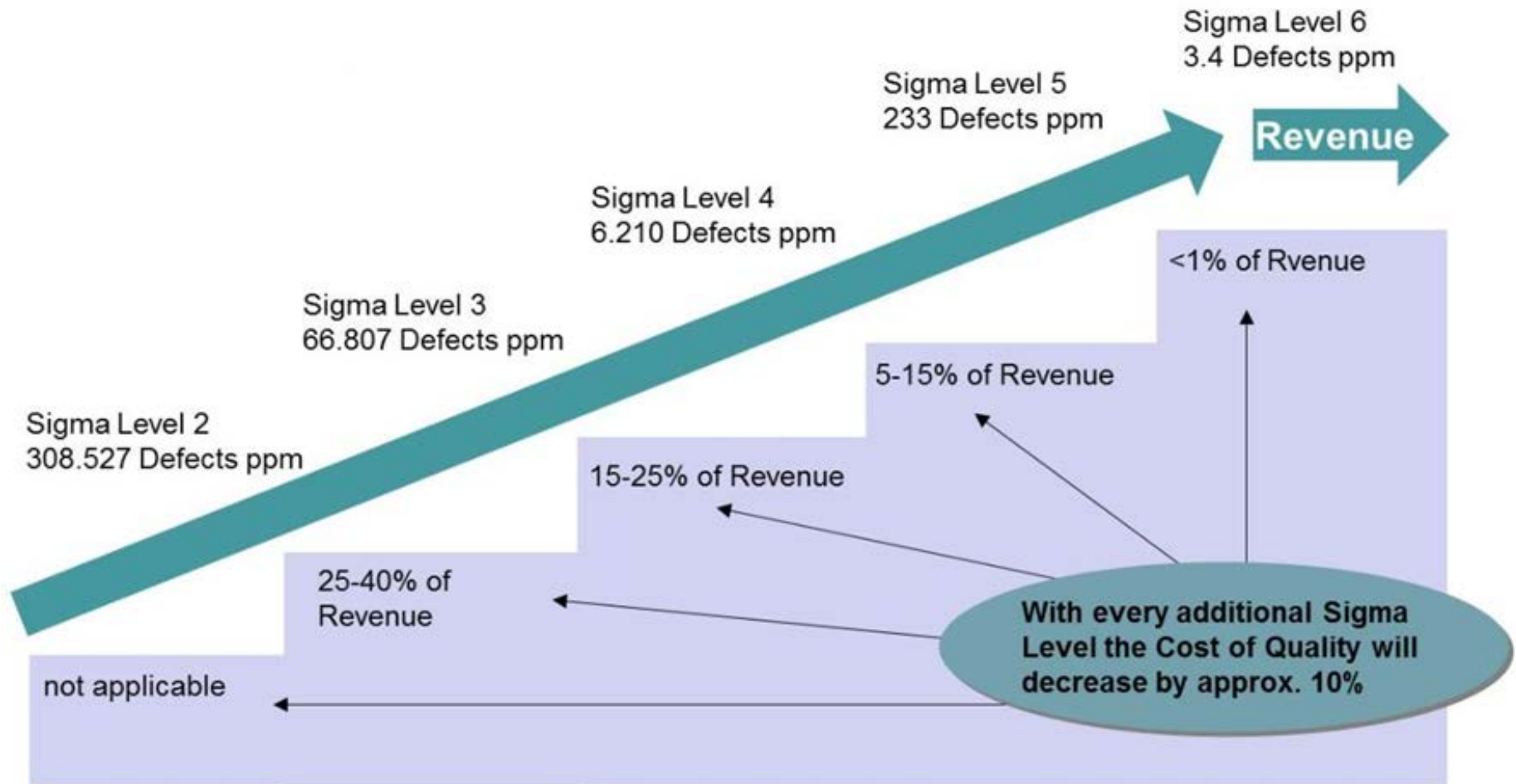


Sigma Levels & Cost of Poor Quality

Sigma	Defect Rate	Cost of Quality	Competitive Level
6	3.4	<10%	 World Class
5	233	10-15%	
4	6,210	15-20%	 Industry Average
3	66,807	20-30%	
2	308,537	30-40%	 Non-competitive
1	690,000	>40%	

<https://www.isixsigma.com/implementation/financial-analysis/cost-quality-not-only-failure-costs>

Sigma Levels & Cost of Poor Quality



Source: Six Sigma, Mikel Harry, PH.D., and Richard Schroeder

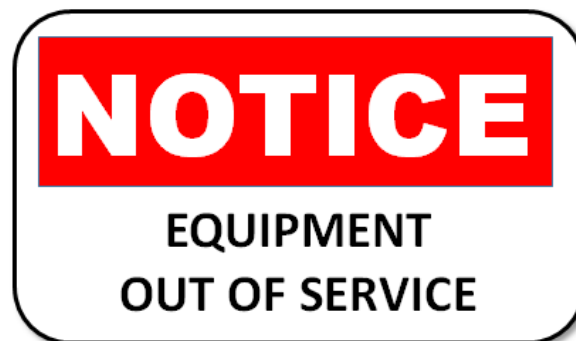


Cost of Poor Quality Calculator

Examples

Example #1: Failing Seals

- In the toxicology laboratory, there are seals that are prematurely failing on instruments. This has led to considerable CoPQ: clean up from solvents spilling on the floor, rerunning testing and significant R&D time as the cause was not known initially. Testing was delayed by a day or longer due to rerunning specimens due to these failures. It was discovered that one of the solvents being utilized was recently changed and is no longer compatible with our seals. Corrective action included an investigation into a new solvent supplier.



Example #1: Failing Seals



Internal Failures – Hard Costs				
Considerations	#	Units	Cost/Unit	Total
Wasted Tech Time	20	Hours	\$15.00	\$300.00
Wasted Reagents	10	Gallons	\$50.00	\$500.00
Process Redesign	3	Hours	\$80.00	\$240.00
Occupational Health Visit	0	Visit	0	\$0.00
Management Time	12	Hours	\$100.00	\$1200.00
Investigation	10	Hours	\$50.00	\$500.00
Overtime	0	Hours	0	\$45.00
Client Education	0	Hours	0	\$0.00
Rework -Failed Run	9	Runs	\$100.00	\$900.00
Complaint Handling	2	Hours	\$15.00	\$30.00
			Total	\$3,715.00

Example #1: Failing Seals



Internal Failure – Soft Costs

Considerations	\$ Estimate
Low Morale	\$0.00
Lost Sales	\$0.00
Equipment Downtime	\$2500.00
Harm to Employees	\$0.00
Total	\$2500.00

External Failure – Soft Costs

Considerations	\$ Estimate
Reputational Damage	\$750.00
Litigation/Malpractice	\$0.00
Corrected Reports	\$0.00
Harm to Patients	\$0.00
Total	\$750.00

Total Hard Costs \$3,715.00

Total Soft Costs \$3,250.00

Total CoPQ \$6,965.00

Example #2: Lost Specimen

- A specimen arrived in the laboratory, was accessioned and placed in the staging refrigerator for testing department pickup. When the lab tech came to pick up the specimens, the specimen was no longer in the rack. After an extensive investigation, the specimen was not recovered. The client was contacted. The specimen was irreplaceable and the client is very angry stating they will never use our lab again.



Example #2: Lost Specimen



Internal Failures – Hard Costs				
Considerations	#	Units	Cost/Unit	Total
Wasted Tech Time	4	Hours	\$15.00	\$60.00
Wasted Reagents	0	Gallons	\$0.00	\$0.00
Process Redesign	0	Hours	\$0.00	\$0.00
Occupational Health Visit	0	Visit	0	\$0.00
Management Time	5	Hours	\$75.00	\$350.00
Investigation	10	Hours	\$50.00	\$500.00
Overtime	2	Hours	22.50	\$45.00
Client Education	0	Hours	0	\$0.00
Rework -Failed Run	0	Runs	\$0.00	\$0.00
Complaint Handling	.25	Hours	\$20.00	\$5.00
			Total	\$960.00

Example #2: Lost Specimen



Internal Failure – Soft Costs

Considerations	\$ Estimate
Low Morale	\$0.00
Lost Sales	\$10,000.00
Equipment Downtime	\$0.00
Harm to Employees	\$0.00
Total	\$10,000.00

External Failure – Soft Costs

Considerations	\$ Estimate
Reputational Damage	\$2500.00
Litigation/Malpractice	\$10,000.00
Corrected Reports	\$0.00
Harm to Patients	\$20,000.00
Total	\$32,500.00

Total Hard Costs	\$960.00
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Total Soft Costs	\$42,500.00
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Total CoPQ	\$43,460.00
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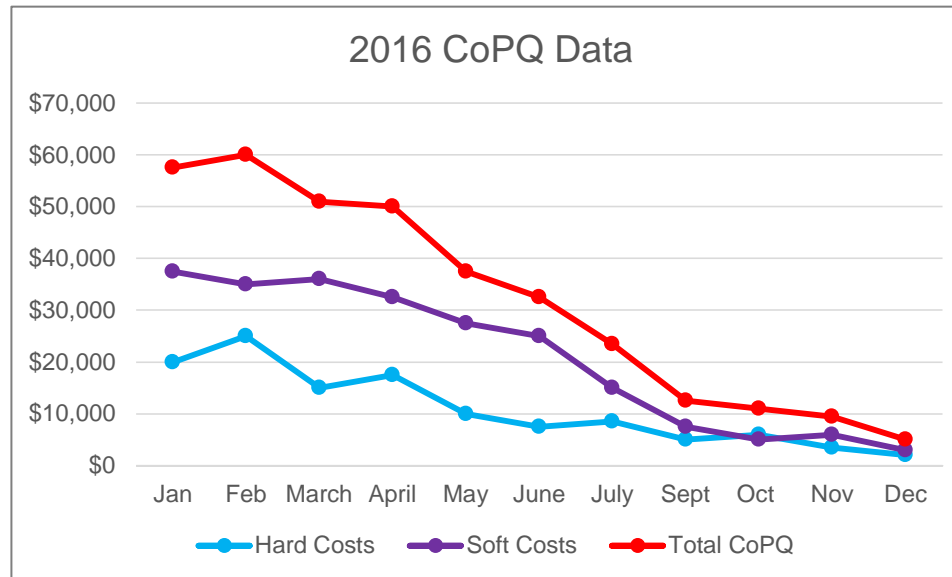
Presenting the CoPQ Data

2016 CoPQ Data

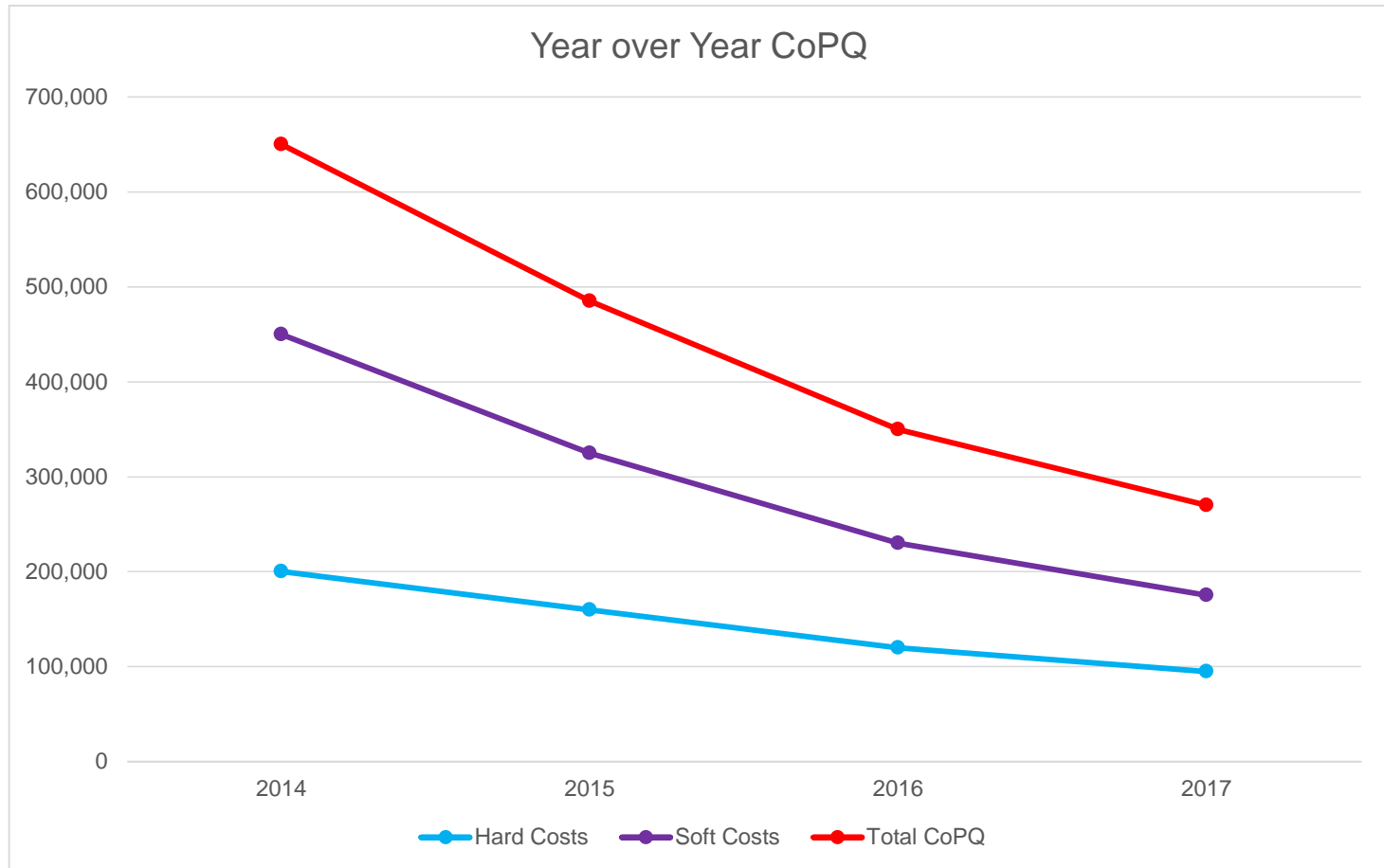
Total Hard Costs \$120,000

Total Soft Costs \$230,000

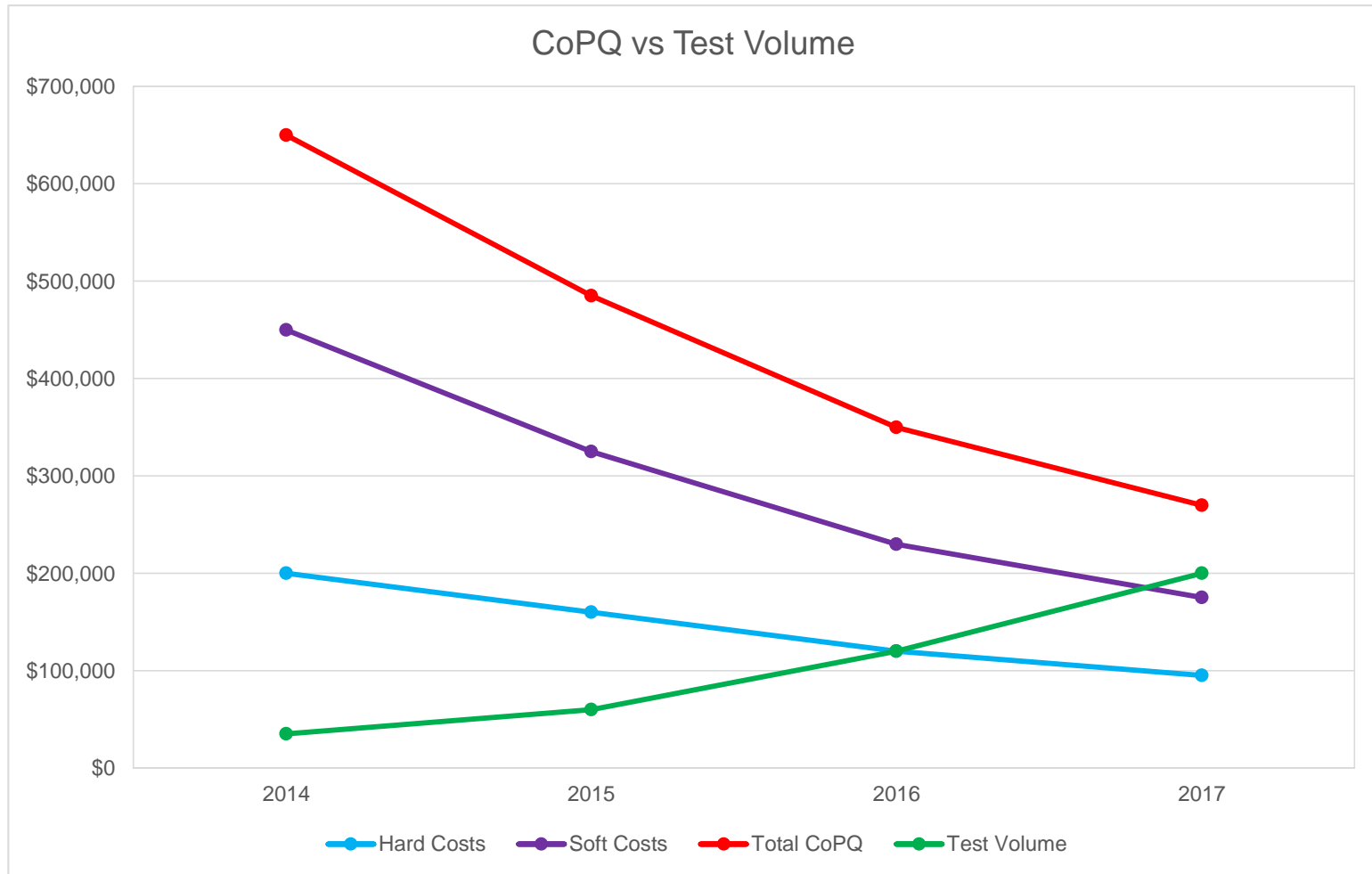
Total CoPQ \$350,000



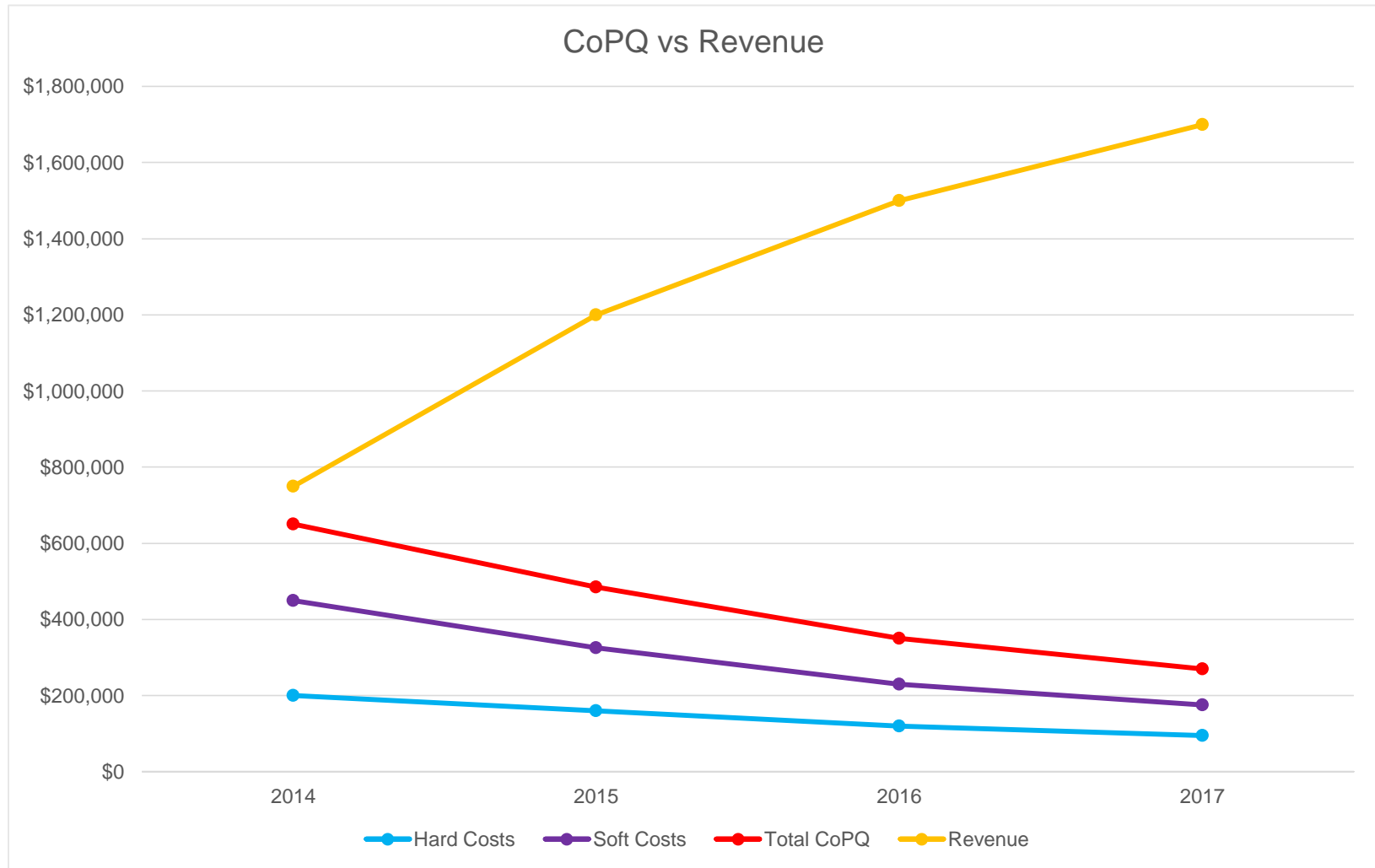
Presenting the CoPQ Data



Presenting the CoPQ Data



Presenting the CoPQ Data



Demonstrating Return on Investment (ROI)

Cost of Good Quality

Prevention
Quality 2.0 FTEs = **\$150,000**

VS

Cost of Poor Quality

Internal/External Failure
Costs

~\$350,000 for 2016
(very conservative estimate)

ROI in 5 months for entire year FTE
devoted to quality program just
considering non-conforming events

*It is always cheaper to do the job
right the first time.*

- Phil Crosby





If you don't have time to do it right, you must have time to do it over.

- Russian proverb

If you don't have time to do it right,
you must have time to ***do it again***,
then do an ***investigation***,
root cause ***analysis***,
implement a ***corrective action*** and
follow up with an ***effectiveness check***.

- Quality Manager proverb

Questions?

Presented by: Jennifer Dawson
jdawson@humanlongevity.com

The information in this presentation is provided for educational purposes only and is not legal advice. It is intended to highlight laws you are likely to encounter, but is not a comprehensive review. If you have questions or concerns about a particular instance or whether a law applies, you should consider contacting your attorney.



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