



Lecture 5: Toolbox for improvement of Quality Behaviors

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- **Management Communication**
- **Quality Improvement Objectives**
- **Error Prevention Program**



Quality Management

EFQM

Best Practice

World Class Manufacturing

Lean

cGMP

Six Sigma

Benchmarking

Operational Excellence

KPIs

CMMI

EN ISO

KAIZEN

Balanced Scorecard

TQM

Time (~)	Focus / Content	Pioneers, Precursor
1900	Quality testing; rejection of defective products	Ford, Taylor
1930	Quality control; based on statistics or control charts (Shewhart charts)	Shewhart
1960	Quality measures in whole organization; preventive measures	Taguchi, Deming
1964	Zero-defects-principle of US Defense Dptd., aims to perfection	Crosby
1985	Zero-defects-strategy, Six sigma	G. Electric, Motorola
1988	EFQM (European Foundation of Quality Management)	EFQM
1990	Comprehensive Quality Concept	Ishikawa, 5-Why
1995	Total Quality Management	Deming, Baldrige, CIP
2014	Request from FDA to develop a Quality Culture (both: industry and authorities)	Janet Woodcock (FDA)

Total Quality Management

has become the dominant quality philosophy of the past 20 years.

Classic Quality Assurance	Total-Quality-Management
People make mistakes	Processes provoke errors
Individual employees are responsible for errors	All employees are responsible for errors
Zero defects is not feasible	The goal is zero defects
Shopping by many suppliers	Partnership with a few suppliers
Customers must take what the company's quality delivers	Everything is aligned towards customer satisfaction

Quality Culture

A good quality culture is established when all employees starting from CEO to shop floor workers are accountable for quality.

Quality culture is a **key management element** for success. However, quality culture does not establish itself but **requires empowerment, communication and daily quality awareness.**

Create a culture in which employees “live” quality in all their behavior, where they are **passionate about quality as a personal value** rather than simply obeying an edict from on high.

We define a “**true culture of quality**” as an environment in which employees

- not only follow quality guidelines but also
- consistently see others taking quality-focused actions
- hear others talking about quality, and
- feel quality all around them.

Harvard Business Review, April 2014, Ahwin Srinivasan and Bryan Kurey

Quality Attributes

These quality attributes are related to management responsibility and are elements of the continuous improvement of the pharmaceutical quality system as mentioned in the ICH guideline Q10 on Pharmaceutical Quality System (PQS).

These attributes are important indicators for quality culture:

1. management communication emphasizing that quality is everyone's responsibility
2. established quality improvement objectives
3. implemented error prevention program

1. Tools for management communication

- Quality Commitment
- Posters, Flyer
- Quality meetings
- Intranet
- Newsletters, E-Mails
- Teambuilding programs
- Leading with SMART Goals
- Ideas Management
- ...

2. Established quality improvement objectives

Define, monitor and communicate about:

- Key Performance Indicators / Key Quality Indicators
- Complaints
- Deviations
- Rejects
- Audit findings
- Error costs / Defect costs
- Fluctuation costs (external and internal)
- ...

3. Implemented error prevention program

- Engagement of adequate qualified and experienced personnel
- Training of new staff regarding quality requirements
- Error / defects management systems: deviations, OOS, complaints, etc.
- Root Cause Investigation
- CAPAs and Effectiveness Checks
- Key Performance Indicators / Key Quality Indicators
- Feedback on KPIs / KQIs
- Documents designed for user guidance (MBR, testing instructions, SOPs, forms, etc.)
- Identification and communication of critical-to-quality processes and process steps
- ...



And the situation is:

Many of the Quality Improvement Initiatives and Quality Management Systems listed above are still **in legal force or in fashion** despite of their mixed record.

Some companies are implementing three or four initiatives at once – thinking more is better, but it is not a guarantee to achieve the company's quality goals and the company's success!

Each initiative **mentions frontline employees**, but does not provide a systematic approach for **addressing the role people play in hindering or improving quality**.

The irony is that **frontline employees' behavior is the fundamental element** in producing a product or service. How frontline employees behave – doing things right, doing things wrong, not doing what they should, doing things they should better not – determines quality results.

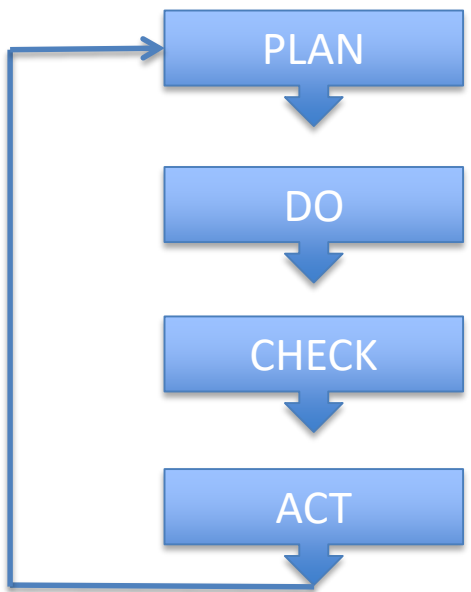
Quality, Behavior and the Bottom Line: The Human Side of Quality Improvement

What are the key triggers

- to make your employees struggle for quality and for the company's success?

- to make your employees
 - accept their responsibility for quality?
 - identify themselves with the company and their job?
 - engage more than required?
 - work flexible according to business needs?
 - work with a team spirit:
 - work together to be strong?
 - support and help each other?
 - go the additional way for the company's success?

If you want to reduce your weight ...

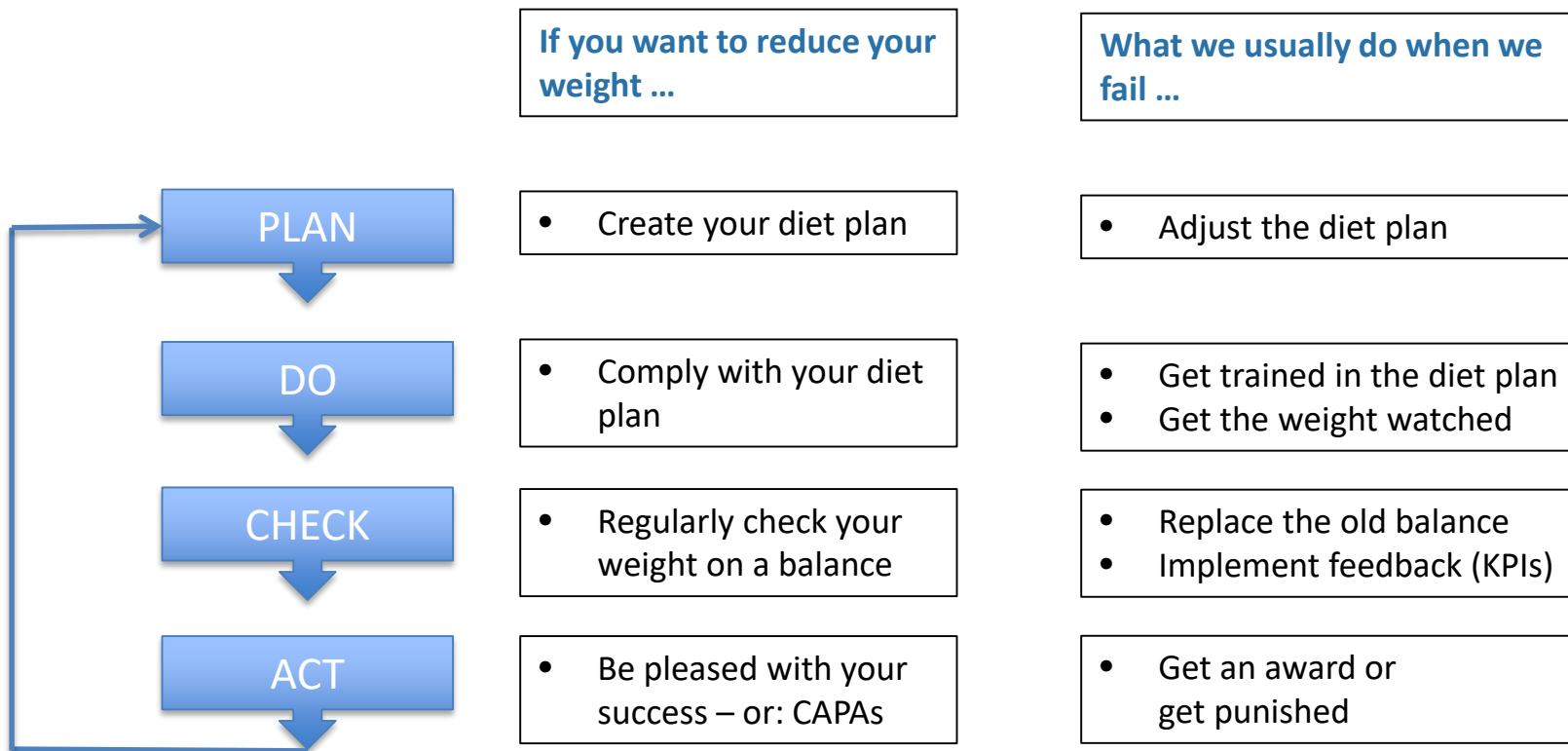


- Create your diet plan

- Cook / eat according to the diet plan

- Regularly check your weight on a balance

- Be pleased with your success - or: CAPAs



This sounds very familiar!





Motivation

Offer your employees the chance

- to earn their money by doing a fulfilling and worthwhile job
- that corresponds to their personal purpose of existing and
- that fits to the purpose of existing of your company.

You can count the extent and results of motivation by two factors:

- Productivity
- Fluctuation

John Strelecky, The Big Five for Life

People having the most fulfilling jobs are

- Florist, Gardener 87 %
- Hairdresser, Beautician 79 %
- Plumber 76 %
- PR, Marketing 75 %
- Scientific Research 69 %
- Staff in tourism 67 %
- Construction worker 66 %
- Physician 65 %
- Lawyer, Jurist 64 %
- Architect, Nurse 62 %

High results:

Lots of contacts with other people, creative manual work, frequent sense of achievement
Despite: low glamour, low salary

Top 6 Factors for a fulfilling job

1. Life-Balance
2. Capable management
3. Suitable company culture
4. Security of employment
5. Perspective for career
6. Good salary

Prof. Howard Gardner, Harvard-University, USA

Being motivated for the job depends on (priority order):

1. Fulfilling, interesting and recognized work
2. Behavior of supervisors
3. Relationship to colleagues
4. Salary
5. Self responsibility
6. Working atmosphere
7. ...

Prof. Howard Gardner, Harvard-University, USA and FAZ, Germany, June 2016

World champions

- don't have **supervisors**,
 - they just have **personal trainers** and **mental coaches**.
- ➔ For what we work determines, how well we work!

If you want to build a ship,
don't round up men to obtain wood,
prepare tools, assign tasks and divide the work,
but teach the men
longing for the vast and endless sea.

Antoine de Saint-Exupéry (assigned, source unclear)

Augustinus von Hippo (354- 430): Only those who burn can start fire in others!

15.05.2017, Germany's 2nd Soccer league:

Arminia Bielefeld (17th) vs. Eintracht Braunschweig (2nd)

- Carsten Rump, Co-Trainer of Arminia Bielefeld shouted to the players in the team cab:
 - You are now playing for 25 thousand visitors
 - You are playing for your children and your families
 - When you come home, they will be proud of you
 - I want you to go out and win
 - Will you fight from the very beginning to the end?
 - Do you wanna win?
- The players shouted: yes, yes, yes!



➔ Bielefeld won 6:0 (their highest victory during the last 31 years!)

<https://www.facebook.com/zeiglerswelt/videos/10155301249562943/>
(Source: youtube/Jürgen Sundermann)

Critical-to-Motivation factors:

Management tasks

- Recognition of the human factor
- Communication
- Teambuilding
- Goal setting
- ...

Recognition of the human factor

Root Cause Tool Ishikawa-Diagram: “People” component should include ...

Subcomponent

- Training:
- Critical-to-Quality Behavior:
- Feedback:
- Consequence experience negative:
- Consequence performance positive:

Possible root cause

was not performed, not effective

have not been defined and communicated

frontline employees do not receive feedback about critical-to-quality behavior

experience after performing of the new critical-to-quality behavior is negative or neutral; no positive feedback

positive in case of poor-quality Behavior; alternative (former) process is faster or easier to do instead of the new behavior

Communication

- Messages have to be consistent (in word and behavior) and easy to understand
- Messages have to comply with the written requirements
- Messages are delivered by respected sources
- Workers find that communications appeal to them personally
- Recognition of good behaviors strengthens good behaviors

**The results of your communication
indicate the quality of your communication!**

Teambuilding

Teams start as a group of individuals that do not know each other.
In the past it took years to come together.
Today, there are fast job changes, work in project teams, etc.

4 Phases according to Bruce Tuckman
(fields: educational psychology, group dynamics):

Forming (Orientierungsphase)

→ Internal program, introduction

Storming (Konfrontationsphase)

→ External programs, games, [sports, climbing, rafting, ... - need to be agreed by each participant!]

Norming (Kooperationsphase)

→ award, incentive event, dinner, ...

Performing (Wachstumsphase)

→ award, incentive event, dinner, ...

Leading with S.M.A.R.T. Goals Setting

Specific

A general goal would be, “Get in shape.” But a specific goal would say, “Join a health club and workout 3 days a week.”

Measurable

To determine if your goal is measurable, ask questions such as.....
How much? How many? How will I know when it is accomplished?

Attainable

You can attain most any goal you set when you plan your steps wisely and establish a time frame that allows you to carry out those steps.

Realistic

A high goal is frequently easier to reach than a low one because a low goal exerts low motivational force.

Timely

A goal should be grounded within a time frame. **T** can also stand for Tangible – A goal is tangible when you can experience it with one of the senses, that is, taste, touch, smell, sight or hearing.
When your goal is tangible you have a better chance of making it specific and measurable and thus attainable.