Building Quality Metrics

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Indicators of mature Quality Culture:

• Led from the top, empowered from below

• Communication of priorities
  • To personnel
  • To shareholders
  • To clients
  • To regulators

• Relevant monitoring
  • Critical review of what metrics are monitored, and the environment in which they are being monitored.
Metrics: careful selection

- Careful selection of metrics is required
  - What behaviours do the metrics demonstrate?
  - What behaviours do the metrics influence?
  - What is the relevance of each metric to product quality or patient safety?

“The only true measures of quality are the outcomes that matter to patients”

Michael E. Porter and Thomas H. Lee, MD
Metrics: careful selection

- Is the company monitoring the right things?
  - NOW
  - IN FUTURE
Metrics: careful assessment

- The need for context is paramount when interpreting metrics

![Graph showing deviations per batch over time.](image)

- Metrics which give context are as important as the metrics themselves
  - *Meta-metrics?*
The importance of context

“Investigations closed within 30 days”

On time

- Poor investigations?
- Poor decision making?
- Poor quality?
- Supply disruption?

Late

- Good investigations?
- Good decision making?
- Improved quality?
- Consistent supply?
- Patient benefits?
MHRA and quality metrics

• Metrics used to augment existing regulatory processes
  • Risk-based inspection intel
  • Compliance management
  • Regulatory action

• Focus on flexible metrics based on compliance specifics
  • Behavioural and performance indicators
  • Company-derived metrics
  • Regulator-derived metrics.
Quality metrics – future considerations

• Enhancing personnel ‘ownership measures’
  • ‘Empowerment measures’ – ability to influence change

• Selecting and reviewing relevant metrics
  • Product / patient, process, compliance and behaviour
  • Providing context for metrics interpretation

• Challenges:
  • **Industry:** approaches to communicating variable metrics and contextual information
  • **Regulators:** normalising diverse metrics as inputs to risk-based inspection planning.
Summary

• Public health emergencies and regulatory action cases provide useful quality culture indicators

• Requirements of a quality culture are diverse, and may not be common in a global setting

• Importance of staff engagement and communication

• Careful selection and assessment of metrics is required to enable good decision making
  • Biggest challenge is the measurement of behaviour using compliance and processed-based metrics.
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