Maintain the effectiveness of a QMS by using Lean Six Sigma approach

« Nobody is perfect, but a team can be »

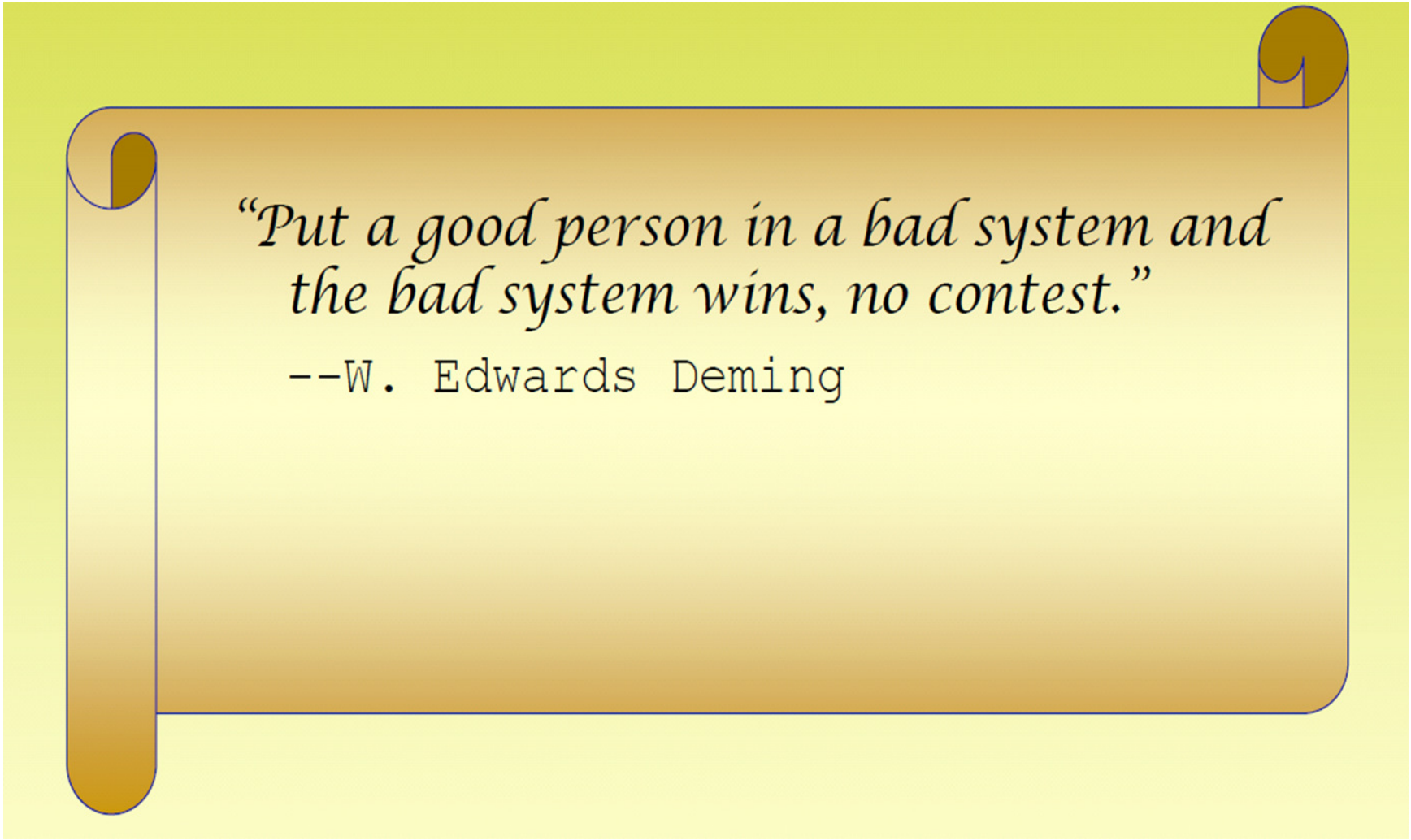
Peter Jehander

3rd International Summit on GMP, GCP and Quality Control

Valencia 25th of September 2014

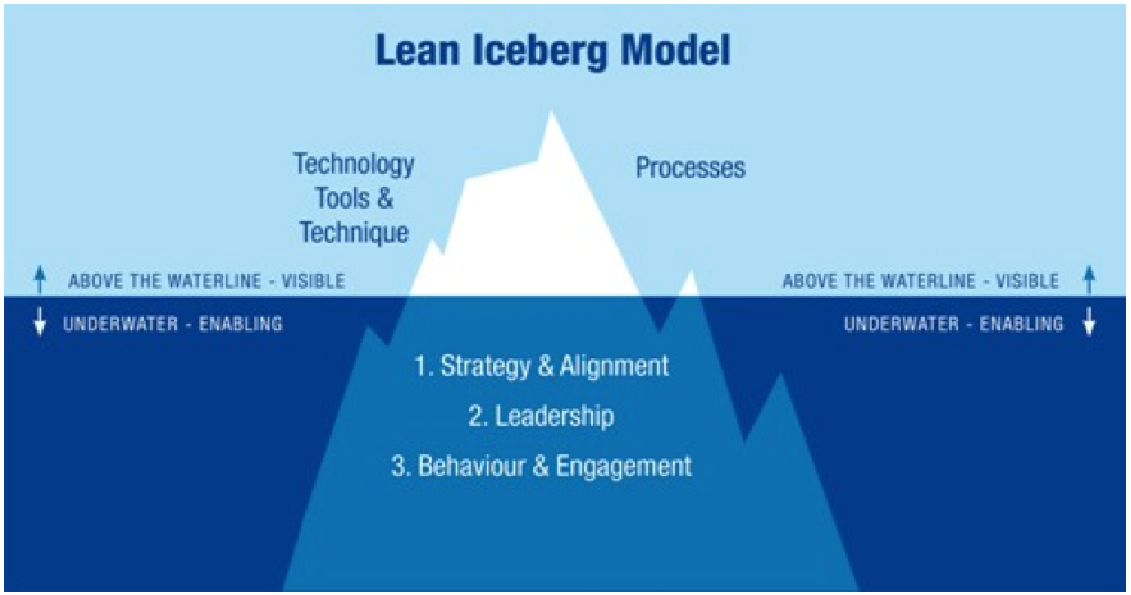
Innovation by experience

LEAN - System approach



Source: PLAN organization, SWEDEN

Sustainable Lean

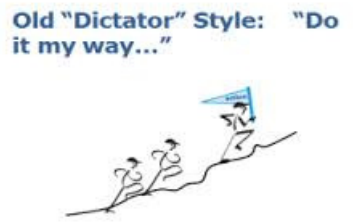


Source: Lean Iceberg Model © 2008 P. Hines, P. Found, G. Griffiths, & R Harrison

Lean management

Traditional leadership – Taylorism; Command and control

Focus on results - management by objectives

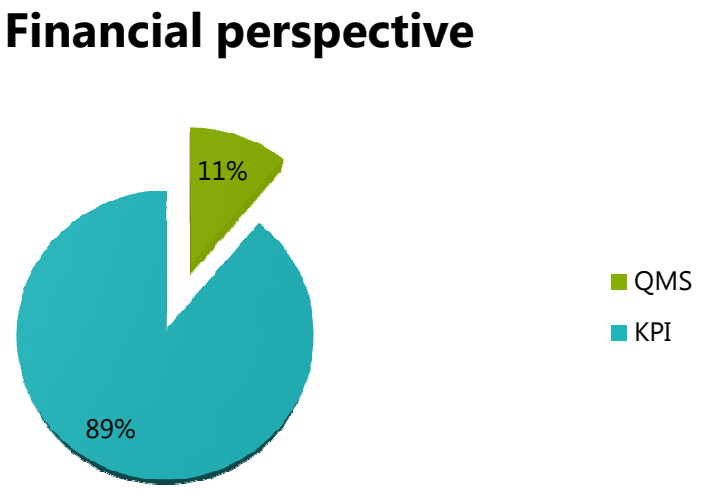


Lean Leadership – Coaching leadership

Process approach and focus on results

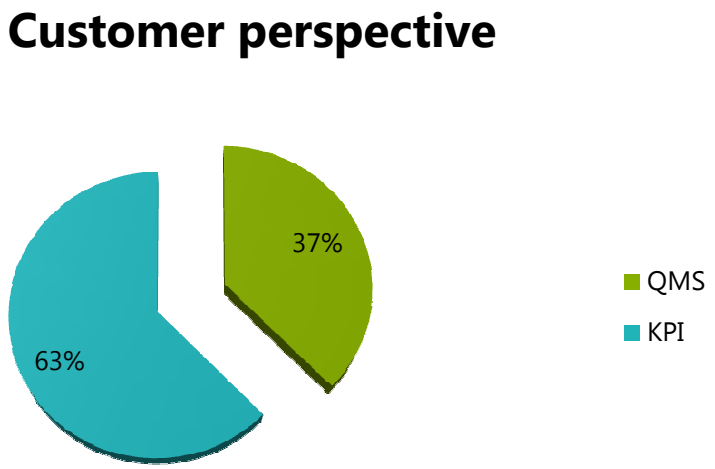


Key Performance Indicators (Taylorism)



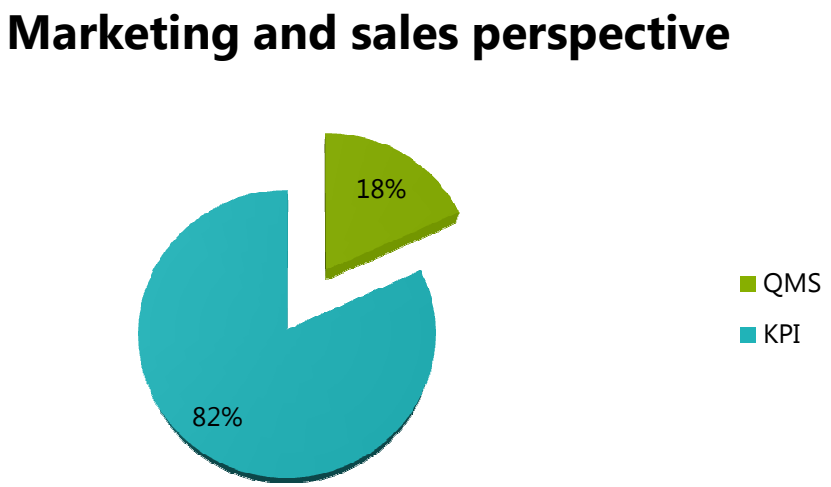
Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators (Lean)



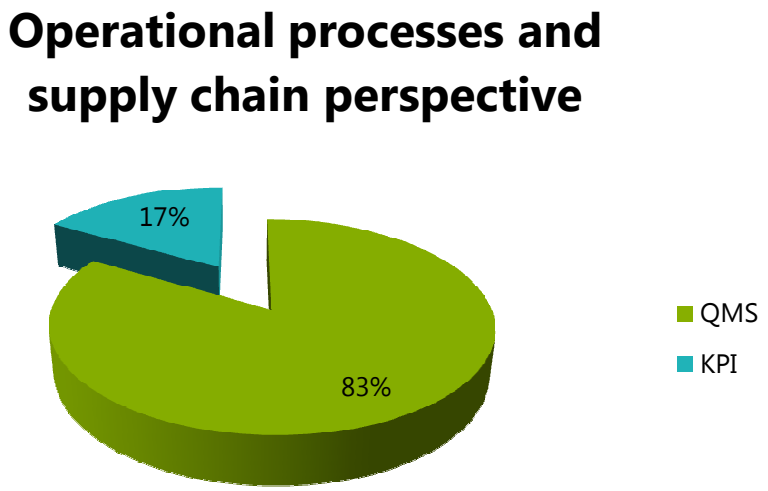
Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators (Taylorism)



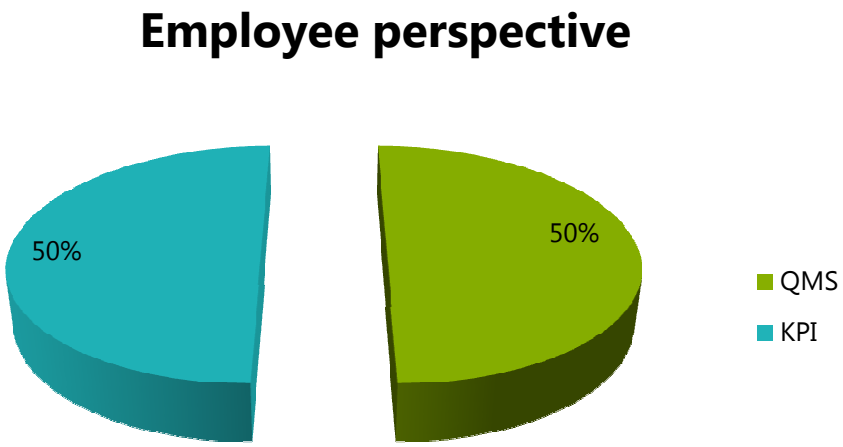
Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators (Lean/Taylorism)



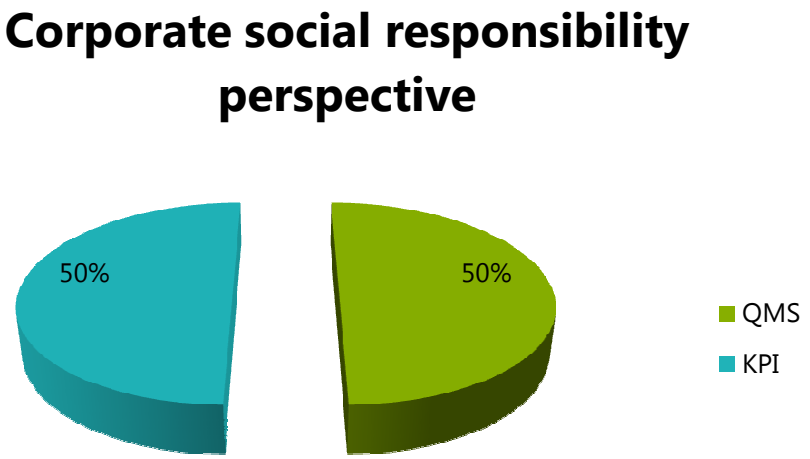
Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators (Lean)



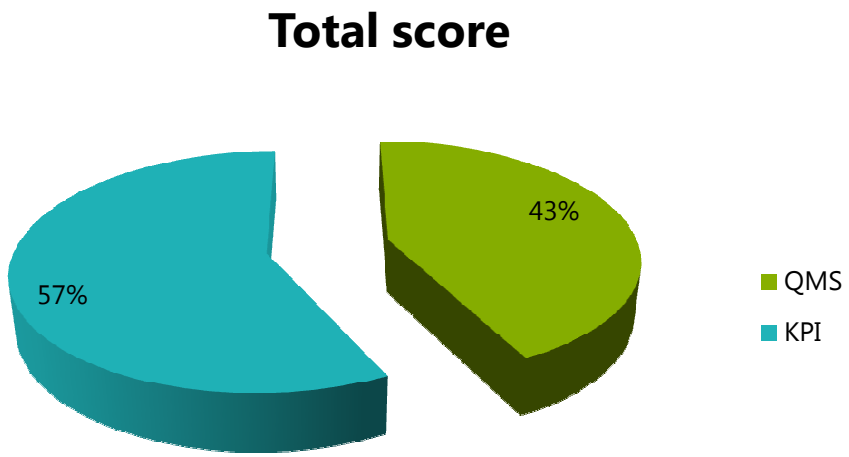
Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators (Lean)



Source: Bernard Marr; Key Performance Indicators

Key Performance Indicators



Source: Bernard Marr; Key Performance Indicators

QMS Effectiveness
Management responsibilities

Main process

Clause 5.1	Management commitment

Subprocesses

Clause 4.4.2	System processes
Clause 6	Resource management
Clause 5.5.3	Internal communication
Clause 8.4	Analysis of data
Clause 8.5	Improvement

Source: ISO EN 13485:2003

BMS instead of QMS

System processes/Resource management

The QMS (Quality Management System) is not integrated with the governance structure on top level, which traditionally focuses on the Financial together with Marketing and sales perspective KPIs.

Top Management should align its KPIs to match the QMS process objectives, and accept this system as a BMS (Business Management System).

Internal communication/Improvement

This is the most efficient way for employees on different levels to contribute and understand their role when adjusting system parameters in organizations.

Performance management needs to adapt to a more flexible approach.


We have a burning passion for consulting and engineering
Thank You!
Questions?
Innovation by experience