Part 3

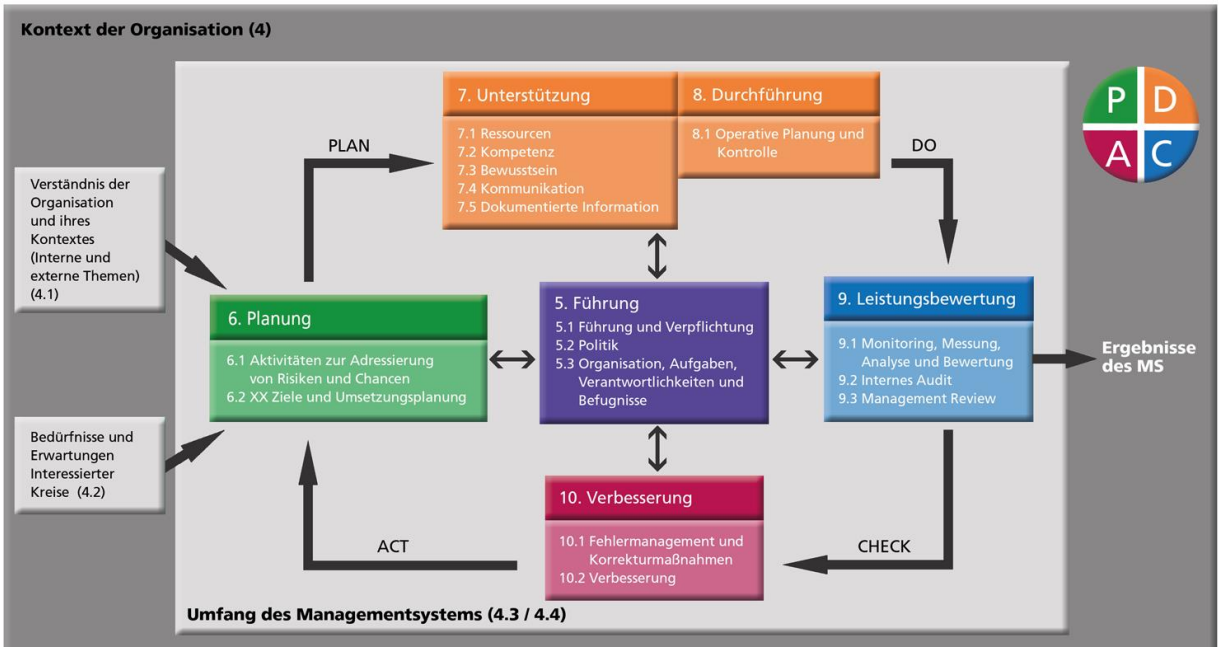
ISO 9001:2015 for SMEs: sensible, uncomplicated, advantageous!

In the third part of our series of focus topics, you will learn more about the control concept (PDCA) and its planning within a quality management system.

What do building a house, the teaching behaviour of a person, the work process of standardisation committees and a management system have in common? Consciously or unconsciously, we always go through the four phases of the so-called PDCA cycle or "deming circle": **Plan - Do - Check - Act**, i.e. plan - implement - check - act on the way to achieving the desired goal and improvement. This tool is used for the further development of products and services and helps to analyse the causes of errors.

The purpose of a quality management system (QMS) is to enable the organisation to achieve objectives efficiently and to improve from year to year.

-



Details of the PDCA cycle (own illustration)

Standardised and established processes, organisational structures, documentation and other obligations are put to the test when optimising all relevant procedures. Another core element of the QMS is the so-called "systematic approach", which serves to continuously improve the company's performance and the management system itself.

The self-maintaining and controlling PDCA process begins with the recording and subsequent description and evaluation of an identified "actual situation". If the process is practised, it ultimately leads to the continuous improvement of process performance.

The PDCA cycle must function in an organisation at all levels: from the filing system on the desk to production and service processes (SPC) through to the entire quality management system. The amount of documentation required depends on the level: As not everything can be documented in a meaningful way, the really important points should be recorded for the processes.

Part 3

Which topics are relevant in the individual phases?

Plan

The first phase involves analysing and planning. The objectives of the QMS, sub-processes and resources are defined, taking into account the company's policy and context. Risks and opportunities are also identified and addressed at this point.

Do

In the second phase, the planned measures are implemented.

Check

This is probably the most important phase of the PDCA cycle. Here it is checked, measured and controlled whether the measures defined in the planning phase have been realised accordingly in the implementation phase. The processes and resulting products and services are monitored and measured, taking into account the policy and objectives, the internal and external requirements and the planned activities.

Act

The fourth phase is about reacting to the review results: Have the objectives been met? If not, what new measures should be taken to improve performance? Have we considered all the lessons learnt? How should future targets and measures be defined to ensure continuous improvement?

In this phase, the company addresses the shortcomings it has identified, but also continuously looks for opportunities for improvement - depending on the means and resources available: How can we become more efficient and faster, be innovative and make work easier in the teams, win new customers, avoid repeating mistakes and develop the company further?

Advantages of the PDCA cycle

- easy to implement
- Versatile, can be used in any industry and in any business area (project management, change management, product development, resource management...)
- Proven methodology of continuous improvement
- prevents recurring errors from disrupting the work process
- Changes deliver results quickly

Constantly repeating the phases of the PDCA cycle leads to continuous improvement in the company's performance - and usually also to increased employee satisfaction, as problems are not repeated and uncertainties are gradually eliminated.

The reactive approach of only going through the cycle once to solve an urgent problem, on the other hand, is of little use. Genuine and sustainable improvements in the company must be thought about in the long term - with a proactive approach.

Part 3

PDCA cycle as the basis for the continuous improvement process (CIP)

The improvement cycle usually begins when an error or problem occurs. According to the PDCA cycle, the cause of the error is sought first. Suitable solutions are developed and appropriate measures are planned. The next step is implementation in order to establish the "target state". All phases are then reflected upon and the new ACTUAL is compared with the TARGET. Then the next planning phase begins. (see illustration).

The success of the PDCA cycle depends on the following factors:

- Consistent application for daily challenges
- Daily commitment and coordination on the part of the management
- Consistent visualisation of figures, data and facts as well as presentation of processes and correlations
- Define complex problems and break them down into individual subject areas
- Internal communication and employee motivation

Phase	Steps
PLAN	1. **Recognise, name and accept the improvement topic**: "What is it about?" 2. **Delineate and analyse the problem** "What exactly happened where, when and how? Who is affected?" 3. **Identify the causes (e.g. Ishikawa diagram)** "Why is the issue an issue? What exactly is the cause? What exactly is the consequence?" 4. **Formulate a goal** "What should it ideally be? How exactly do we recognise that the goal has been achieved? What exactly will be different/better when the goal is achieved? What exactly is the goal?" 5. **Develop an action plan** "What is preventing us from achieving our goal today? What measures are necessary to remove these obstacles? What exactly needs to be done, with whom, when and how?"
DO	6. **Implementation of the planned measures** 7. **Status reporting (documentation and visualisation of the results)** "Is everything going as planned?"
CHECK	8. **Check implementation (target/actual comparison)** "Have the defined goals been achieved?" To what extent have the objectives been achieved? Why did the deviations occur?"
ACT	9. **When the goal is achieved: reflection and safeguarding of experience** **If "target not achieved": initiate improvements**

CIP principle of error/problem solving based on the PDCA cycle - own table according to QZ-Online

Part 3

With the help of the following different problem-solving methods, conceivable causes of errors can be quickly and systematically identified, interdependencies can be clearly illustrated and preventive and corrective measures can be easily described:

- Ishikawa diagram / cause-effect analysis
- 5Why method
- FMEA (Failure Mode and Effects Analysis)
- FTA (Fault Tree Analysis)
- Flowcharts & process analysis
- 8D- Reports
- Q7- 7 Quality tools, etc.

How much improvement is "enough"?

The desired improvement results from the targets set by top management. These should include various factors: At a minimum, they should lead to an improvement in internal efficiency so that the company remains competitive, they should take into account individual customer needs and the level of performance that the market normally expects[1] .

None of these factors on their own can ever be considered "sufficient" or "insufficient".

The following parameters are checked in the ISO 9001 certification audit:

- Have the objectives been set in such a way that the company's goals, customer needs and market expectations have been equally taken into account?
- How have the overarching corporate objectives been translated into internal requirements in the corresponding processes? Are these requirements also communicated and monitored?
- Is there evidence that the organisation analyses the data from process monitoring and uses the results to evaluate process efficiency and/or improve process output?
- Is the way in which the improvement of a process contributes to the achievement of the overall objectives consistent?
- Are the improvement objectives coherent overall and do they match the company's objectives, customer needs and market expectations?

ISO 9001 lists a number of areas that an auditor can assess to obtain evidence of both the planning and actual implementation of improvements, including: internal communication, follow-up, documented procedures, the effectiveness of management meetings, customer feedback systems, training programmes (e.g. for management or internal auditors).

[1] Source: APG-ISO 9001 Auditing Practices Group Guidance on Improvement, 2016

Part 3

Conclusion part 3

The PDCA cycle is suitable for every industry and can be used for different purposes.

As a proactive approach, it is based on continuous application and thus on lasting success. Active participation and supervision from the management level and employee involvement as part of regular training, meetings and performance reviews help to establish a culture of improvement and develop a pattern of behaviour.

In the next part of the publication series, we look at the topic of scope: How is the scope of the QMS according to ISO 9001 defined and determined? When are the standard requirements not applicable after a development/research process in the company? When should "logistics" or "sales" appear in the scope of application?

-

Your contact:

Miroslava Dubinetska

+49 30 233 20 21 - 533 | miroslava.dubinetska@gut-cert.de

Andreas Lemke | Head of the certification body

+49 30 233 20 21 - 411 | andreas.lemke@gut-cert.de