Quality Objectives & Performance Indicators

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Quality Policy guides Quality Objectives

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

a) is appropriate to the purpose and context of the organization and supports its strategic direction;

b) provides a framework for setting quality objectives;

c) includes a commitment to satisfy applicable requirements;

d) includes a commitment to continual improvement of the quality management system.

ISO 9001 Quality Management Systems - Requirements (2015)

Senior Management sets the Quality Policy.

Who sets the Quality Objectives?

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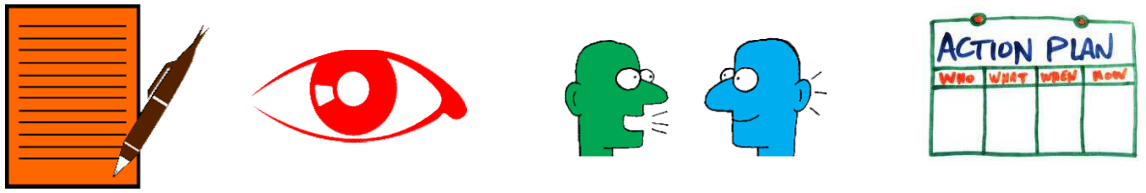
Quality Objectives and Performance Indicators

2.3 Quality Planning

(a) Senior management should ensure the quality objectives needed to implement the quality policy are defined and communicated.

(e) Performance indicators that measure progress against quality objectives should be established, monitored, communicated regularly and acted upon as appropriate as described in Section 4.1 of this document.

Management Review



ICH Q10: Pharmaceutical Quality System (2008)

http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html

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Quality Objectives and Performance Indicators

Senior management has the ultimate responsibility to ensure an effective Pharmaceutical Quality System is in place to achieve the *quality objectives*

… and should ensure continuing suitability and effectiveness of the Pharmaceutical Quality System and GMP compliance through participation in management review.

EU (2013) and PIC/S (2017) Chapter 2

No specific mention of quality objectives

Eudralex: https://ec.europa.eu/health/documents/eudralex/vol-4_en
PIC/S: https://www.picscheme.org/en/publications?tri=gmp

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Quality Objectives and Performance Indicators … and Quality Metrics

Quality metrics:

"objective measures used by management … to monitor the overall state of quality of a GXP organization, activity or process."

"They include measures to assess the effective functioning of quality system controls, the performance, quality and safety of medicinal products and reliability of data."

WHO TRS 966 Annex 5 Guidance on good data and record management practices (2016)

http://www.who.int/medicines/areas/quality_safety/quality_assurance/guidelines/en/

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Regulator quality metrics initiatives

FDA has set up an initiative to use Quality Metrics for risk based inspections and published a draft Guidance for Industry in July 2015 and a Technical Performance Guide in June 2016.

In Europe agencies also use Quality Metrics. They are aiming to help regulators to separate manufacturing sites with poor standards from those continuously working on quality improvement.

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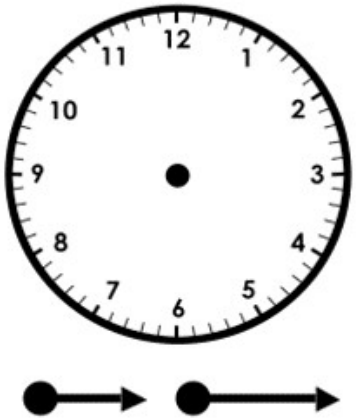
Examples?

- Quality Objectives
- Performance Indicators / Metrics (Measures)



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Examples?

- Quality Objectives
- Performance Indicators / Metrics (Measures)

Leading Metrics: predicts future performance

- % Right First Time
- CpK / product

Lagging Metrics: outputs reports past performance

- OOS
- Reworks

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Parenteral Drug Association Conference on Quality Metrics 2013

Top metrics @ conference

Per Product:	
1	Process Capability
2	Critical Investigation Rate
3	Batch Rejection Rate
4	Confirmed OOS rate (DS and DP)
5	Confirmed Product Quality Complaint Rate

For the Site:	
1	Critical Investigation Rate
2	Batch Failure Rate
3	Confirmed OOS Rate
4	Grade A&B EM excursion Rate
5	CAPA Effectiveness Rate
6	% Right first time

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	Per Product
1	Process Capability
2	OOT (DS and DP)
3	Critical Investigation Rate
4	Line Clearance Failures
5	Batch Rework / Reprocess Rate
6	Batch Rejection Rate
7	Finished Product Reject Rate
8	Confirmed OOS rate (DS and DP)
9	On-time CAPA closure
10	% CAPA effective at check (DS and DP)
11	On-time Stability Testing
12	Stability Failure
13	Confirmed Product Quality Complaint Rate
14	AE rate / Safety Signal Detection
15	Health Authority Notifications
16	Recall Rate by Product

	For the Site
1	Process Capability metric
2	Confirmed OOT rates per site
3	Critical Investigation Rate per site
4	Batch Failure Rate
5	Cycle Times (disposition, end-to-end)
6	Confirmed FP OOS rate (DS and DP)
7	Analytical Invalid Rate by site
8	EM Grade A&B excursions
9	% overdue PM for critical equipment
10	CAPA effectiveness
11	CAPA timeliness
12	Recapitalization and PM as % asset value
13	Training effectiveness metric
14	# critical and major / PICS inspection
15	Risk Profile changes
16	Inspection commitment completion

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Challenges?

- Quality Objectives
- Performance Indicators / Metrics (Measures)

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How many? Too many = overload

- Beware: some measures need a lot of input data! (e.g. percentage readings or rates)
- A few key measures needed at senior management level, maybe more for regular monitoring meetings

Quality can be measured on different levels and for many processes.

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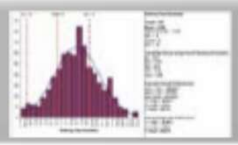
I Look at 4 Metrics!

- Disposition Cycle Times 
- Safety Incidents 

- Compliance Indicators 

- Process Capabilities 

Martin van Trieste, Amgen, 2015
SVP Quality, Environment, Health & Safety

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Performance Indicator	Information	< Expected	Accept-able	Objective	> Expected
Authority Inspections	# Authority Inspections passed # Total Authority Inspections received	< 85%	85% - 99%	100%	100% passed <= 2 major
Customer Audits	# Customer Audits with NO critical observations # Total Customer Audits received	< 80%	80% - 90%	91% - 95%	96% - 100%
Internal Audit	# Completed # Total planned	< 70%	70% - 80%	80% - 84%	85% - 94%
Repeat Deviations	# Repeat Deviations # Total Deviations	> 20%		< 20%	<10%
Overdue Deviations	# Overdue Deviations # Total Deviations	> 10%		<= 10%	<1%
Human Deviation Reduction	# Human Error Deviations # Total Deviations	> 30%		<= 30%	<= 10%
Overdue CAPA's	# Overdue CAPAs # Total CAPAs	> 10%		<= 10%	<= 1%
On Time PQR	# completed on time # Total	< 85%		>= 85%	100%
Overdue SOPs	# Overdue # Total	< 95%		>= 95%	100%
Reprocessing rate (API, FP)	# Batches NOT conforming with specification # Total batches produced	> 5%		<= 5%	0%
OOS rate	# Confirmed OOS # Total batches produced	> 5%		<= 5%	0%

Adapted from Klaus Pitterschatscher, personal communication

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How many? Too many = overload

- Beware: some measures need a lot of input data! (e.g. percentage readings or rates)
- A few key measures needed at senior management level,
- More for regular monitoring meetings?

Which to Select?

- Use objectives to drive the behaviour you want to see.
- Starting point: what behaviour do you want to change?
- Then: select measurements
- Beware: unintended consequences

See Martin Lush's Webinar on KPIs from August 2016, DCVMN Website

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Go from	To	Goal
Reduce # Deviations by xx %	% on target incident-to-ranking time	<60 min
	% overdue	Set goals to drive closing: e.g. • Minor: investigated and closed in 1 day • Major: investigated and closed in x days
	# Repeat Deviations	< x%

Unintended consequences?

- Underground, not reported
- "Problems are bad" attitude
- Blame culture

"Get it done" culture

Promotes good investigations, not "quick fix"

Spend more energy on important things

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FDA 6 (sub) SYSTEMS OF PQS

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FACILITIES AND EQUIPMENT DASHBOARD

Performance Indicator	Information	< Expected	Accept-able	Objective	> Expected
Calibration %	# Overdue / Total				
Planned Maintenance %	# Overdue / Total Planned				
Unplanned Maintenance #	# Breakdowns				
SLAs - in place %					
Pest Control ?					

J	F	M	A	M	J

MATERIALS HANDLING DASHBOARD

Performance Indicator	Information	< Expected	Accept-able	Objective	> Expected
Supplier Qualification					
Supplier Complaints					
Confirmed Materials OOS					

J	F	M	A	M	J

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Link to Management Review

4.1 Management Review of the Pharmaceutical Quality System

Management should have a formal process for reviewing the pharmaceutical quality system on a periodic basis. The review should include:

(a) Measurement of achievement of pharmaceutical quality system objectives;

(b) Assessment of performance indicators that can be used to monitor the effectiveness of processes within the pharmaceutical quality system, such as:

(1) Complaint, deviation, CAPA and change management processes;

(2) Feedback on outsourced activities;

(3) Self-assessment processes including risk assessments, trending, and audits;

(4) External assessments such as regulatory inspections and findings and customer audits.

ICH Q10: Pharmaceutical Quality System (2008)

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ISO outline for Management Review

1. Welcome and Introduction
2. **Input information**
   - Actions from Prior Meeting
   - Changes with impact on QMS
   - Presentation: QMS Effectiveness
   - Matters arising from Monthly Meetings
3. **Management Outputs**
   - QMS Evaluation
   - Opportunities for Improvement
   - Resource needs
   - General Concerns

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Thank You