



Driving effective quality governance using Quality Metrics

IPA Advanced GMP Workshop | November 2018

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Perspectives on best practices in Quality Metrics

Group exercise



Regulatory agencies and industry players are increasingly highlighting the importance of governance and management review



“Management review should provide **assurance** that **process performance and product quality** are managed over the lifecycle. ...management review can be a **series of reviews at various levels** of management and should include a **timely and effective communication and escalation process...**”

– *ICH Q10 Pharmaceutical Quality System*

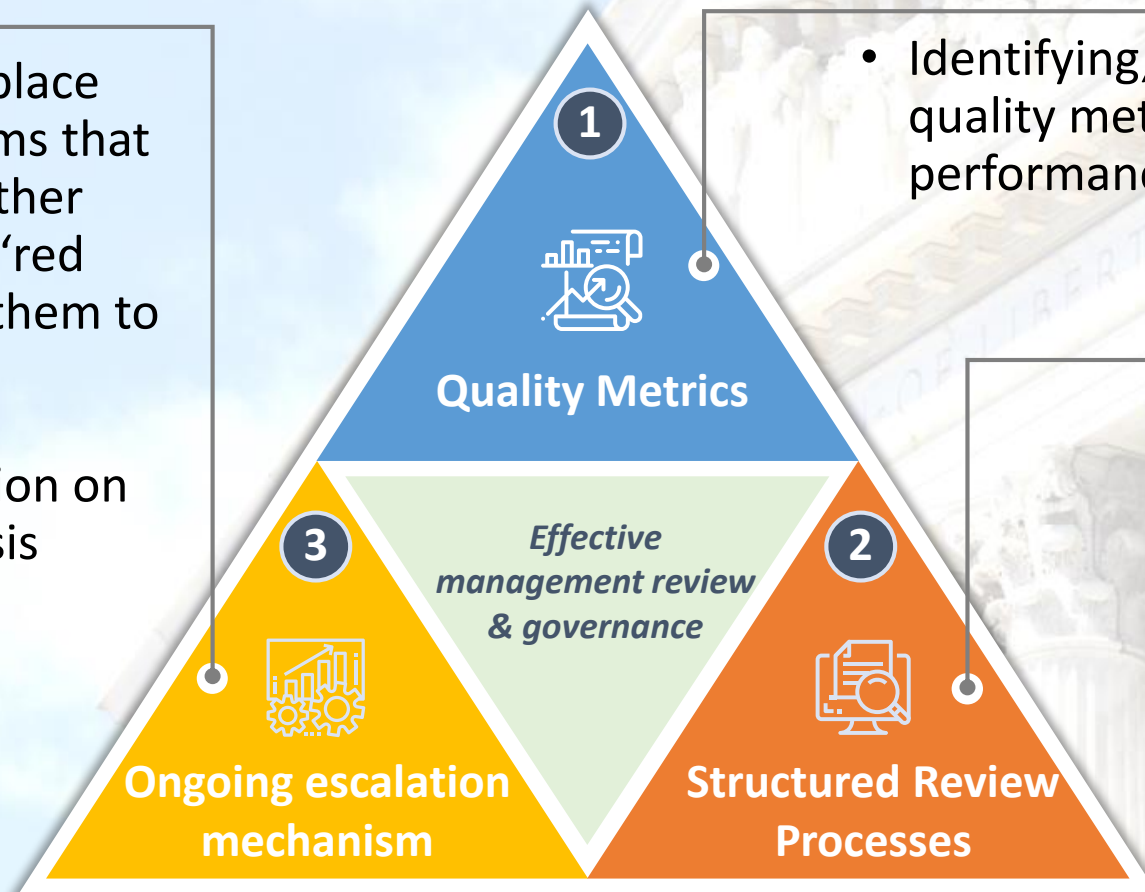


“Management with executive responsibility shall review the **suitability and effectiveness of the quality system at defined intervals** and with **sufficient frequency** according to established procedures to ensure that the quality system satisfies the requirements of this part and the manufacturer’s established **quality policy and objectives**”

– *21 CFR, Part 820.20(c)*

Robust management review & governance system has 3 key elements

- Putting in the place the right systems that help identify other gaps and raise 'red flags' to bring them to management's attention for immediate action on an ongoing basis



- Identifying, baselining & benchmarking the right quality metrics to provide robust assessment of performance & health of an organization's quality

- Setting up review forums that enable effective cascading of quality metrics to the shop floor level
- Driving effective reviews that enable effective problem solving & identifying root cause of issues

Governance system must be aligned to the quality management system & overall quality vision of any organization

1 2 types of KPIs are key to ensure all required information is available to prevent quality issues

Lagging indicators



Leading indicators

Value

- Show **final outcome** of an action
- Confirm that a **pattern is occurring**
- Provide broad area where improvement **need to be focused**

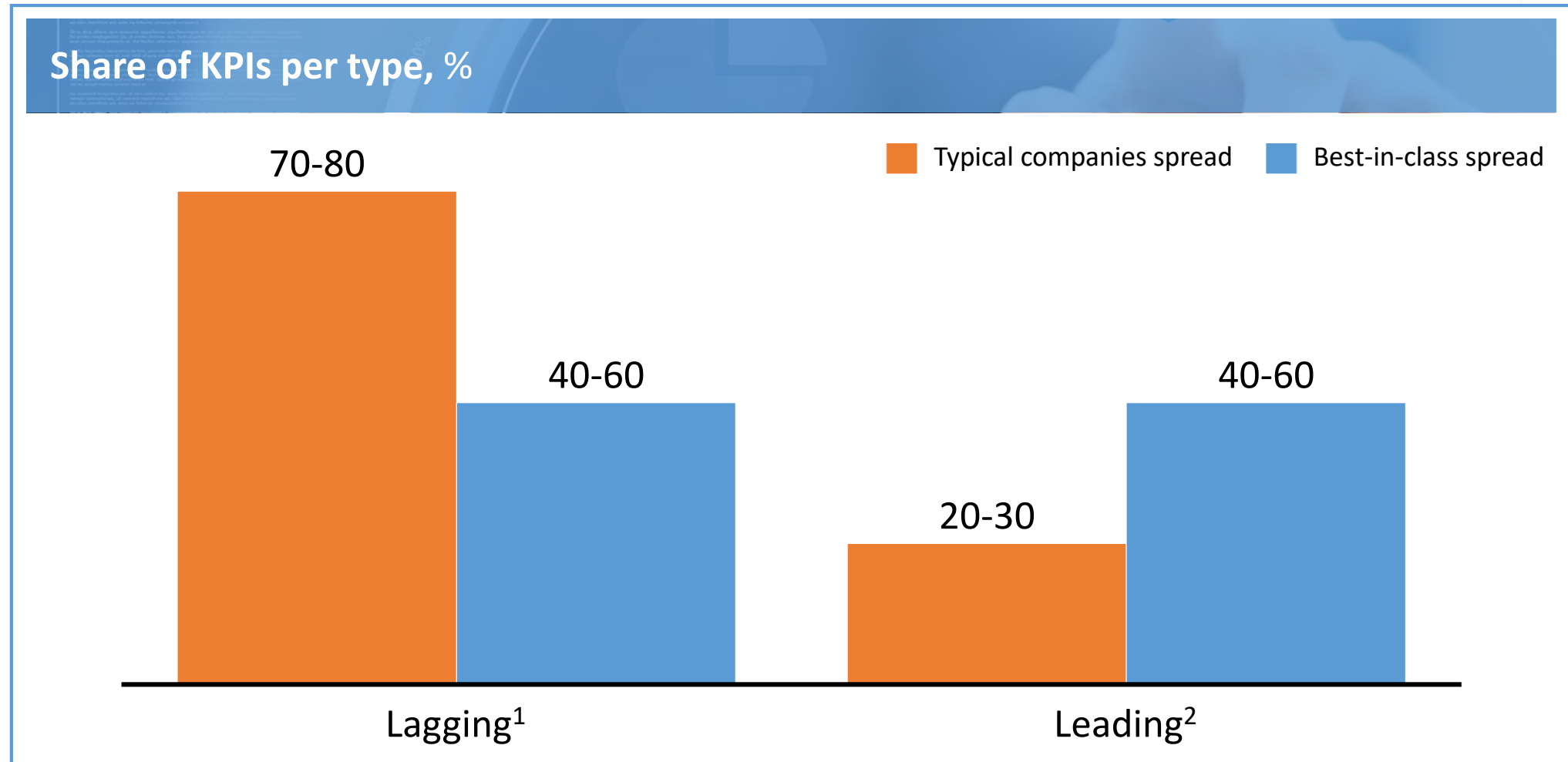
- Provide an **early indication** about impact of strategy/process
- Give indication of **future outcomes**
- Anticipate failure and avoid **potential costs**

Pitfalls

- Data arrives **too late** to take action
- **Time lag between** improvement and effect
- “Managing to the metric” can lead to **short term/sub-optimal decisions**

- Input metrics are often more **subjective and open** to ambiguity
- Some are **difficult to measure**
- Delivered results usually **result in long term** improvement

1 Typically, we observe an unbalance in Quality KPIs towards lagging metrics, limiting prediction and prevention



¹ KPIs that show past performance

² Indicators that give an indication of future outcome

1 Three metrics are gathering wide consensus with regard to their value as leading indicators

✓ Consistent use¹

✗ Limited or inconsistent use

	Preferred as leading indicator ¹	Correlation to outcomes
Operational maturity (process and product robustness)	• Right first time (or lot acceptance)	✓
	• Reject rate	✗
	• Deviations rate	✓
Quality system maturity	• CAPA effectiveness	✗ ²
	• Recurring (repeat) deviations	✓
	• Supplier certification	✓
Timeliness	• Investigations cycle time/ closed on time	✗
	• CAPA implemented on time	✗
	• Audit findings closed on time	✗

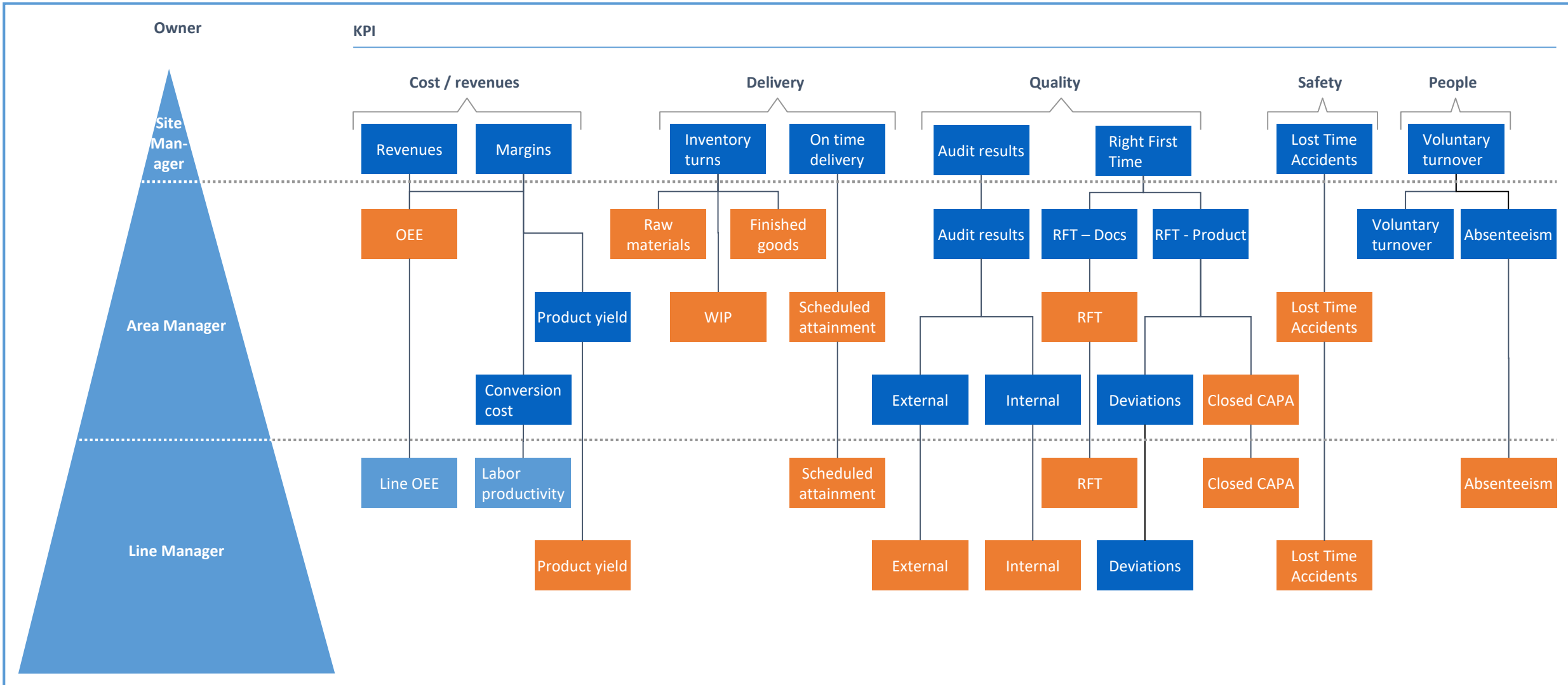
¹ Over 40% of surveyed companies are using or planning to use it

² Tested only with small sample of sites

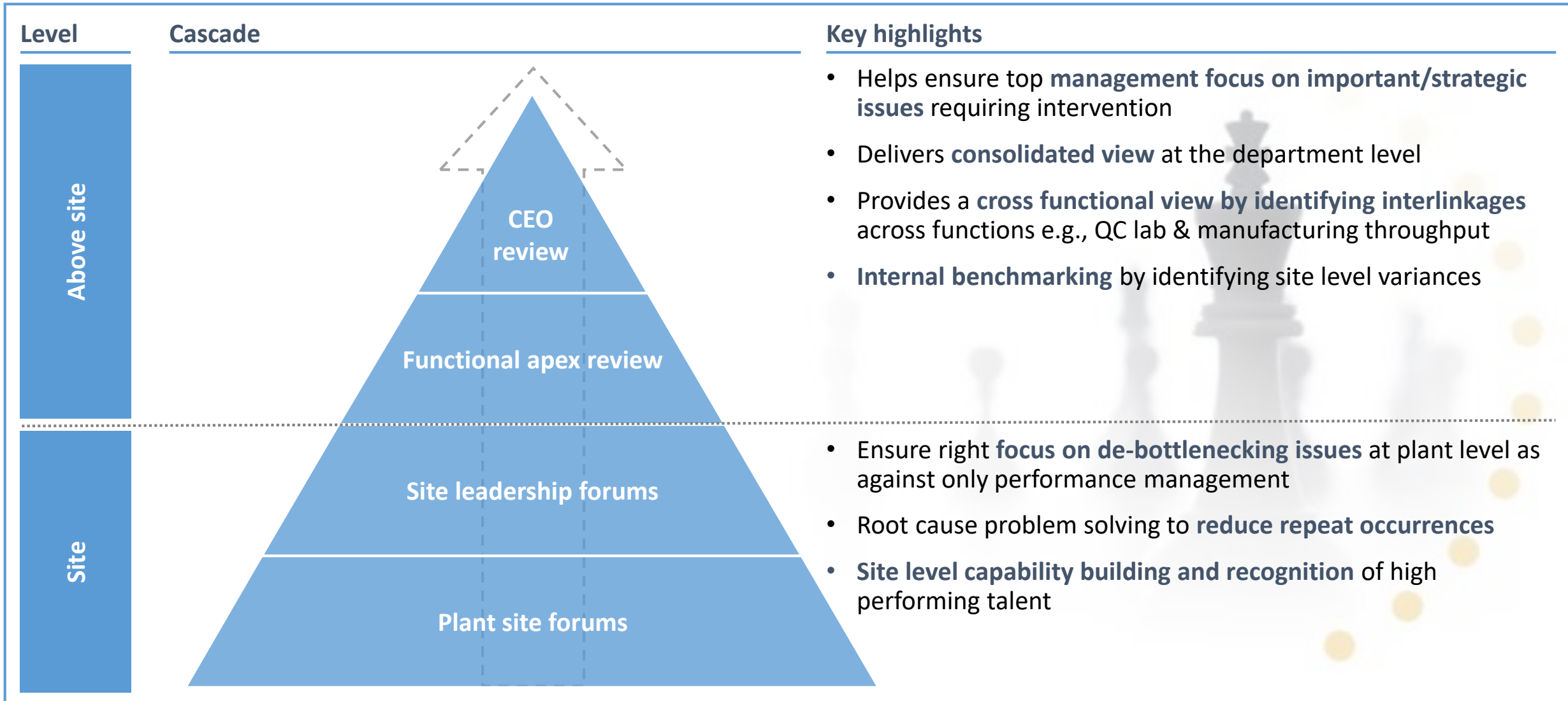
1 Metrics should be cascaded to the shop floor level in an exhaustive and inter-linked manner

- 1 KPIs
- 2 Boards
- 3 Huddles

- Monthly reviewed
- Weekly reviewed
- Daily reviewed



2 Streamlined and interconnected review forums are critical to align priorities and focus areas across the organization



2 Effective reviews result in identification and follow through of concrete action steps for quality improvement

What does a good review look like?

This ...



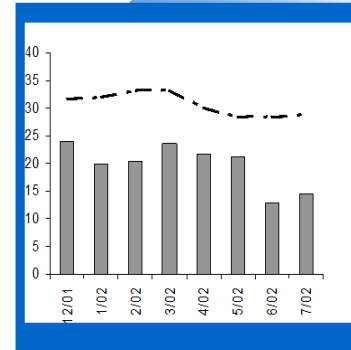
- Productive team working session
- Joint issue identification and problem-solving
- Value-adding spirit - focus on what can be achieved
- Challenging the accepted norms – “How can we do it better?”
- Delegating responsibility for achievement to the appropriate people

Not this ...



- Only reporting of facts
- Judgmental, apportionment of blame for things gone wrong
- Critical or defensive attitudes
- Compliance or acceptance of the norm
- Micro-management

Key questions for effective discussions



What is happening?

- What are the gaps to target?
- Are any trends causing concern?

5 Whys?

- What happened to cause the performance gap?
- Do we really understand the root causes?
- Do we need to investigate further?

What needs to be done?

- What can we do to correct the problem and prevent this from happening again?
- Will these actions completely resolve the problem?
- Do we need to do anything else to close the gap?
- Do we need to take any short-term containment action?

Who is going to do it?

- Who will take responsibility for completing the action?
- Does the owner need support from any of the other team members?

When is it going to be done?

- Is it a priority action?
- What is the deadline for completion?
- When are the intermediate milestones?

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Breakout

Objective



- **Identify the top 10 most important Quality KPIs / metrics**
 - Define the metrics
 - Assign ownership across management levels
 - Assign review frequency

Instructions



- Participants would work in **groups of 10**
- **List priority KPIs** in the assigned template sheet

Time



- **20 minutes** for activity
- **10 minutes** for discussion

Data Provided



- Each group would receive a list of **KPIs/Metrics**
- A template sheet to fill in their responses

Total time given



30 minutes



Guiding principles for the case study

1 Not more than 8-10 metrics should be selected for review

2 Metrics selected should include a combination of leading and lagging KPIs

3 Metrics should be effectively cascaded from the top management to the shop floor

4 Metrics should be harmonized across levels

Group activity Template

Top 10 Metrics	Cascade level (Above site / Site leadership / Middle management / Shop floor)	Frequency of evaluation (Daily/weekly/monthly/quarterly)
1		
2		
3		
4		
5		
6		
7		
8		
9		
10		