



Best practices in Quality Metrics

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Management reviews & quality metrics have existed for a while

“

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)* —

”

Quality metrics have become increasingly important for the pharmaceutical industry

What are Quality metrics?

- Important component of an **effective quality management system**; enables **thorough oversight of drug quality**
- **Objective measurements** of quality performance and maturity of a site or the entire manufacturing network
- Critical tool to ensure **robust manufacturing process and operational reliability**; enables **continuous improvement** of process performance and product quality
- Tool to **baseline & benchmarking** quality across sites/organizations

Why are KPIs / metrics becoming increasingly important ?



Increasing focus on customer safety & regulatory compliance

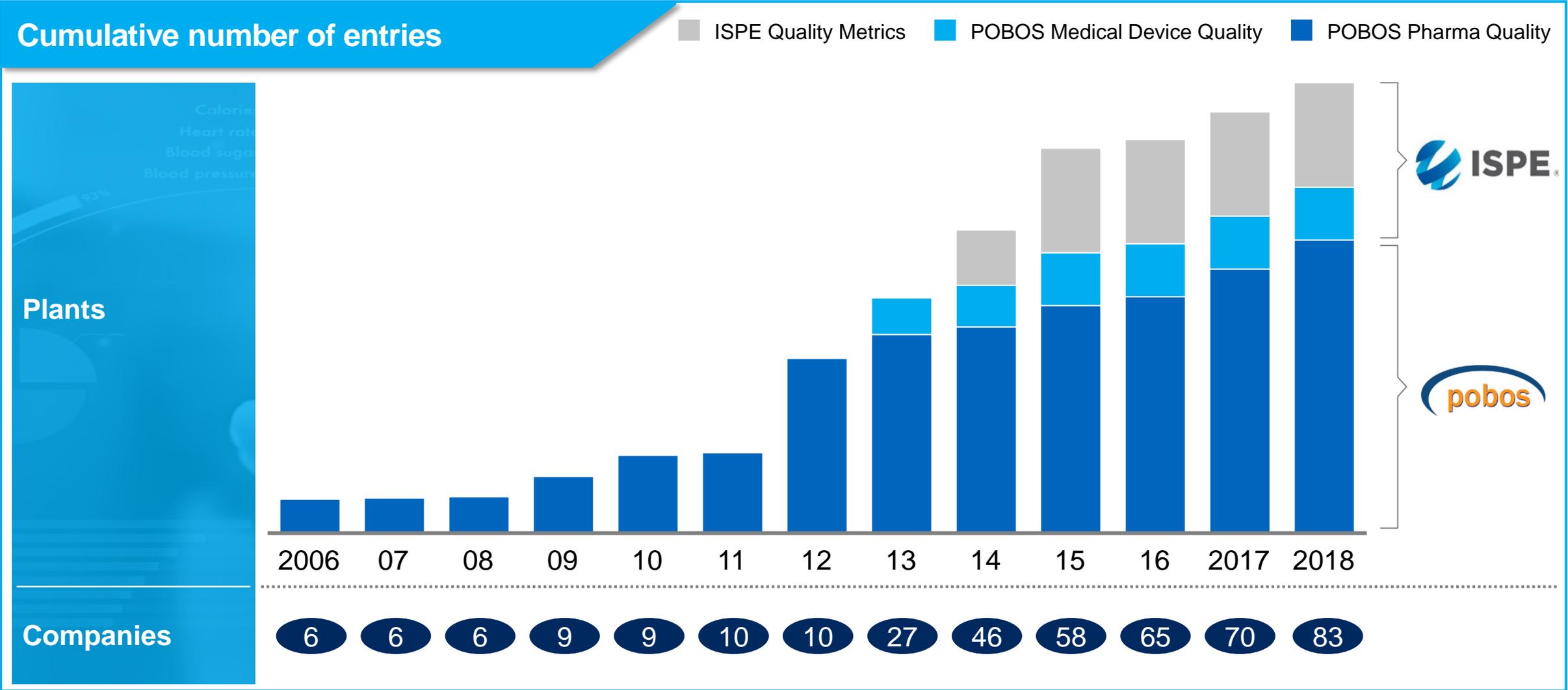


Increasing cost of non-conformance



Need to drive continuous improvement

We have studied quality metrics for years through several industry-wide efforts



SOURCE: POBOS Pharma Quality; POBOS Medical Device Quality; ISPE Quality Metrics initiative

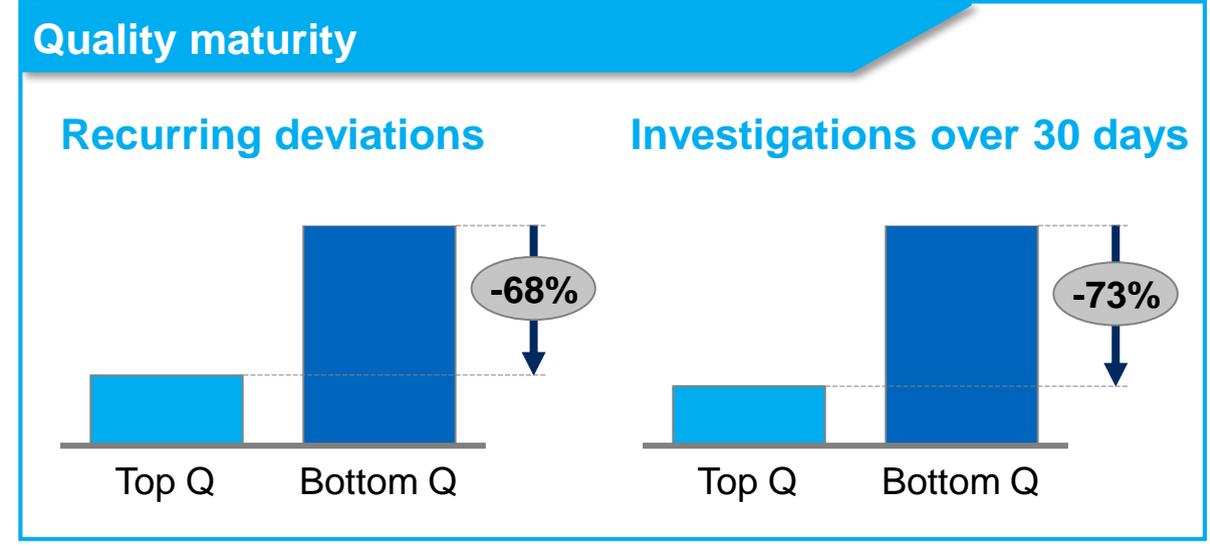
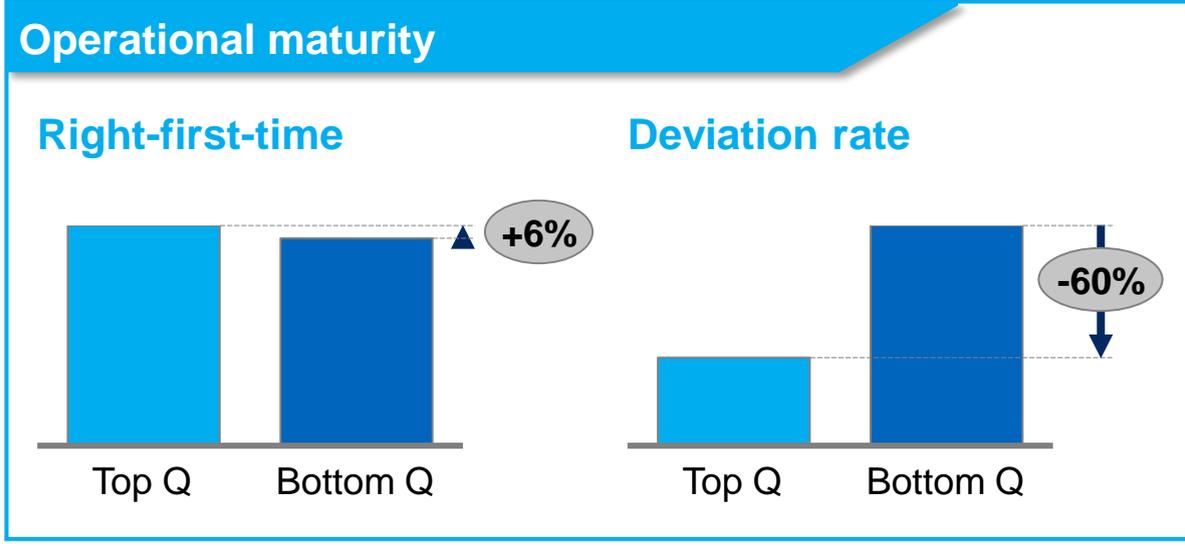
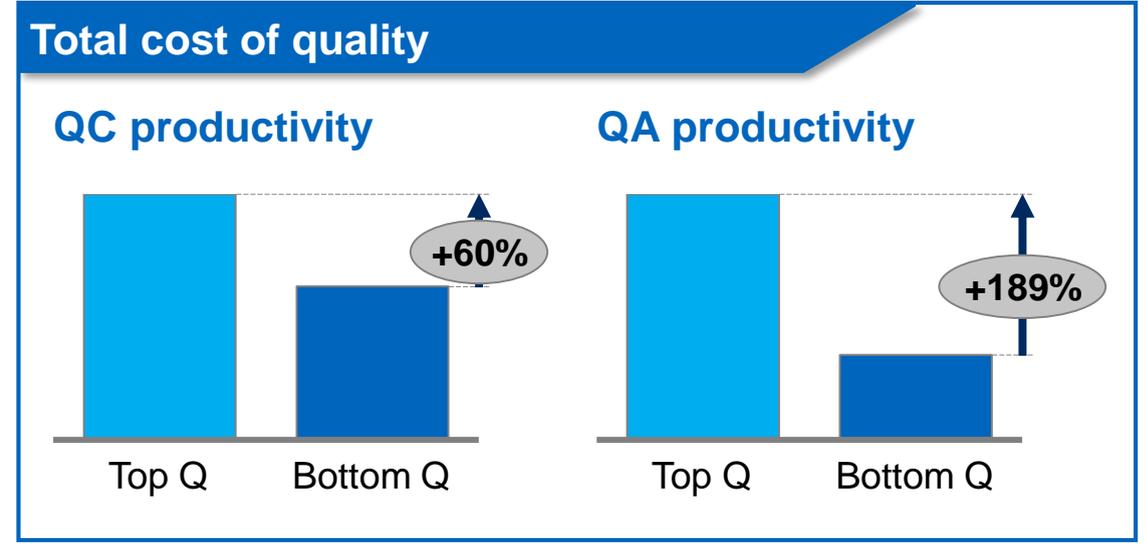
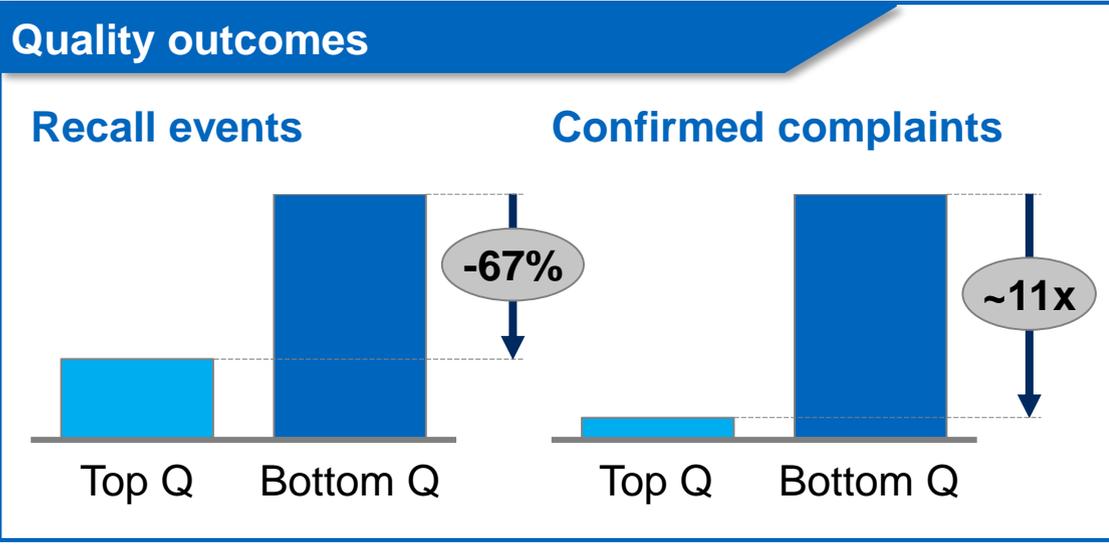
7 key learnings from our quality metrics research

- 1 Good sustainable quality outcomes are driven by three foundational blocks
- 2 There is significant variability in performance across pharma companies in India & across different sites
- 3 Unbalance observed towards lagging metrics vis-à-vis leading metrics which limits prediction and prevention
- 4 Advanced companies use leading metrics to predict & correct quality outcomes proactively
- 5 Metrics need to be cascaded down to the shop floor level and linked to performance KPIs
- 6 Effective cross-functional review forums are critical for root cause assessment & decision making
- 7 Digital & Advanced Analytics approaches significantly reduce manual effort required and improve quality of insights & decision making

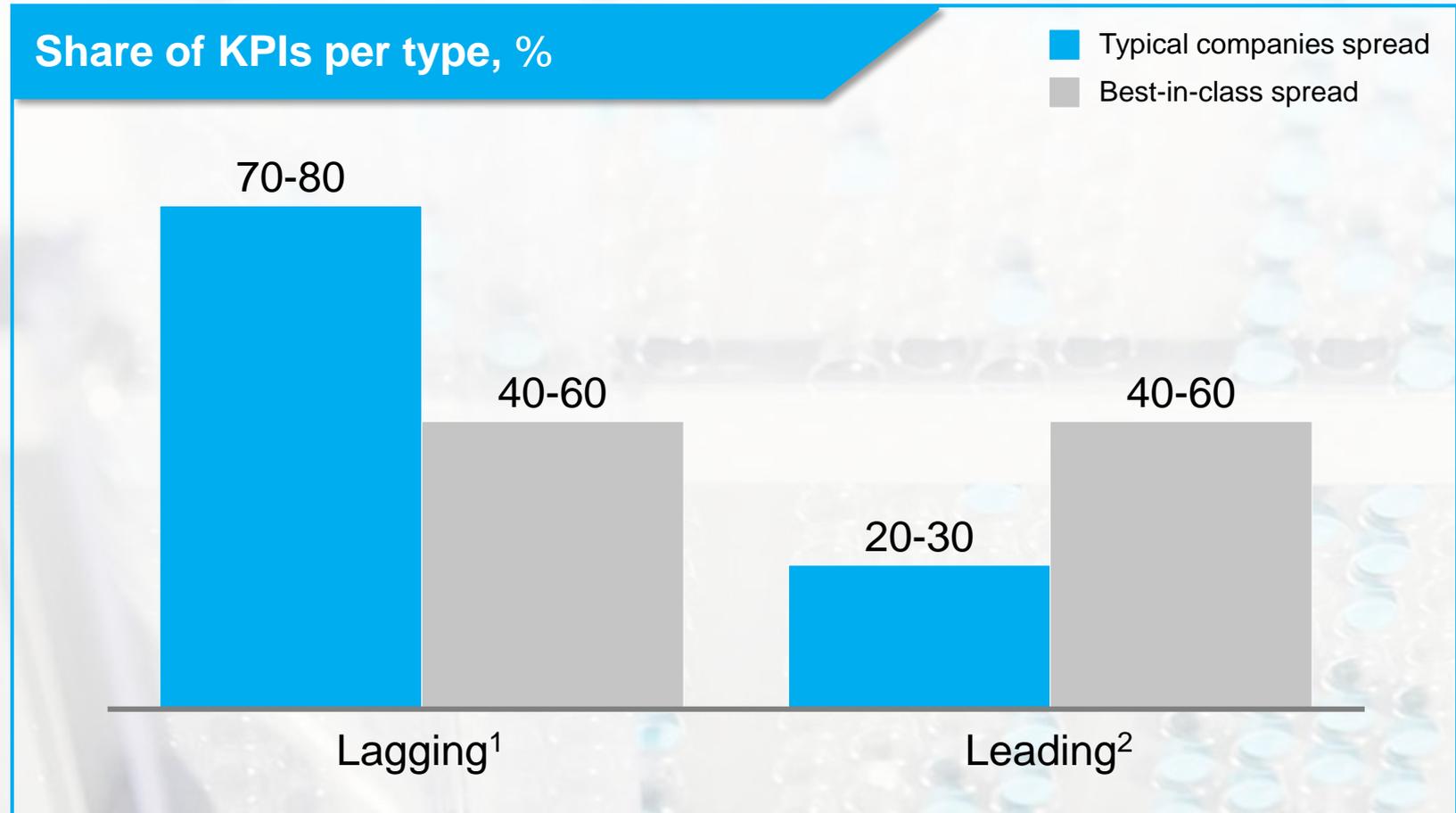
1 Good sustainable quality outcomes are driven by three foundational blocks



2 We observe significant variability in performance across Indian pharmacos / sites- Select example



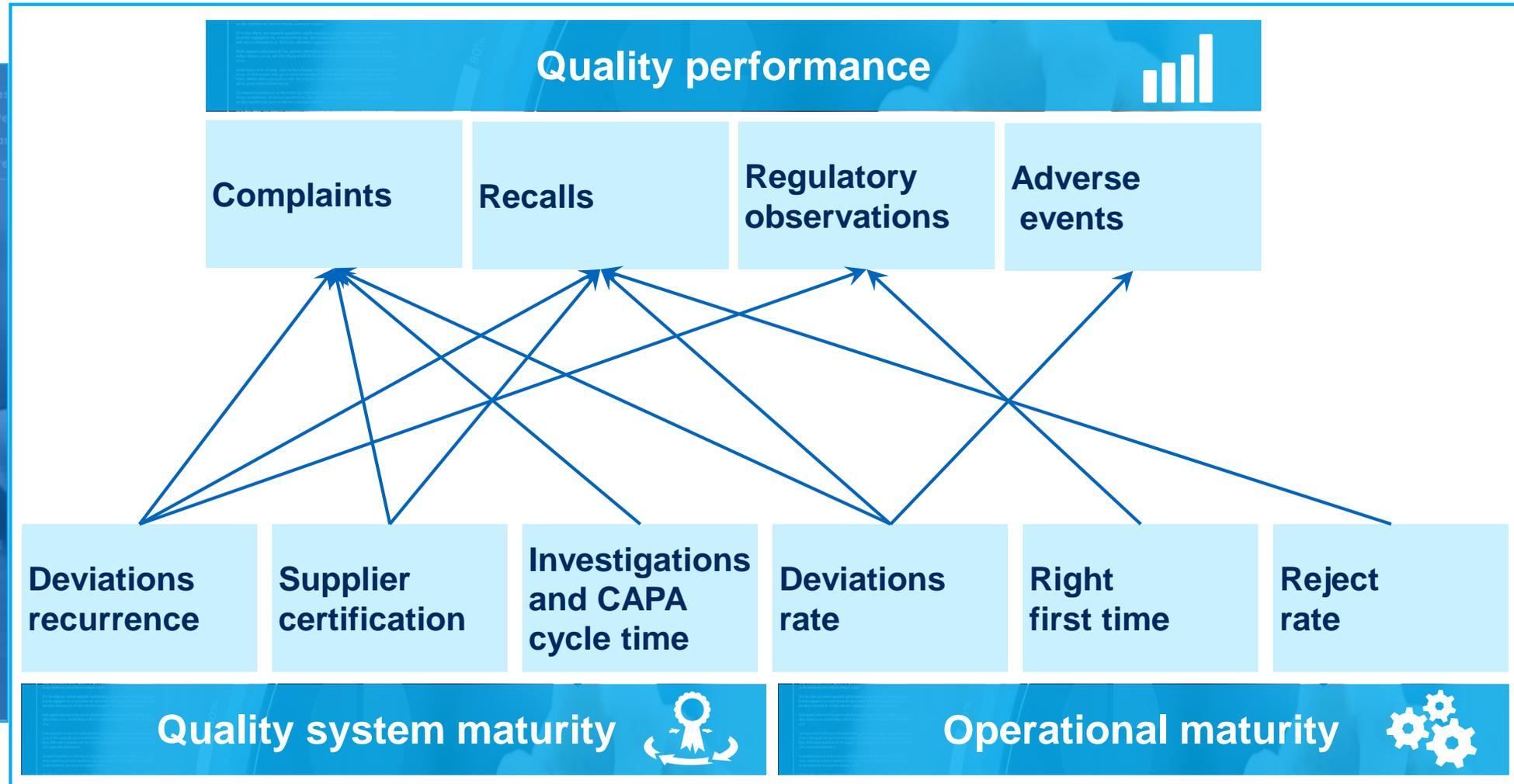
3 Typically, we observe an unbalance in Quality KPIs towards lagging metrics, limiting prediction and prevention



¹ KPIs that show past performance; ² Indicators that give an indication of future outcome

3 We have shown a link to quality performance (lagging) indicators for certain operational and quality system maturity (leading) indicators

→ Correlations with p-value <0.05

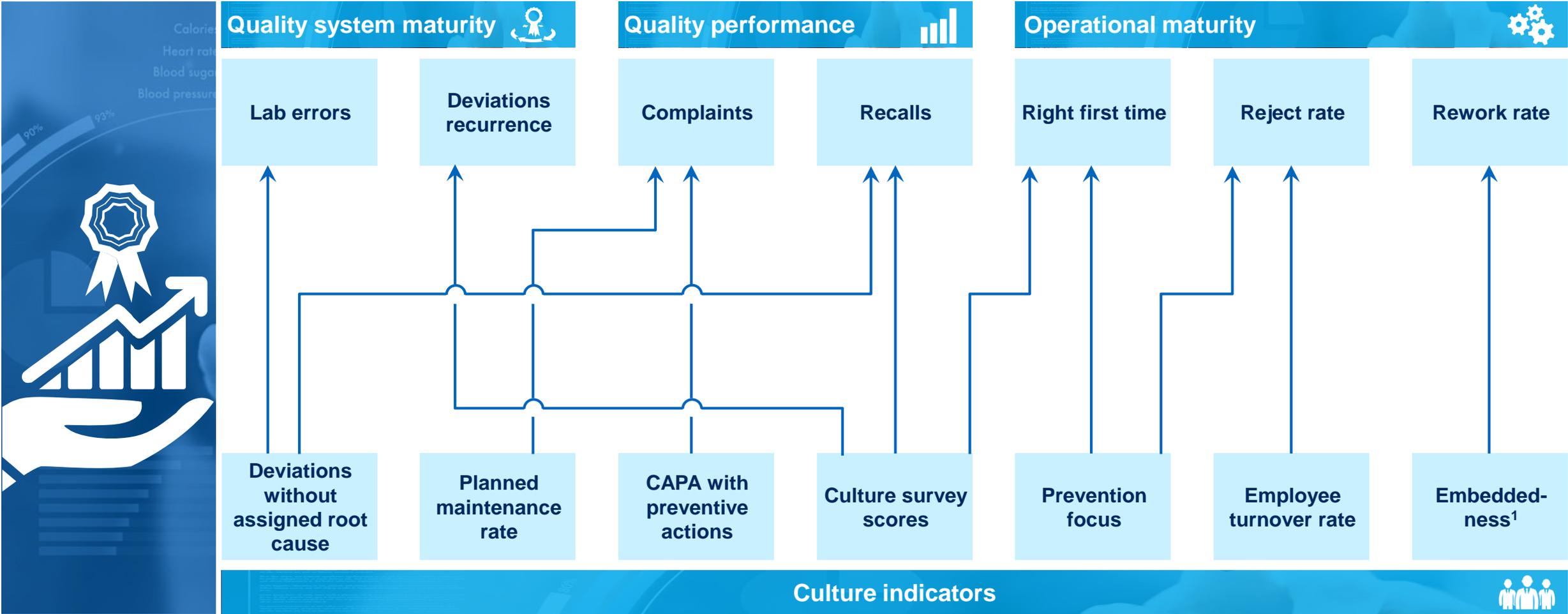


P-value is probability that correlation between X and Y is zero, value below 0.05 indicates statistically significant results

SOURCE: POBOS Pharma Quality; POBOS Medical Device Quality; ISPE Quality Metrics initiative

3 We have shown how quality culture indicators influence quality maturity and performance

→ Correlations with p-value <0.05

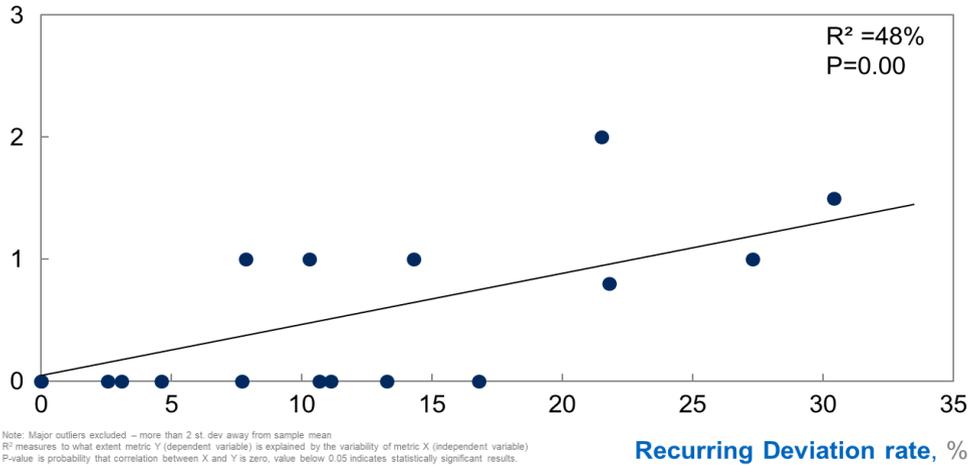


P-value is probability that correlation between X and Y is zero, value below 0.05 indicates statistically significant results
 1 Operations FTEs engaged in quality work out of total FTEs engaged in quality work (Quality or Operations personnel)

3 Examples of these correlations

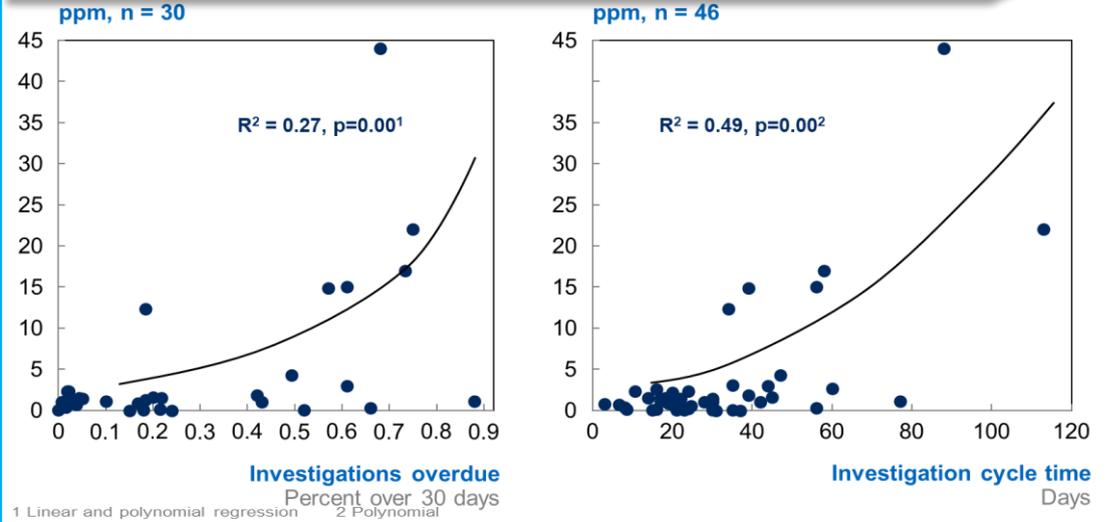
Total recalls with Recurring deviation rates

Total Recall Events, # of annual recalls



Note: Major outliers excluded – more than 2 st. dev away from sample mean
 R^2 measures to what extent metric Y (dependent variable) is explained by the variability of metric X (independent variable)
 P-value is probability that correlation between X and Y is zero, value below 0.05 indicates statistically significant results.

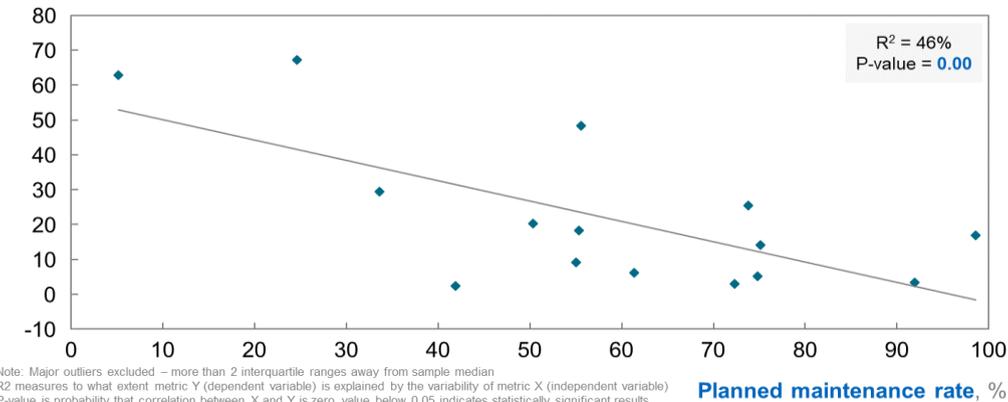
Confirmed complaints with Investigation quality



1 Linear and polynomial regression 2 Polynomial

Total complaints with Planned maintenance rate

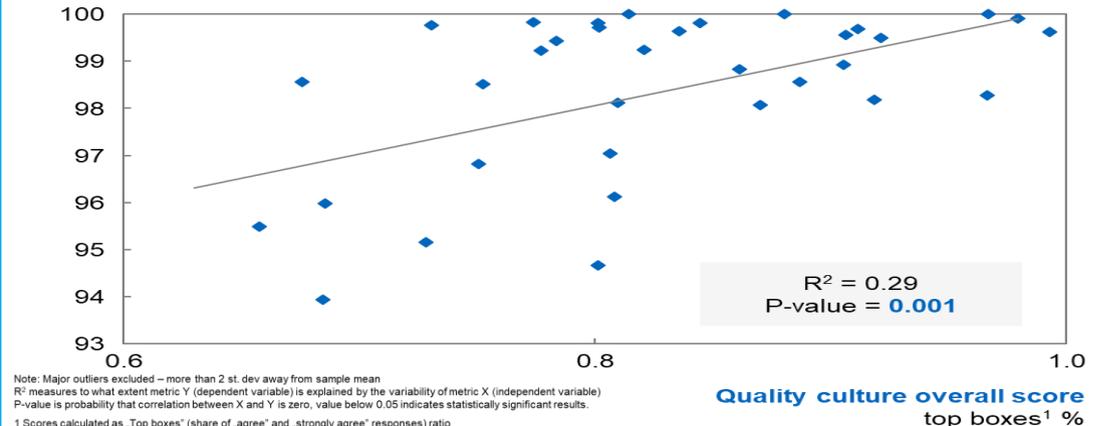
Total complaints rate (including LOE) per million pack



Note: Major outliers excluded – more than 2 interquartile ranges away from sample median
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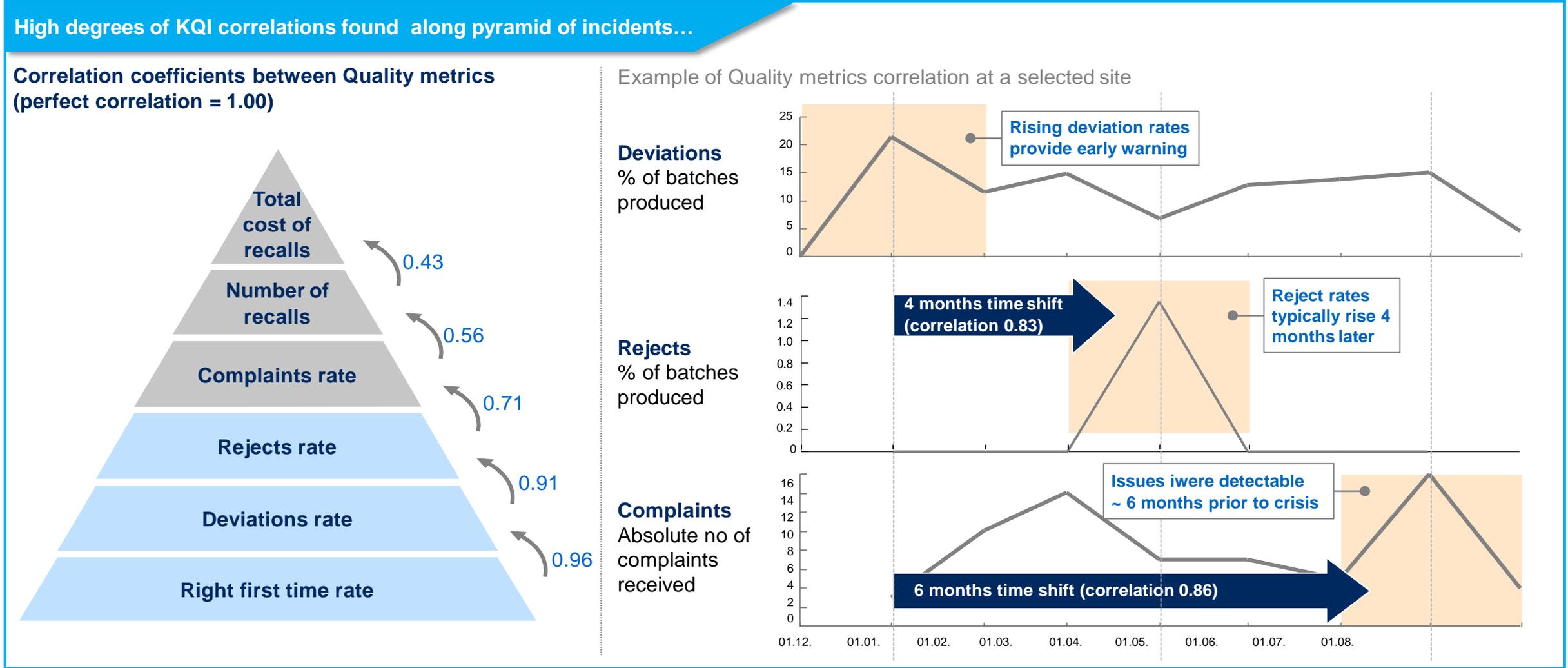
Lot acceptance rate with Quality culture scores

Lot acceptance rate, % of lots dispositioned (not rejected)



Note: Major outliers excluded – more than 2 st. dev away from sample mean
 R^2 measures to what extent metric Y (dependent variable) is explained by the variability of metric X (independent variable)
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 1 Scores calculated as „Top boxes“ (share of „agree“ and „strongly agree“ responses) ratio

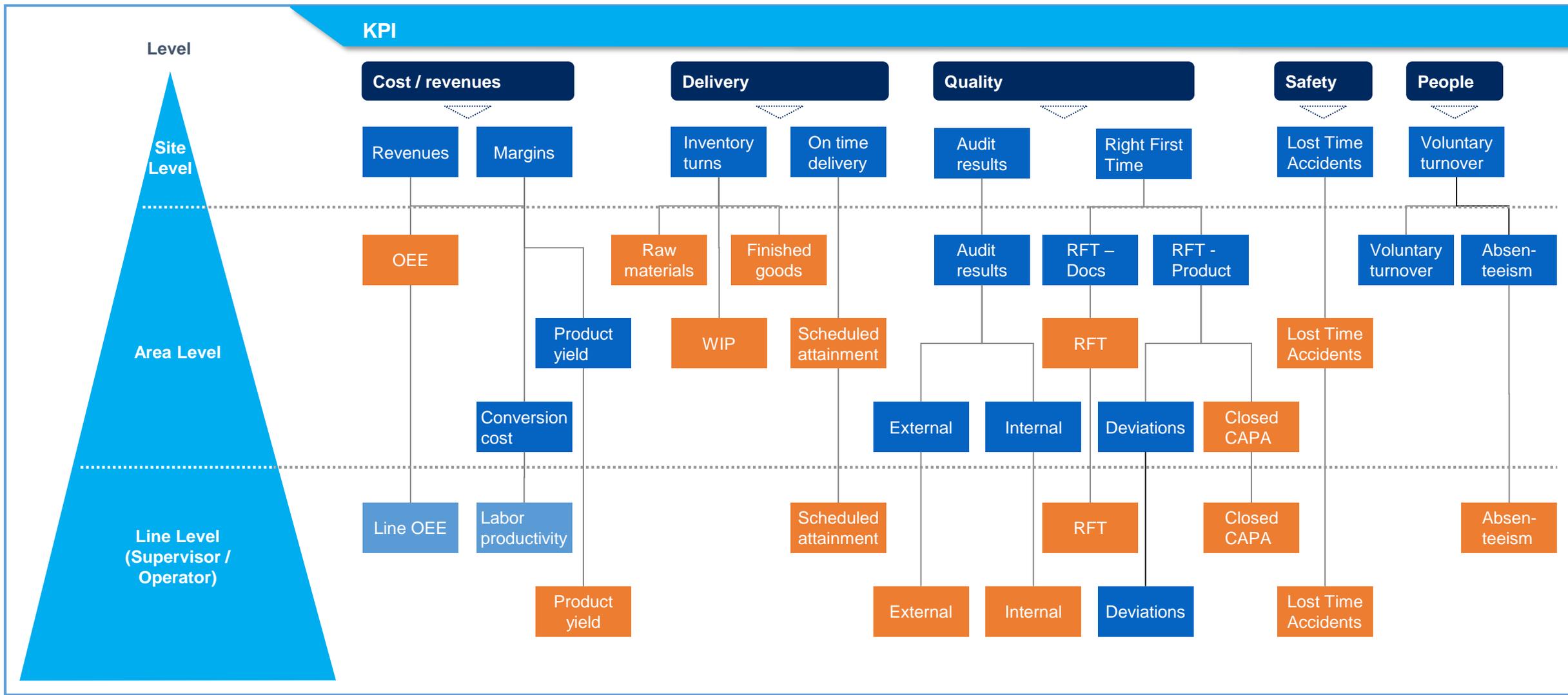
4 Advanced companies use leading metrics to predict & correct quality outcomes – Case Example



5 Metrics need to be cascaded down to the shop floor level and linked to performance KPIs- Pharma plant example

- Monthly reviewed
- Weekly reviewed
- Daily reviewed

- 1 KPIs
- 2 Boards
- 3 Huddles



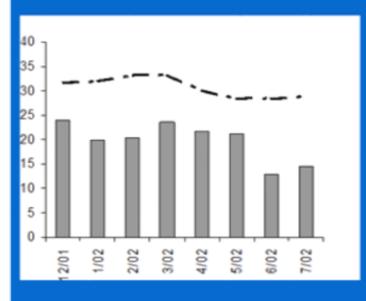
6 Effective cross-functional review forums are critical for root cause assessment & decision making

What does a good review look like?

This ... 	Not this ... 
<ul style="list-style-type: none"> 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 	<ul style="list-style-type: none"> Only reporting of facts Judgmental, apportionment of blame for things gone wrong Critical or defensive attitudes Compliance or acceptance of the norm Micro-management



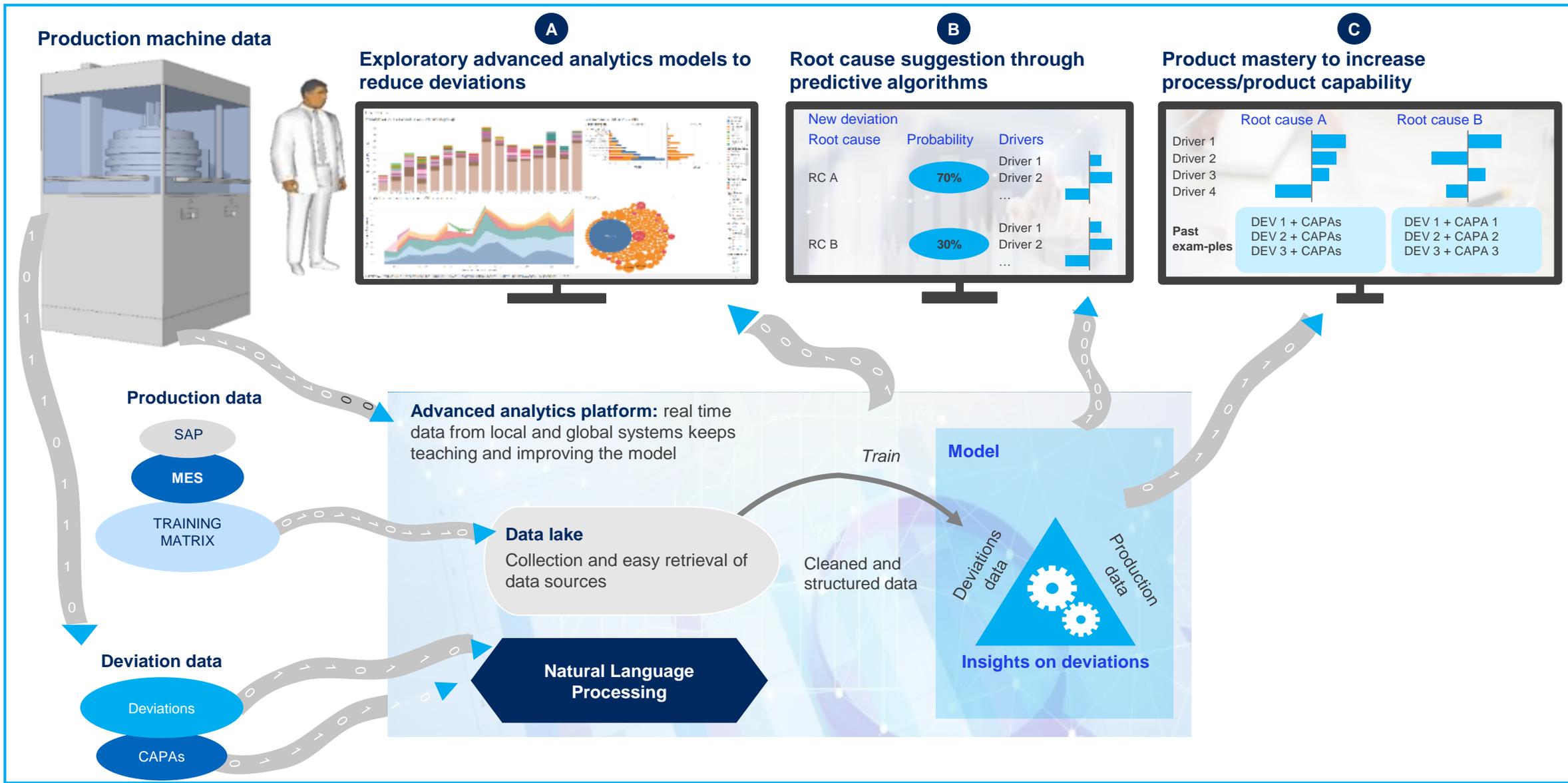
Key questions for effective discussions



Month	Value
12/01	25
1/02	20
2/02	20
3/02	25
4/02	22
5/02	22
6/02	15
7/02	18

What is happening?	<ul style="list-style-type: none"> What are the gaps to target? Are any trends causing concern?
5 Whys?	<ul style="list-style-type: none"> 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?	<ul style="list-style-type: none"> 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?	<ul style="list-style-type: none"> 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?	<ul style="list-style-type: none"> Is it a priority action? What is the deadline for completion? When are the intermediate milestones?

7 Digital & Advanced Analytics approaches significantly reduce manual effort required and improve quality of insights & decision making- Deviation reduction example



THANK YOU



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