Reducing the Cost of Poor Quality & Improving Efficiency with Quality Management

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Today's Topics

- Risk Mitigation and Quality Management Systems
- Cost of Poor Quality
- Managing Efficiency Improvements
- Resources

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Risk Mitigation

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Example of Corporate Goals

- Enhance Customer Satisfaction
- Achieve Operational Excellence
- Minimize Risk
- Expand Market Share and Revenue
- Increase Profit through Innovation
- Ensure Product Quality Leadership
- Improve Return on Assets
- Improve Employee Satisfaction

Example Challenges

- Evolving regulatory requirements
- Utilizing new technologies and test methods
- Limited resources (time, personnel, equipment)
- Health and Safety
- Staff training, development and retention
- Innovation
- Change management

Quality Risk Mitigation Function

Protecting Top Line Revenue

- Lab disqualification by client due to poor metrics
- Client regulatory non-compliance or NOVs
- Certification loss/gaps
- Client fires lab for service/quality issues or lack of confidence/trust

Protecting Bottom Line Profit

- Fines / penalties
- Payment refusal due to data rejection for quality failures
- Data recalls
- Holding time violations
- Late reports – monetary penalties/loss of quick TAT premiums

Quality Systems are Risk Based

TNI 2016

- Requires root cause and corrective actions
- Requirements for written procedures
- Requirements for staff training & qualifications
- Annual Management Review

ISO 17025: 2017

- Requires root cause and corrective actions
- Requirements for procedures
- Requirements for staff training & qualifications
- Management Review
- Evaluation of risks and opportunities

DoD QSM 6.0

- Same as ISO 17025:2017
- Additional evaluation of risks and opportunities for 15 specific laboratory activities.

Key Elements of a Quality Management System

- Quality Culture
- Organizational Structure
- Standard Operating Procedures
- Document Control
- Training and Competency Management
- Calibration, Maintenance and Checks on Instrument and Equipment
- Sample Management
- Quality Control and Quality Assurance:
  - Corrective Action
  - Internal Audit and External Accreditation
- Risk Management, and
- Continuous Improvement

Cost of Poor Quality (risk perspective)

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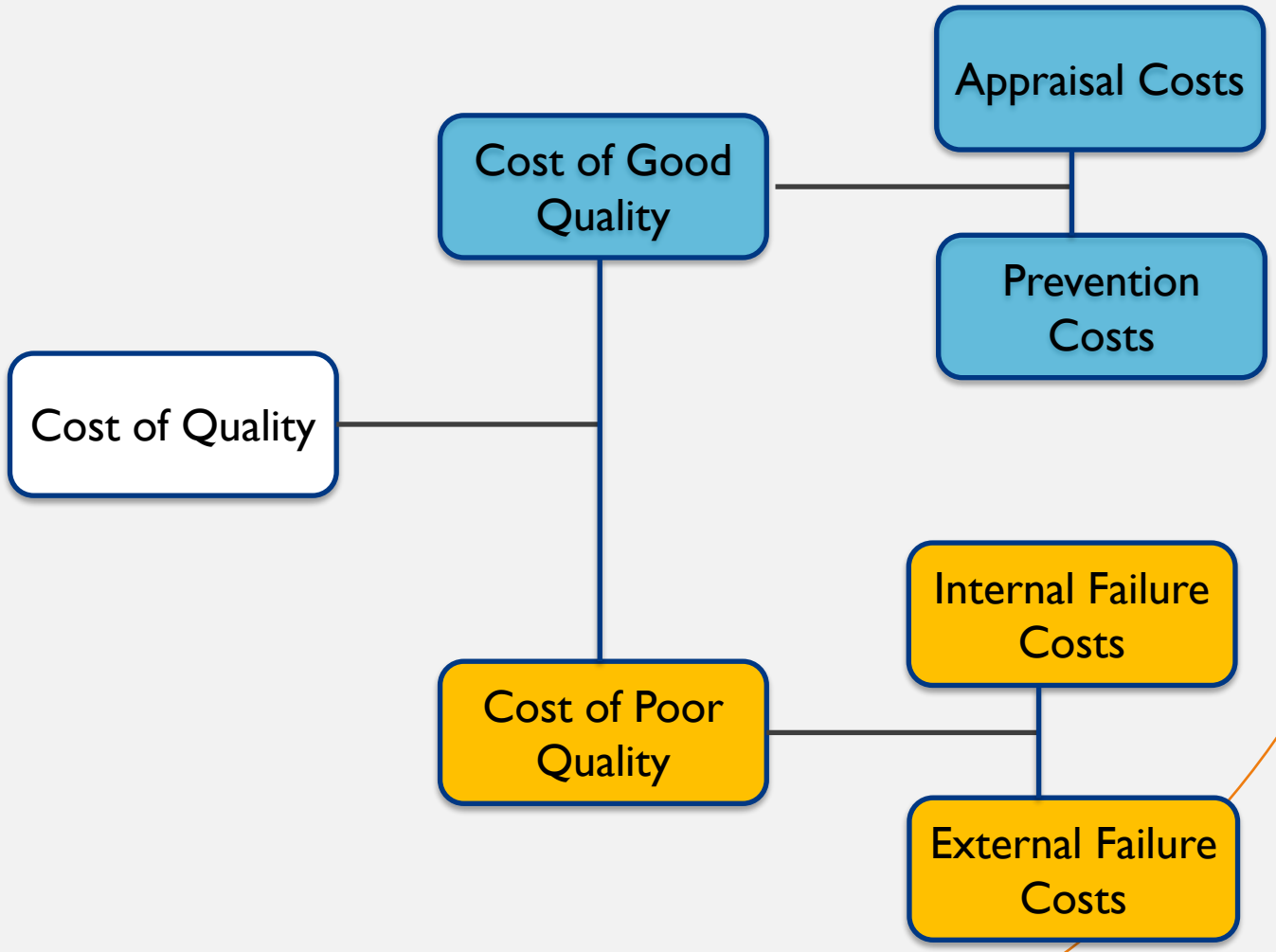
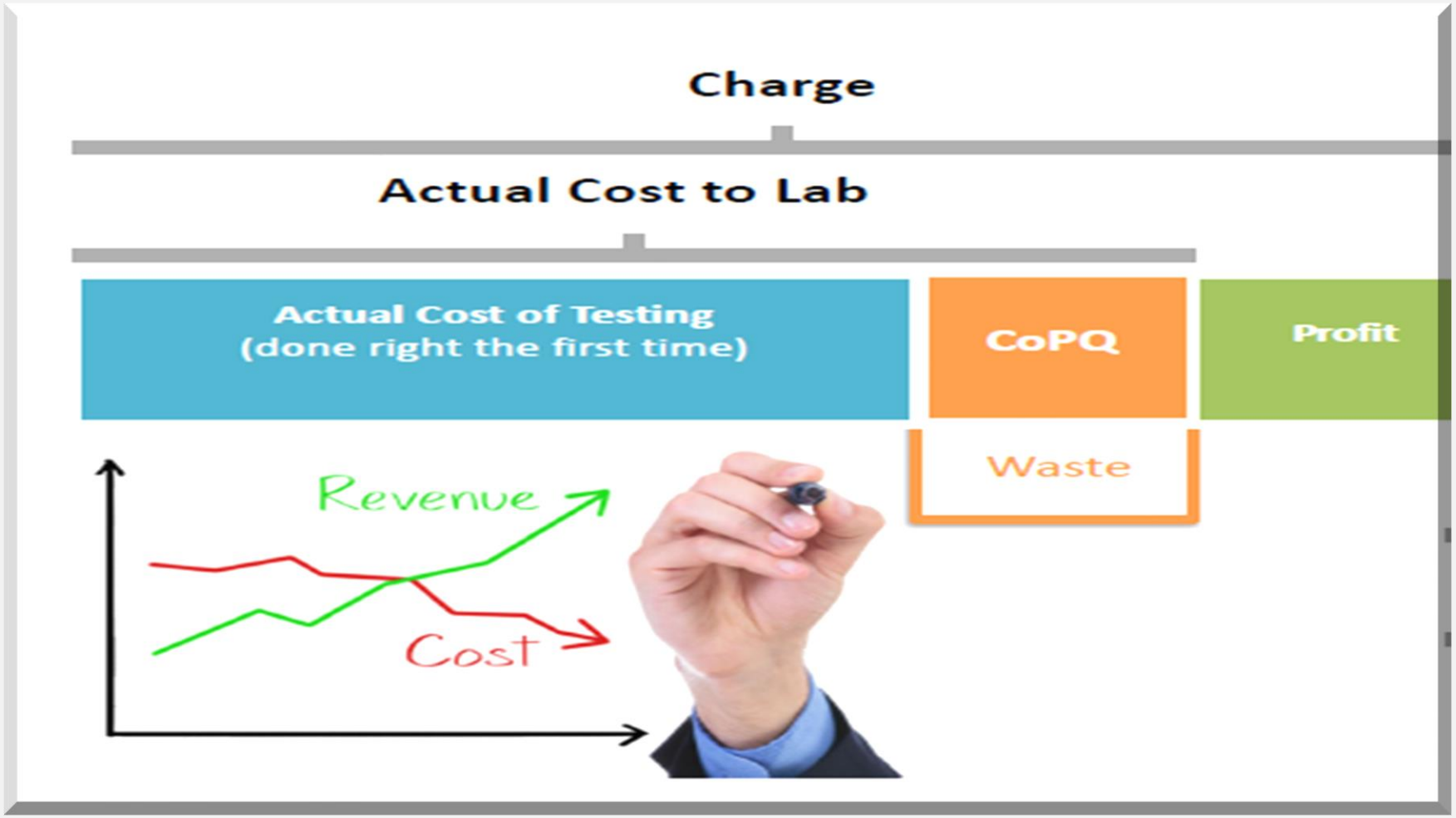
Cost of Quality(COQ)

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 failures. *



* American Society for Quality

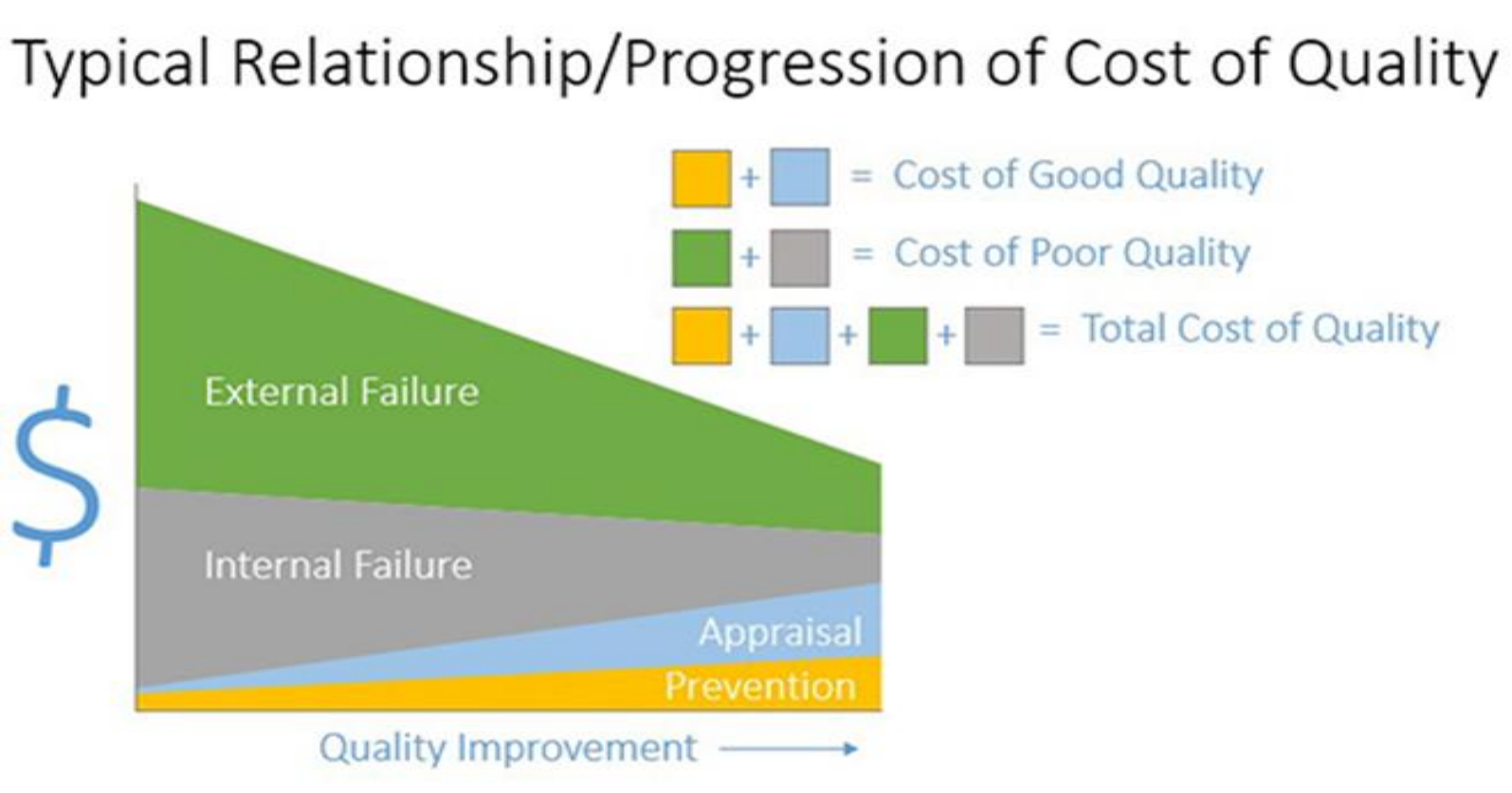
Labs are Businesses



Goal
COPQ
< 15% of sales

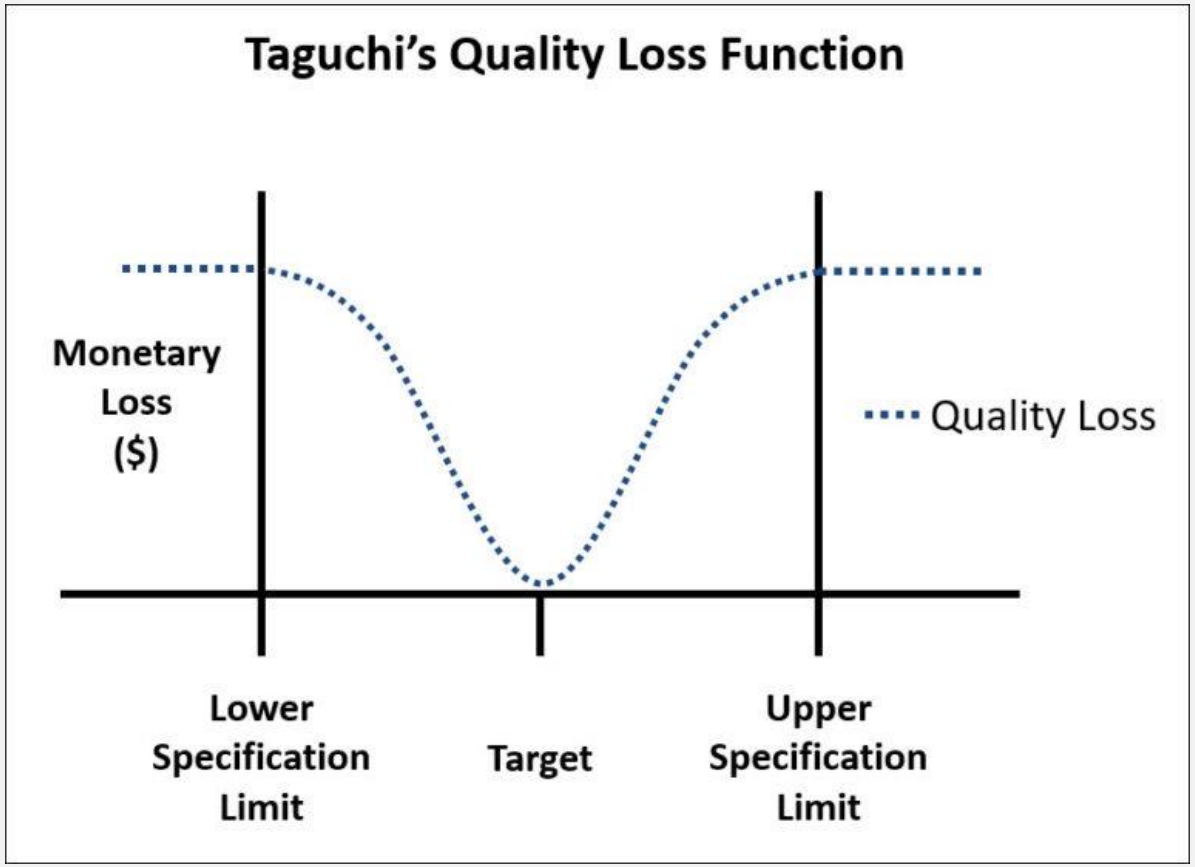
Not all Poor Quality Costs are Visible

Do You Track the Cost of Quality?



- Total cost of quality?
- Cost of poor quality?
- Cost of good quality?
- ROI on quality improvements?

Taguchi's Quality Loss Function Principle



- Cost can be reduced by improving Quality
- Cost can be reduced by decreasing Variation
- Quality can be improved without affecting Cost
- Cost cannot be reduced without affecting Quality

Quality System Focus on Prevention and Appraisal

When done correctly and consistently can make a lab more effective and efficient.

- Communicate the Significance of QC and QA in Environmental Testing (can't just say its required)
- Proper Calibration and Maintenance
- Participation in Proficiency Testing
- Documentation of Traceability and Quality Control Data
- Data Review
- Trend Analysis
- Corrective Action
- Internal Audits
- Customer Compliant Process
- Importance of and Role of Accreditation (TNI or ISO 17025)
- KPIs, Performance Indicators and Metrics
- Management Review
- Change Management
- Risk Management

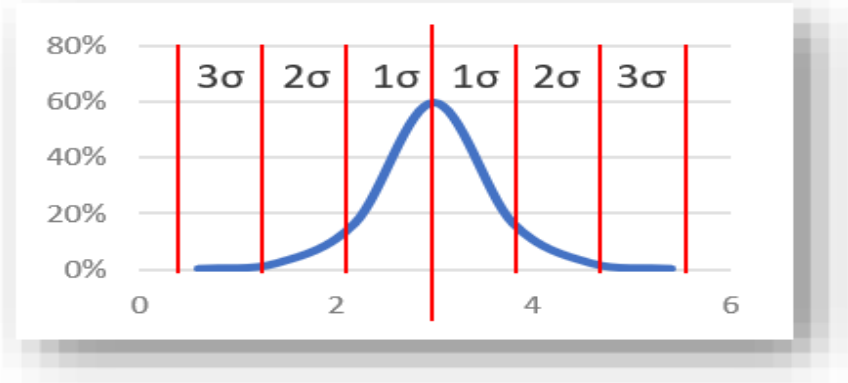
Financial Impact of Quality Solutions is Hard to Define

Numbers People are Not the Same as Numbers People

Quality Numbers

$$s = \frac{\sum (x - \bar{x})^2}{n - 1}$$

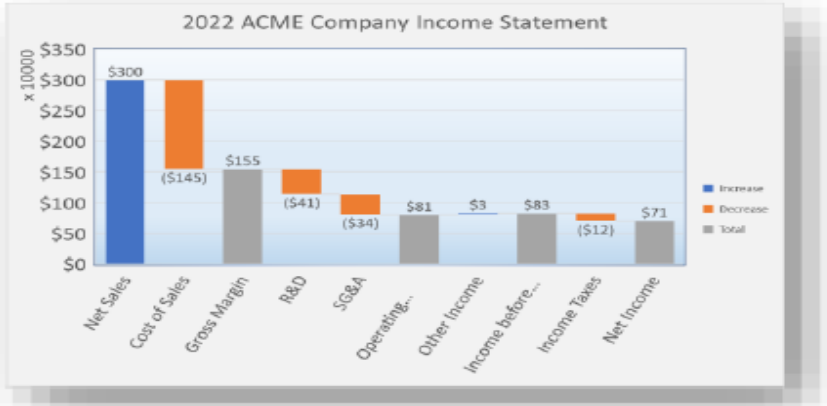
$$COQ = PC + AC + IFC + EFC$$



Finance Numbers

$$0 = NPV = \sum_{t=1}^{T} \frac{C_t}{(1 + IRR)^t} - C_0$$

$$Payback\ Period = \frac{Unrecovered\ Amount}{Cash\ Flow\ (Annual)}$$



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Quality Transactions by Quality Cost Category

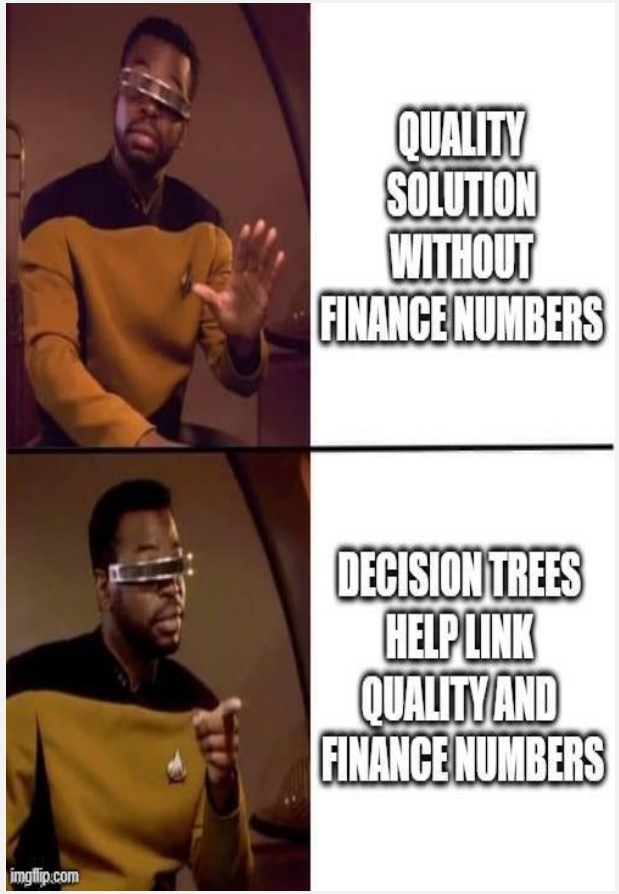
Prevention	Appraisal	Internal Failure	External Failure
• Training • Sufficient staff • Process design • Equipment maintenance • Equipment calibration • SOPs / Work Instructions • Positive/Negative controls • Supply specs.	• Internal audits • Secondary data review • Customer surveys • Management reviews • Supplier evaluations • Control Charts	• Rework • CAPA • Equipment repair • Down time • Employee turnover • Capacity loss	• Rework • CAPA • Revised reports / Data recall • Lost sales • Lost trust • Complaints • Recollection fees

Example Quality System Cost Types

Quality System Component	Prevention	Appraisal	Internal Failure	External Failure
Audit	X	X		
Calibration & Metrology	X	X	X	
Document Management	X	X		
Reference Materials	X		X	X
Project Management	X		X	X
Risk & Opportunities	X	X	X	X
Employee Training	X	X		
Corrective Action	X	X	X	X
Supplier Evaluation	X	X		

Various studies demonstrate that externally discovered failures are 5-10X more expensive than internally discovered failures.

Numbers People are Not the Same as Numbers People



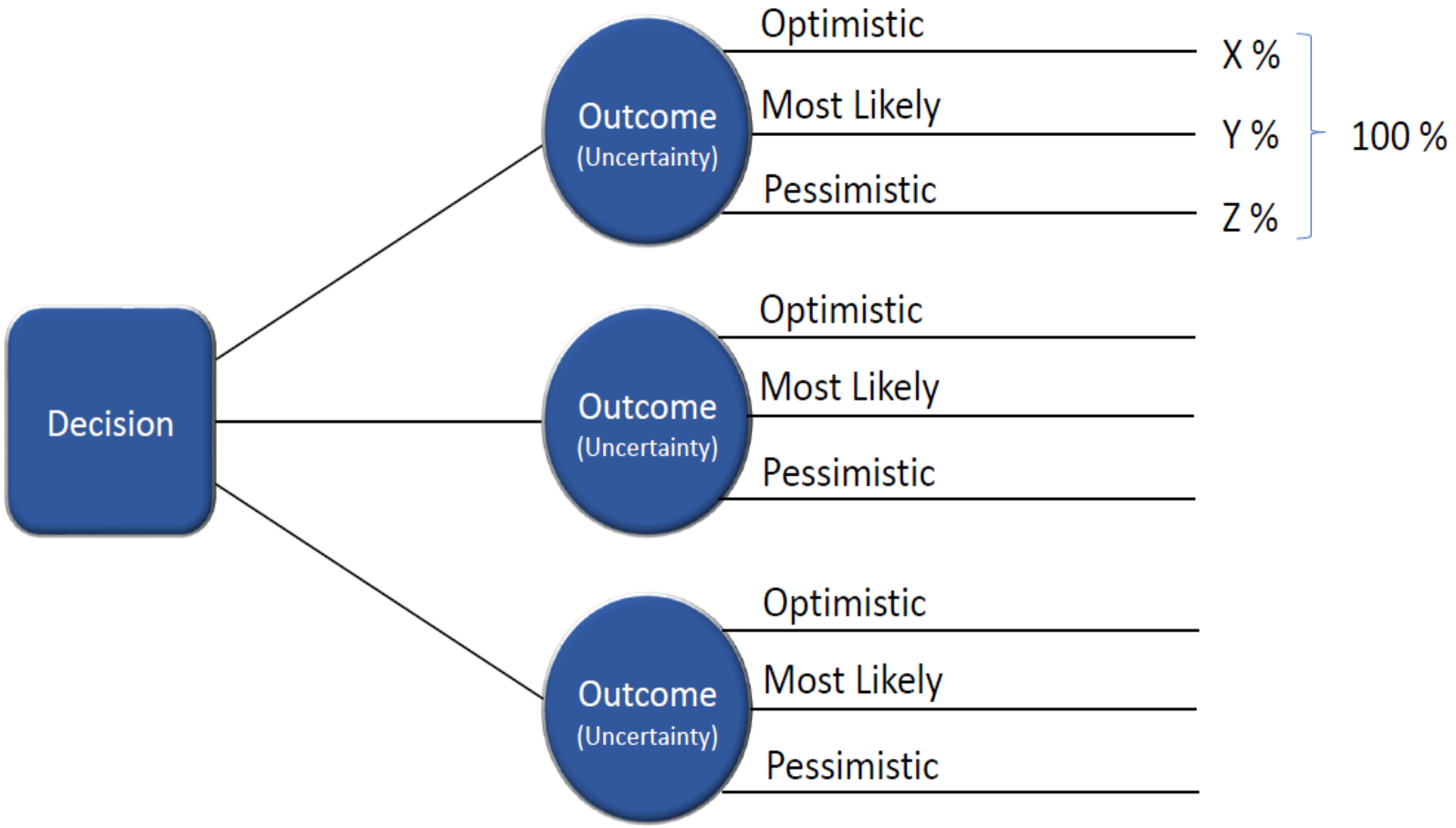
Cost of Poor Quality

- Cost of Re-Analysis
- Cost of Investigation
- Cost of Correction
- Cost of Customer Dissatisfaction

Financial Allocation

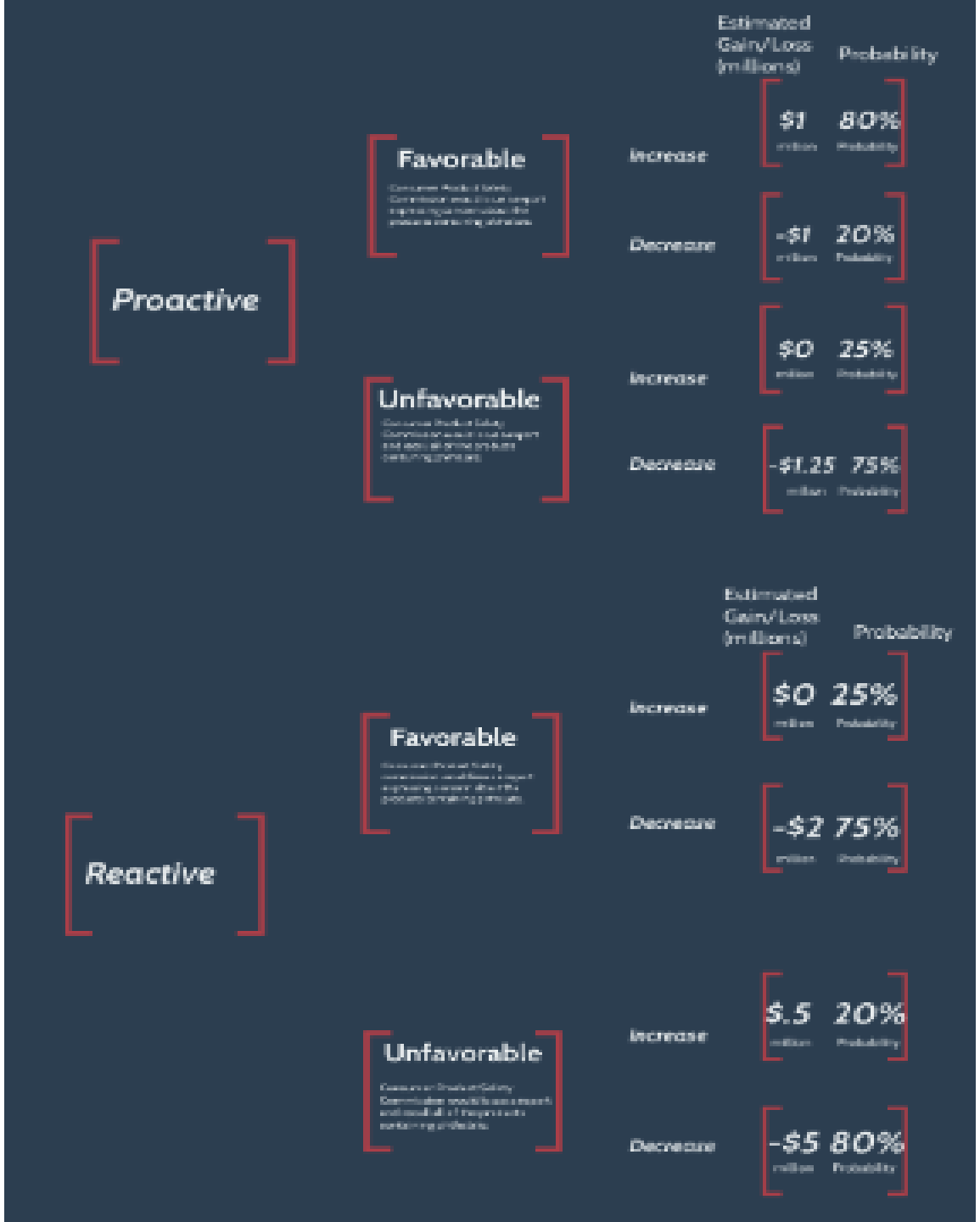
- Cost of Goods (Income Statement)
- Cost of Rework (Variance)
- Lost Sales (Future – not accounted for)

Decision Trees – Evidence Based Decision Making



1999 Gerber Event

A possibly harmful chemical, phthalates, was reported to appear in the company's products. The Consumer Product Safety Commission, Greenpeace, and the national media were all applying pressure.



Proactive recall was determined to be more financially advantageous.

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Managing Efficiency Improvements

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Automation and Technology Adoption

- Developing or Acquiring and Maintaining a LIMS That Best Meets the Labs and Clients Needs
- Utilizing Quality Management Software
- Instrument and Data Acquisition Systems
- Advanced Analytical Techniques (ex: GC/MS/MS, microextraction)
- Internet of Things (IoT) in Lab Equipment
- Robotics and Sample Handling and Tracking Automation
- High-throughput Screening Technology
- Electronic Data Management and Reporting
- Use of AI for Data Analysis and Quality Control
- Cloud Computing and Data Management

Innovation = ↑ Reward and ↑ Risk

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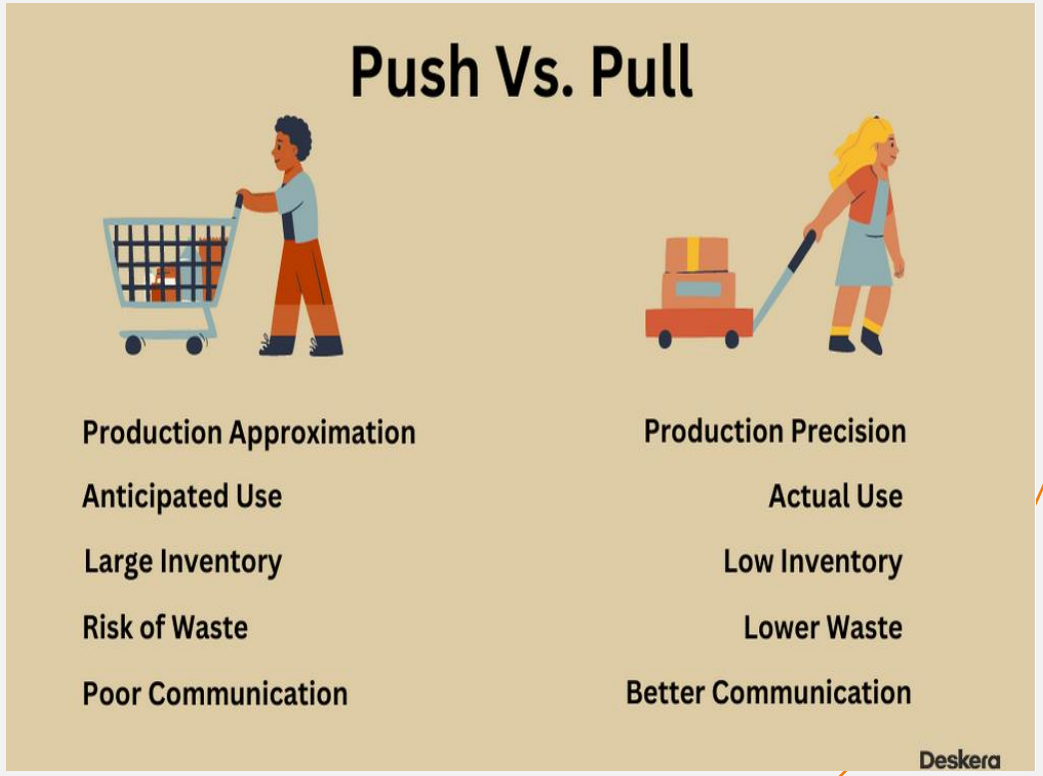
Process Optimization

- Define Value From The Customer's perspective
- Map The Value Steam (what is your desire future state)
- Create the Flow by Streamlining Processes
- Establish Pull-Based Systems for Efficient Workflow
- Pursue Continuous Improvement Through Feedback, Use of Metrics and Data Analysis



LEAN is a Process Optimization Technique

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Change Management

1. Define the change and have an implementation plan.
2. Develop a communication plan.
3. Train people.
4. Execute the change.

Summary

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Summary

Utilize the Quality Management System to:

- Focus on preventive and assessment costs of quality
- Evaluate Risks and Opportunities
- Manage change

References

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