



Lecture 6: Cost-Time-Quality-Dilemma

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Costs incurred to prevent failures or to reduce appraisal costs

1. Quality Planning
2. Vendor Approval System
3. Training
4. Procedures
5. Preventive Maintenance
6. Product/Process Design and Validation
7. Process Assessments
8. Trend Analysis
9. Process Improvement
10. New Product Review
11. Process Control
12. Quality Data Acquisition and Analysis

Costs of inspection, testing, quality evaluation to assure conformance to standards

1. Inspection and testing of raw and packaging materials
2. Inspection and testing of in-process materials
3. Inspection and testing of finished products
4. Stability testing
5. Audits
6. Document review
7. Checking, reviewing, inspecting
8. Approvals
9. Calibration (?)

Costs associated with nonconforming material still in the companies possession

1. Rejects
2. Reworks
3. Re-inspections
4. Retests
5. Wastage, scrap, low yields
6. Troubleshooting
7. Failures/deviations investigations
8. Documentation errors
9. Sorting substandard material
10. Downtime

Costs associated with a nonconformance condition after the product has left the companies ownership

1. Recalls
2. Complaints
3. Returns
4. Product Shortages
5. Warning Letters, Consent Decrees

Traditional:

standard financial data.

Defect Document:

track defects, determine average cost of a defect, multiply number of defects by average cost.

Time and Attendance:

document time for selected activities,
develop list of codes, train, develop collection system.

Assessment:

Select areas to be assessed, form team of trained assessors who understand area(s) to be assessed, train process/area managers, collect data, evaluate, act.

Why are Good Investigations Important?

- Allow for an environment of continuous improvement
- Prevents recurrence of exceptions/errors
- Reduces rework and rejection
- Improves Cost of Quality
- Drives Efficiency
- Improves work environment, thus reducing errors
- Mitigates regulatory concerns
- Ensures product Quality!
- Ensure patient safety!!

Well Performed Investigations and Well Written Investigation Reports are **GBP** because.....

1. Help identify repetitive problems
2. Opportunity for continual improvement
3. May lead to adoption of more efficient and cost-effective processes
4. Should reduce the failure and rework rate
5. “Hidden factory”: Reworks cost a firm 3 times!
 1. Wasted time and money to produce a failed batch
 2. Wasted time and money to rework the batch
 3. Lost time which could be devoted to other production during the rework process



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