Cost of Quality

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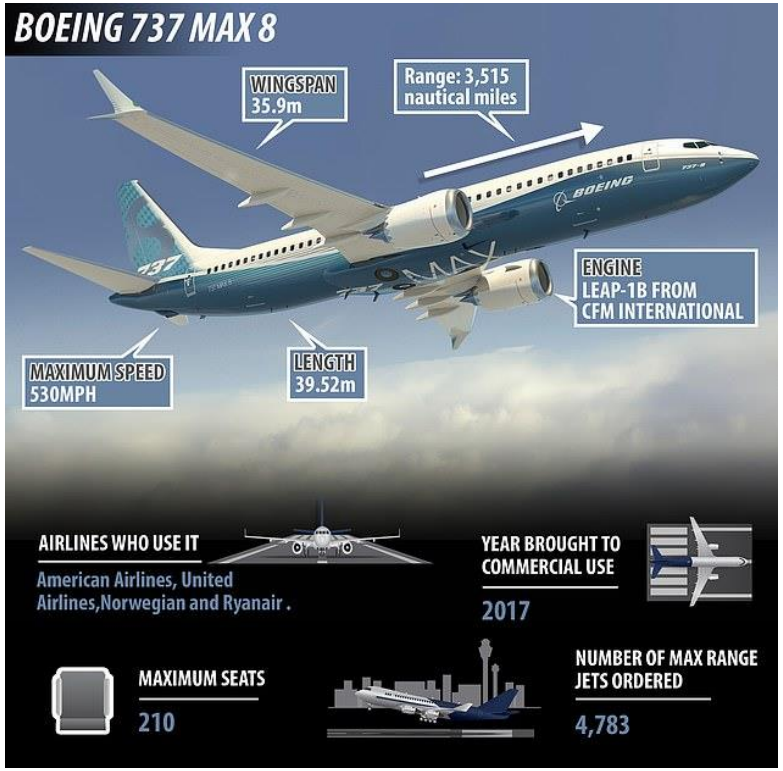
5th INDIA PHARMACEUTICAL FORUM 2020

IPA
Innovation, Quality and Global Reach

What is cost of quality

Cost of Quality is a comprehensive methodology to measure the organization's resources being used for **prevention, detection and maintaining product quality (both direct and indirect costs) as opposed to the direct costs resulting from internal and external failures**

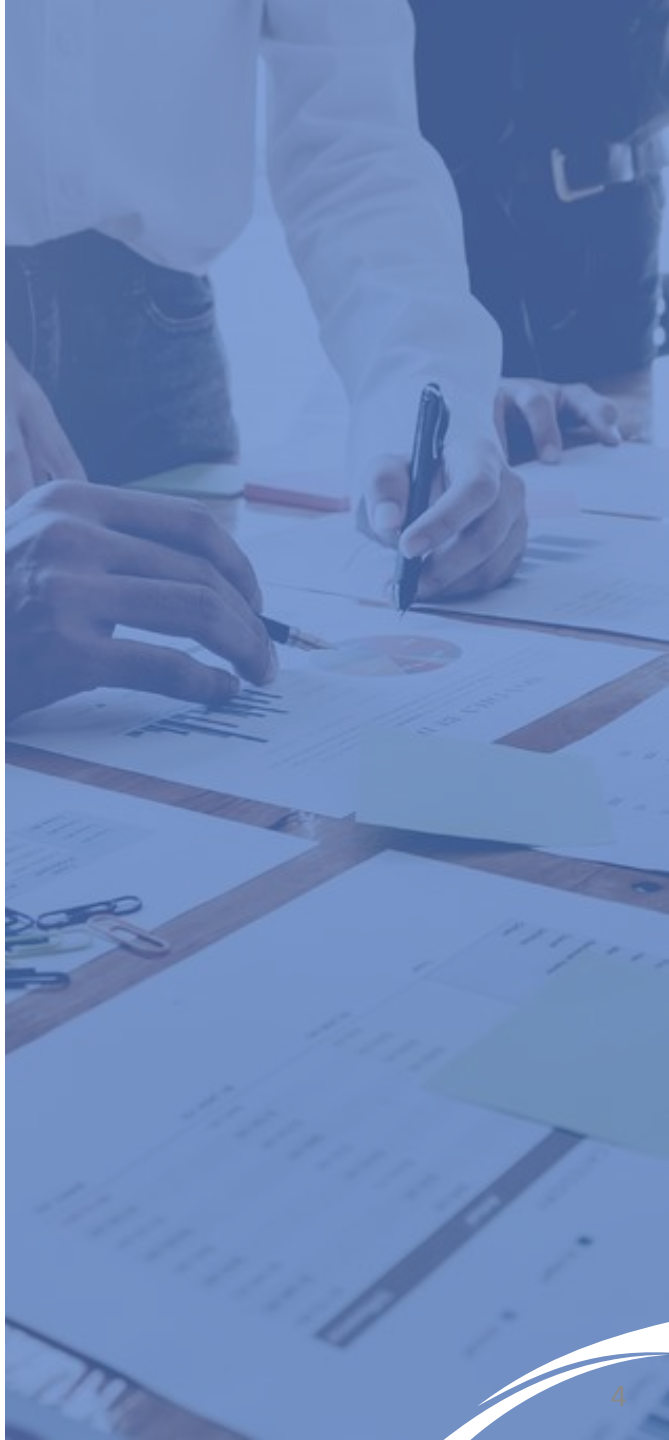
Why is cost of quality important



Small mistakes often lead to a high drain on costs / resources

Let’s discuss few cases to help us better realize the cost of Quality; i.e. how small mistakes in GMP documentation / practices can cost a lot to an organization; three examples to discuss:

- **Training questionnaire evaluation**
- **Equipment cleaning**
- **ANDA application**



Case 1: Training questionnaire evaluation

Issue: Employee forgot to mark answer and same was missed by reviewer

Risk: Data reliability concern

Issues	Cost	Remediation	Cost
Employee forgot to mark answer and same was missed by reviewer	10 sec	Review of all previous training records of the individual and associated employees. (2 Hrs. each for 50 employees)	100 Hrs.
		Review of all associated activities performed by the concern employee for last 2 years. (10 days of time)	80 Hrs.
		Retraining on all applicable SOP's to all employees. (CAPA) 30 days of time, 2 hrs. each day.	60 Hrs.
		Time involved in writing of response. (3 days)	72 Hrs.
		Hiring external consultancy for independent and comprehensive review. (10 days)	80 Hrs.
		Total Cost in Hrs.	**392 Hrs.**

Conclusion: For the negligence of 10 seconds, organization has to spend 392 Hrs. of time and associated financial cost for its remediation; such a huge cost of resources !!!!

Case 2: Equipment cleaning

Issue: White powder found on a process equipment due to improper cleaning and same was not identified during the line clearance

Risk: Cross contamination

Issues	Remediation	Cost
White powder found on a process equipment due to improper cleaning and same was not identified during the line clearance.	Time required for testing of white powder for its identification	Time, laboratory occupancy and Manpower
	Cleaning of equipment chain	Time, utility and Manpower
	Testing of reserve samples to eliminate the possibility of cross contamination	Time and Manpower
	Investigation and impact assessment	Time and Manpower
	Product recall in case of observed traces leads to cross contamination issue	Financial loss
	Compliance to warning letter and import alert	Loss of business and brand image
	Independent review through third party consultant to overcome the cross contamination issues.	Time and financial cost
	Re-inspection and its compliance	Time, money and manpower

Conclusion: Negligence of an individual costs time, money, manpower and reputation of organization

Case 3: ANDA review

Issue: Typographical error in area classification in ANDA application

Risk: Significant delay in approval

Issues	Remediation	Cost
Typographical error in area classification in ANDA application	Review of all submitted ANDA's.	Time and Manpower
	Notification to customers and regulatory agencies	Time and Manpower
	Independent review through third party consultant	Time, money and Manpower
	Investigation and impact assessment	Time and Manpower
	Corrections and re-submission of supplementary ANDA applications	Time, money and Manpower
	Response to inspection findings	Time and Manpower
	Re-inspection and its compliance	Time, money and manpower

Conclusion: Negligence in preparation and review of ANDA application costs time, money and manpower

As a result, cost of poor quality has a significant impact on key operational outcomes

Cost of poor quality – waste and rejects

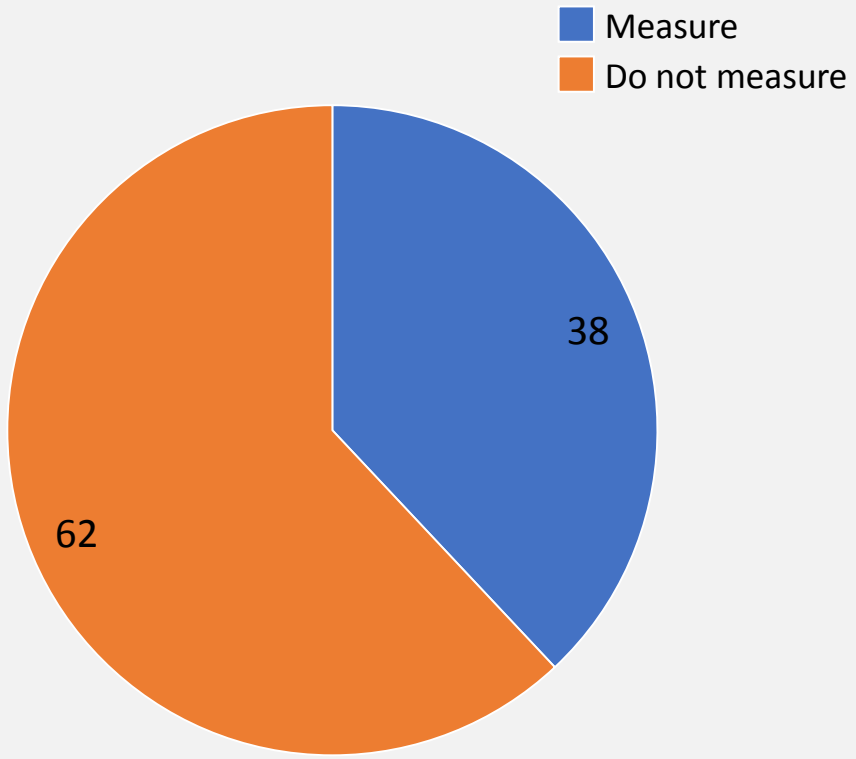
	CpK value	Mfg. performance (σ)	Defects (ppm)	Yield (%)
Poor quality	0.67	2	308,537	69.2
	1	3	66,807	93.3
Average quality	1.33	4	6,210	99.4
	1.67	5	223	99.98
World class quality	2	6	3.4	99.99966

SOURCE: FDA Science Board Meeting November 16, 2001

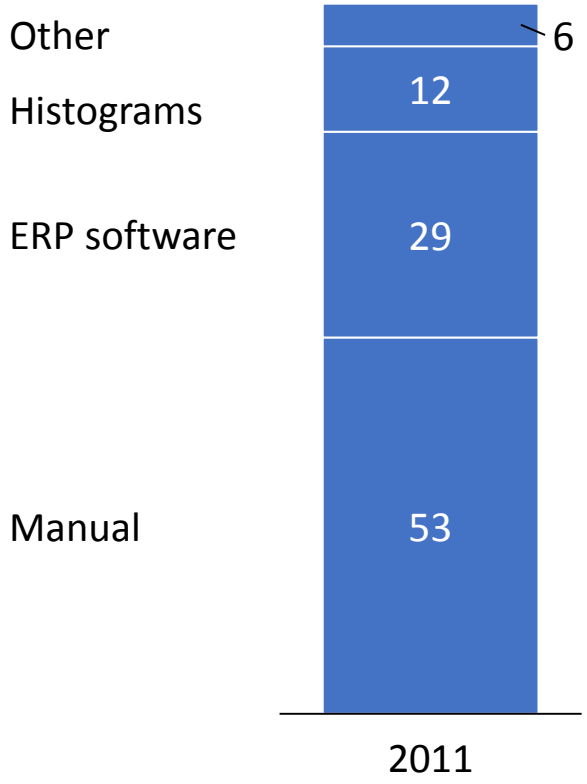
A large part of the cost of quality is hidden (e.g. cost of lost sales); only those parts that are ‘obvious’ are visible

Companies either do not measure cost of quality, or rely heavily on manual systems for measuring cost of quality

Most companies do not measure cost of quality . . .



…. And those which do, use mostly manual methods



SOURCE: Parenteral Drug Association survey Sep 2011 (reported in Gold Sheet Sep 2012)

Very often, pharma companies significantly underestimate total cost of poor quality: Deviations example

DISGUISED PHARMA SITE

Costs associated with deviations

Materials and conversion cost: Cost of rejected batches as measured at the site

Quality Labor: 30-50% of time of Quality FTEs is spent on investigations, CAPA, etc. associated with deviations

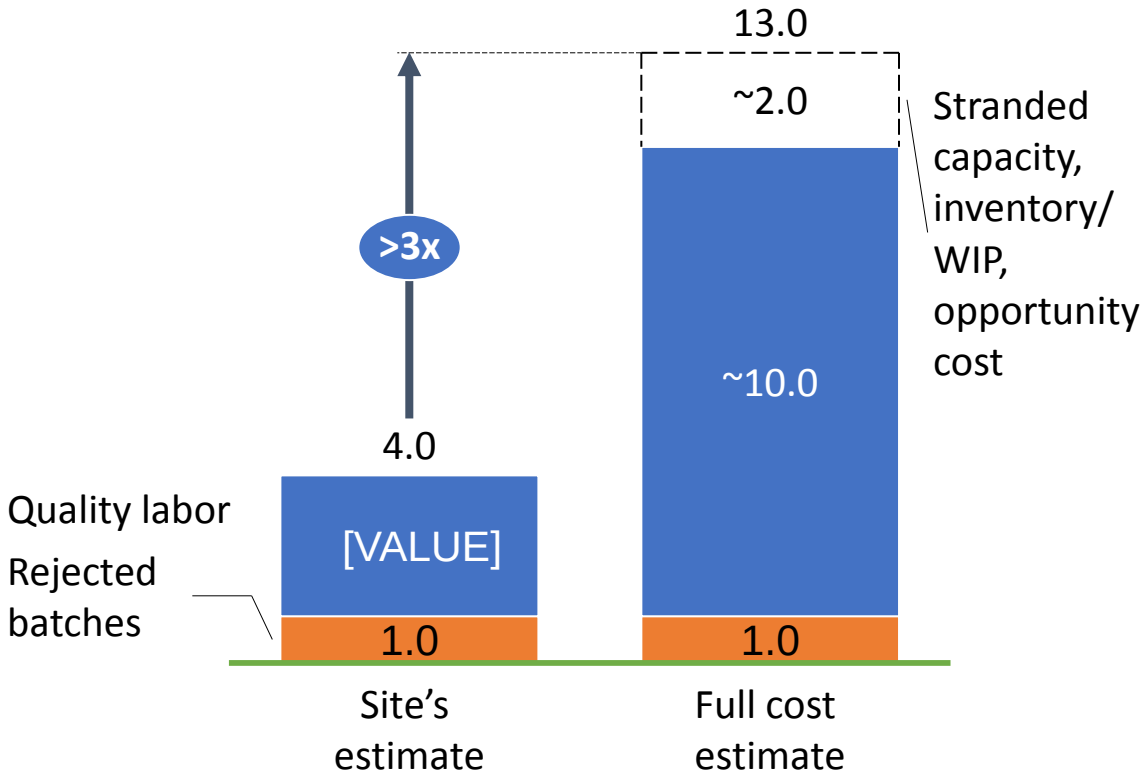
Capacity stranded due to deviations: step function, relevant for growing volumes and determining need for new lines/investments

Foregone or postponed revenues

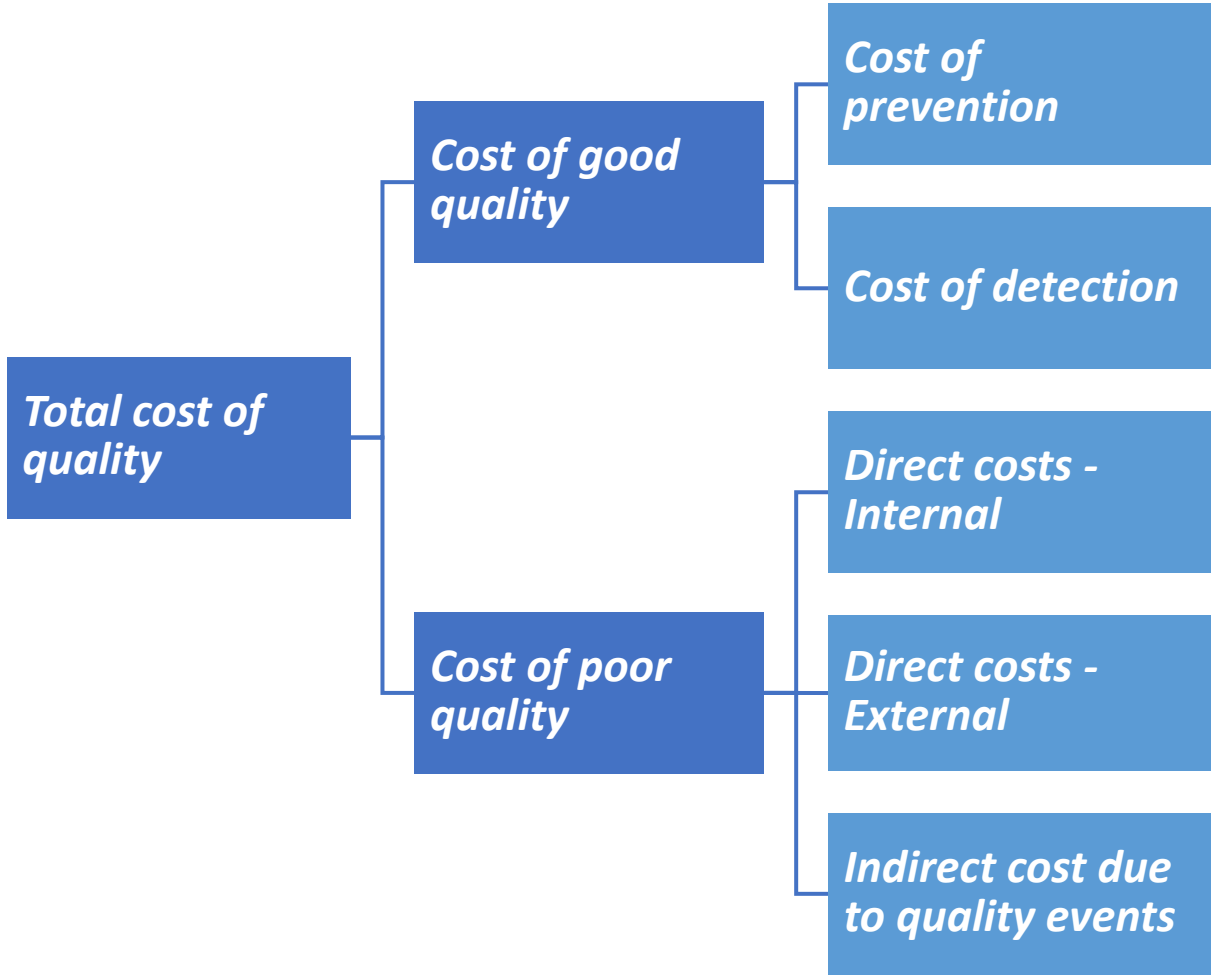
Other cost, e.g., inventory/WIP, additional safety stock at the marketing company – **not considered site cost** but is part of the total company's cost

Total estimated cost of deviations at a well performing site

$ Millions



5 elements constitute the ‘Total Cost of quality’, covering both the Cost of good quality and the Cost of poor quality

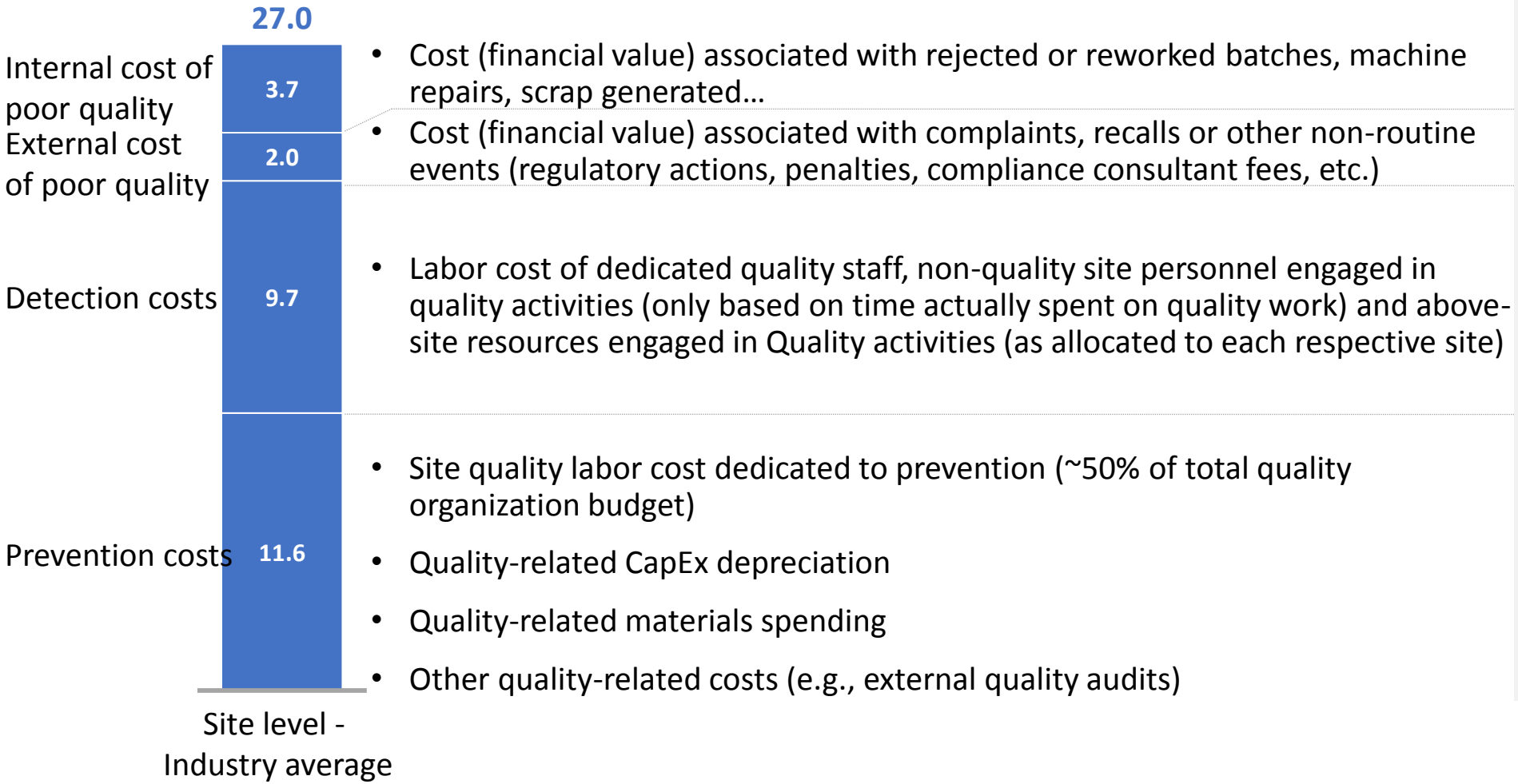


Definition

Cost of prevention	Costs associated with the prevention of future losses (unplanned problems, waste, breakdowns, stoppages)
Cost of detection	Costs associated with appraisal of the process / product to ensure quality is met
Direct costs - Internal	Costs associated with internal losses to correct or replace products that fail to meet specifications prior to delivery
Direct costs - External	Costs associated with correction or replacement of products/services that fail to meet specifications/service level after delivery
Indirect cost due to quality events	Estimated lost revenues — e.g., related to missed sales, out-of-stock, loss of goodwill

Total cost of quality goes well beyond the quality organization spend, and on avg. accounts for upto 25% of conversion costs at a site level

Cost of Quality in Pharma as % of conversion cost (site level)



- Cost (financial value) associated with rejected or reworked batches, machine repairs, scrap generated…
- Cost (financial value) associated with complaints, recalls or other non-routine events (regulatory actions, penalties, compliance consultant fees, etc.)
- Labor cost of dedicated quality staff, non-quality site personnel engaged in quality activities (only based on time actually spent on quality work) and above-site resources engaged in Quality activities (as allocated to each respective site)
- Site quality labor cost dedicated to prevention (~50% of total quality organization budget)
- Quality-related CapEx depreciation
- Quality-related materials spending
- Other quality-related costs (e.g., external quality audits)

- At site level total **cost of quality is 25%+ of conversion cost. At company level it's 10-12% of COGS**
- **Median financial cost of a recall is ~$35K and can exceed $500K for major recalls,** without even considering reputation and market share loss
- On average **revenue losses for companies with quality issues is estimated at 4-5% of COGS**

SOURCE: POBOS Quality

How can companies think about monitoring their ‘true’ Cost of Quality?

To drive any improvement effort geared towards quality, the first step will be to create transparency

Create transparency around true cost of quality

- **Benchmark** total cost and their individual components **against peers and best performing sites** within internal network
- Identify **areas of high cost and** their **drivers**
- **Assess standard cost** per unit **for key drivers** of quality cost

Define improvement program and initiatives

- Align on **highest impact areas** (based on diagnostic or benchmarking)
- Define **improvement initiatives**, relevant **investments**, and **target impact**
- Define **systems and processes** to establish for a scalable effort
- Set up **execution by** functional area or **cross-functional teams**, plans, and timelines

Execution and performance tracking

- **Establish systems and processes** needed for **efficient and continuous process**
- Establish **performance monitoring based on key drivers** of improvement (e.g., no. of deviations, recalls)
- Setup **regular analysis** of the **total cost of quality** and **impact of improvement** initiatives

Three options for creating transparency detailed further

OPTION

NOT EXHAUSTIVE

Transparency option 1: Detailed tracking of quality costs at activity level

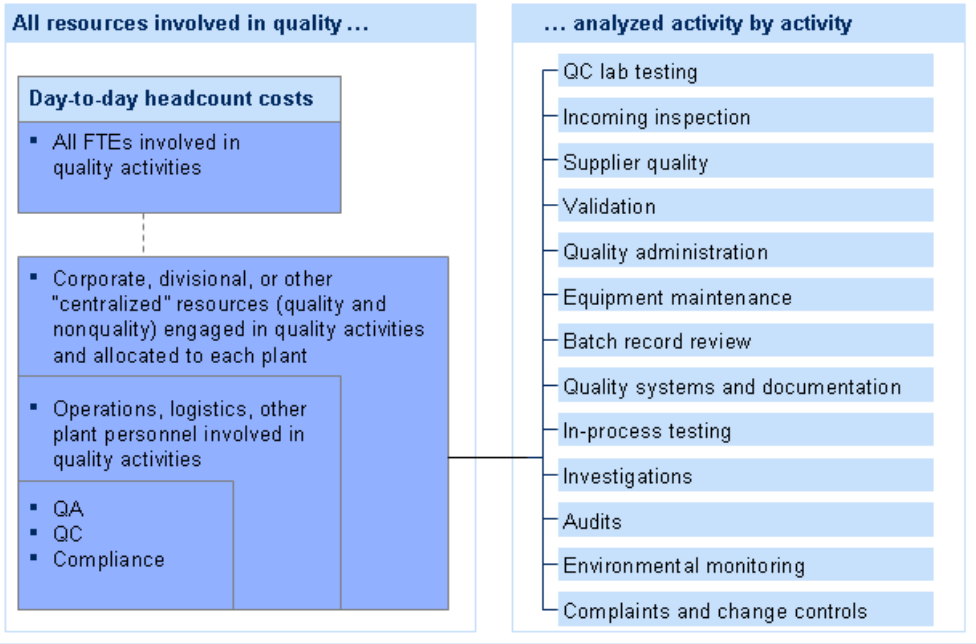
Approach

Identify **key quality activities**

Establish **activity based tracking** for quality and non-quality personnel using HR data and hourly rates

Add **tracking of direct poor quality cost** (e.g., rejected batches, fees and penalties)

Analyze results on a regular basis identifying impact and areas for improvement



Pros

- Detailed information from accounting and HR
- High level of accuracy

Cons

- Complex to set up and execute monitoring and analysis
- Time consuming tracking
- Not at product level

OPTION

NOT EXHAUSTIVE

Transparency option 2: Poor quality costs measured through “standard” costs of issues

Approach

- **Identify key drivers of the poor quality cost** (deviations, complaints, OOS, 483s, re-testing, batch record errors)
- **Assess average** (standard) **cost per unit for each driver** (Quality and non-quality labor, cost of rejected products, regulatory consulting fees, etc)
- Use **standard cost to assess cost of poor quality based on the key drivers** on the ongoing basis
- **Example drivers**
  - Number of deviations by source
  - Number of batch record errors
  - Right-first-time
  - # of environmental and maintenance OOS (not triggering a deviation)
  - # of customer complaints
  - # of 483s, etc.

Pros

- Easy to estimate on an ongoing basis and analyze performance based on key drivers
- Easy to set at product level based on typical issues levels

Cons

- Requires detailed diagnostic to define standard costs
- Doesn’t account for high variability of poor quality costs
- Doesn’t account for day-to-day costs (prevention and inspection)

Transparency option 3: Product allocation costs by activity and type of issue

Approach

- Identify **key quality activities and workload driver for each** (e.g., number of batches for QC testing, number of formulations for quality documentation, number of deviations for investigations work)
- **Assess average** (standard) **resource level per unit of the workload driver for each activity** (e.g. QC testing FTE per batch, Investigations FTE per deviation)
- **Allocate workload drivers by product** based on actual volume, number of issues, number of SOPs, points of use, etc (adjusting for double counting) and **estimate "standard resources cost" by product**
- **Estimate non-labor poor quality costs** (e.g. as in Option 2) and **allocate by product based on typical issues levels**

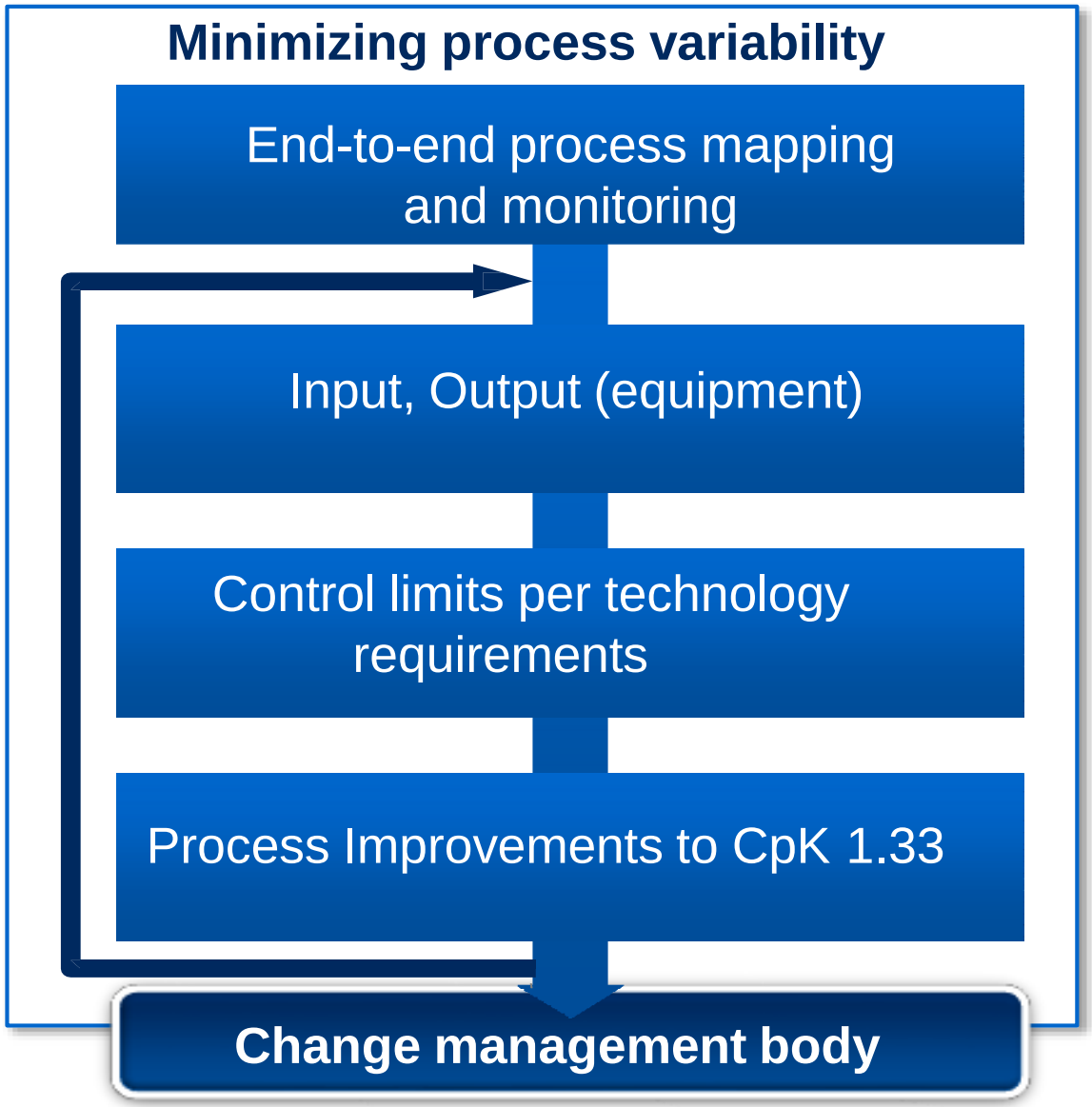
Pros

- Set at product level and possible to use for portfolio analyses
- Once set, easy to estimate on the ongoing basis and analyze performance based on key drivers

Cons

- Requires detailed diagnostic to define standard costs and allocations
- Does account for high variability of poor quality costs
- Possible overlap of workload drivers (multiple product for one point of use, for one piece of equipment)

Case example: Company imbibed a rigorous approach to minimizing variability in manufacturing processes



Process monitor parameters

- **End-to-end process mapping** and **monitor parameters** defined by **technology development team**
- More added as appropriate in manufacturing

Target Cpk of 1.33

- At introduction of a technology, every monitor CpK may not be at 1.33
- Identify below target monitors and **reduce variabilities** (tool to tool, inputs, transfer functions, etc.)

Empowered change management

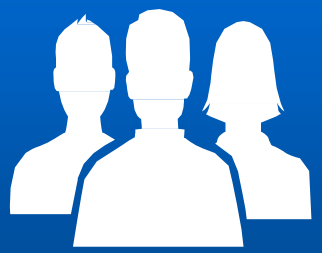
- Any process change must be approved by **change management body**

Case example: Approach to minimizing variability was also complemented by an organization wide strong, objective focus on quality

Quality mindset across the organization

Extensive automation to minimize human errors

Enabling employees to execute quality mindset



Data driven objective decision making

Thank you

If you have any questions, kindly write to

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