Turība University

Quality management and systems

What is quality?

- In manufacturing, a measure of excellence or a state of being free from defects, deficiencies and significant variations. It is brought about by strict and consistent commitment to certain standards that achieve uniformity of a product in order to satisfy specific customer or user requirements.

What is quality?

Quality is defined as the summation of the affective evaluations by each customer of each attitude object that creates customer satisfaction.

Understanding of Quality

Colloquial, often referring to products:

- Free from defects
- Lasting
- Of higher value

Definition of quality

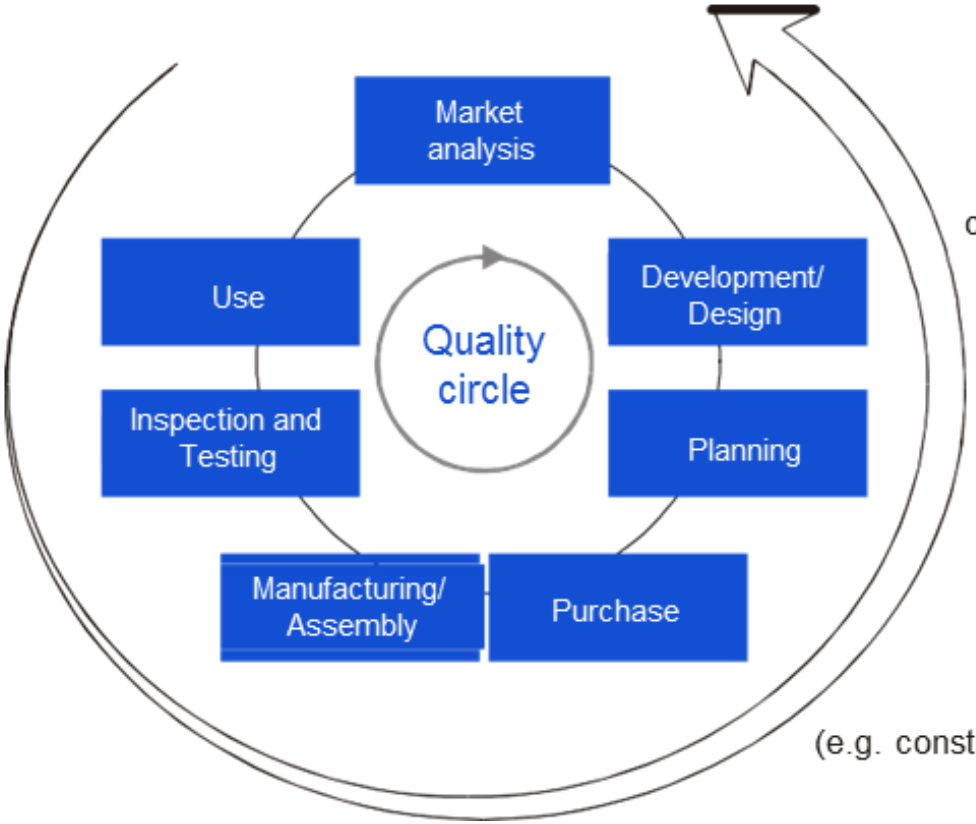
„Quality is the overlap rate of explicit as well as implicit customer demands with the supplied product characteristics."

20‘s

Grading and Sourcing out

30‘s

Development of statistical methods for process control and sample inspection



90‘s

Total quality thinking with adaption of the company´s culture through e.g. TQM or integrated Quality Management

80‘s

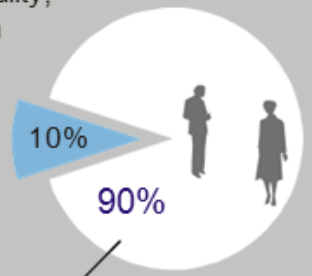
Development of methods for the prevention of failure within planning phases (e.g. construction or process FMEA)

Impacts of quality:

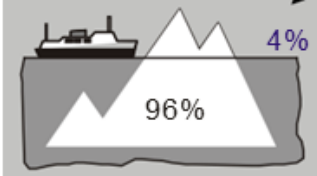
- Customer satisfaction
- Market share
- Brand value
- Efficiency
- Security
- Costs
- Traditions (customer behavior)
- Service (post production, warranty)
- Health (i.e. In food industry, healthcare)

Consequences of Bad Quality - At a Glance

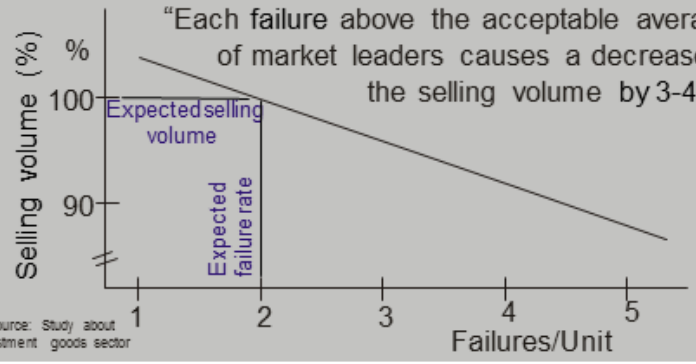
"90 % of customers, which are dissatisfied with the product quality, avoid the product in the future."



"Each customer will communicate his dissatisfaction to at least 9, sometimes 20, people."



"Only 4% of the dissatisfied customers complain about the bad quality."



Source: Study about investment goods sector

1 Mio. €
Warranty costs

1 Mio. €
Costs for elimination of defects

5 Mio. €
Missed sales and corresponding profits

Source: Desatnik, Brunner

Consequences of Bad Quality – At a Glance

	Consequences of bad quality
Product quality	-Customer dissatisfaction -Image damage -Reduction of market value -Complaints -Product recalls -High financial effort -...
Process quality	-Waste -Deficiency of efficiency and eventually even effectiveness -Internal customer dissatisfaction -Demotivation -...
System quality	-Bad differentiation from competition -Demotivating company culture -Disorientation caused by imprecise responsibilities -Demotivation by lack of attraction -Fear caused by lack of competence -...

An Example From the Past: The „Ford - Pinto Desaster“

Situation:

- High competition, especially in the compact car segment
- Short development period demanded
- High cost pressure

Product specifications („Green Book“):

- „Low Cost of Ownership“
- Purchase price below 2000 $
- Weight below 2000 pounds.
- Big trunk
- „Safety doesn´t sell“

Risks Have to Be Analysed in a Hholistic Way

(Pre-) Start of production:

- Crashtest showed a high fire risk in case of rear impact, even at low speed
- Technical solution (11$ additional expenses per car vs. 180 expected dead people at a „price“ of 200.000$)

Actual consequences:

- Conservative approximation 500 dead people
- Recall of 1,2 Mio Pinto not until 5 years after SoP
- Absolute additional costs of more than 300 Mio $

Spectacular Product Recalls

Damaged tires

In the year 2000 tires of the Japanese company were responsible for the overbalancing of Ford Explorer all-terrain vehicles. This problem ended in the biggest callback worldwide.

BRIDGESTONE

Recall amount **14,4 million tires**

Poison in cans

In 1999 the beverage company had to callback Coke-cans in Belgium and Luxembourg. While transportation on wood pallets the cans were contaminated by timber preservatives before bottling.

Coca-Cola

Cost for recall **800 million US-Dollar**

Dangerous side effects

The cholesterol-downer Lipobay was taken out of worldwide commerce by the pharmaceutical company. In case of combination with another substance serious side effects occurred.

BAYER

Cause for recall **52 deaths**

Fire in the engine compartment

In september 2001 the automotive company starts a callback for the brands Chrysler and Jeep. Causes: Risk of fire in the engine compartment, problems with the automatic and defective welding seams at the gear box.

DAIMLERCHRYSLER

Recall amount **3,1 million cars**

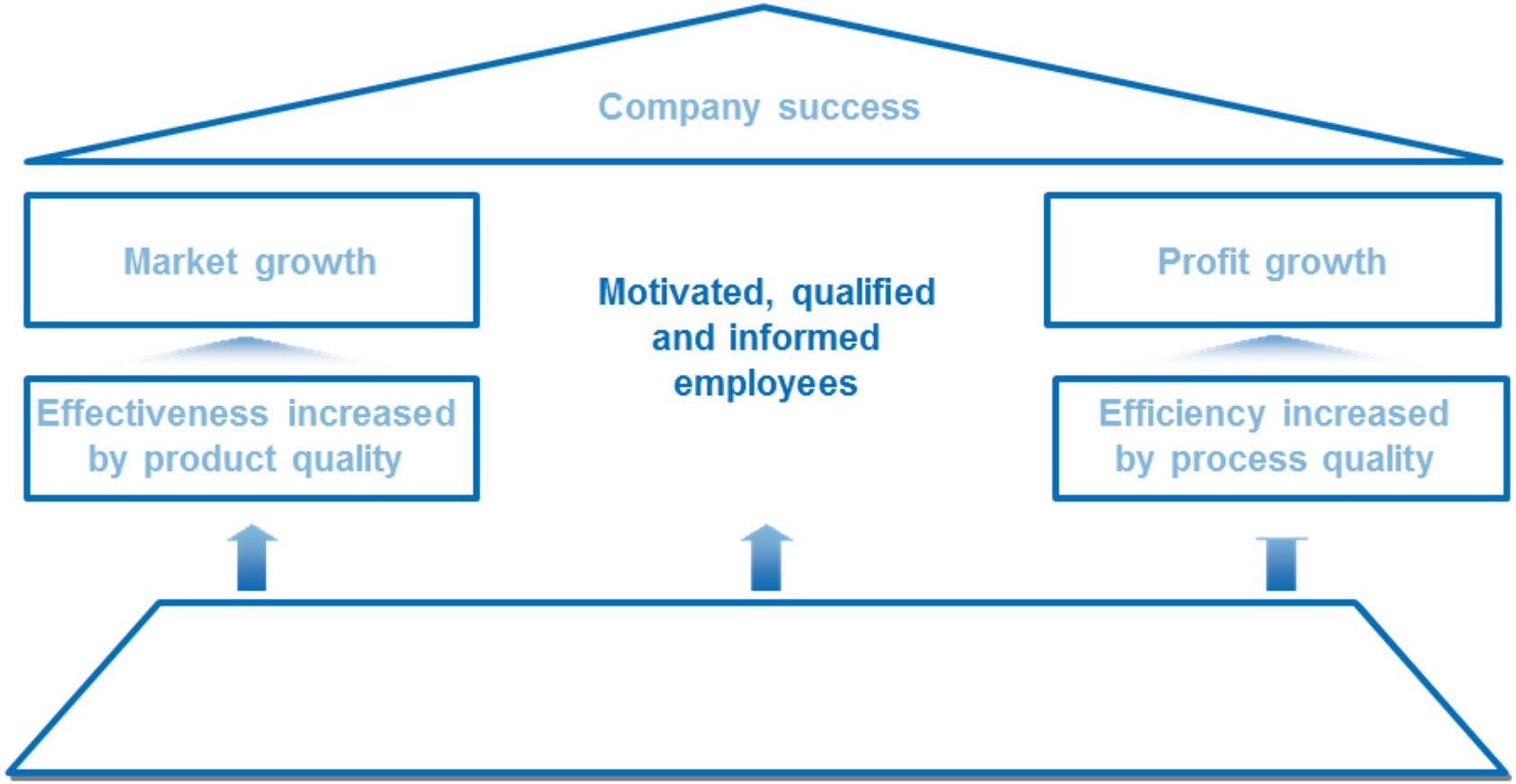
Oily protheses

In the year 2000 the swiss medical technology-company had to callback artificial knee- and hip-joints. The protheses were polluted by mineral oil.

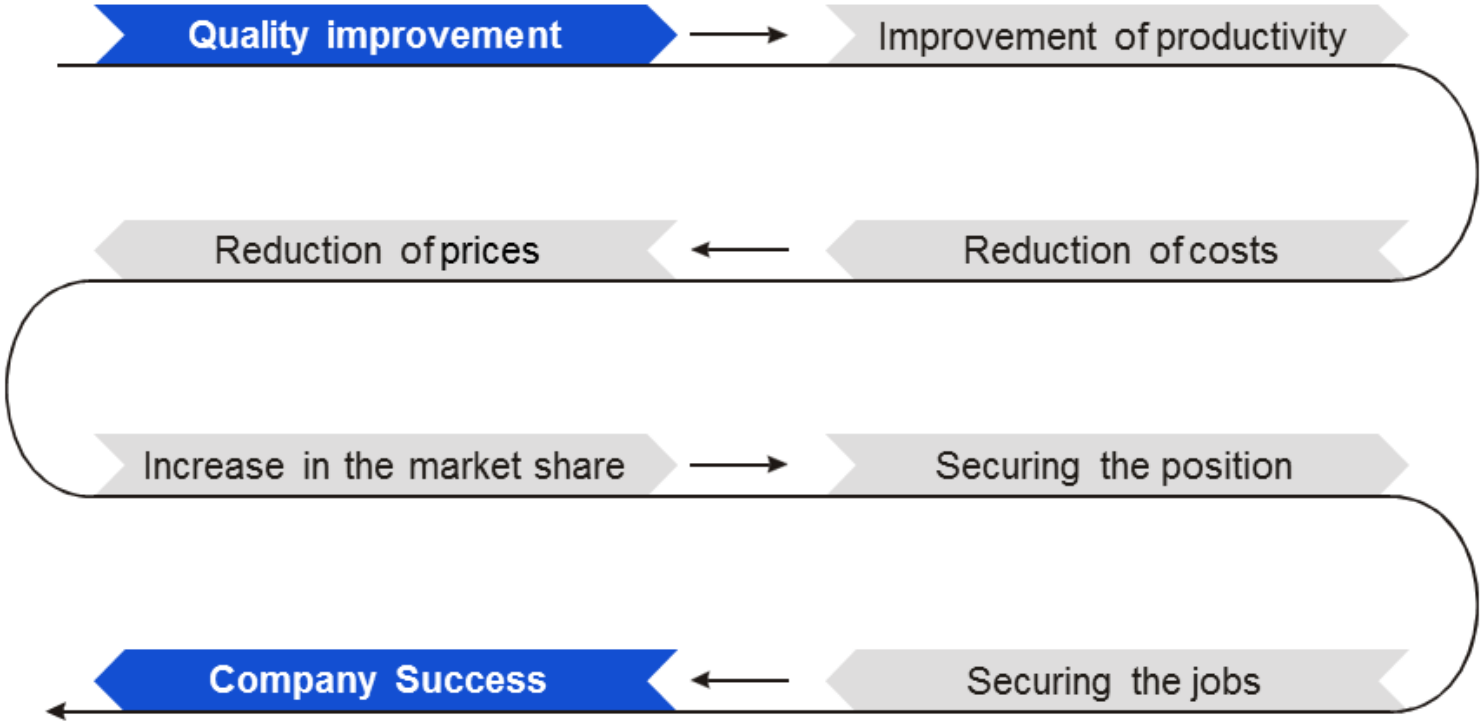
SULZER MEDICA

Paid damages **1 billion US-Dollar**

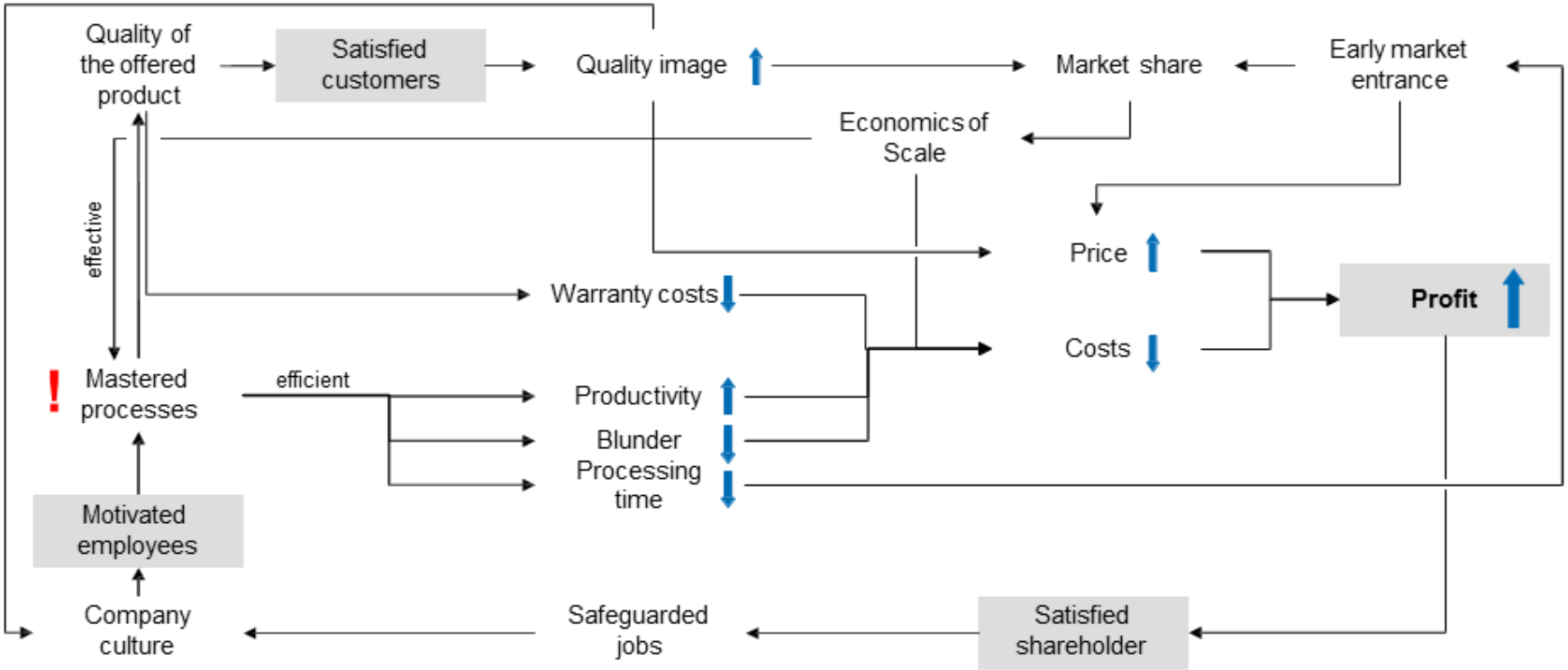
Company Success Through Product and Process Quality



Deming-Chain: Connection Between Quality and Company Success



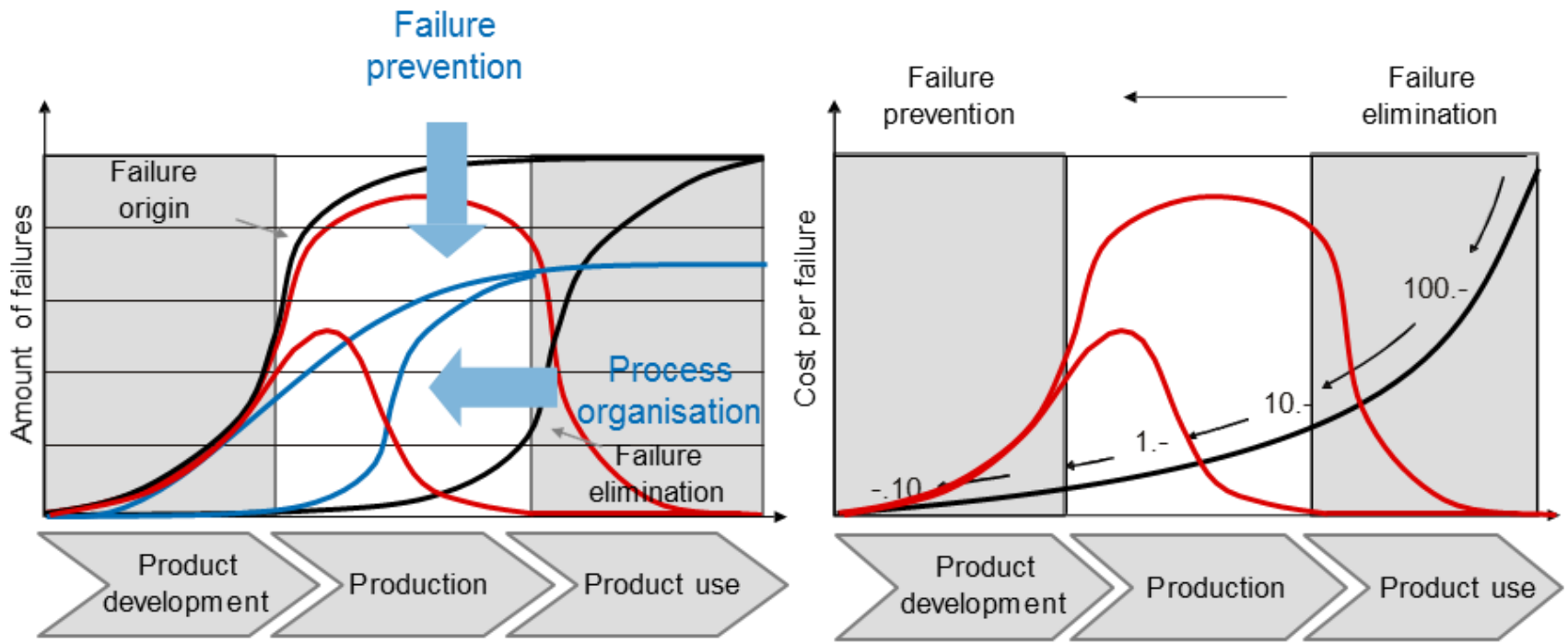
Importance of Quality Management



Success is Based on Several Columns

		Incentive	+	Ability	+	Instru-ment	+	Action Plan	=	Con-fusion
Vision	+			Ability	+	Instru-ment	+	Action Plan	=	Little Effect
Vision	+	Incentive	+			Instru-ment	+	Action Plan	=	Fear
Vision	+	Incentive	+	Ability	+			Action Plan	=	Fru-stration
Vision	+	Incentive	+	Ability	+	Instru-ment			=	False Start
Vision	+	Incentive	+	Ability	+	Instru-ment	+	Action Plan	=	Success

Determining the Time for Improvement Is Important



Failure prevention in the early phases does not only save time and money, but increases the customer satisfaction.

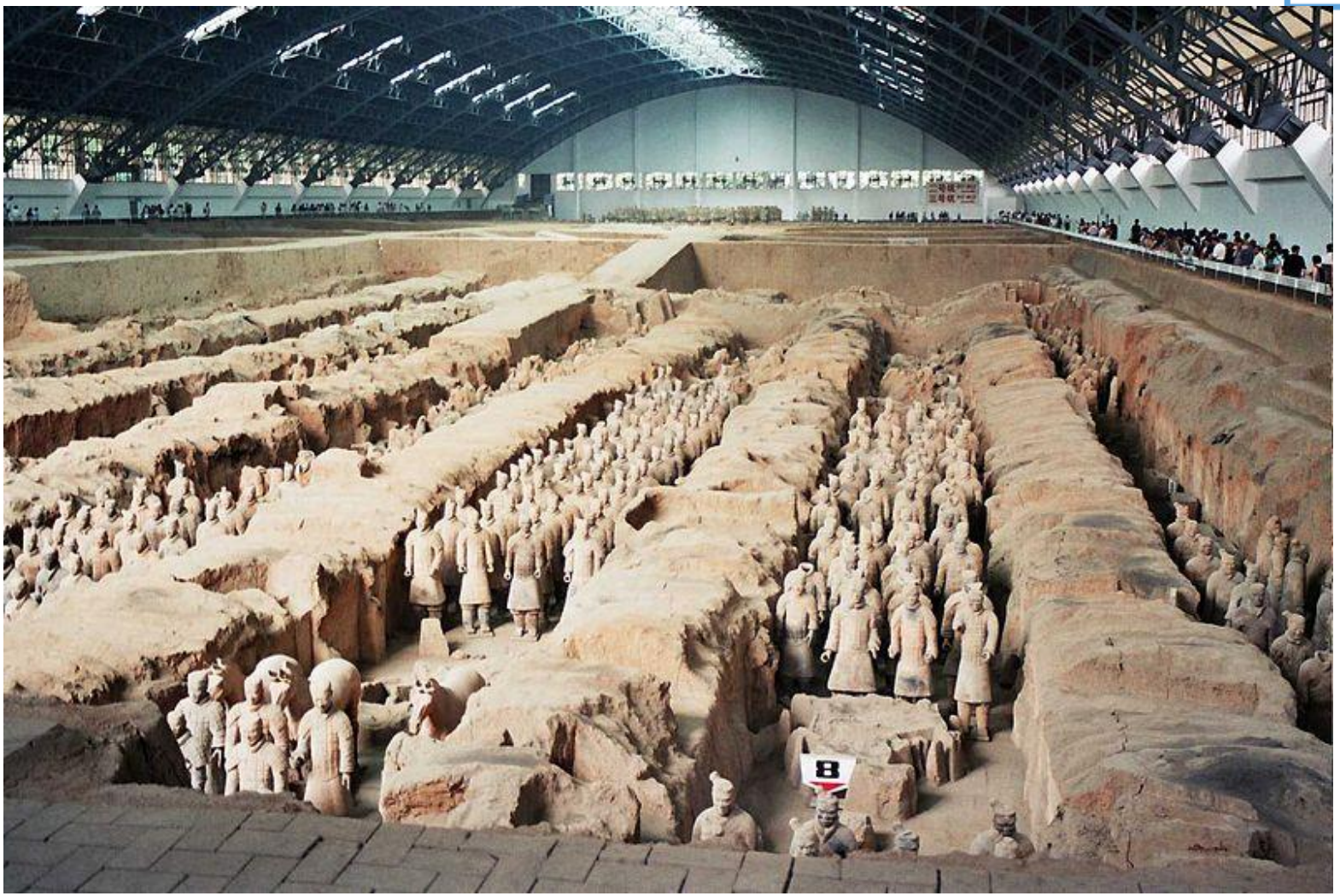
Quality management system:

- Quality management system is a ”set of interrelated or interacting elements to establish policy and objectives and to achieve those objectives to direct and control an organization with regard to quality” [ISO9000].
- Management discipline focused on quality issues to deliver products and services according to the defined requirements.
- Quality management is not just checking measurable characteristics of produced goods and materials.

Quality management

The term quality management has a specific meaning within many business sectors. This specific definition, which does not aim to assure 'good quality' by the more general definition, but rather to ensure that an organization or product is consistent, can be considered to have four main components: quality planning, quality control, quality assurance and quality improvement.

Terracotta Army



Japanese gardens

POOR Quality…

- https://www.youtube.com/watch?v=jYj_R4oCTPI

Steps towards a quality management system:

- There are many ways a small enterprise can go about implementing a quality management system (QMS).
- The steps below are applicable to all kinds of organizations, including the service industry and not-for-profit organizations.

It is provided solely as an example and should not be regarded as the only method of implementation or the best method of implementation.

For a successful implementation these seven steps are recommended :

- Fully engage top management.
- Identify key processes and the interactions needed to meet quality objectives.
- Implement and manage the QMS and its processes (using process management techniques).
- Build your ISO 9001-based QMS.
- Implement the system, train your staff and verify the effective operation of your processes.
- Manage your QMS.
- If necessary, seek third party certification of the QMS or alternatively, issue a self-declaration of conformity.

Step 1 Fully engage top management to:

- define why you want to implement ISO 9001
- define your organization's strategic direction (e.g. its mission, vision, values, and strategic/business objectives)
- define your organization's context (interested parties, employees, society, etc.)
- determine your risks and opportunities
- define your quality policy
- establish and align organizational objectives and related product and service quality objectives

Step 2 Identify key processes and the interaction needed to meet quality objectives

Examples of key processes might include:

- quoting or contract negotiation
- purchasing
- scheduling
- technical support
- manufacturing/servicing activities
- inspection and test
- packaging
- inventory management
- provision of a service, such as training or field installation

Step 3 Implement and manage the QMS and its processes (using process management techniques)

This will include such activities as :

- determining customer requirements ;
- defining activities ;
- planning the sequence of activities/processes ;
- establishing objectives for products, services and processes ;
- assessing competence requirements ;
- ensuring adequate resources, including such things as :personnel ;
- tooling ;
- equipment ;
- software ;
- measuring instruments ;
- materials ;
- safety apparel ;
- establish monitoring and measurement methods ;
- producing or identifying needed documented information and providing for its storage.

Step 4 Build your ISO 9001-based QMS

- Identify the ISO 9001 requirements
- map these requirements with your implemented QMS, where applicable
- perform a gap analysis: identify where in your existing system the requirements are fulfilled and where they are not
- include in your QMS processes the activities, documented information and controls needed

Step 5 Implement the system, train personnel and verify effective operation of your processes

- As you implement your system, make sure that you properly determine and manage what kind of training different members of your personnel require. For example, you may want to ensure that anyone who may be required to review or revise documentation (such as work instructions and specifications) understands the need for consistency in documented information.

Step 6 Manage your QMS:

- Focus on customer satisfaction
- monitor and measure the operation of your QMS
- conduct scheduled internal audits
- strive for continual improvement
- consider implementing excellence models in your organization’s operations.

Step 7 Certification or self-declaration

- If necessary, seek third party certification of the QMS or, alternatively, issue a self-declaration that your QMS conforms to ISO 9001.

Conclusion

- **Remember**: Small steady changes that are well thought out will be effective and lead to improvements that will have long term advantages. These seven steps can help you take advantage of the quality management system approach and allow it to contribute to the prosperity, reputation and sustainability of your organization.

Quality management principles

- To lead and operate an organization successfully, it is necessary to direct and control it in a systematic and transparent manner. Success can result from implementing and maintaining a management system that is designed to continually improve performance while addressing the needs and expectations of all relevant interested parties. Managing an organization encompasses quality management amongst other management disciplines.
- Seven quality management principles have been identified that can be used by top management in order to lead the organization towards improved performance.

The challenge of today's business:

- Variable external environment
- Development of digitalisation
- Export promotion
- The rapid development of information technology
- Knowledge-based business
- Production process transformation
- Remote work

1. Exports. Business ideas.

Only 9% of Latvian SMEs are planning to increase their turnover this year, compared with 23%, which believes that their turnover will decrease.

Positive examples, for example, are companies in the construction industry who have started to go abroad and successfully offer their services in Scandinavia or Germany.

New world. Value change.

- The robot
- Millennium Generation
- 4D printing
- Unmanned control
- Artificial Intelligence
- Social Networks

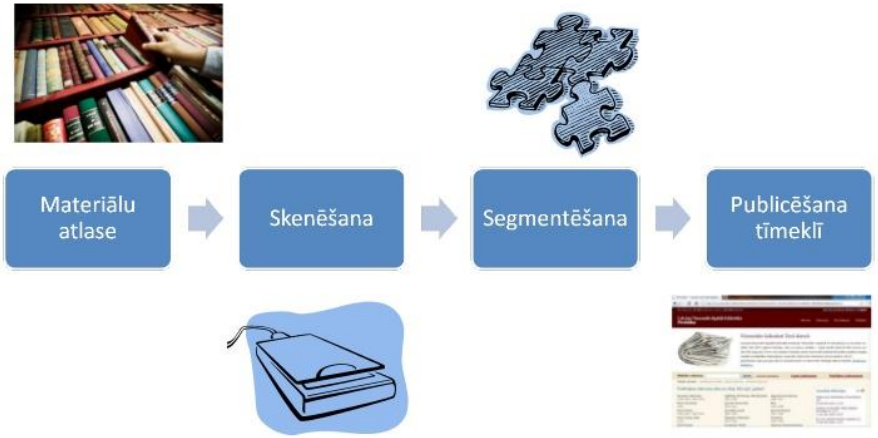
Results of research on the positive effects of SME activity in different countries of the world:

- Importance in the national economy
- Global Competitiveness
- Employment growth rate
- Creating new products
- SMEs employ 55-65%
- Japan's SME policy
- Up to 70% of exported products
- Labor productivity
- Satisfaction with work

2. Digitalization. Technology.

"The state tone in the direction of digital change has become more pronounced, and it gives hope. In recent years, there has been a growing body of care for the management of their digital farms. There is a greater understanding of the need for document management systems in optimizing office work, automating processes, and gradually creating trust in cloud services »

Digitalizācijas process



3. Creativity. Competence.

Creativity can be seen from three aspects:
as a personality trait (originality, innovation, anti-conformism, courage, etc.)
- as a process (creative intuition, rich fantasy, divergent thinking, inspiration, plasticity of the psyche, subconscious and unconscious activity)
as a product (innovation and social significance).
(D.Melbard)

Ability to wake up, analyze, generate!

4. Eco innovation. Knowledge

Eco-innovation is an innovation that contributes significantly to the achievement of sustainable development goals by reducing the environmental impact of our production methods, strengthening the natural resistance to environmental pressures and achieving more efficient and responsible use of natural resources

How and what to do?

- Effectiveness
- **Focus on ACTIVITIES**
- What Where? When? How to? etc. participates in the production process ...

- Effectiveness
- **Focus on RESULTS**
- Does the product have a market demand ???

1.

Customer focus

- The primary focus of quality management is to meet customer requirements and to strive to exceed customer expectations.

2.

Leadership

- Leaders at all levels establish unity of purpose and direction and create conditions in which people are engaged in achieving the organization’s quality objectives.

3.

Engagement of people

- Competent, empowered and engaged people at all levels throughout the organization are essential to enhance the organization’s capability to create and deliver value.

4.

Process approach

- Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

5.

Improvement

- Successful organizations have an ongoing focus on improvement.

6.

Evidence-based decision making

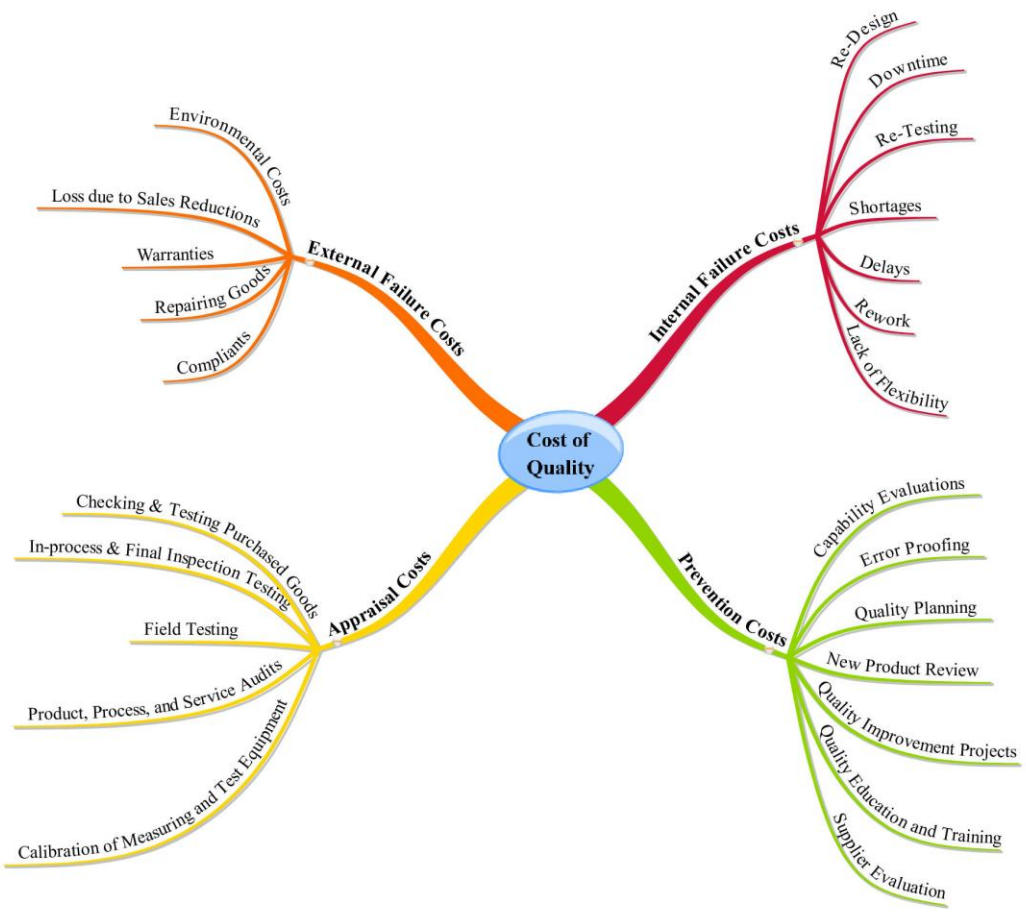
- Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.

7.

Relationship management

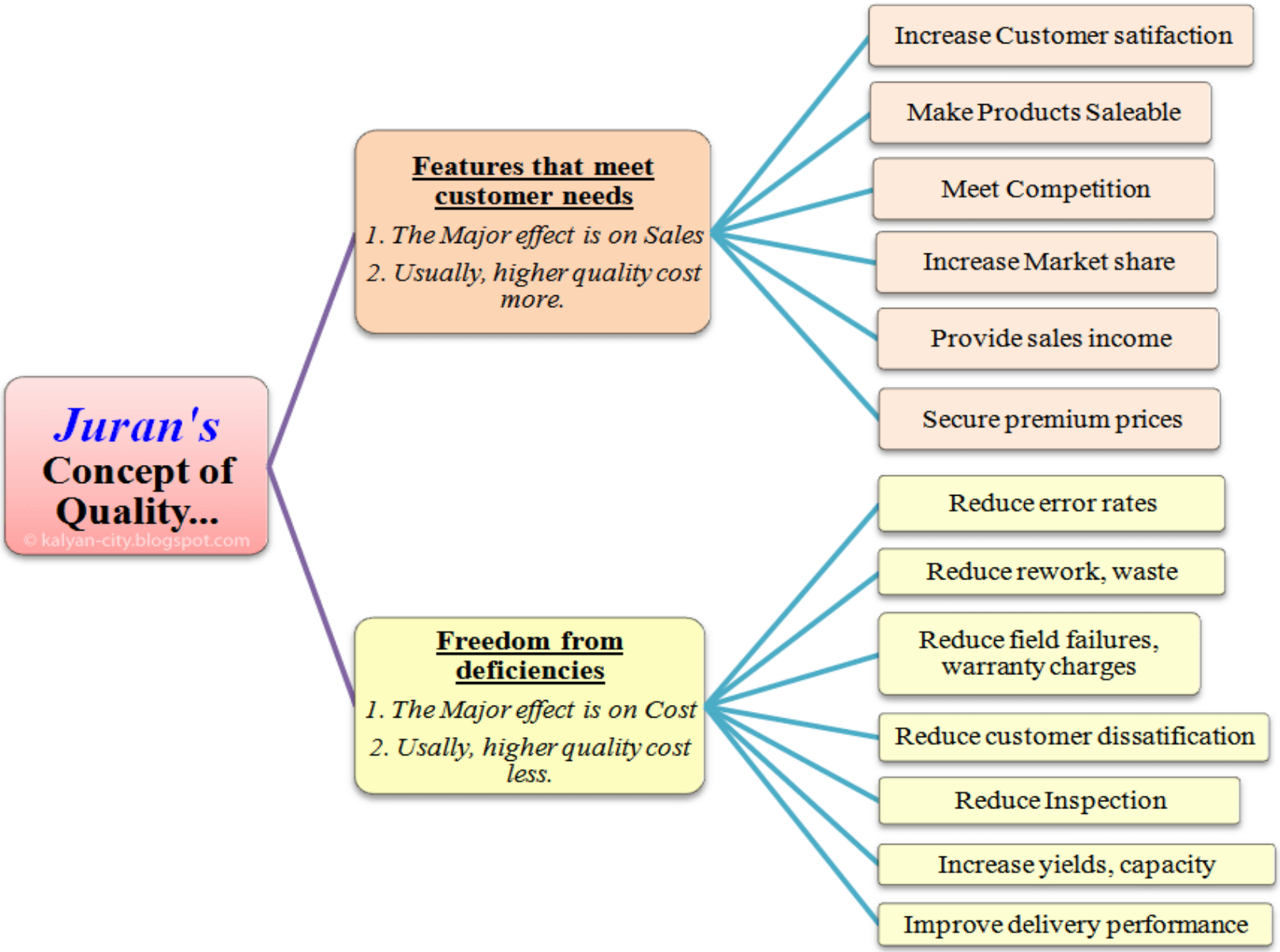
- For sustained success, organizations manage their relationships with relevant interested parties, such as providers.

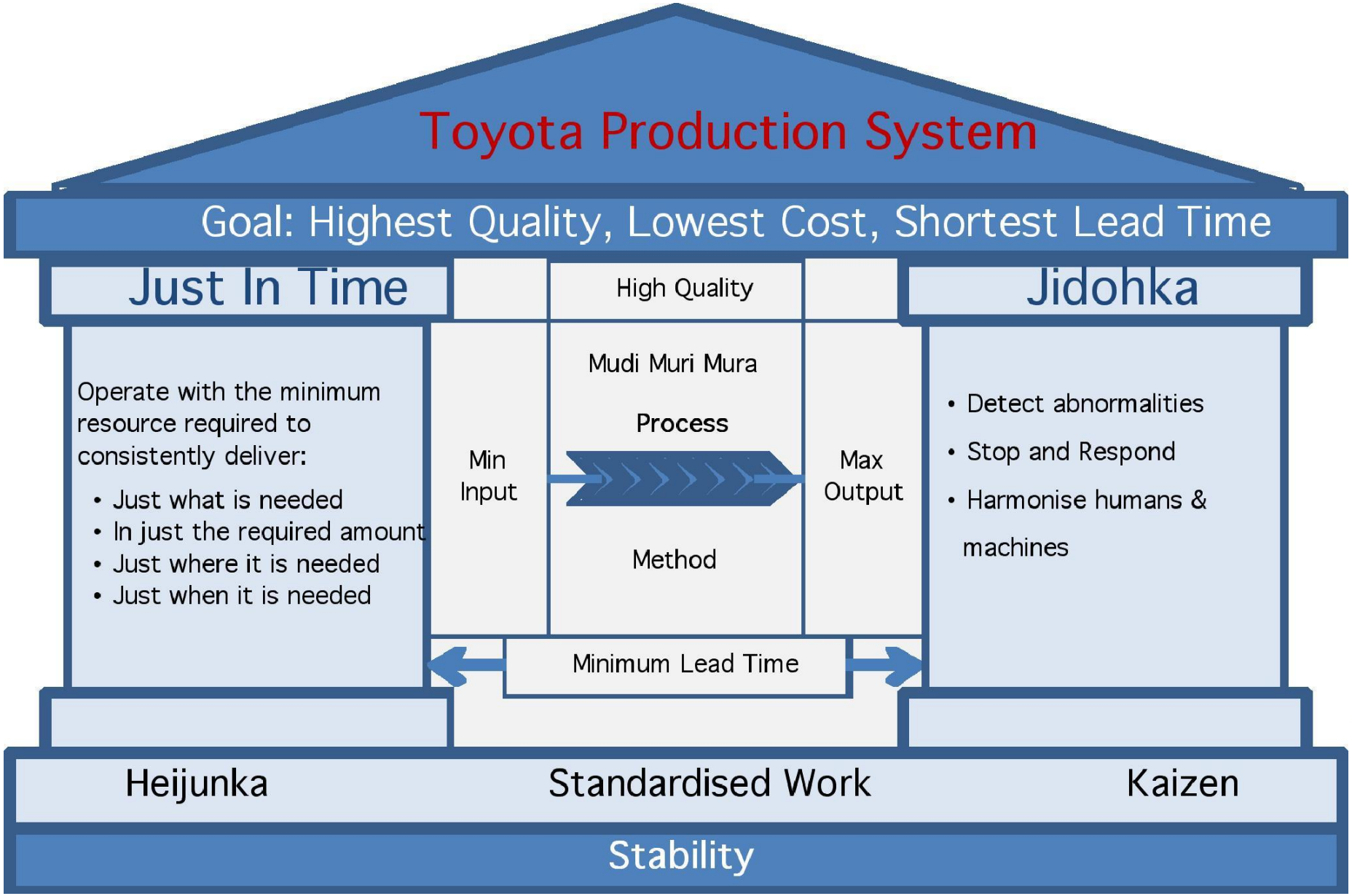
Quality costs



http://www.youtube.com/watch?feature=player_profilepage&v=a6cNdhOKwi0

Concept of quality




Toyota Production System
Goal: Highest Quality, Lowest Cost, Shortest Lead Time
Just In Time
High Quality
Jidohka
Operate with the minimum resource required to consistently deliver:
• Just what is needed
• In just the required amount
• Just where it is needed
• Just when it is needed
Min Input
Mudi Muri Mura
Process
Method
Max Output
• Detect abnormalities
• Stop and Respond
• Harmonise humans & machines
Minimum Lead Time
Heijunka
Standardised Work
Kaizen
Stability

Quality characteristics

...measured

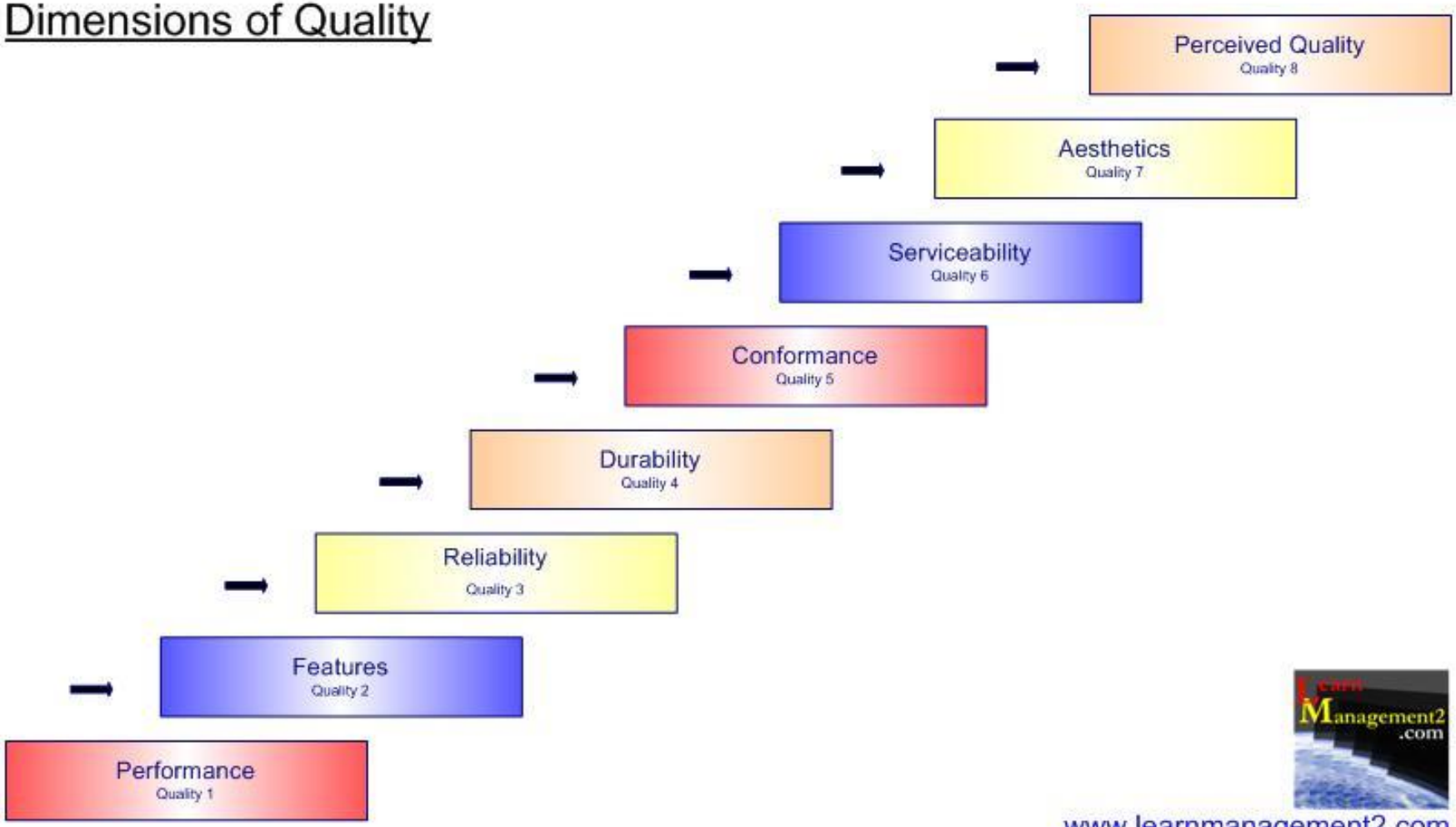
...depends on customer taste

Porter Henry created itself in the five pillars as the five dimensions of our quality training. These five dimensions include many factors.

Quality levels

Modern quality concepts

Dimensions of Quality



www.learnmanagement2.com

Supplier-customer relationship Examples:

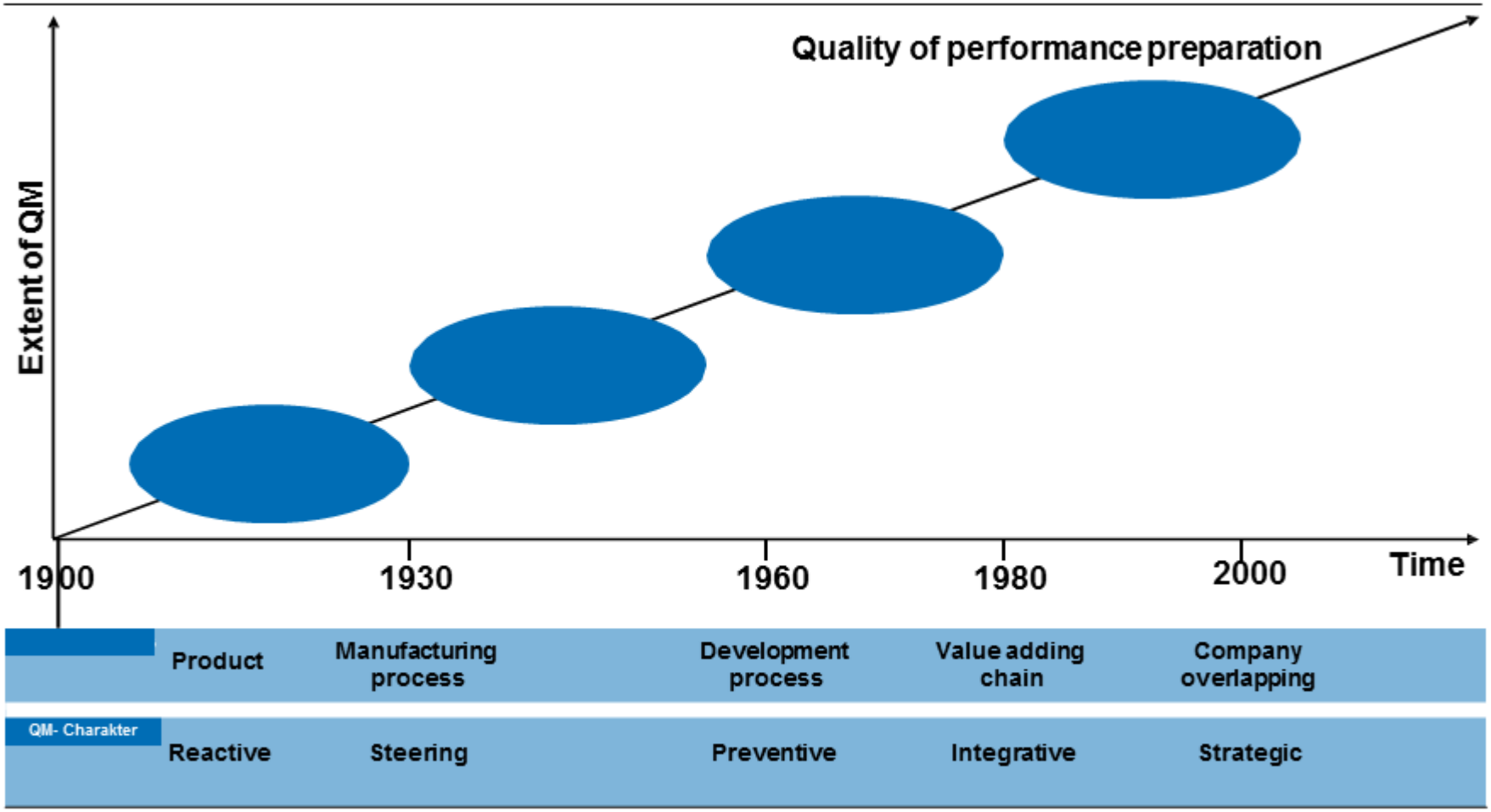
Supplier-customer relationship examples		
Supplier	**Customer**	**Product or Service**
Automobile manufacturer	Individual customers	Cars
Automobile manufacturer	Car dealer	Sales literature, etc.
Bank	Checking account holders	Secure check handling
High school	Students and parents	Education
County recorder	Residents of county	Maintenance of records
Hospital	Patients	Healthcare
Hospital	Insurance company	Data on patients
Insurance company	Hospital	Payment for services
Steel cutting department	Punch press department	Steel sheets
Punch press department	Spot weld department	Shaped parts
All departments	Payroll department	Data on hours worked, etc.

QUALITY ASSURANCE TOOLS

	Certification
	Project-focused company
Quality assurance tools:	Quality policy
	Process management
	Data processing
	Corporate social responsibility

... The Turnaround Starts With the First Stroke

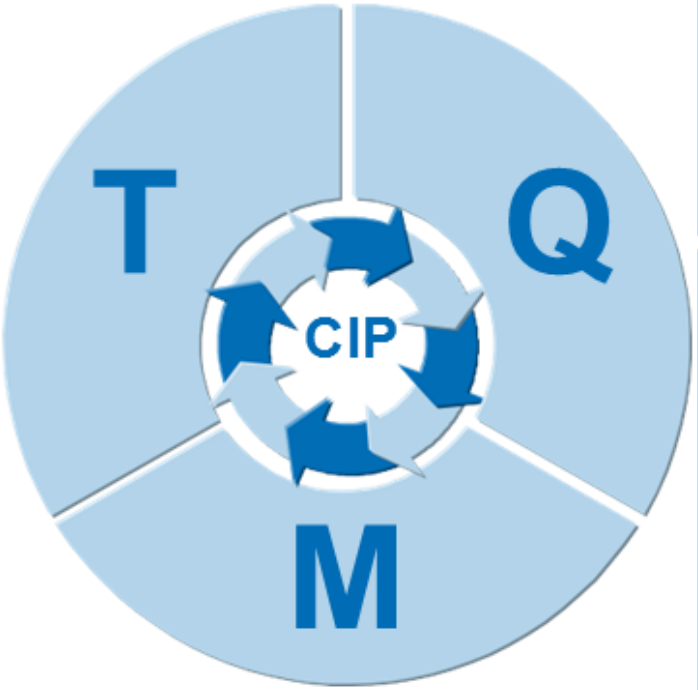
Change in the unterstanding of quality



The Term „Total Quality Managements“

TOTAL

- **Process orientation**
  Trans-sectoral
- **Customer orientation**
  Good relationship to custormers and suppliers
- **Employee orientation**
  Involvement of the whole personnel of the organisation
- **Society orientation**
  Dialogue- and participation-oriented public relations



QUALITY

- Quality of the company
- Quality of work
- Quality of potentials
- Quality of processes
- Quality of results

MANAGEMENT

- Quality as leadership task
  - Well-considered actions
- Leadership quality (exemplar role)
  - Team- und learning capability
  - Perseverance

Characteristics of TQM

Normative Quality Management Systems (L2)

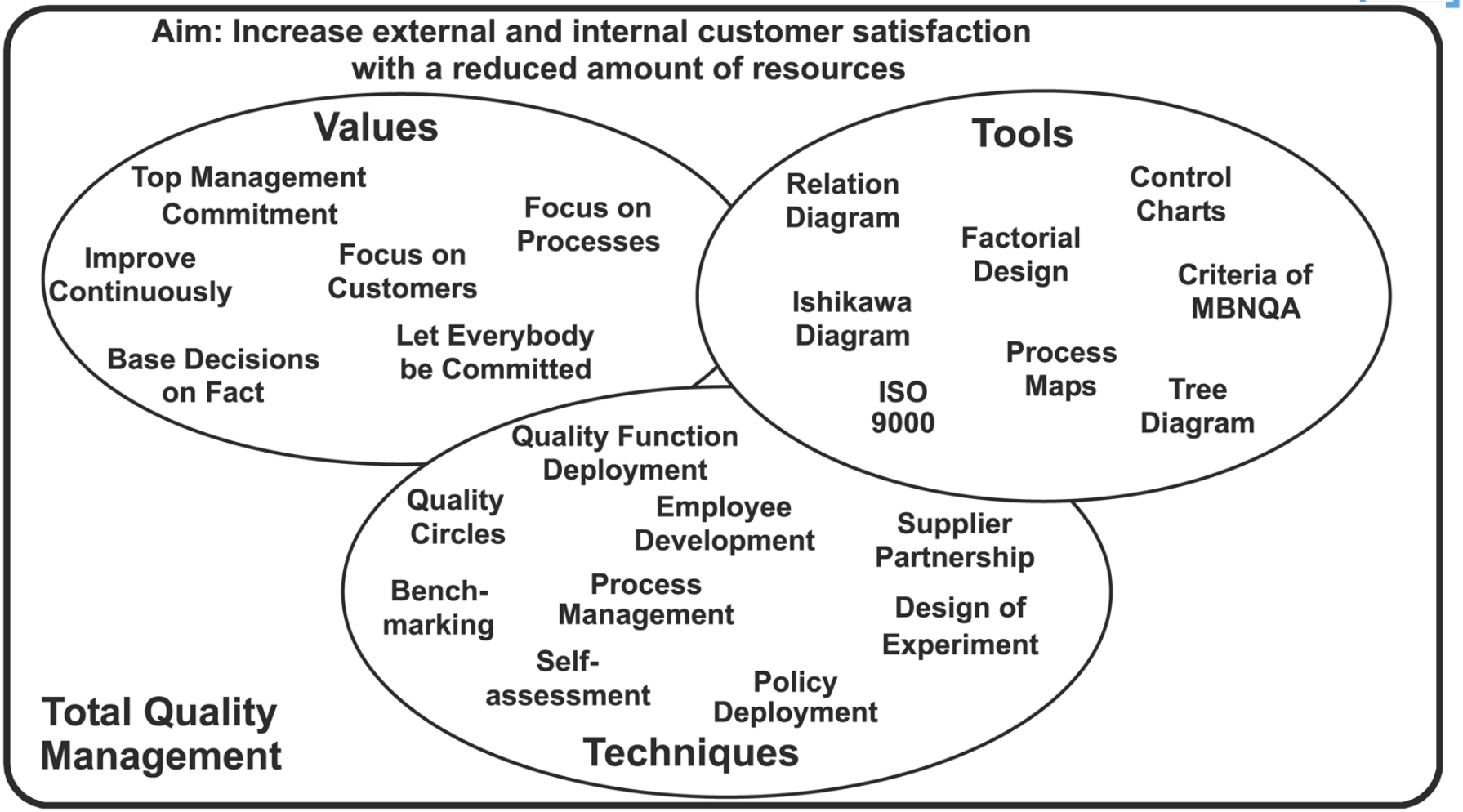
- DIN EN ISO 9000ff.
- ISO/TS 16949:2002
- etc.

Strategic Quality Programmes (L3)

- EFQM
- Six Sigma
- AC-QM-M
- etc.

TQM principles:
(Total Quality Management)

- Senior management interest in achievement of the required quality level;
- Focusing on business activities for the outside and domestic customers;
- Conscious participation of the staff in quality improvement and continuous improvement;
- Staff training;
- Approach to processes - process control based on the operating facts;
- Fact-based decision making.

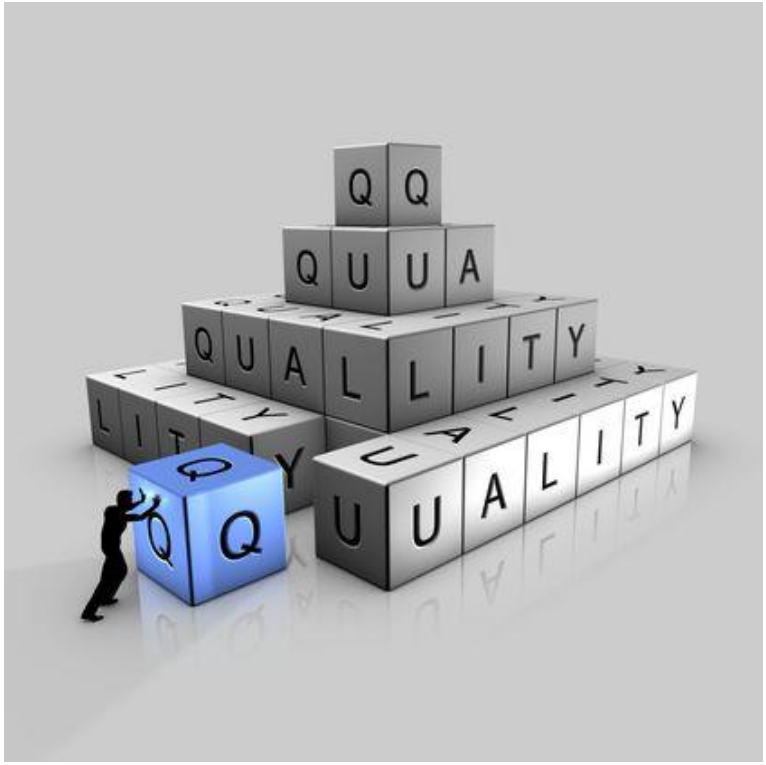


Note: The techniques and tools in the figure are just examples and not a complete list. In the same way the values may also vary a little between different organisations and over time

Source: From Hellsten and Klefsjö (2000)

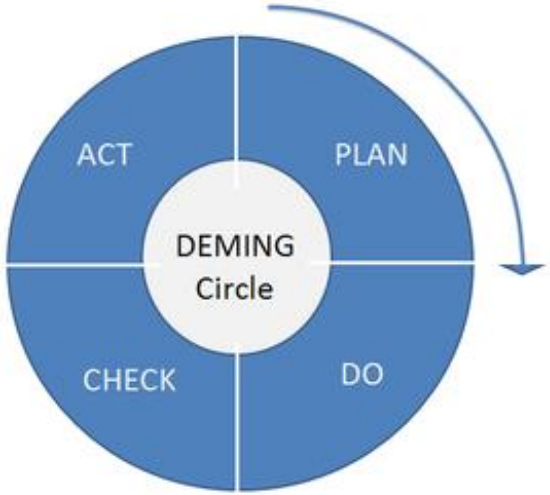
Nowdays...

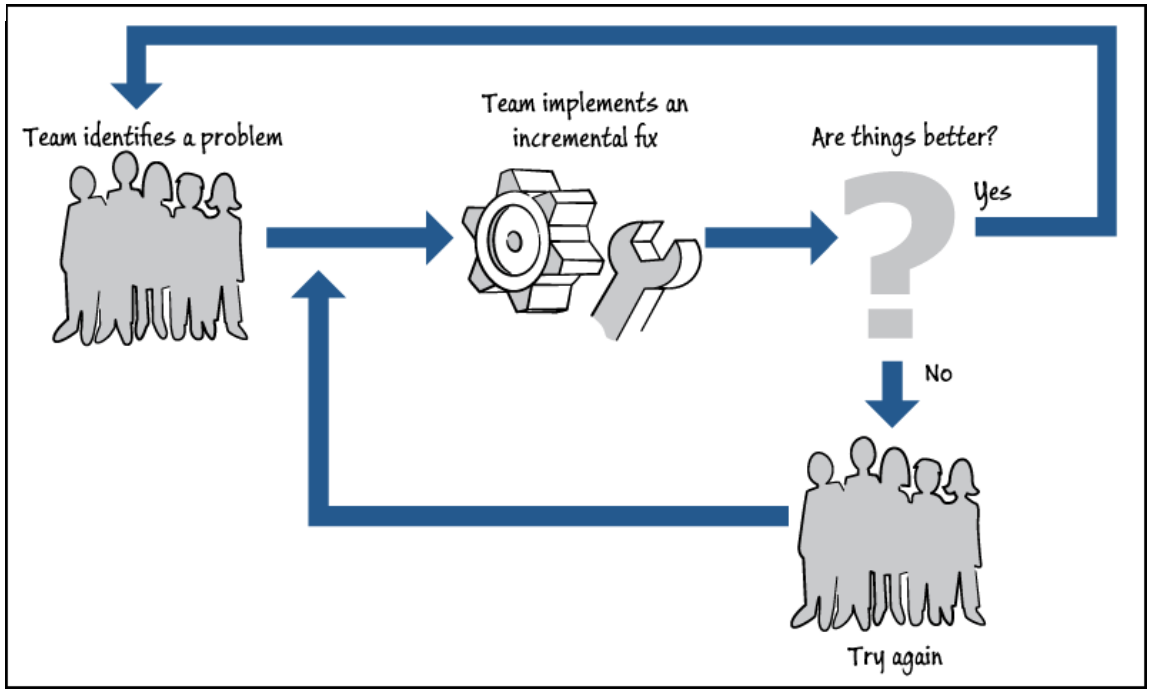

Employees
Management
Shareholders
Internal Stakeholders
Suppliers
Candidates for Employment
Customer/ Interested Parties
Partners
Competitors
External Stakeholders

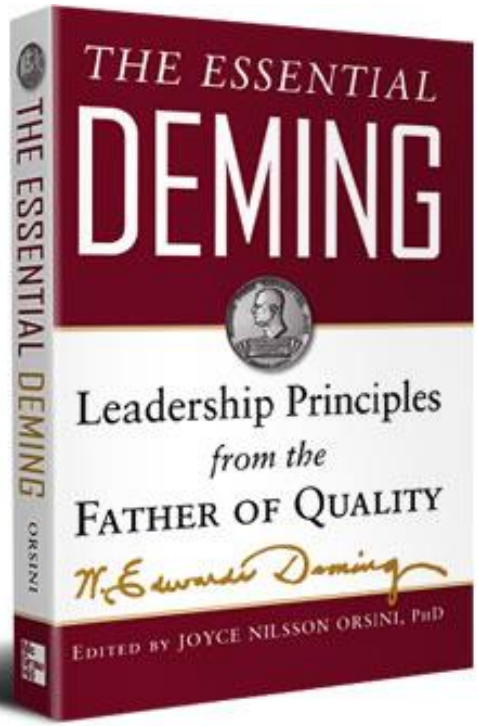


Motto of TQM philosophy:
"Before we start to make things, we build people"

Edvard Deming

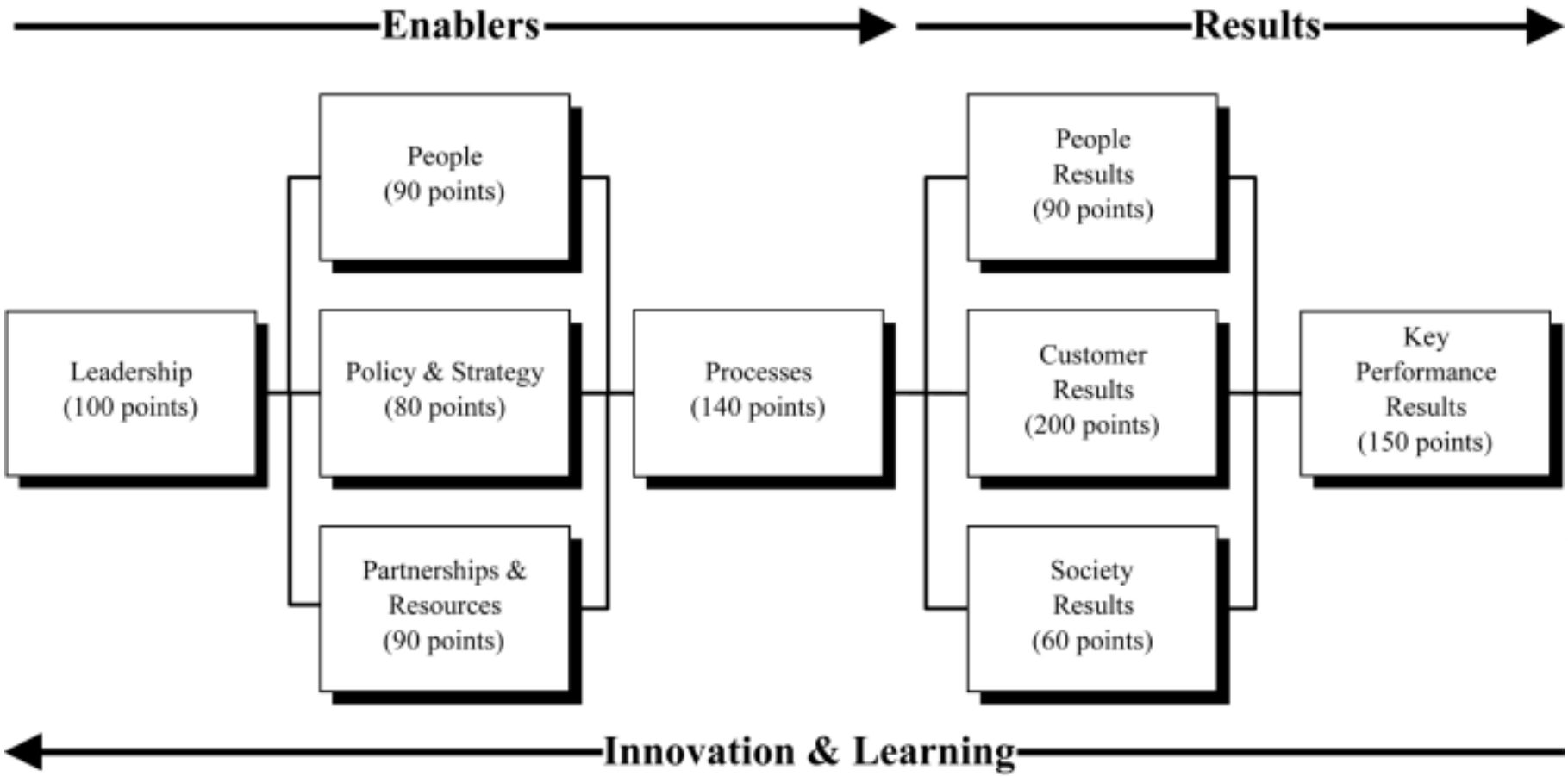






Introducing
The Essential Deming Book.

EFQM Excellence Model



Classwork in a group:

You are planning to open chocolate bar and have secured the necessary capital. Your aim is to attract both regular customers and passing trade. Discuss the key implications of this for the management of the business.

INTERCONNECTION WITH OTHER MANAGEMENT DISCIPLINES

STAKEHOLDERS

•Characteristics of product (service)
•Price and availability

•Salaries
•Individual achieviements
•Succesful carriers
•..

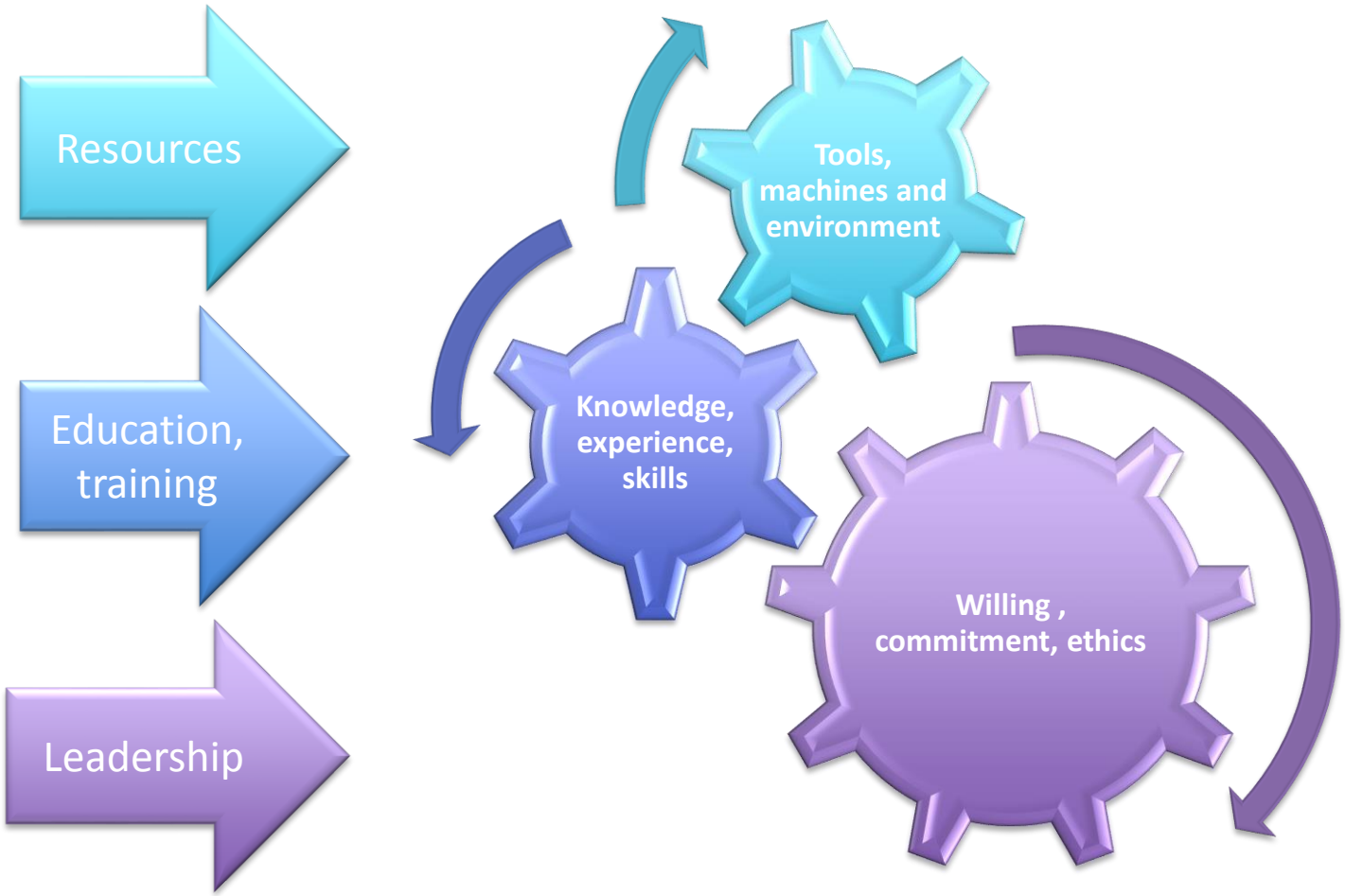
•Financial measures

•Social impacts
•...

Types of stakeholders include:

- Primary stakeholders: are those ultimately affected, either positively or negatively by an organization's actions.
- Secondary stakeholders: are the ‘intermediaries’, that is, persons or organizations who are indirectly affected by an organization's actions.
- Key stakeholders: who can also belong to the first two groups have significant influence upon or importance within an organization.

THE "QUALITY GEAR"

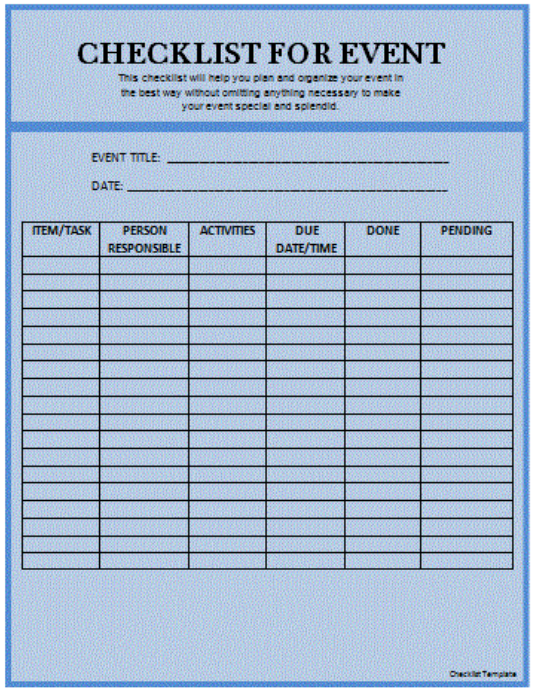


Process management

Tools and Techniques

TOP Tools and Techniques

- Checklists (inspection or validation checklists)



CHECKLIST FOR EVENT

This checklist will help you plan and organize your event in the best way without omitting anything necessary to make your event special and splendid.

EVENT TITLE: _____

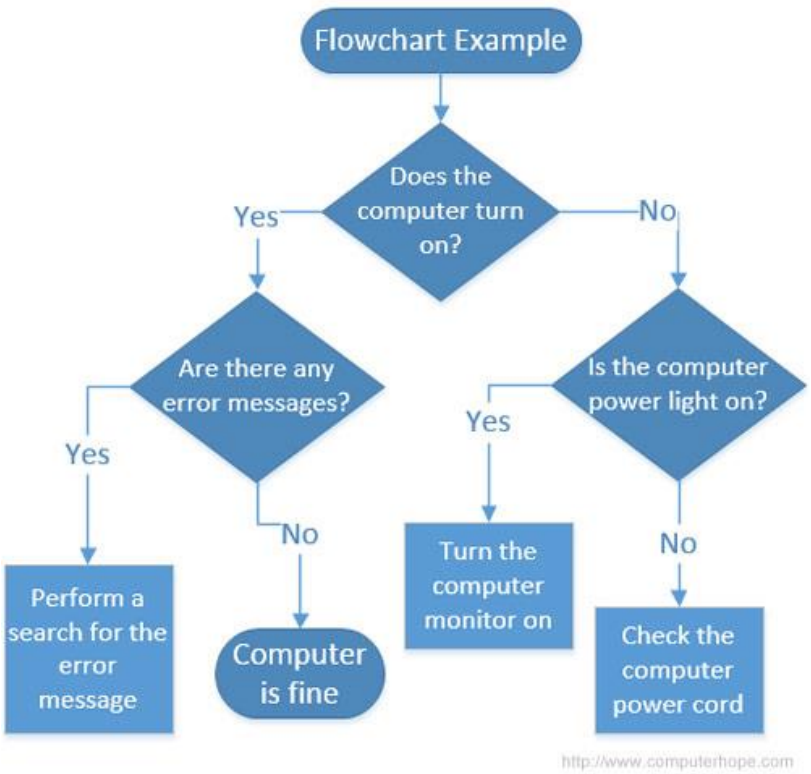
DATE: _____

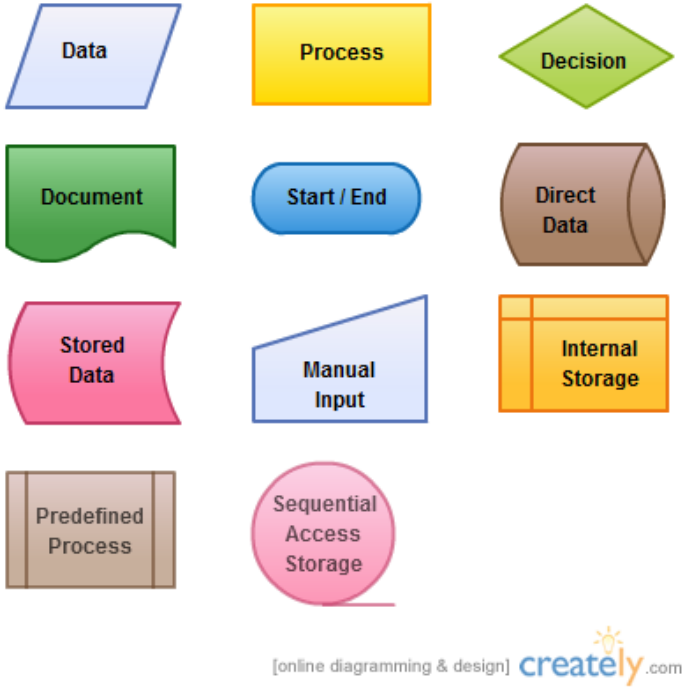
ITEM/TASK	PERSON RESPONSIBLE	ACTIVITIES	DUE DATE/TIME	DONE	PENDING

Checklist Template

TOP Tools and Techniques

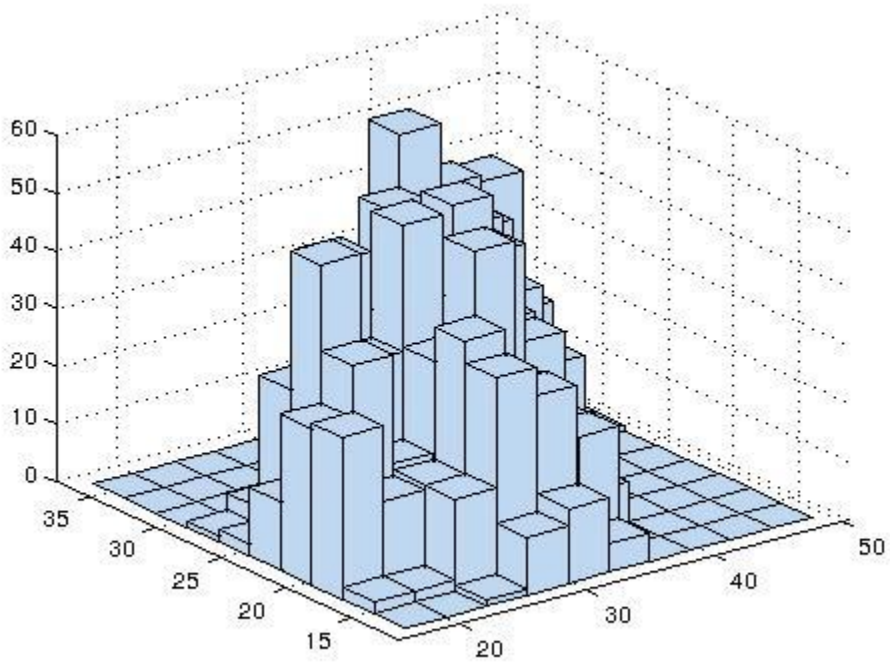
- Flowcharts (process modeling)





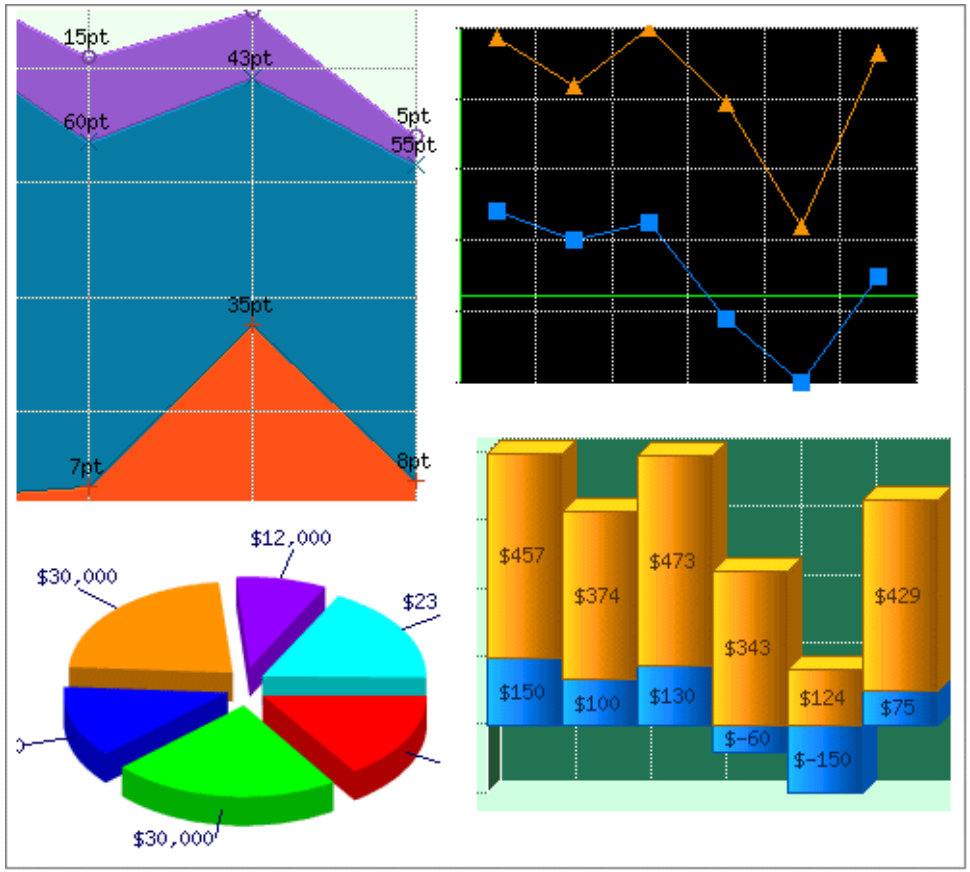
TOP Tools and Techniques

- Histograms



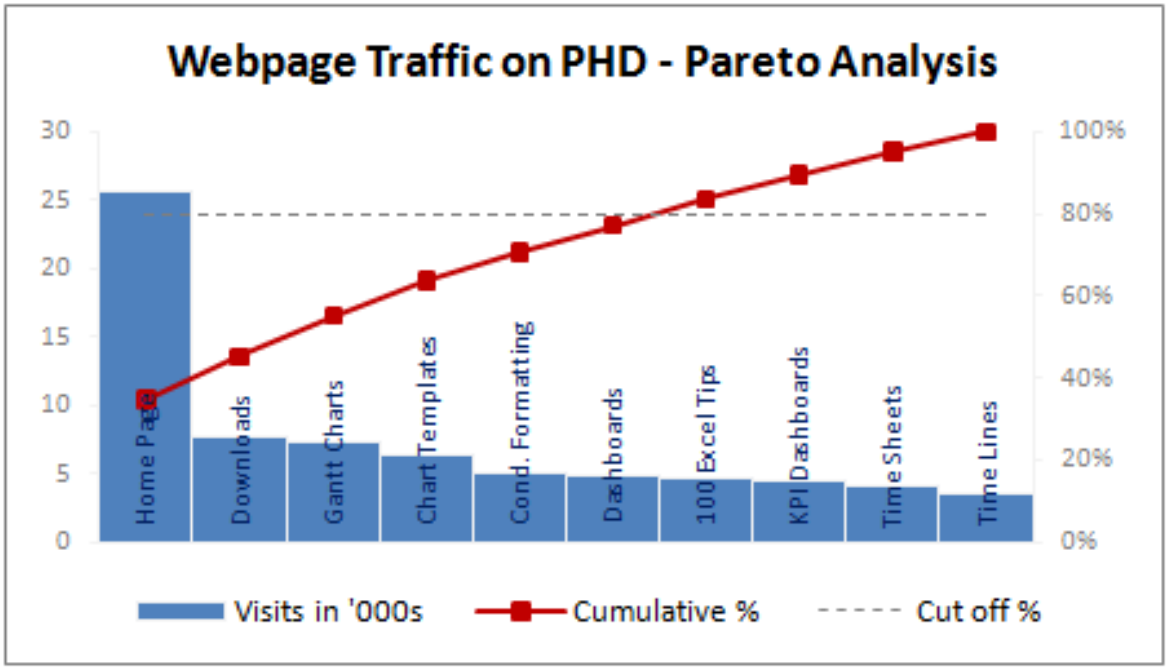
TOP Tools and Techniques

- Graphs



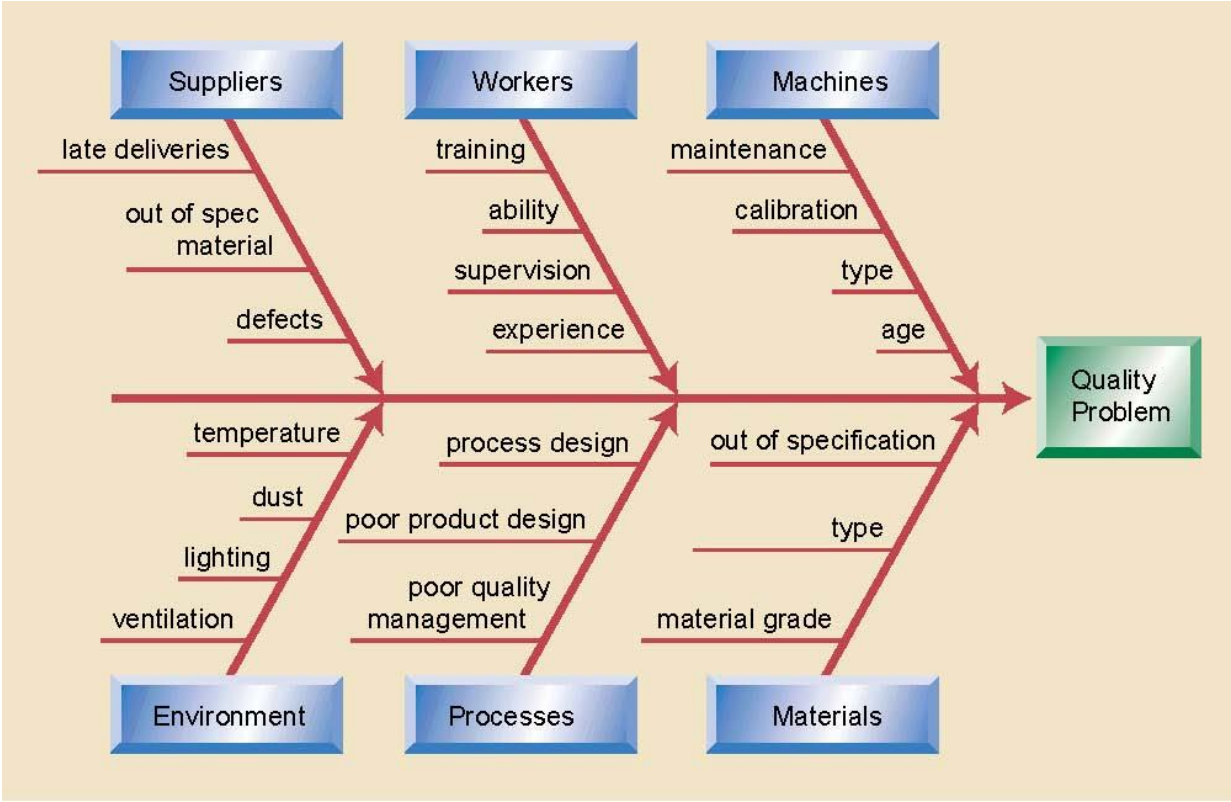
TOP Tools and Techniques

- Pareto Analysis



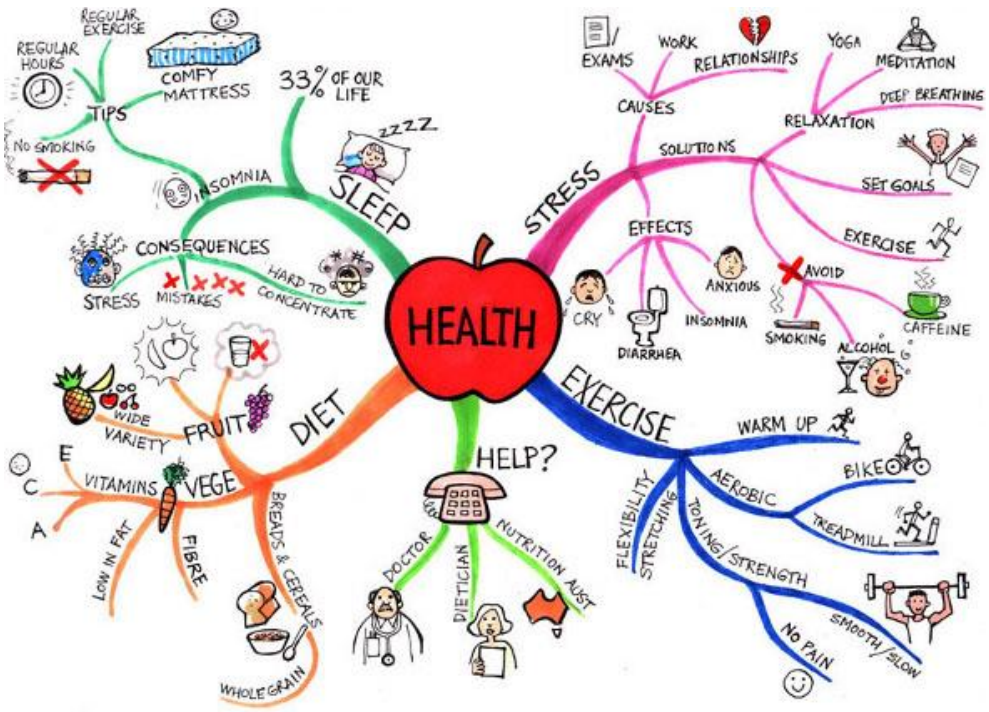
TOP Tools and Techniques

- Cause and Effect Diagrams



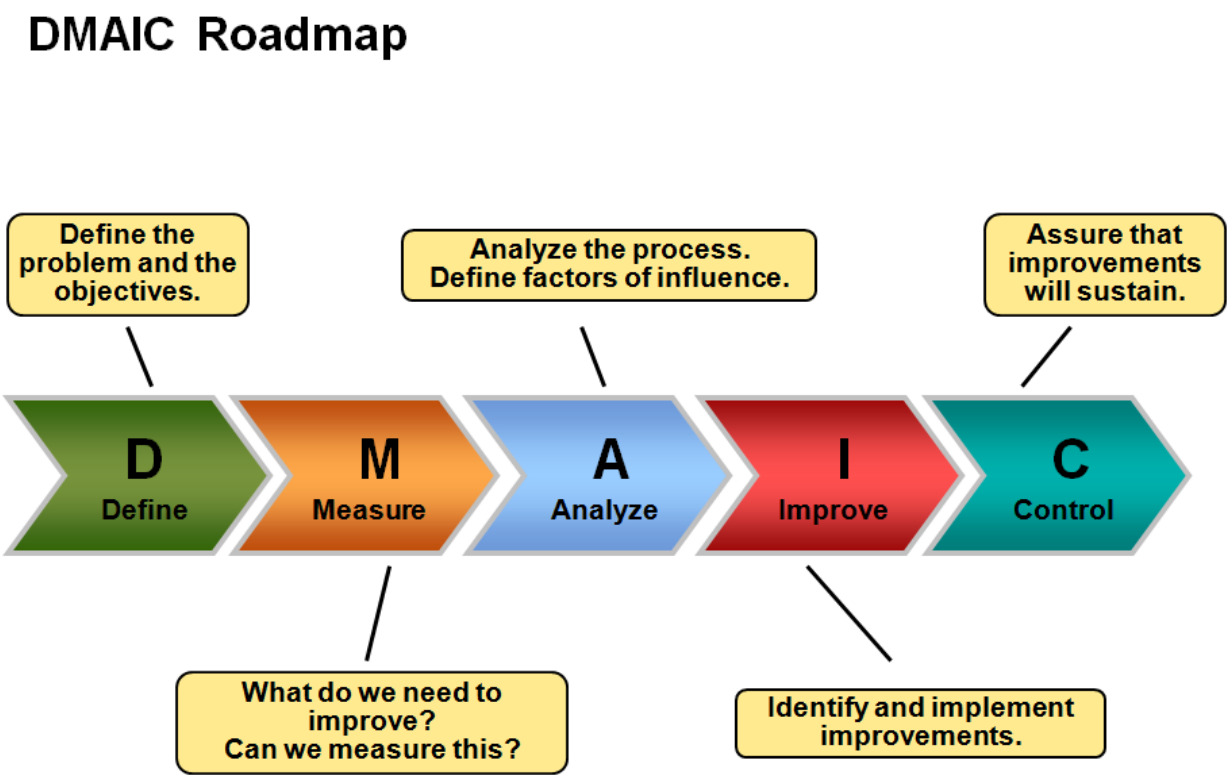
TOP Tools and Techniques

- Brainstorming



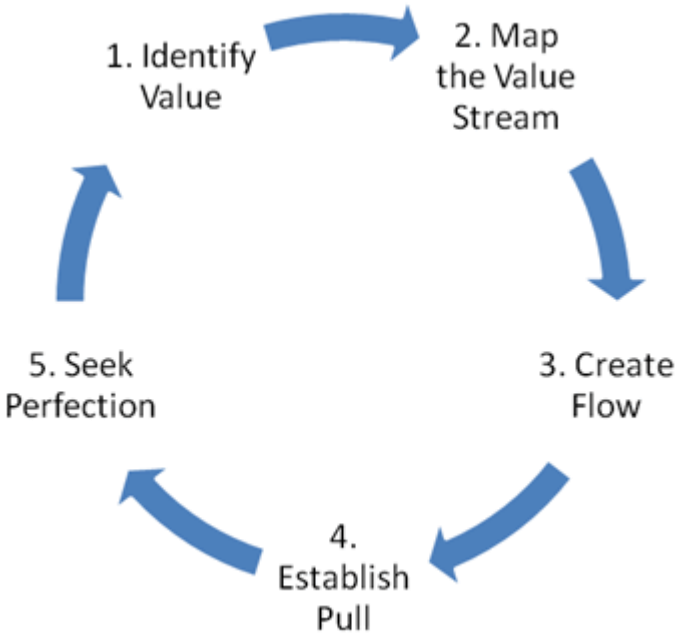
TOP Tools and Techniques

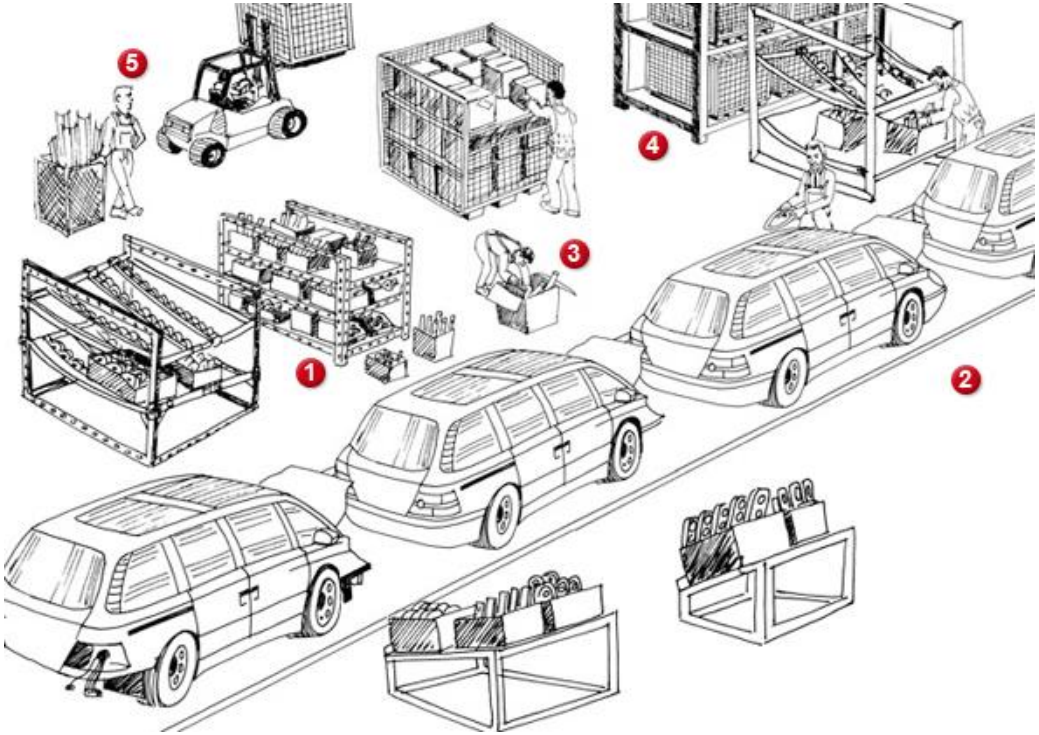
- SIX Sigma



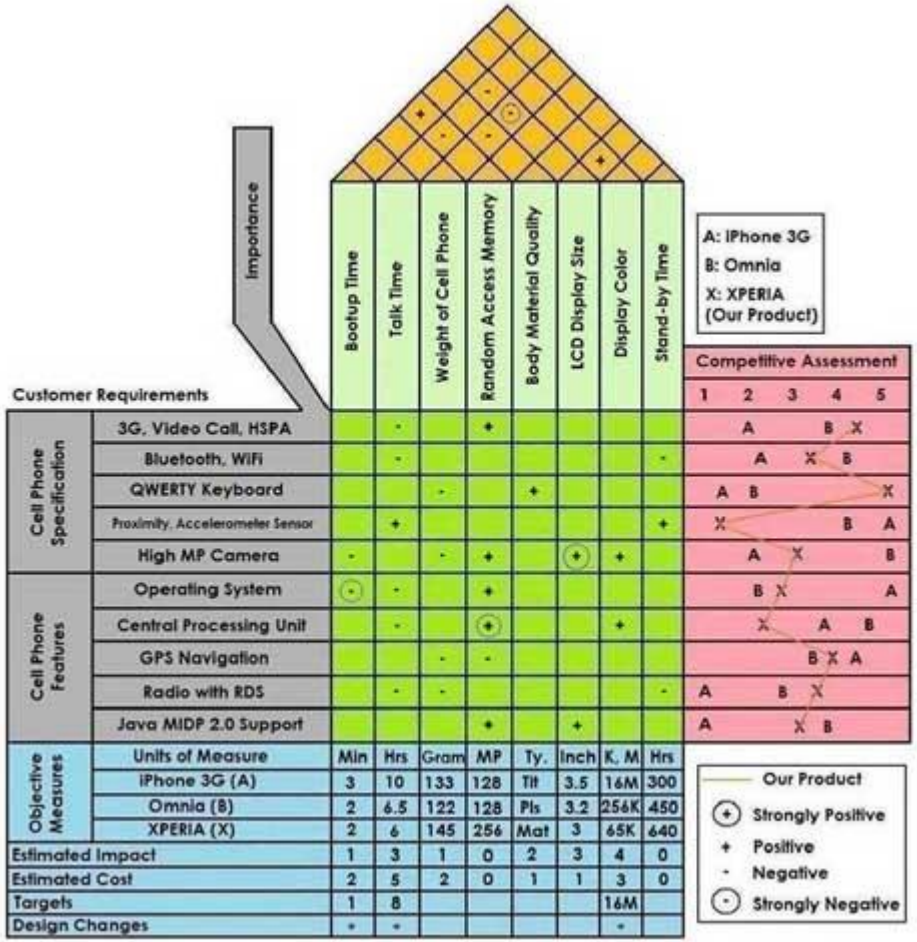
TOP Tools and Techniques

- Lean thinking





TOP Tools and Techniques

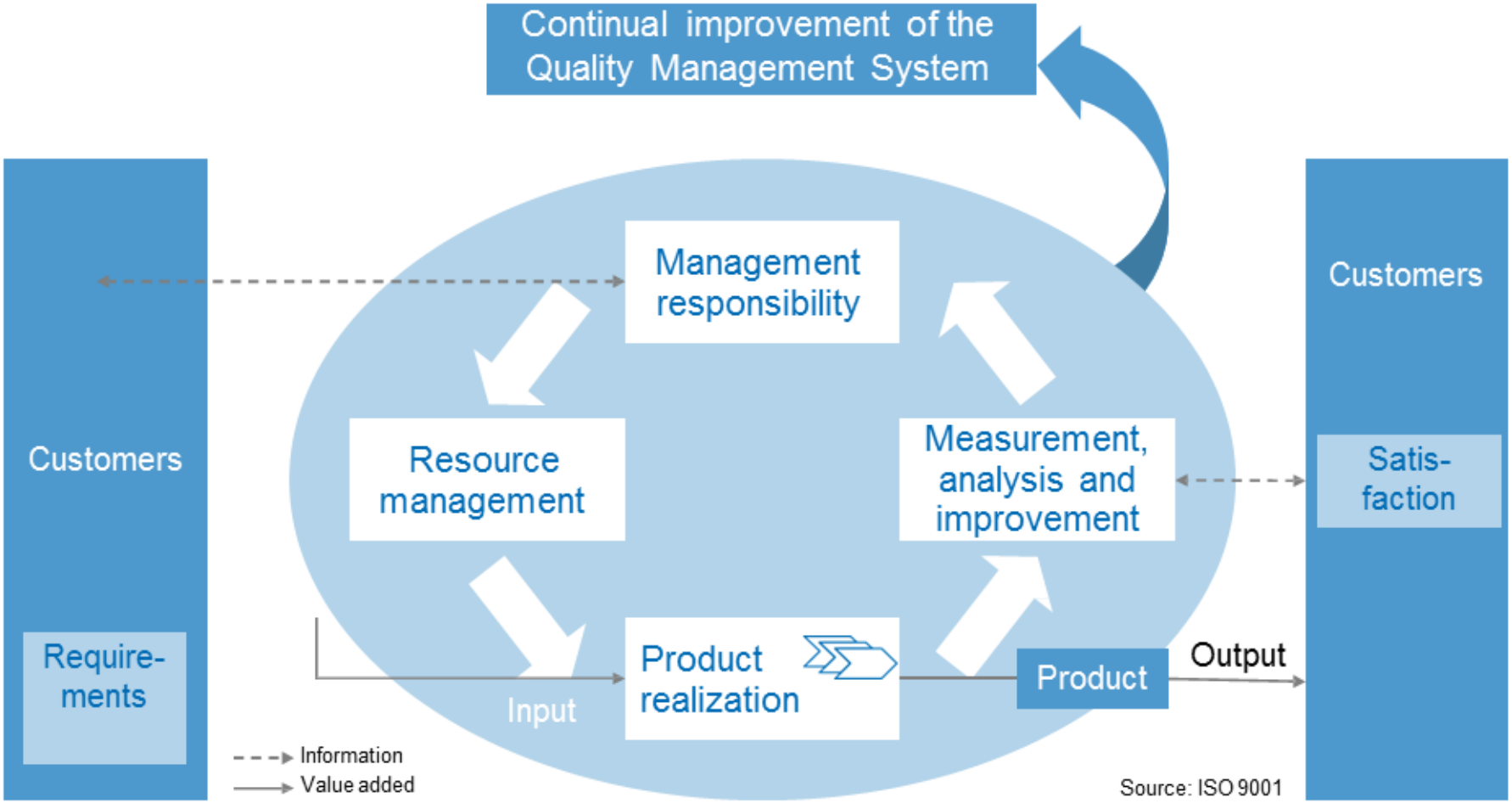


Customer Requirements		Bootup Time	Talk Time	Weight of Cell Phone	Random Access Memory	Body Material Quality	LCD Display Size	Display Color	Stand-by Time
Cell Phone Specification	3G, Video Call, HSPA		-		+				
	Bluetooth, WiFi		-						-
	QWERTY Keyboard			-		+			
	Proximity, Accelerometer Sensor		+						+
	High MP Camera	-		-	+		(+)	+	
Cell Phone Features	Operating System	(-)	-		+				
	Central Processing Unit		-		(+)			+	
	GPS Navigation			-	-				
	Radio with RDS		-	-					-
	Java MIDP 2.0 Support				+		+		
Objective Measures	Units of Measure	Min	Hrs	Gram	MP	Ty.	Inch	K, M	Hrs
	iPhone 3G (A)	3	10	133	128	Tit	3.5	16M	300
	Omnia (B)	2	6.5	122	128	Pls	3.2	256K	450
	XPERIA (X)	2	6	145	256	Mat	3	65K	640
Estimated Impact		1	3	1	0	2	3	4	0
Estimated Cost		2	5	2	0	1	1	3	0
Targets		1	8					16M	
Design Changes		*	*					*	

Your Tools in business?

Quality Management Principles

- Customer focus
- Leadership
- Involvement of people
- Process approach
- System approach to management
- Continual improvement
- Factual approach to decision making
- Mutually beneficial supplier relationships


Continual improvement of the Quality Management System
Customers
Require-ments
Management responsibility
Resource management
Measurement, analysis and improvement
Product realization
Product
Input
Output
Customers
Satis-faction
Information
Value added
Source: ISO 9001

Management responsibility
- Quality policy and quality objectives
- Quality planning
- Management review
- Definition of responsibilities and authorities
- Quality manual
- Control of document and records

Resource management
- Personnel
- Facilities
- Work environment

Measurement, analysis and improvement
- Measurement of customer's satisfaction
- Analyses of processes and products
- Internal audits
- Control of nonconformity
- KVP
- Corrective and preventive actions

Product realization
- Reconciliation of customer and product expectations
- Management of development, purchasing and manufacturing processes
- Test equipment management

Factors in a QM System

Factors controlled by a QM System

- Employee
- Methods and procedures
- Processes and activities
- Machinery and plant
- Information and experience
- Organisational unit
- Other systems

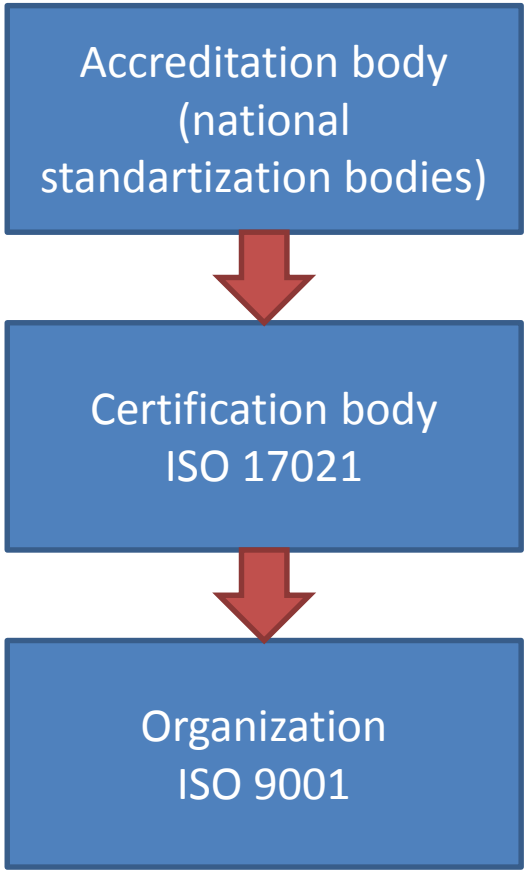
Tasks of an effective QM System

- Identification of the factors
- Documentation of the factors and their interaction
- Design and control of each factor
- Coordination of the factors
- Maintenance of the system factor

ISO 9001:2015 standard

- Formal internationally recognized
- Certification process
- Preparing for external audit
- Supported by ISO (**International Organization for Standardization** – www.iso.ch)

ISO Certification scheme

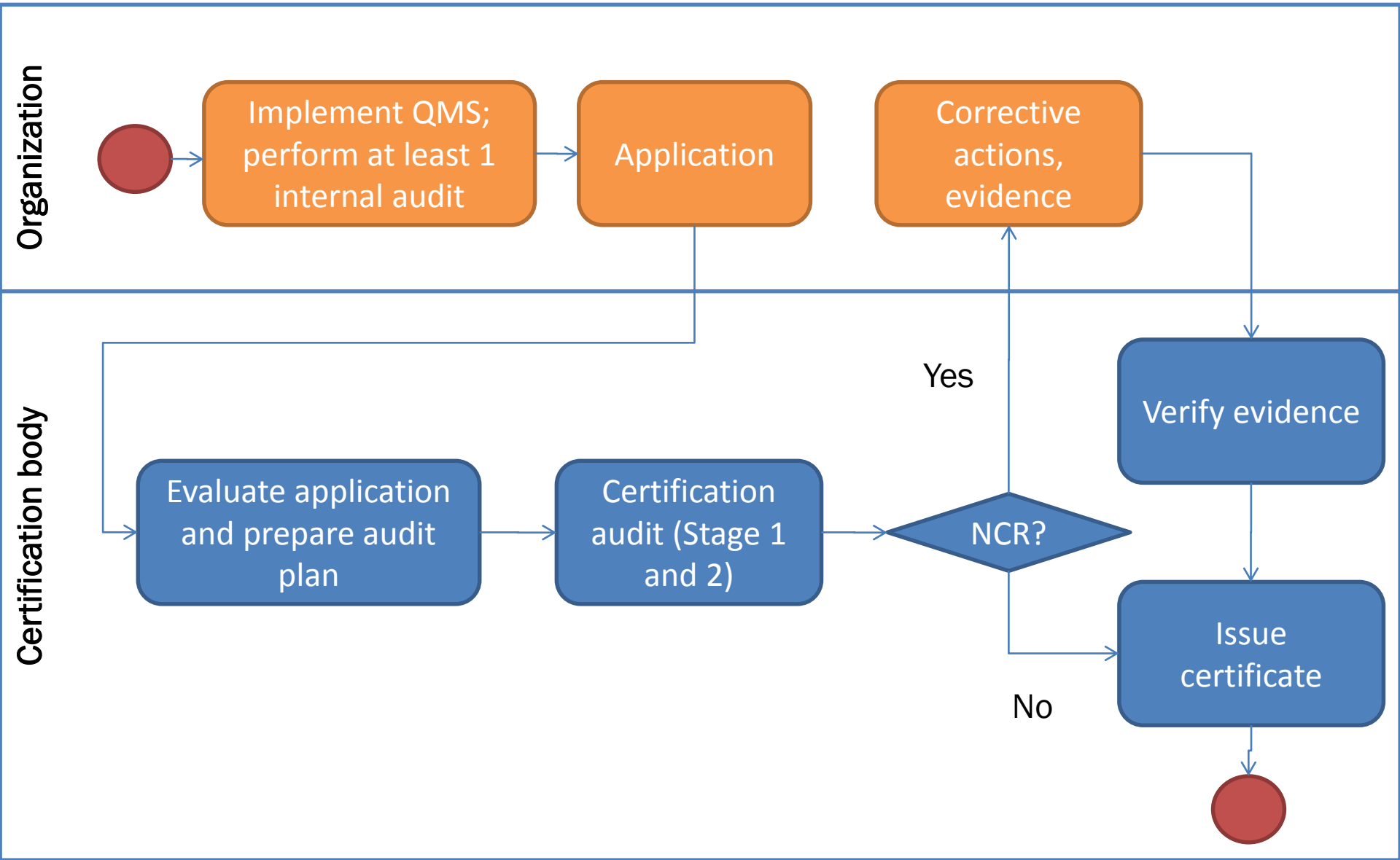


* Assess certification body

* Performs certification audit
* Issue certificates

* Apply for certification

Certification process



Accreditation body sign

Dates

Logo of certification body

Scope

UKAS MANAGEMENT SYSTEMS

012

Certificate Number
6222

Date of initial registration
7 September 2008

Date of last issue
27 September 2011

Date of expiry
1 September 2014

REGISTRATION CERTIFICATE

BM TRADA CERTIFICATION

BM TRADA certify that the Quality Management System of

SIA "AA PROJEKTS"
Dzirnavu iela 72-2
Rīga, LV-105
LATVIA

complies with the requirements of ISO 9001:2008

Scope of Certification
ICT, legal and management consultations, audit and training.

Signed on behalf of BM TRADA Certification Ltd
Dr Peter Beele, Chief Operating Officer
Chiltern House, Stocking Lane, High Wycombe, Buckinghamshire, HP14 4ND

Further clarification regarding the scope of this certificate and verification of the certificate is available through BM TRADA at the above address or at www.bmtrada.com

This certificate remains the property of BM TRADA Certification Ltd. The certificate and all copies or reproductions of the certificate shall be returned or destroyed if requested by BM TRADA Certification Ltd

For multiple sites the scope of certification shown above includes processes/activities that are performed by the network of sites shown in Appendix A

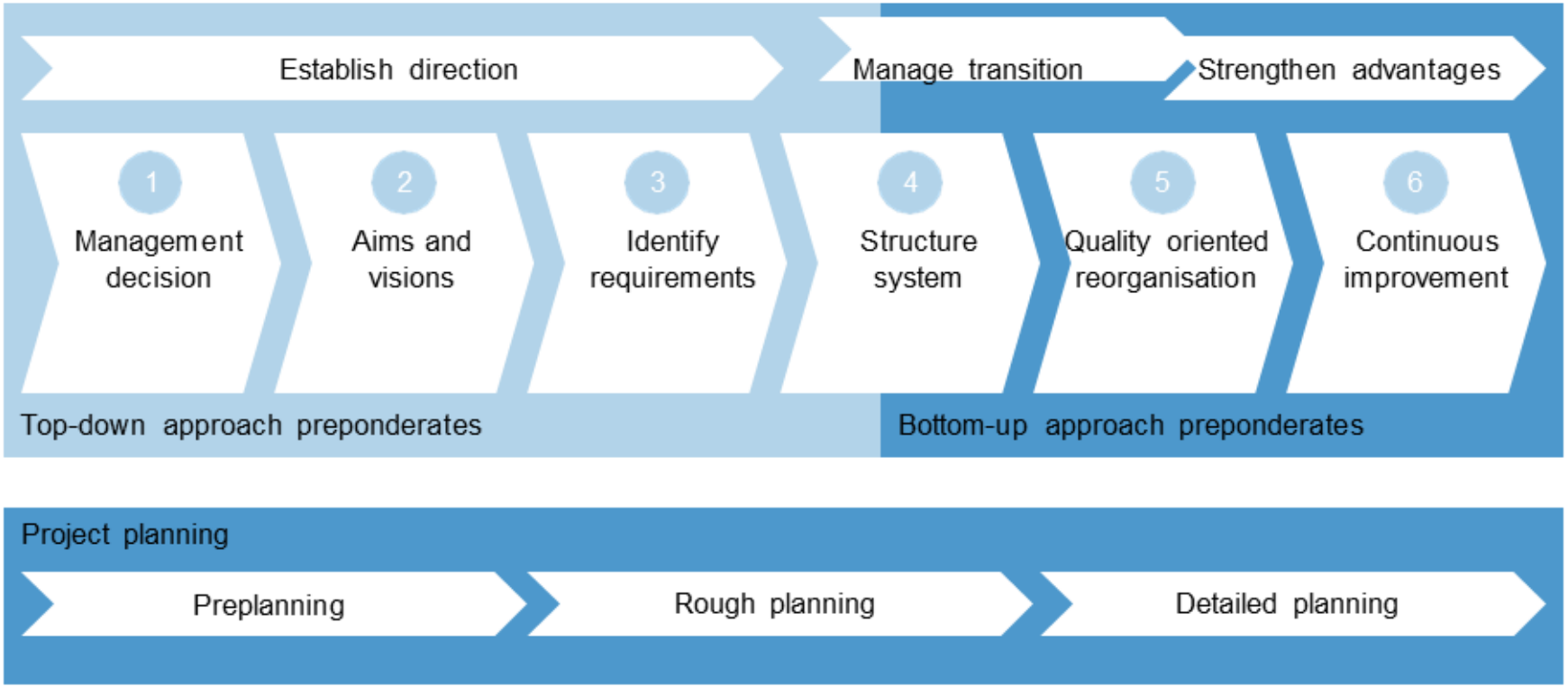
Certificate maintenance cycle

Initial audit	• Stage 1 • Stage 2
Surveillance audits	• 2..3 in 3 year period
Recertification audit	• Repeats Initial audit

Quality Management Systems Approach

1. Determine the needs and expectations of customers and other interested parties.
2. Establish the quality policy and quality objectives of the organisation.
3. Determine the processes and responsibilities that are necessary to achieve the quality objectives.
4. Determine and provide the resources necessary to achieve the quality objectives.
5. Establish methods to measure the effectiveness and efficiency of each process.
6. Apply these measures to determine the effectiveness and efficiency of each process.
7. Determine means of preventing nonconformities and eliminating their causes.
8. Establish and apply a process for continuous improvement of the quality management system.

Potential Approach to Implement a QM System



Management Decision

- Management decision
- Training managers
- Informing employees

Strategy Planning

Customer focus
Who are our stakeholders? And what do they want?

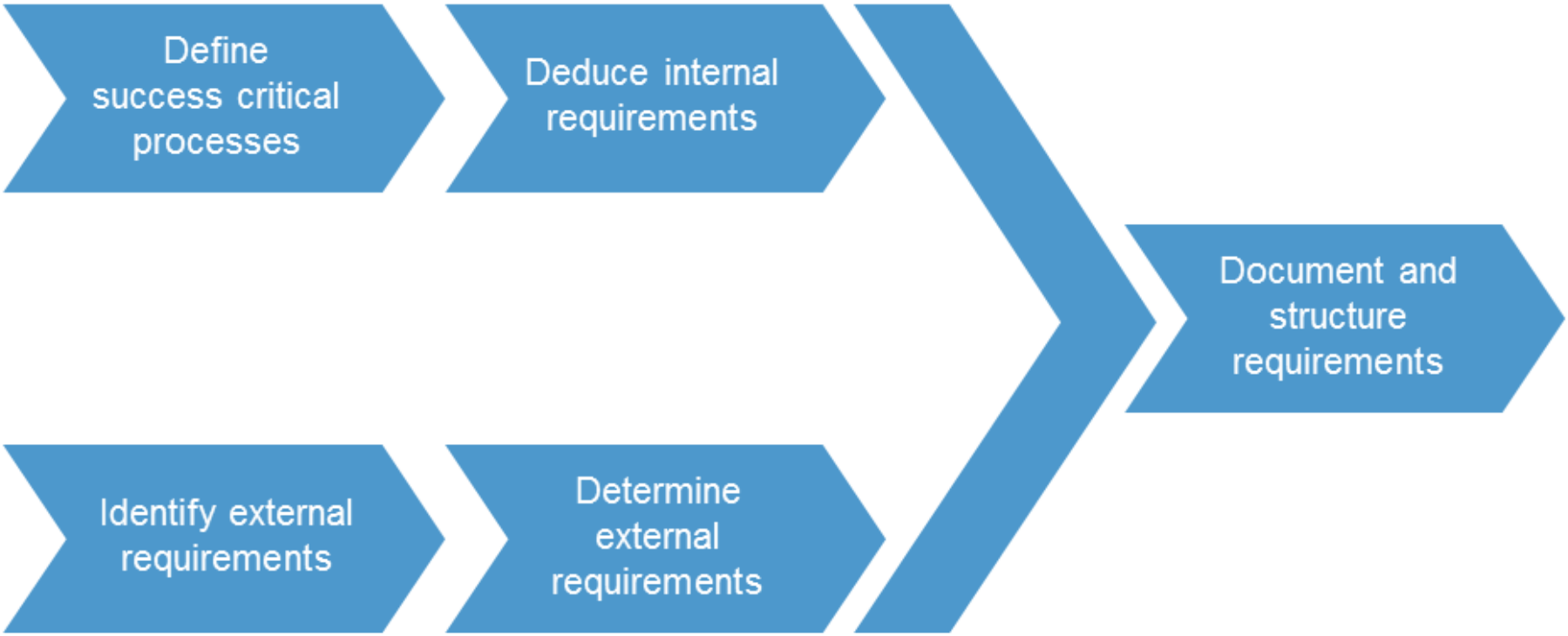
Strategic objectives
What will the organisation achieve in the future?

Deduce sub objectives
How can we achieve higher objectives?

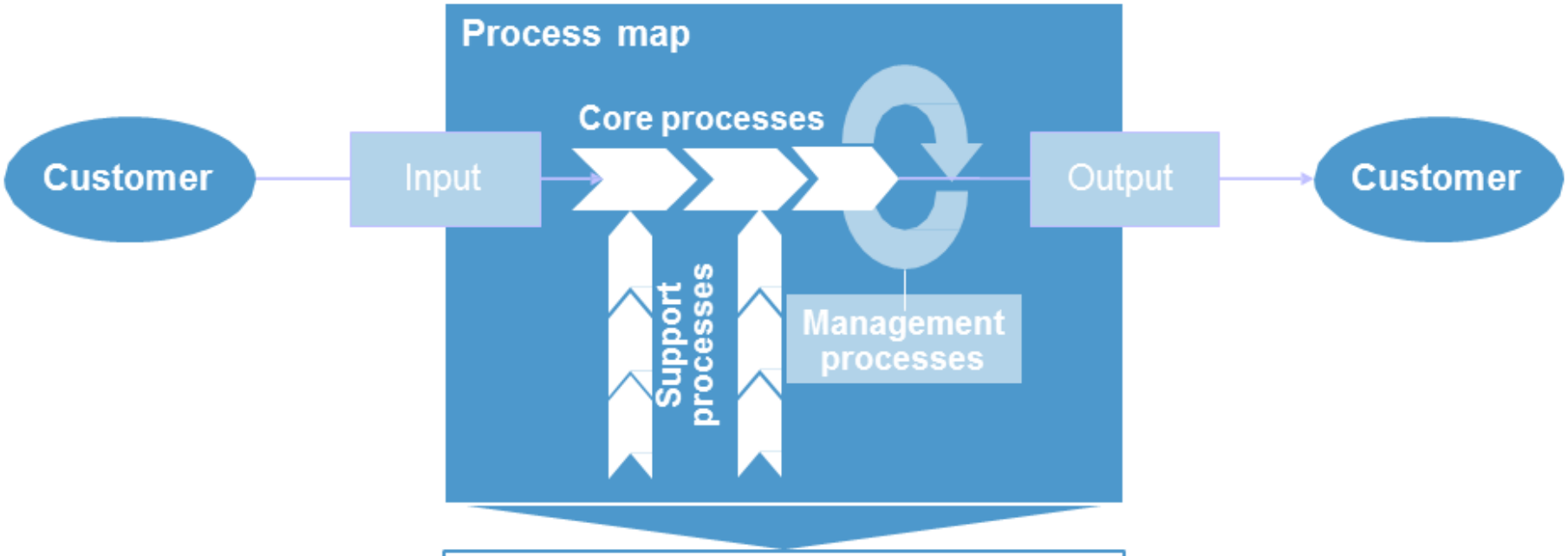
Objectives coordination
What are the conflicts between the objectives?
How can they be eliminated?

Key: Management Managers Employees

Identify Requirements



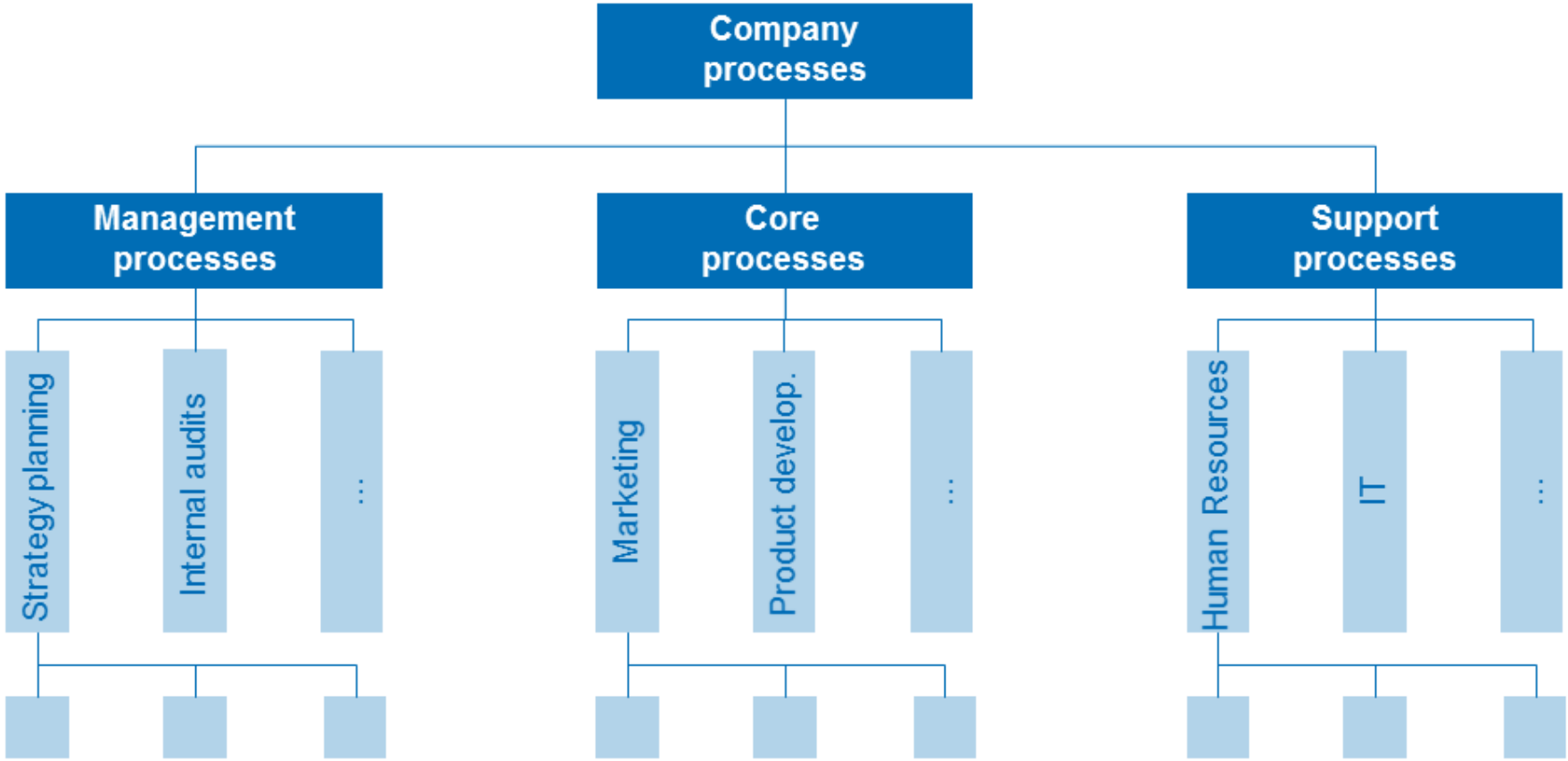
Structuring System



The QM System defines:

- Responsibilities and authorities
- Equipments and resources
- Objectives and measures
- Methods and tools

Structure System



Quality Oriented Reorganisation

Phase 1: Analysis

- Determine actual state
- Show need for action
- Plan approach

Phase 2: Design

- Build teams
- Develop actions
- Plan implemen-tation
- Document results

Phase 3: Realisation

- Adjust actions
- Establish actions
- Follow up effects

Involved area:

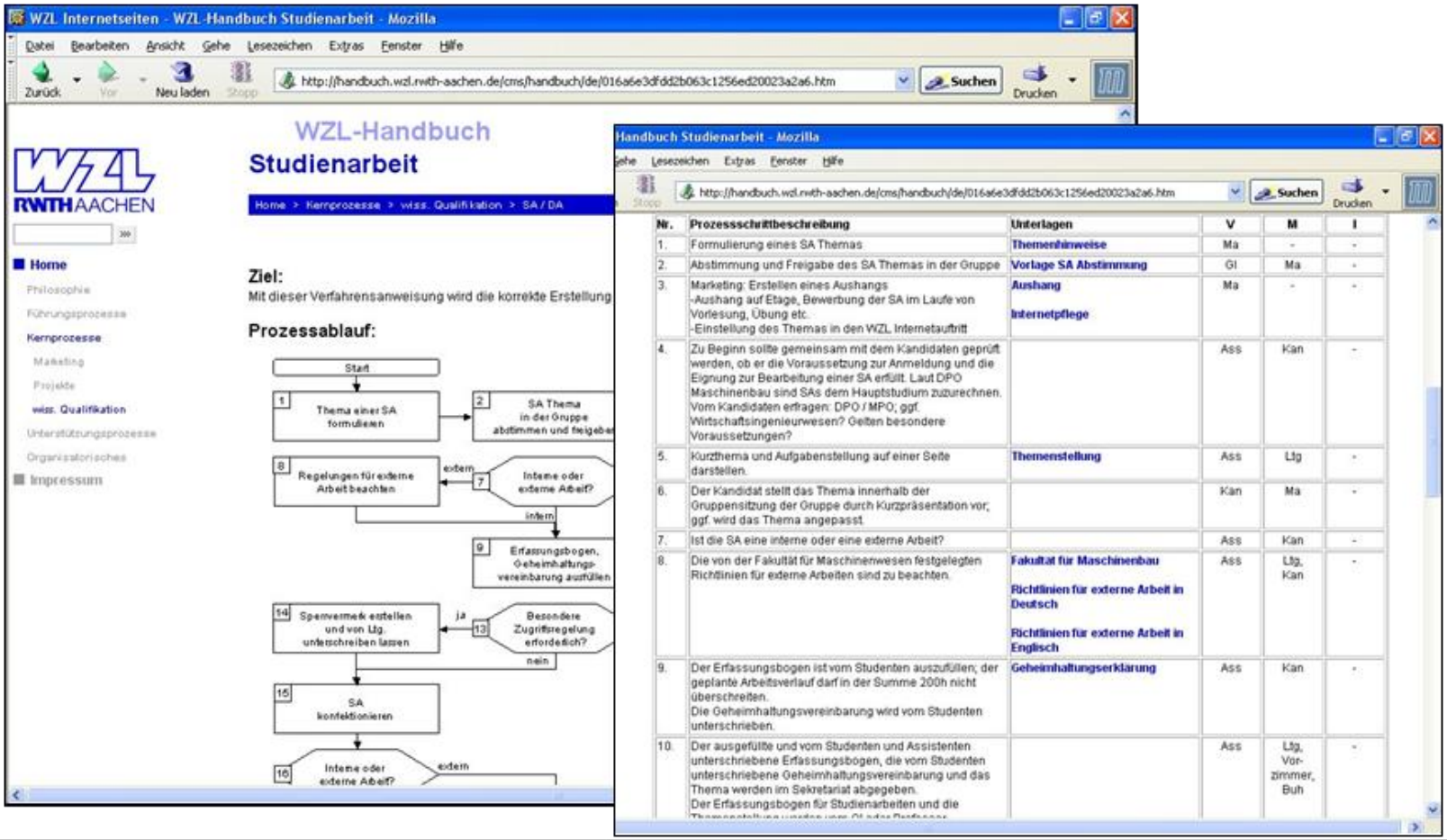
Enterprise

Teams

Types of Documents

Quality manuals	Information about the Quality Management System
Quality plans	Description how Quality Management is applied
Specifications	Requirements
Guidelines	Recommendations or suggestions
Documented procedures, work instructions and so on	Information, how to perform activities and processes consistently
Records	Objective evidence of activities performed or results achieved

Electronic Documentation of a QM System



Nr.	Prozessschrittbeschreibung	Unterlagen	V	M	I
1.	Formulierung eines SA Themas	Themenhinweise	Ma	-	-
2.	Abstimmung und Freigabe des SA Themas in der Gruppe	Vorlage SA Abstimmung	Gl	Ma	-
3.	Marketing: Erstellen eines Aushangs -Aushang auf Etage, Bewerbung der SA im Laufe von Vorlesung, Übung etc. -Einstellung des Themas in den WZL Internetauftritt	Aushang Internetpflege	Ma	-	-
4.	Zu Beginn sollte gemeinsam mit dem Kandidaten geprüft werden, ob er die Voraussetzung zur Anmeldung und die Eignung zur Bearbeitung einer SA erfüllt. Laut DPO Maschinenbau sind SAs dem Hauptstudium zuzurechnen. Vom Kandidaten erfragen: DPO / MPO; ggf. Wirtschaftsingenieurwesen? Gelten besondere Voraussetzungen?		Ass	Kan	-
5.	Kurzthema und Aufgabenstellung auf einer Seite darstellen.	Themenstellung	Ass	Ltg	-
6.	Der Kandidat stellt das Thema innerhalb der Gruppensitzung der Gruppe durch Kurzpräsentation vor; ggf. wird das Thema angepasst.		Kan	Ma	-
7.	Ist die SA eine interne oder eine externe Arbeit?		Ass	Kan	-
8.	Die von der Fakultät für Maschinenwesen festgelegten Richtlinien für externe Arbeiten sind zu beachten.	Fakultät für Maschinenbau Richtlinien für externe Arbeit in Deutsch Richtlinien für externe Arbeit in Englisch	Ass	Ltg, Kan	-
9.	Der Erfassungsbogen ist vom Studenten auszufüllen; der geplante Arbeitsverlauf darf in der Summe 200h nicht überschreiten. Die Geheimhaltungsvereinbarung wird vom Studenten unterschrieben.	Geheimhaltungserklärung	Ass	Kan	-
10.	Der ausgefüllte und vom Studenten und Assistenten unterschriebene Erfassungsbogen, die vom Studenten unterschriebene Geheimhaltungsvereinbarung und das Thema werden im Sekretariat abgegeben. Der Erfassungsbogen für Studienarbeiten und die		Ass	Ltg, Vor-zimmer, Buh	-

Audit Objective

- Proficiency review of procedures and processes for product development, production and dispatch
- Use and efficiency review of the documented procedures and arrangements

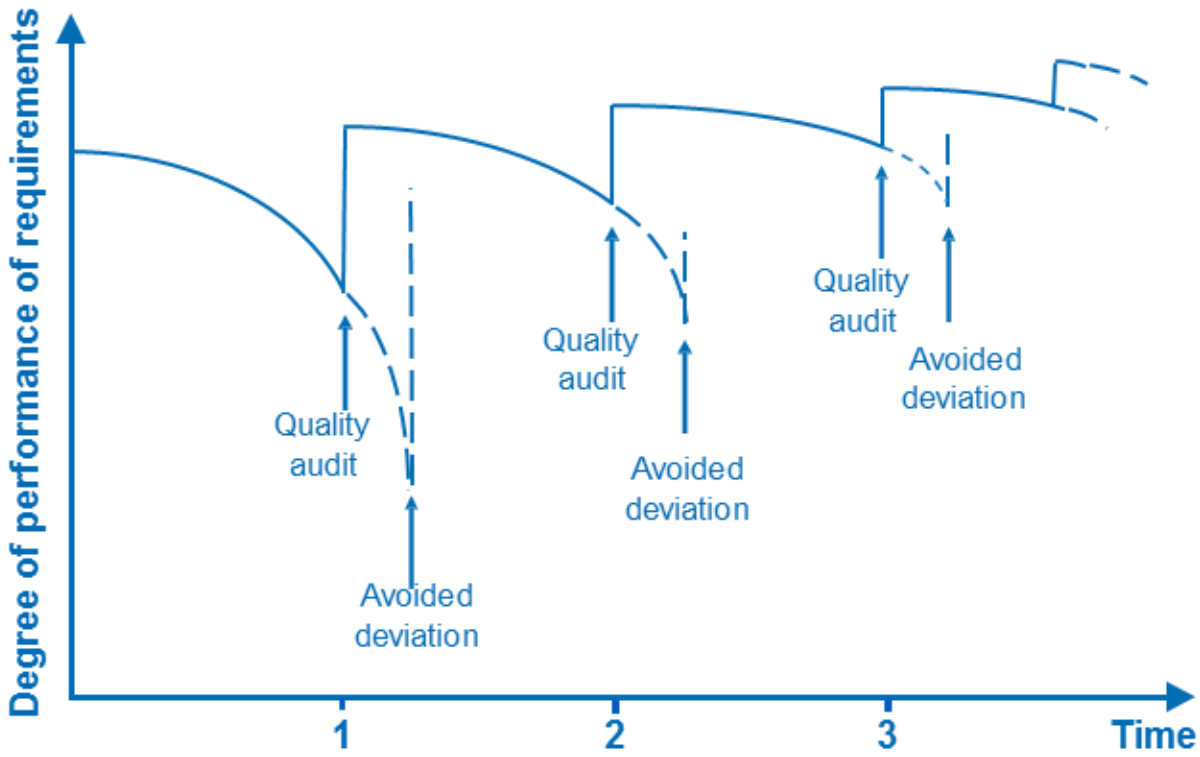
Process description

QM documentation

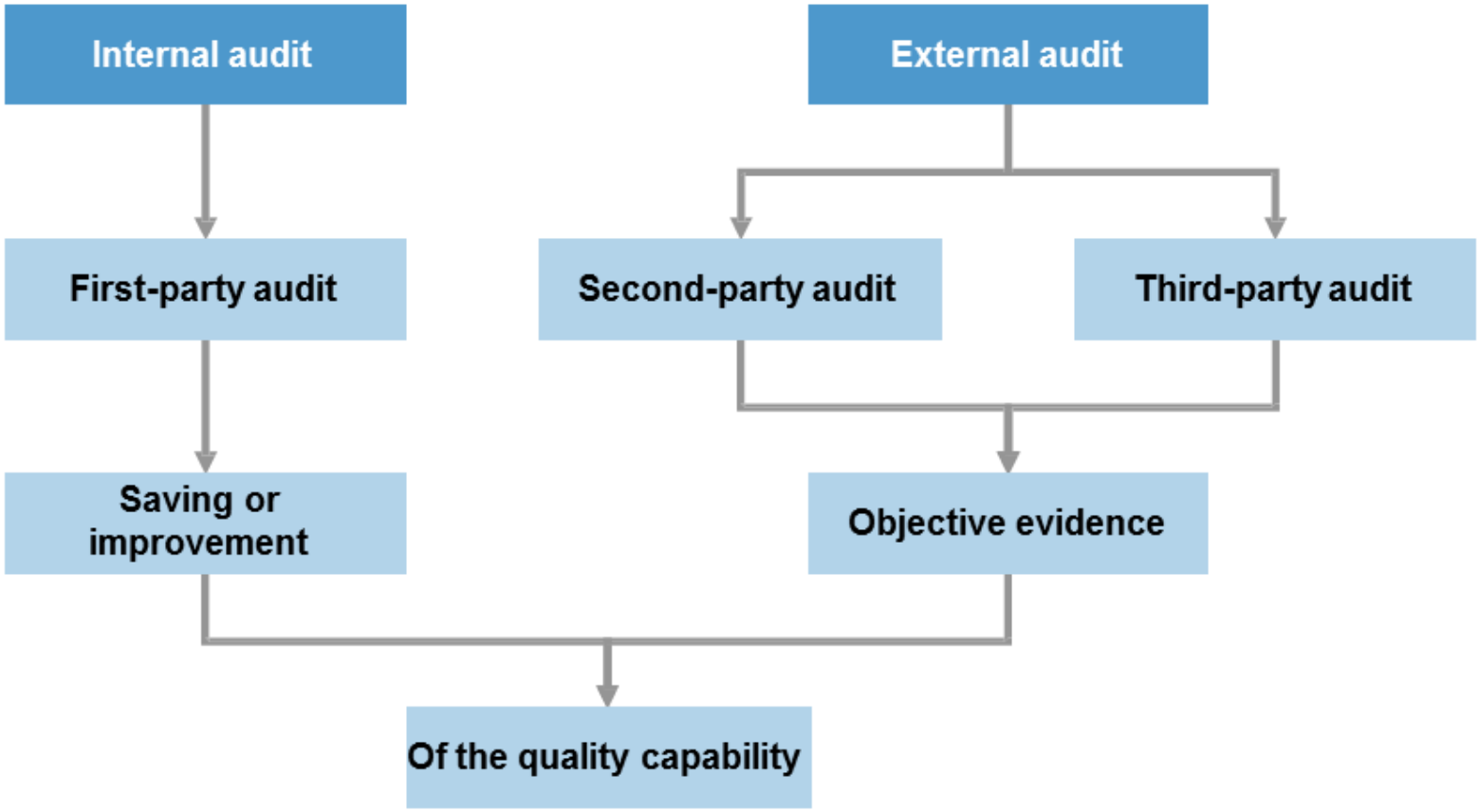
In this context

- weak points are identified,
- interface problems are identified,
- potential process improvement defined and
- organisational improvements (e.g. qualification action) determined.

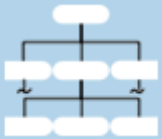
Avoidance of Error Rates by Quality Audits



Audit Forms


Internal audit
External audit
First-party audit
Second-party audit
Third-party audit
Saving or improvement
Objective evidence
Of the quality capability

Audit Types

Type	Quality system audit	Process audit	Product audit
Purpose	Completeness and effectiveness evaluation of the basis requirements to the management system	Quality capability evaluation of the processes for special products and product groups	Quality characteristic evaluation of a specific number of end products and/or parts
Regarded object	Procedural organisation  Structural organisation 	Relevant processes Personnel 	Individual parts or products  
Documentation & optimisation potential	▪ Quality manual ▪ QM instruction ▪ Order documents ▪ Directives of the management ▪ …	▪ Processes (Development, production, dispatch) ▪ Personnel qualification ▪ Documents of process performance, monitoring and inspection ▪ …	▪ Quality directives ▪ Inspection and manufacturing procedures, documents and equipment ▪ …

Certification Procedure

Company / Organisation	Certification body
Select certification body	
Provide information about organisation	Revise existing documentation
Sign contract	Submit an offer
	Plan project
Approve project plan	
	Checking of the QMS-documentation
	If not serious deficiencies
	Realise audit
	Evaluate organisation
	Write report
	If not serious deficiencies
	Issue certificate
	After 1st and 2nd year
	Conduct surveillance audit
	In 3rd year
	Conduct reassessment

Internal audit Documentation

- Audit programme
  - Audit schedule
- Audit plan
- Execution of audit
  - Checklists
  - Auditor notes
  - Non-conformity records
  - Audit report
- Follow-up audits

Audit programme

- Usually prepared and approved for 1-year period
- Indicates
  - auditable areas/ units
  - audit criteria and extent
  - planned timeframe

Example:

Unit	Standard ref.	Audit days	When
1. Management operations		1	Jan-2013
2. Sales and marketing	7.2, 8.2.1	3	Mar-2013
3.Production	7.1, 7.4	7	Jul-2013
…	…	…	…

Audit plan

- Precise audit plan for specific unit(s)/location(s)
- Specifies:
  - Functions to be audited
  - Auditees
  - Auditors
  - Audit criteria
  - Time and length

Audit plan - example

Expected time and duration	Identification of Areas / Processes to be Audited	Scheme	Auditor(s)
10:00 - 10:15	Opening Meeting - Including Review of Stage One Audit Findings, Actions and Status (as applicable), Confirmation of scope of certification - Processes, sites, employees etc and confirmation of changes to the scope of certification (as applicable)	ISO 9001:2008	Mārtiņš Šitcs
10:15 - 13:30	Board Member - Customer related processes. Sales and marketing. Preparation of proposals. Cost estimation. Customer feedback and satisfaction measurements. Quality Manager - QMS- Documentation, records and general provisions. Quality policy, Objectives, Documentation and records management, Internal audit, Nonconforming product, Corrective and preventive actions. Management review. Allocation of resources.		
13:30 - 14:00	Working Lunch		
14:00 - 16:00	Production Manager - Production process. Maintenance of machinery and measurement tools. Procurement and management of subcontractors. Personnel Manager - Personnel management processes. Qualification, competence and training records.		
16:00 - 16:30	Preparation for closing meeting		
16:30 - 17:00	Closing meeting		

Audit notes (Audit trails)

Standard / Clause	Auditor Notes (e.g. Department, Evidence, Samples, Document References, People Interviewed)	Accept / NCR / OFI

Checklists

ISO 9001:2008 Standard Requirements	Clause Audited	Number of NCR(s) issued
4.1. General Requirements	☐	
4.2. Documentation Requirements	☐	
4.2.2. Quality Manual	☐	
4.2.3. Control of Documents	☐	
4.2.4. Control of Records	☐	
5.1. Management Commitment 5.2. Customer Focus	☐	
5.3. Quality Policy	☐	
5.4.1. Quality Objectives	☐	
5.4.2. Management System Planning	☐	
5.5.1. Responsibility and Authority 5.5.2. Management Representative 6.1. Provision of Resources	☐	

Non-conformity REPORT (NCR) forms

Section 1 Nonconformity Details - To be completed by the auditor

Auditor Name:			
Nonconformity ref. number:		**Date issued:**	
Nonconformity type:		**Agreed response date:**	
Standard:			
Clause:		**Issued at:**	
Details of nonconformity:			

NCRs(2)

Section 2. Correction(s), Root Cause Analysis and Corrective Action(s) - To be completed by the client

Correction:	
Root cause:	
Corrective action:	
Description of evidence attached:	
Date of response:	

NCR(3)

Section 3. Acceptance and Verification of Correction, Root Cause Analysis and Corrective Action

Auditor comments:

Nonconformity status

- Correction & corrective action accepted for verification at the next audit - Nonconformity Open (Not applicable for major NCRs) ☐
- Correction & corrective action verified and nonconformity closed ☐
- Further action / evidence required - Nonconformity open ☐

Date

Audit report

- Indicates areas that are audited
- Audit dates, standard and doc.referances, auditors
- Gives summary of findings
- Conslusions and recommendations

The Audit Process

1 Planning

Assignment of audit staff

Preliminary research and information gathering

Identify audit objectives and scope

Conduct entrance conference with auditee

2 Fieldwork

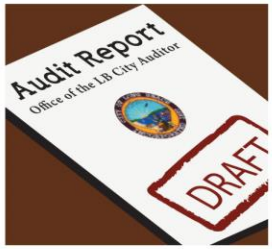
Collect and assess evidence

Identify any audit issues

Workpaper documentation

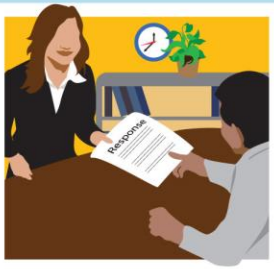
Conduct exit conference with auditee

3 Reporting

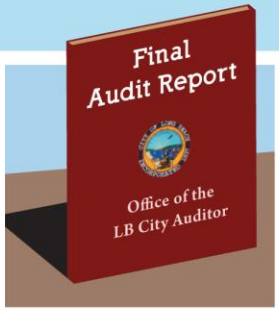


Draft audit report

Quality control review



Auditee response



Final audit report

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Long Beach, California 90802

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Fax: (562) 570-6167

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auditor@longbeach.gov