



*Quality Management
System (QMS)*

- **Ninja Services**
- **ISO 9001:2015**
- **Questions & Answers**

Ninja Services: *What is it?*



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Objectives of this presentation

- **ISO 9001** as a QM Basis
- **Principles** (foundations)



- **PDCA and ISO** explained
- **The Benefits** in application



ISO 9001

What's behind it?

- **QM Basis**
- **The 7 Principles**
- **PDCA and ISO**
 - **Overview Quality Methods**
 - **PDCA in the ISO context**
 - **PDCA and the 7 Principles**
- **PDCA and ISO**
 - **The Benefits**
- **Communication**

ISO 9001 → Quality Management Basis



- **ISO 9001 is the globally recognized standard for quality management (QM).**
 - It defines how an organization designs its processes so that quality is reproducible, controllable and continuously improved.
- **Core Idea :** Quality is not ensured by individuals, but by structured, documented and lived processes.
- **Key Elements :**
 - Customer focus
 - Process orientation
 - Clear responsibilities
 - Risk-based thinking
 - Continuous Improvement (PDCA)
- **The Benefits**
 - Higher customer satisfaction
 - Improved organizational efficiency
 - Increased employee retention
 - Competitive advantage
 - Risk management and compliance
- **Goal :** To set up an organization in such a way that it delivers reliably, manages risks, and develops systematically.

ISO 9001

The 7 Principles

The 7 Principles

A central element of ISO 9001 is the seven principles of quality management (QM), which serve as a framework to increase customer satisfaction, optimize processes and promote continuous improvement.

1. Customer focus
2. Leadership
3. Involvement of people
4. Process-oriented approach
5. Improvement
6. Fact-based decision-making
7. Relationship management

ISO 9001 → The 7 Principles



- 1. Customer Focus:** The core principle is a consistent focus on the needs and expectations of customers. The goal is not only to meet these needs but to exceed them – in order to foster loyalty and strengthen the organization's reputation.
- 2. Leadership:** Effective leadership creates an environment in which employees are motivated and empowered to achieve the organization's goals. Top management is responsible for the strategic direction and actively supports all quality-related initiatives.
- 3. Involving People:** Quality management thrives on the commitment of employees. People at all levels should be empowered to take on responsibility, pursue further training, and actively contribute to success. Recognition and participation promote performance and development.
- 4. Process-oriented Approach:** The organization must understand how individual processes are interconnected and contribute together to achieving its goals. Effective management of these processes increases efficiency, reduces waste, and creates added value.
- 5. Improvement:** Continuous improvement is a key element of a dynamic quality management system. Organizations should regularly review their performance and systematically develop their processes, products, and services.
- 6. Fact-based decision-making:** Decisions should be based on reliable data and transparent analyses. The use of key performance indicators (KPIs) enables well-founded decisions and supports effective management.
- 7. Relationship Management:** Organizations do not operate in isolation, but rather within a network of suppliers, partners, and other stakeholders. Building and maintaining stable, mutually beneficial relationships is crucial for long-term success.

ISO 9001

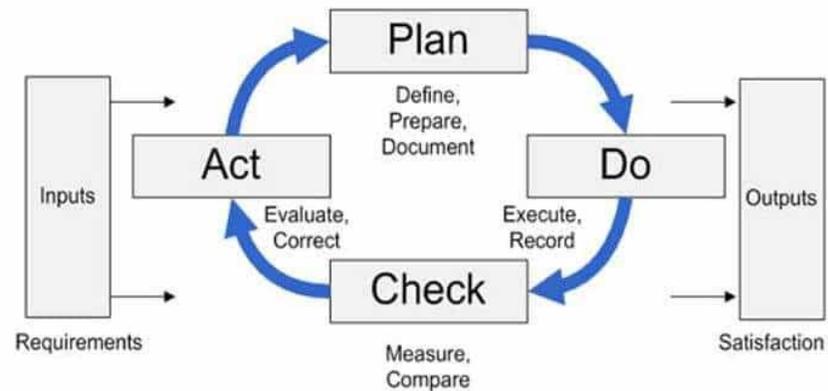
PDCA and ISO

How PDCA relates to ISO 9001

ISO 9001 is **structurally based on the PDCA cycle**. The standard is structured so that each requirement can be assigned to one of the four steps:

- **Plan (Define):** Context, risks/opportunities, quality objectives, resources, process planning
- **Do (Implement):** Operational processes, product/service delivery
- **Check (Audit):** Monitoring, measurement, internal audits, management review
- **Act (Improve):** Corrective measures, continuous improvement

In short: **PDCA is the methodological backbone of ISO 9001** – the standard forces organizations to apply this cycle permanently and systematically.



PDCA → Overview Quality Methods



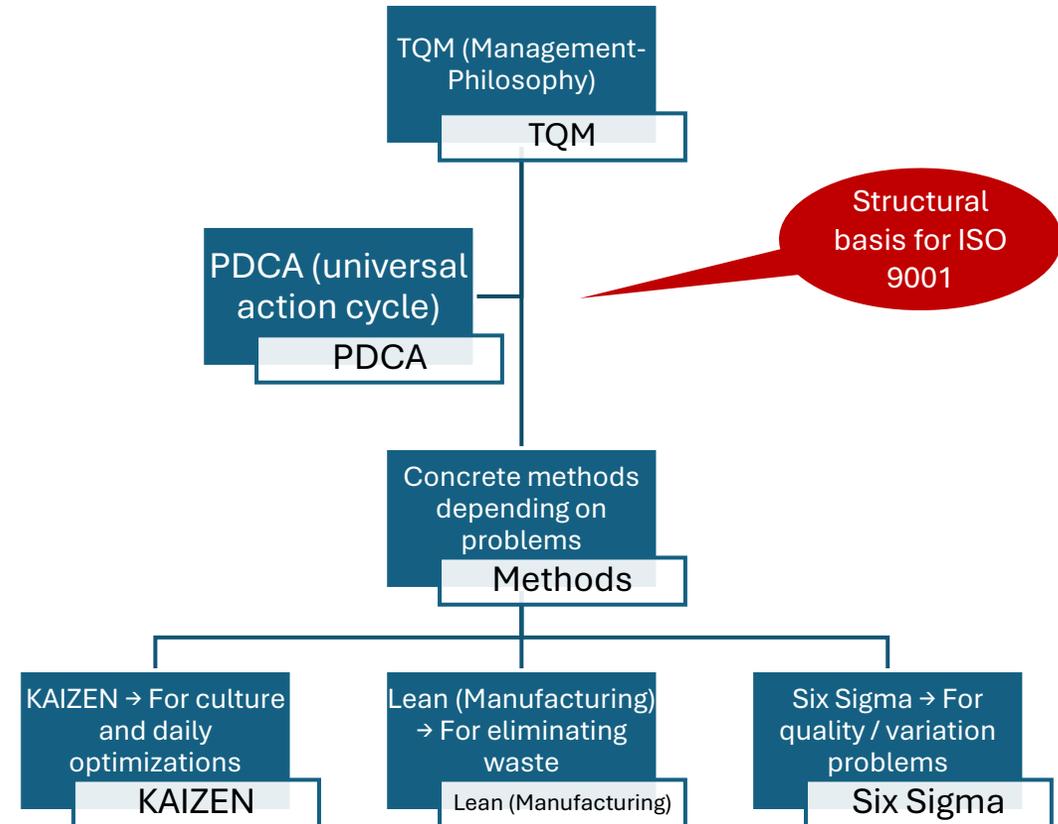
ISO 9001 defines the framework and minimum requirements for a quality management system.

TQM (Total Quality Management) is the overarching management philosophy that creates a holistic system of concrete methods and a culture of continuous improvement within this framework.

The PDCA cycle is the universal action and learning cycle underlying all improvement.

Concrete methods depending on the type of problem:

- **KAIZEN** → Philosophy of continuous improvement
 - For fostering the improvement culture and daily, small-scale optimizations.
- **Lean (Manufacturing)** → Methodology toolkit
 - For eliminating waste and optimizing process flows.
- **Six Sigma** → Methodology toolkit
 - For solving complex quality problems and reducing variation.



PDCA → In the ISO context



PLAN

4. Context of the Organization

- 4.1 Understanding the organization and its context
- 4.2 Understanding the needs / expectations of interested parties
- 4.3 Scope of the QMS
- 4.4 QMS and its processes

5. Leadership

- 5.1 Leadership and Commitment
- 5.2 Q-Policy
- 5.3 Roles, responsibilities, authorities

6. Planning

- 6.1 Dealing with Risks & Opportunities
- 6.2 Q-Goals
- 6.3 Planning of changes

DO

7. Support

- 7.1 Resources
- 7.2 Competence
- 7.3 Consciousness
- 7.4 Communication
- 7.5 Documented Information

8. Operation

- 8.1 Operational Planning and Control
- 8.2 Determining requirements for products and services
- 8.3 Development
- 8.4 Procurement
- 8.5 Production and Service Provision
- 8.6 Release of Products and DL
- 8.7 Controlling non-conforming process results

CHECK

9. Performance Evaluation

- 9.1 Monitoring, measurement, analysis, evaluation
- 9.2 Internal Audit
- 9.3 Management review

ACT

10. Improvement

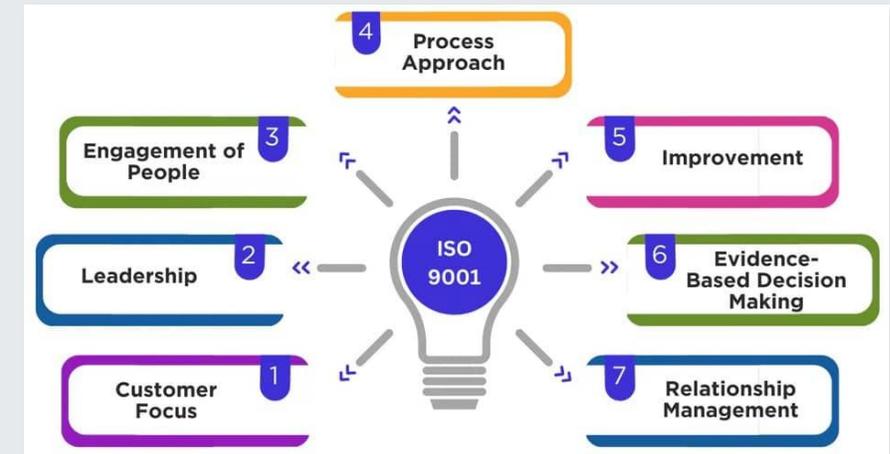
- 10.1 Improvements
- 10.2 Nonconformity and corrective actions
- 10.3 Continuous Improvement

PDCA → And the 7 Principles



PDCA	ISO Standard Chapter	Priority assigned Principles
PLAN	4. Context of the Organization	1. Customer focus (interested parties) 6. Fact-based decision-making (analysis as a basis)
	5. Leadership	1. Customer orientation (policy alignment) 2. Leadership
	6. Planning	5. Improvement (planning approach) 6. Fact-based decision-making (risks, objectives)
DO	7. Support	3. Involvement of people (competence, awareness) 7. Relationship management (communication)
	8. Operation	1. Customer orientation (requirements, development, delivery) 4. Process-oriented approach
CHECK	9. Performance Evaluation	2. Leadership (management evaluation) 6. Fact-based decision-making
ACT	10. Improvement	5. Improvement (practical action) 6. Fact-based decision-making (root cause analysis)

The 7 Principles



ISO 9001

PDCA and ISO

PDCA and ISO → Benefits

PDCA makes processes controllable: Plan, execute, check, correct.

In an ISO 9001 system, this is the mechanism to make deviations visible and to implement improvements in a binding manner.

Result: Fewer errors, stable processes, reproducible quality.

- **Plan** (Define)
- **Do** (Implement)
- **Check** (Audit)
- **Act** (Improve)

PLAN → 4. Context of the Organization



4. Context of the Organization	What is it about?	What is the benefit?
<ul style="list-style-type: none">• We know, understand and take into account all important information from our environment (market, culture, technology, laws, social issues, competition, etc.)• We understand the expectations of our key stakeholders and take them into account in our strategy• The processes of our organization are defined and their relationships to each other are shown• All processes are managed effectively	<p>The organization must understand its context in order to build an effective quality management system (QMS). This includes:</p> <ul style="list-style-type: none">• Analysis of the environment: market, technology, legislation, culture, competition, social factors• Expectations of relevant stakeholders• Definition of system boundaries and exclusions• Structuring and continuous improvement of relevant processes, taking into account opportunities and risks.	<ul style="list-style-type: none">• Understanding and fulfilling stakeholder expectations forms the basis for a viable strategy and sustainable success.• The clear definition and description of key processes creates security and enables targeted improvements.• The representation of process relationships (e.g., using a process map) promotes cross-functional thinking and reduces interface problems.

PLAN → 5. Leadership



5. Leadership	What is it about?	What is the benefit?
<ul style="list-style-type: none">• All managers are credible role models regarding leadership behavior and customer orientation• We have defined binding rules of the game (quality policy, mission statement or similar) and adhere to them conscientiously• The purpose and long-term goals of our organization are defined and known to everyone• All employees know their tasks, what they are authorized to do, and what they are responsible for	<p>The organization must ensure that top management fulfills its leadership responsibilities and actively exemplifies a focus on quality and customer orientation. This includes:</p> <ul style="list-style-type: none">• Exemplary leadership behavior and consistent customer focus• Clear value base and defined quality standards• Understandable purpose and long-term objective• Transparent regulation of tasks, powers and responsibilities	<ul style="list-style-type: none">• Top management takes responsibility and fosters a culture of learning and continuous improvement.• It creates a unified direction and enables employees to contribute their commitment in a targeted manner.• Clear roles and responsibilities reduce friction and boost motivation.• The organization will be enabled to systematically meet customer requirements and legal regulations.

PLAN → 6. Planning



6. Planning	What is it about?	What is the benefit?
<ul style="list-style-type: none">• Potential risks to our organization are known and appropriate measures have been defined to deal with them• We consciously seize the opportunities that present themselves to us• We define clear, achievable goals and work consciously towards them• We implement changes in our organization systematically and in a planned manner	<p>The organization must ensure that it plans systematically to achieve its quality objectives and effectively manage opportunities, risks, and changes. This includes:</p> <ul style="list-style-type: none">• A structured approach to opportunities and risks• The definition of specific, measurable quality objectives with clear resource planning.• The controlled implementation of changes to the quality management system and processes	<ul style="list-style-type: none">• Seizing opportunities creates competitive advantages and supports the sustainable success of the organization.• A conscious approach to risk management increases safety and stability.• Clear, achievable goals promote employee engagement and goal orientation.• Planned changes ensure the integrity of the quality management system and minimize negative impacts.

DO → 7. Support



7. Support	What is it about?	What is the benefit?
<ul style="list-style-type: none">• We have the right, qualified employees• We have the necessary infrastructure to effectively create and monitor our products and/or services• Our organization possesses the necessary knowledge and acquires additional knowledge as needed• We ensure the competence and quality awareness of our employees• We ensure internal and external communication and have good document management	<p>The organization must ensure that all supporting elements are available and effective for establishing, implementing, and continuously improving the quality management system (QMS). These include:</p> <ul style="list-style-type: none">• Provision of human and material resources• Ensuring and developing knowledge and skills• Promoting quality awareness• Structured internal and external communication• Control of documented information	<ul style="list-style-type: none">• An appropriate infrastructure enables efficient work and promotes economic efficiency.• The targeted deployment and empowerment of employees contribute significantly to the success of the organization.• Clear communication avoids mistakes, duplication of effort, and demotivation.• A streamlined and clear QMS documentation facilitates access to relevant information and supports accountability.

DO → 8. Operation



8. Operation	What is it about?	What is the benefit?
<ul style="list-style-type: none">• The way we deliver our services is suitable for our products and/or services• We gather information about expectations and requirements for products and/or services• We use systematic project management for the development of new products and/or services• We ensure the quality of supplied products and/or services• Our production and/or service provision demonstrably achieves the desired results	<p>The organization must ensure that all operational processes are planned, controlled, and monitored to meet product and service requirements. This includes:</p> <ul style="list-style-type: none">• Planning and control of operational processes• Handling customer requirements and communication• Development, manufacturing and supply of products and services• Management of external providers and outsourced processes• Measures for release, monitoring, traceability and handling of nonconformities	<ul style="list-style-type: none">• The systematic planning and control of operational processes ensures the conformity of products and services.• Clear communication with customers and suppliers builds trust and reduces errors.• Managing external suppliers ensures quality throughout the entire supply chain.• A structured approach to non-conformities protects the organization from consequential damage and strengthens customer loyalty.

CHECK → 9. Performance Evaluation



9. Performance Evaluation	What is it about?	What is the benefit?
<ul style="list-style-type: none">• We monitor, measure, analyze and evaluate the performance of our organization, the services provided and the resulting customer satisfaction• We use meaningful internal audits and periodic management reviews for monitoring and use the results for continuous improvement	<p>The organization must ensure that the performance of the quality management system (QMS) is systematically monitored, measured, analyzed, and evaluated. This includes:</p> <ul style="list-style-type: none">• Collection and evaluation of relevant information on process and product performance• Customer satisfaction survey• Conducting internal audits• Management review for the overall assessment of the QMS	<ul style="list-style-type: none">• Systematic performance evaluation enables informed decisions and targeted improvements.• Customer satisfaction surveys provide insights into strengths and weaknesses.• Internal audits create transparency and promote compliance with requirements.• Management review ensures that the QMS remains effective and is strategically developed further.

ACT → 10. Improvement



10. Improvement	What is it about?	What is the benefit?
<ul style="list-style-type: none">• Our organization has a continuous improvement process	<p>The organization must ensure continuous improvement – both of its quality management system (QMS) and its ability to provide compliant products and services. This includes:</p> <ul style="list-style-type: none">• Response to nonconformities• Initiation and implementation of corrective measures• Identification of improvement opportunities• Promoting a culture of learning and development	<ul style="list-style-type: none">• Systematic error handling prevents repetitions and strengthens process reliability.• Corrective measures build trust with customers and stakeholders.• Continuous improvement increases the organization's performance and competitiveness.• The organization will become more resilient to internal and external changes.

QMS *Communication*

- **Communication**
 - **Conflict Management**



Communication → Conflict Management



Conflicts are part of further development

Change creates friction. Where transparency increases or working methods change, tensions arise. A professional approach to conflict management is therefore crucial for implementing improvements / transformations in a stable and sustainable way.

Typical forms of conflict

Type of Conflict	Description
Conflicting goals	Conflicting goals hinder cooperation
Evaluation conflict	Differing opinions, values, and norms lead to disagreement.
Distribution conflict	Dispute over resources such as time, money, tasks
Relationship conflict	Personal hurt, misunderstandings, lack of appreciation
Role conflict	Unclear responsibilities, hidden power struggles
Power struggle	Competitive behavior towards superiors or colleagues
Value conflict	No common ground for viewpoints, moral tensions

Why are conflicts so difficult?

- Emotional tensions often operate beneath the surface.
- Objective solutions are ineffective when dealing with personal injuries.
- Lack of communication exacerbates the dynamics

Dealing with conflicts

- Recognize and name conflicts early on
- Treat the causes, not the symptoms.
- Clarify roles and responsibilities
- Use moderation or external support

Communication Share	Description	Influence
Body language	Gestures, mimics, breathing, clothing	> 50%
Voice	Quiet, loud, listless	> 30%
Factual statement	Message content	< 20%
Gestures and facial expressions significantly influence the effect of feedback! → Nonverbal communication = 80%		



« *It's the tone that makes the music* »
« *What goes around comes around* »



Questions & Answers

