Quality Operational Excellence

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25 years of experience in Pharmaceutical Operations and Quality, designing and leading transformations across Europe, Americas and Asia through Operational Excellence and Lean Labs

For 6 years working at Abbott Laboratories, EPD (Pharma division) as Business Excellence and HPR Director, with main focus on Quality Continuous Improvement and Capital and Strategic investments

MSc in Industrial Chemistry, LeanSixSigma Black Belt, passionate about Strategy Deployment and People Engagement and Development

Motto is: "If you feel uncomfortable, don't worry. It's probably just because you're learning something new"

IT'S TEST TIME!

Scan QR Code with your phone to join the quiz

https://play.kahoot.it/v2/lobby?quizId=cec79977-eddf-4989-9c7f-160ab4bb556f

Disclaimer. This presentation is a general overview and is not based on Abbott Laboratories confidential information or common practices. It isn't aimed at suggesting to purchase any specific tools or services.

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1

INTRODUCTION

About today topic

2

WHY OPERATIONAL EXCELLENCE AND QUALITY

Cost of Quality

Lean Production

3

LEAN QUALITY LEVERS & EXAMPLES

Quality and performance

Measuring improvements

4

SO WHAT?

Where to start

ONE thing

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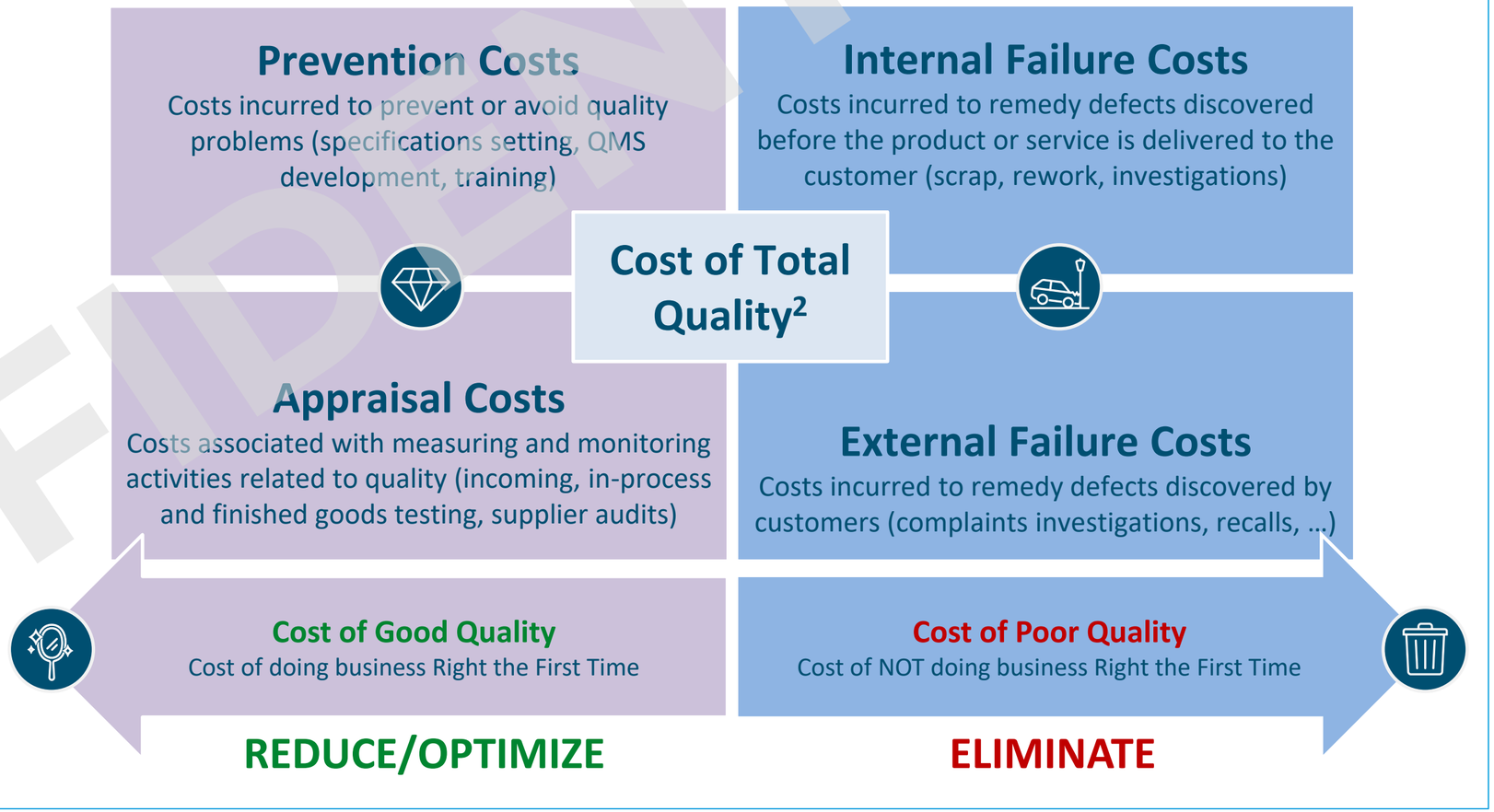
Cost of Quality (COQ). Methodology that allows an organization to **determine the extent** to which its resources are used for activities that **prevent poor quality**, that **appraise the quality** of the organization's products or services, and that result from **internal and external failures**. Having such information allows an organization to determine the potential **savings to be gained by implementing process improvements.**[1]

The framework



1. Source: ASQ (American Society for Quality) glossary. 2. Adapted, not exhaustive lists.

START

1 **Define Value**

What is the Customer **willing to pay** for within my product? Are all features really needed?

2 **Map the Value Stream**

Do we know the **workflow from start to finish**? Which activities add value? Which are superfluous and not really needed?

3 **Create Flow**

How can we establish a **smooth flow** and avoid bottlenecks? Where is the process stopping?

4 **Establish Pull**

Are **products pulled** from the next customer? How is inventory reduced while ensuring necessary materials are available?

5 **Pursue Perfection**

How are Lean thinking and continuous process improvement embedded into **organizational culture**?

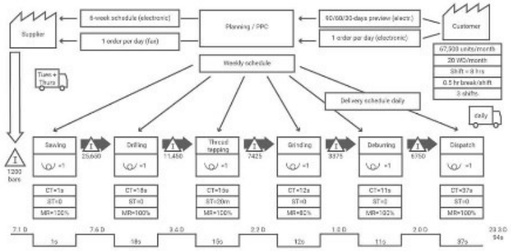
The Toyota way

Continuous improvement with respect and involvement of people

- Originated in 1948 (Taiichi Ohno, Shigeo Shingo and Eiji Toyoda)
- Inspired by W. Edwards Deming (PDCA cycle), Henry Ford
- Structured approach of exposing problems and making improvements
- Main objectives are to **design out overburden** (MURI) and **inconsistency** (MURA), and to **eliminate waste** (MUDA)
- Every process is perfectly designed to deliver the expected results
- Add value to the organization by **developing your people** and partners
- Most known for the relentless pursuit of perfection by eliminating the 7 (8) deadly wastes through rapid cycle improvement (KAIZEN)

Taiichi Ohno – Father of the Toyota Production System

Value Stream Mapping (example)



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QUALITY CONNECT

Digitalization opportunity: High / Low

What we observe	What we can do	Lever
▪ Too many SOPs ▪ Complex and/or unstructured SOPs, different from each other ▪ Manual logbooks used to capture data already captured by systems ▪ Long batch record review time due to complex structure	▪ Reduce SOPs number ▪ Standardize SOPs with visuals driving through process flow ▪ Validate systems to ensure robust data usage ▪ Focus on critical to quality items (fill-in-the gaps entries)	▪ Lean documentation ▪ VR training
▪ Poorly arranged laboratory workstations, time wasted searching for tools/reagents	▪ Optimize Lab workplace with dedicated cells, kanban systems	▪ 5S
▪ Idle production time due to quality checks (e.g. test, documentation, signatures, …)	▪ Focus checks on critical points, non-critical tasks are handled to operations	▪ PAT
▪ Not-RFT process and difficulty to prevent process deviations	▪ Identify process parameters associated with Deviations through data analysis	▪ Advanced Analytics

Consider…

… instilling a strong and sustainable change culture is key to long lasting results

- Setting and endorsing **clear objectives**
- Keeping people **accountable**
- **Proactive** management (Tollgate Review Process)

… entering in a confused arena can be inefficient

- **Challenge information flow** and no. of entries before digitalizing batch records
- VR training on inefficient SOPs will only **unlock a small part** of the opportunity
- **Re-engineering the value chain** is THE way (consider ERP changes)

If you want to read about case studies, change stories and impact: World Economic Forum – Global Lighthouse Network white paper, December 2023
https://www3.weforum.org/docs/WEF_Global_Lighthouse_Network_Adopting_AI_at_Speed_and_Scale_2023.pdf

Benefits: PREDICTABILITY - STABILIZATION - COMPLIANCE

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KPI[1]	Labs	QA	Focus
Productivity	x	x	Cost
Utilization	x		Cost
WIP	x	x	Cost
Cycle Time	Test	DR, Change	Cost
Schedule attainment	Testing	Documentation	Cost
Right First Time	Test/OOS	SOP, Change, …	Delivery
5S score	x	x	People
OLEE	x		Cost
Std Time adherence	x	x	Cost
GMP Internal audits		x	Compliance
DR Initiated	x		Compliance
Lost Time accidents	x	x	Safety
Voluntary Turnover	x	x	People
CAPA closure		x	Delivery
Near misses	x	x	Safety
Waste	x	x	Sustainability

DO

Execute and track activities, monitor results

ACT (ADJUST)

Develop action plans, assign owners, check effectiveness and update standards

PLAN

Establish objectives & standards. Define your schedule (Production planning, Stability & Projects)

CHECK

Unveil opportunities by evaluating results vs. standards

Consider…

… best practices for Quality performance management systems

- Keep in mind **final users** when developing your PMS
- **Link** to your situation, upper level KPIs and **overall goals**
- Balance performance (e.g. Cost, Delivery) with **organizational health, quality, safety**
- Do NOT over-engineer
- Use to enable **expected behaviors** and actionability
- Identify **all deviations** from standards (“reds”)
- Go deep to the **root cause**
- Assign activities with **clear deadlines**
- Track actions and **follow up regularly**
- **Recognize people** for results

1. Non-exhaustive list.
Acronyms: WIP (Work in progress), DR (Deviation Reports), OOS (Out-of-Specifications), SOP (Standard Operating Procedure), OLEE (Overall Laboratory Equipment Effectiveness), CAPA (Corrective Action Preventive Action)

Lessons of the Square Watermelons

- Japanese grocery stores had a problem. They're much smaller than their US counterparts and therefore don't have room to waste.
- Watermelons, big and round, wasted a lot of space.
- Most people would simply tell the grocery stores that watermelons grow round and there's nothing that can be done about it.
- But some Japanese farmers took a different approach. If the supermarkets wanted a square watermelon, they asked themselves, "How can we provide one?"
- It wasn't long before they invented the square watermelon…

What top-performance teams and leaders say…

Do we understand the true root causes?

What small projects can I activate in my department?

What's the breakthrough change I can do?

Do we have early warning detections in place to address problems in advance?

How can I build ownership to day-to-day small improvements?

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MAY 2024						
SUN	MON	TUE	WED	THU	FRI	SAT
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5	6	7	8	9	10	11
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19	20	21	22	23		
26	27	28	29	30		
2	3	4	5	6		

Thanks for your attention

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