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DEPARTMENT OF  
INDUSTRIAL ENGINEERING 

# Data Analytics fundamentals: Quality engineering

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Product/service quality

# Product quality in the global market

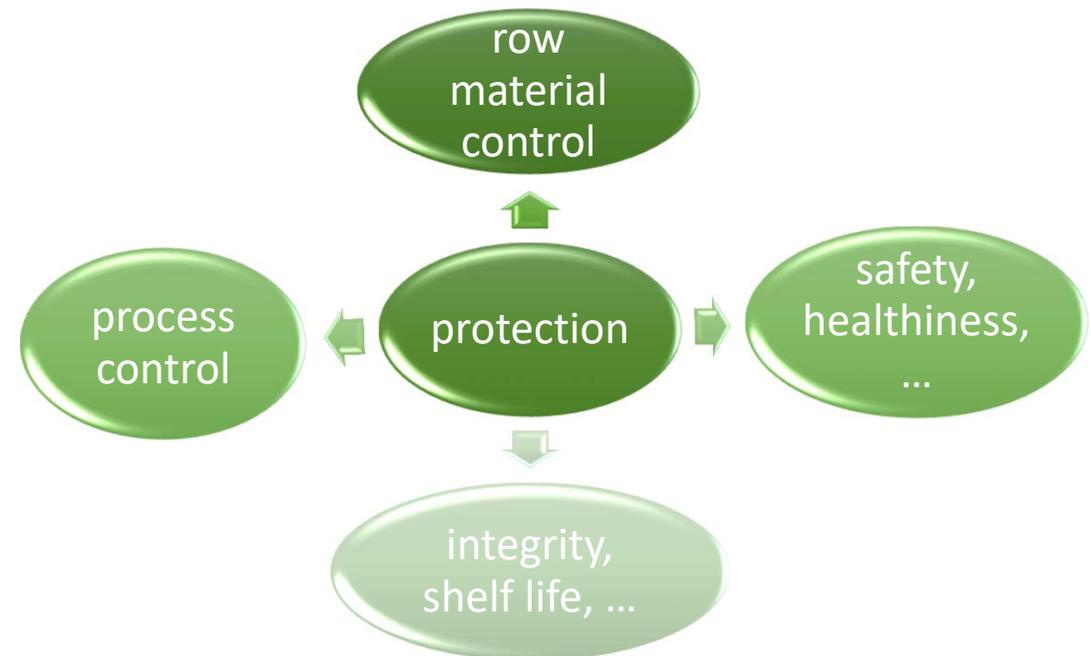
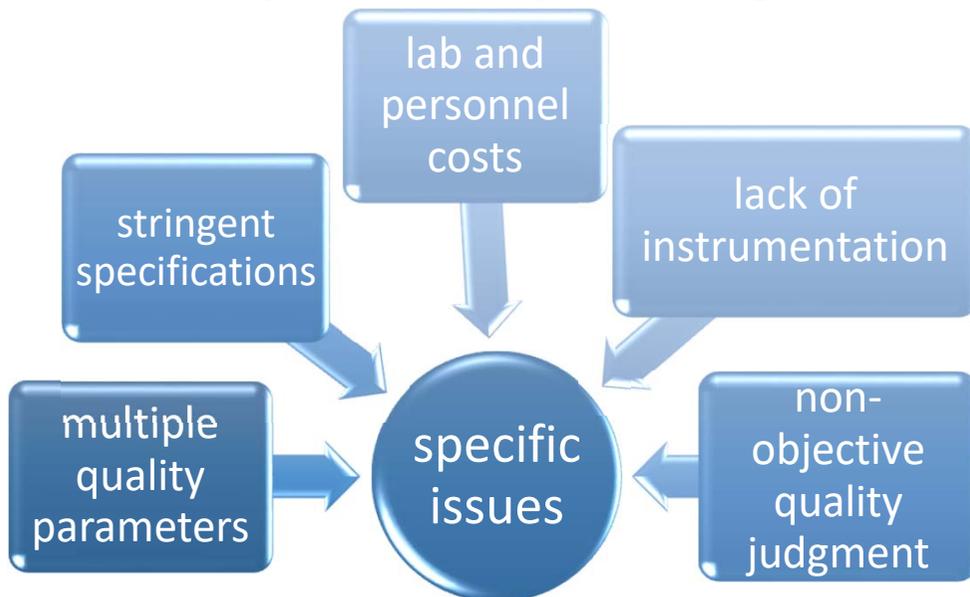
- How can be obtained the **economic success** in today global market?



*Ensuring absolute excellence to the product quality!*

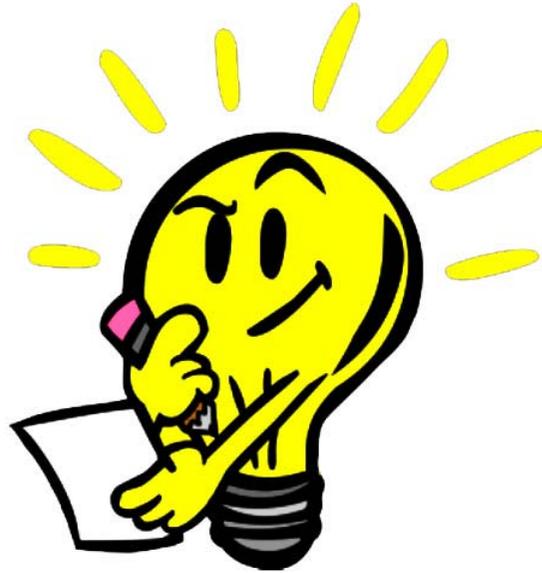
# Issues on product quality

- Ensuring:
  - high product quality
  - reproducible processes
- Guaranteeing regular process runs and timely corrections of anomalies and malfunctions
- Development of products within predetermined desired specifications
  - full product characterization
  - protections from frauds
  - protection from contaminations
- Concept of Quality-by-design



# What is quality?

- What is quality in your opinion?
- Could you give a definition of quality?



# Definition of quality

- Quality = fitness for use!
  - **quality of design:**
    - differences in the design of the product
      - different grades
      - different levels
      - different materials, components, accessories, etc...
  - **quality of conformance:**
    - product conformance to the specifications required by the design
    - influenced by:
      - choice of manufacturing processes
      - training and supervision of the workforce
      - types of process controls, tests, inspection activities that are employed
      - motivation of the workforce to achieve quality
- A modern and “mathematical”/engineering definition of quality is:  
**quality is inversely proportional to variability**

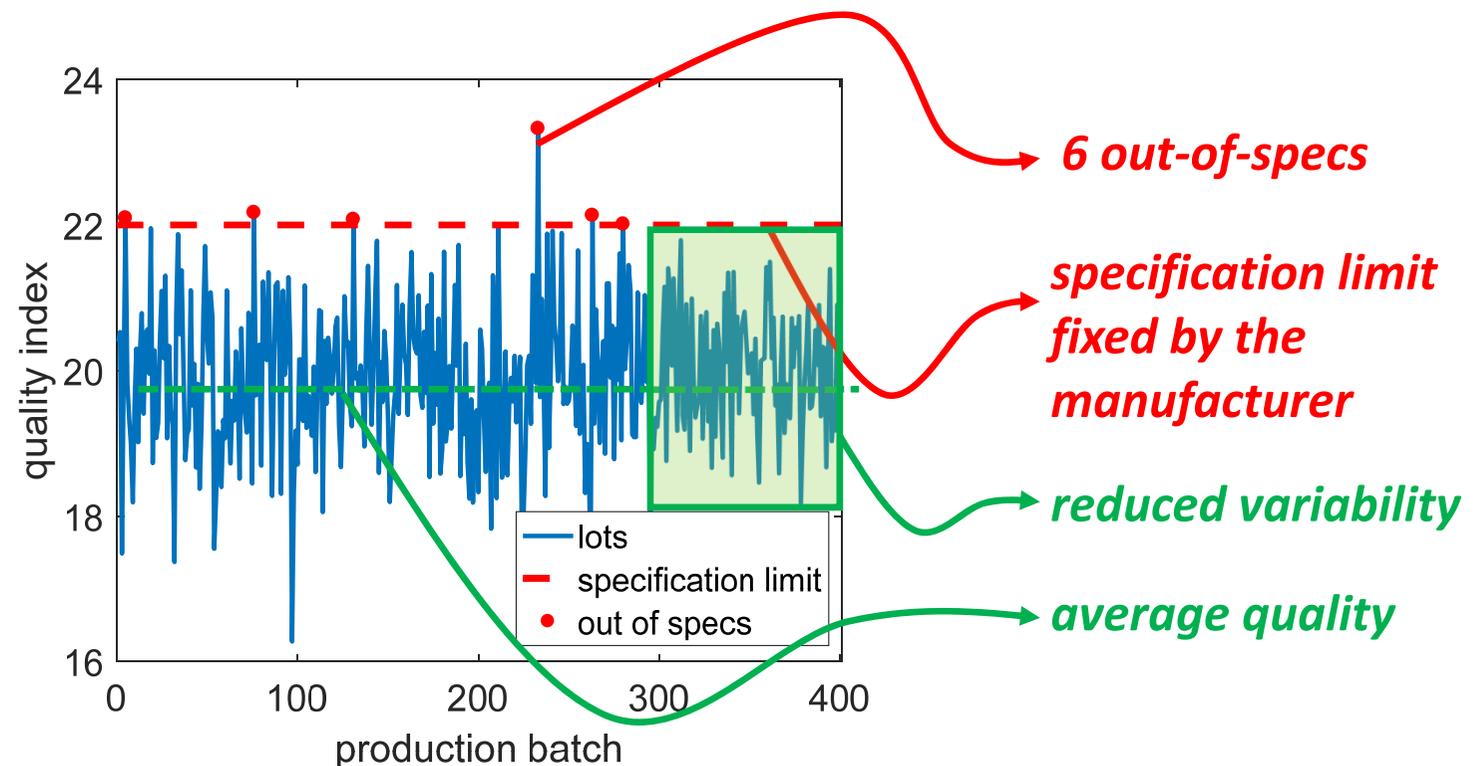


**Improving quality means reducing the variability of processes and products important features**

# Customer perspective

- The customer perceives the variability, not the average quality of the product

*quality index of 400 production lots of a drug are analyzed*



- Few repair and warranty claims determine:
  - less rework
  - decrease in wasted time and efforts
  - reduced expenses

## 1. Product **performance**:

- will the product perform a specific functions? How well it performs?

## 2. **Reliability**:

- complex products usually require some repair over their service life
- customer's view of quality is greatly impacted by the reliability

## 3. **Durability**:

- effective service life of the product
- the product should perform satisfactorily over a long period of time

## 4. **Serviceability**:

- how easy is it to repair the product?
- how quickly and economically a repair/routine maintenance are accomplished

## 5. **Aesthetics:**

- visual appeal of the product
  - takes into account several factors; style, color, shape, packaging, tactile, sensory features, etc...
- differentiate the product from competitors

## 6. **Features:**

- what does the product do?
- very customers associate high quality with products that have added features (beyond the basic performance)

## 7. **Perceived quality:**

- the reputation of the company and product
- directly influenced by failures of the product or product recalls
- closely interconnected with customer loyalty and repeated business

## 8. **Conformance to standards:**

- does the product meet the requirements placed on it?
- manufactured parts that do not exactly meet the designer's requirements can cause significant quality problems (components of a more complex assemblies)

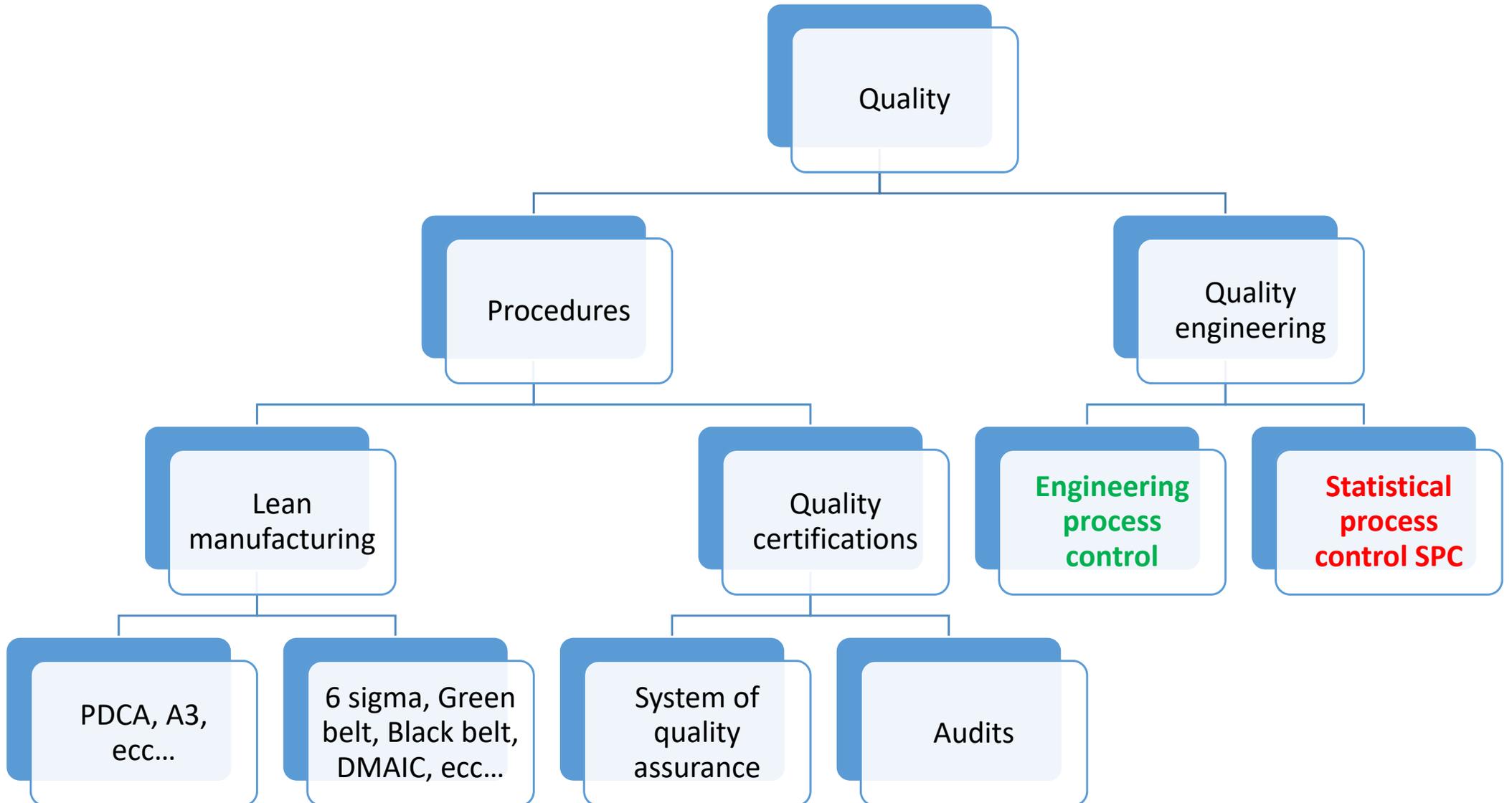
# Quality engineering

- The **critical-to-quality characteristics/attributes** are the characteristics of the product that jointly describe what the user thinks of as quality
- Quality characteristics (directly or indirectly related to the quality dimensions) are of several types:
  1. **physical:** length, weight, voltage, viscosity
  2. **sensory:** taste, appearance, color
  3. **time orientation:** reliability, durability, serviceability



- **Quality engineering** is the series of activities that a company uses to guarantee that the critical-to-quality characteristics meet the nominal required values and that the variability around these desired levels is minimum
- Quality engineering activities embrace several actions:
  - operational
  - managerial
  - engineering

# Strategies for quality improvement



# Quality improvement activities

- Quality improvement activities:
  - eliminating scraps
  - limiting reworks
  - limiting dead times and non-operating phases
  - diminishing waste
  - improving the services
  - etc...



- Objective: decreasing the costs related to quality

# Quality engineering

- To provide the customer with products that have always identical quality characteristics from unit to unit is difficult and expensive (even impossible!) for most companies in different sectors because of **product variability**
  - a certain amount of variability is present in every product
  - two products are never identical
- If the variations in product quality are “too” large, then the customer perceives the unit to be undesirable or unacceptable
- **Sources of this variability** include differences in:
  - materials
  - performance
  - operation of the manufacturing equipment
  - way the operators perform their tasks

# Quality engineering through statistical methods

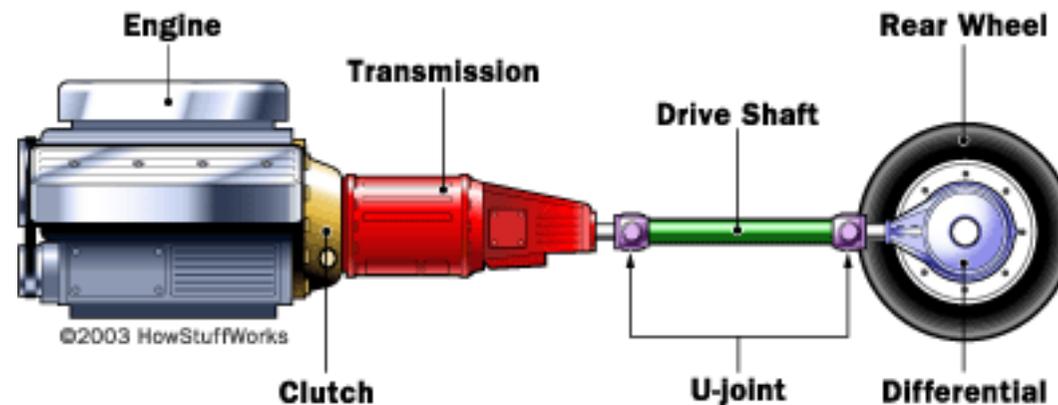
- Variability can only be described in statistical terms



- **Statistical methods** play a central role in quality improvement
- In quality engineering data are typically classified on:
  - **variables**, usually continuous measurements:
    - length
    - voltage
    - viscosity
  - **attributes**, usually discrete data taking the form of counts
    - number of loan applications that could not be properly processed because of missing required information
    - the number of emergency room arrivals that have to wait more than 30 minutes to receive medical attention
- Statistical-based quality engineering deals with both types of data

# Specifications

- Quality characteristics are often evaluated relative to specifications
- The **specifications** are the desired measurements values for the quality characteristics in the final product
  - example in automobile transmission: the diameter of a shaft
    - cannot be too large to fit into the mating bearing
    - cannot be too small, resulting in a loose fit and causing vibration and early failure of the assembly



# Target value and specification limits

- The desired value for that quality characteristic is called the **nominal** or **target value**
- Target values are usually bounded by a range of values sufficiently close to the target so as to not impact the product performance
  - the largest allowable value for a quality characteristic is called **upper specification limit USL**
  - the smallest allowable value for a quality characteristic is called **lower specification limit LSL**
  - some quality characteristics have specification limits on only one side of the target
    - example, the compressive strength of the components of automobile bumpers
- Specifications are usually the result of the engineering design process for the product using an **over-the wall approach**:
  - product design configuration through the use of engineering principles
  - prototype construction
  - testing
  - specifying the target values for the critical design parameters
  - the final product is released to manufacturing



# Nonconformities and defects

- Unfortunately, specifications are often set without regard to the inherent variability in the system:
  - materials
  - processes
  - parts, etc...
- **Nonconforming products** fail to meet one or more specifications
  - a specific type of failure is called a **nonconformity**
  - a nonconforming product is not necessarily unfit for use
    - for example, a detergent may have a concentration of active ingredients that is below the lower specification limit, but it may still perform acceptably if the customer uses a greater amount of the product
- **Defects** are nonconformities that are serious enough to significantly affect the safe/effective use of the product
  - failure of a company to improve its manufacturing processes can cause nonconformities and defects



# Concurrent engineering approach

- To overcome the problems with the over-the-wall approach to design, there is the need of a science-based design process to effectively translate the specifications into manufacturing activities and processes
  - engineers need to receive the background in quality improvement
- The recent emphasis on **concurrent engineering** has stressed:
  - **team approach to design**, with specialists in:
    - manufacturing
    - quality engineering
    - product designer, etc...
  - the effective use of the quality improvement methodologies for:
    - technology commercialization
    - product design
    - development
    - product realization and manufacturing
    - distribution
    - customer support, etc...

# History of quality improvement and control

**13-th century:** craftsman began organizing into «guilds»

- suggesting rules on products and services
- inspection committees
- special marks for flawless goods

**late 1800 – early 1900:** first examples of product inspections, checking, testing

**1908:** quality control statistical methods are patented for Guinness

**the 20s:** works on both design of experiments (DOE) and univariate control charts are first published

**the 30s:** first extended industrial applications:

- textile industry, military applications, chemical industry

**from the 40s:** the concept of «total quality» is introduced

- inspection technologies are adopted
- ministries start to embrace this discipline
- ISO and ASQC are formed
- control charting and DoE are highly improved

**late 80s and 90s:** ISO publishes the first the quality systems standard

- ISO 9000 certification is adopted by industries
- six-sigma approach spreads in the industrial world

**the 2000s:** a more complex concept of quality is adopted:

- supply chain management
- finance
- utilities
- health care
- insurance

**NOW:** IV INDUSTRIAL REVOLUTION

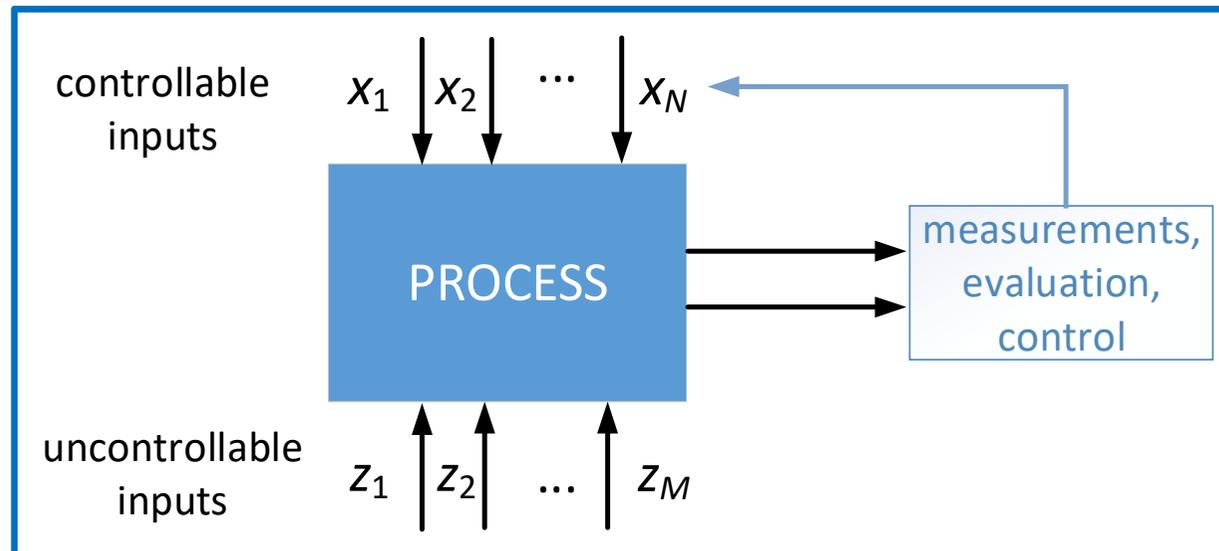
- industry digitalization
- cloud connection

# Areas of quality control and improvement

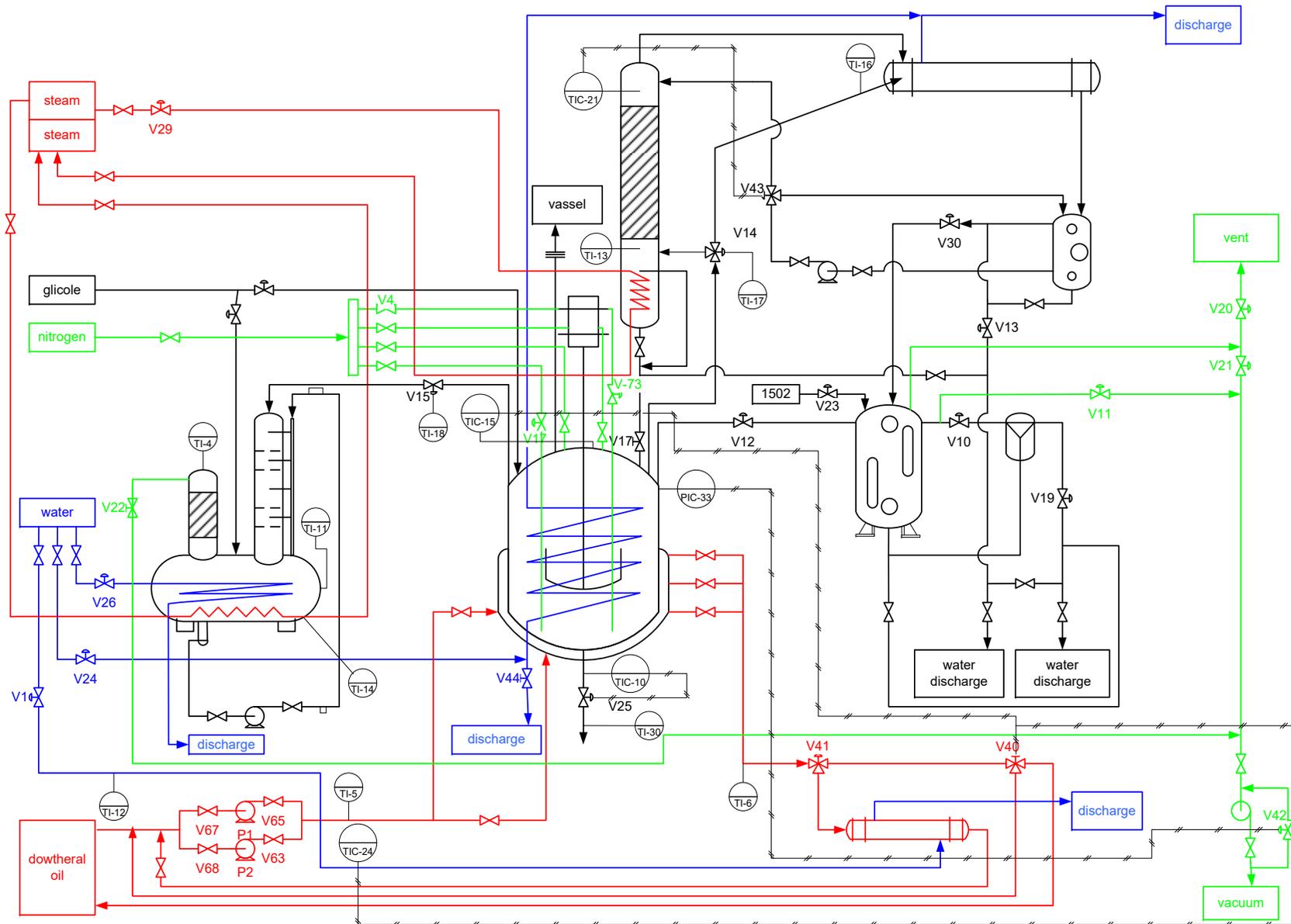
- Major areas of quality control and improvement are:
  - **design of experiments DoE**
    - in the development stage: to systematically varying the controllable input factors in the process and determining the effect these factors have on the output product parameters
  - **descriptive statistics**
    - process understanding and troubleshooting
  - **statistical process control SPC**
    - during manufacturing: to understand if a process is running in normal conditions or a product conforming to the standards or anomalies/malfunctions are taking place, and possibly diagnose the causes of anomalies
  - **acceptance sampling**
    - inspection and testing of product: inspection and classification of a sample of units selected at random from a larger batch or lot and the ultimate decision about disposition of the lot
    - usually occurs at two points: incoming raw materials/components, or final production
- These methodologies are useful in analyzing quality problems and improving the performance of **processes** (together with a number of other statistical and analytical tools)

# Process

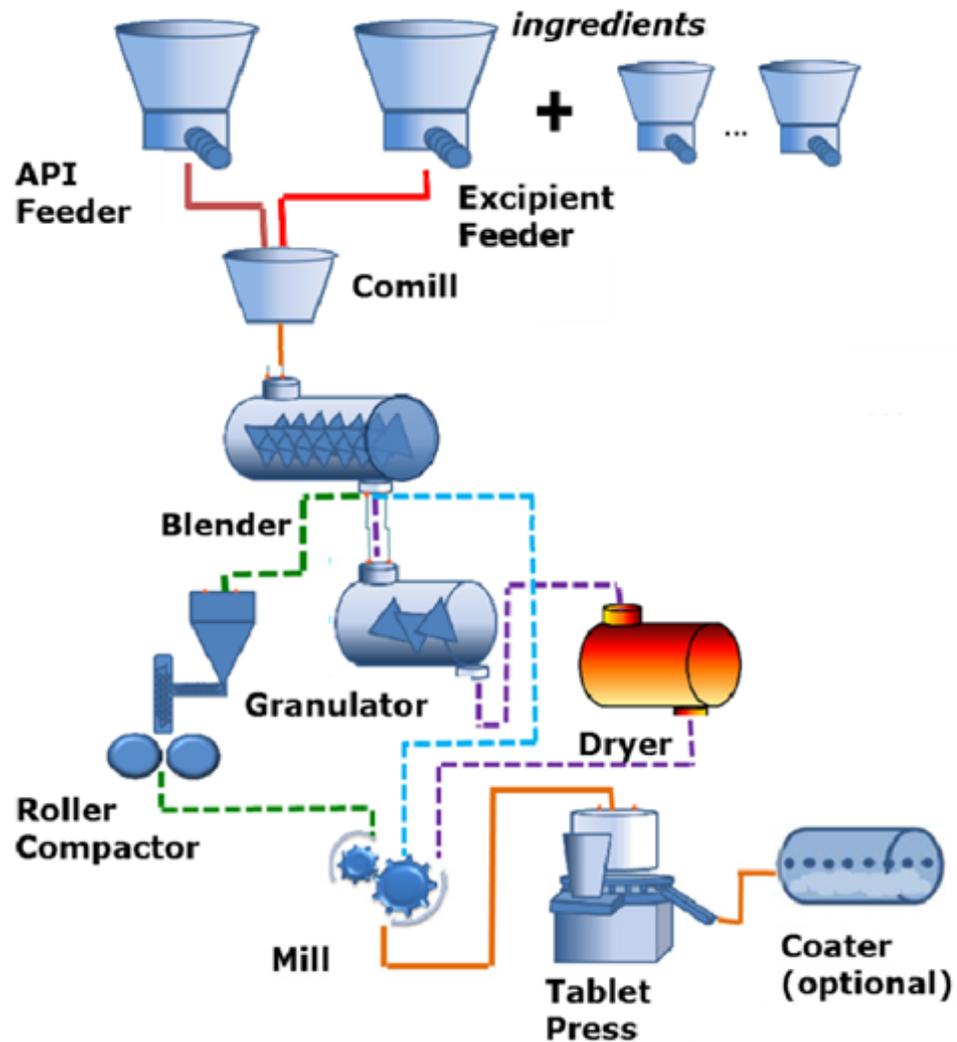
- A **process** is a series of transformations to convert the fed raw materials in a finished product , often through energy exchange
  - the term «process» often identifies both the transformations and the equipment
- A process as a system with:
  - inputs
    - controllable inputs
      - temperatures, pressures, flowrates, etc...
    - uncontrollable inputs
      - environmental factors, properties of the raw materials by external suppliers
  - outputs
    - finished product quality features
      - a measure of process and product quality



# Production of resins for coating

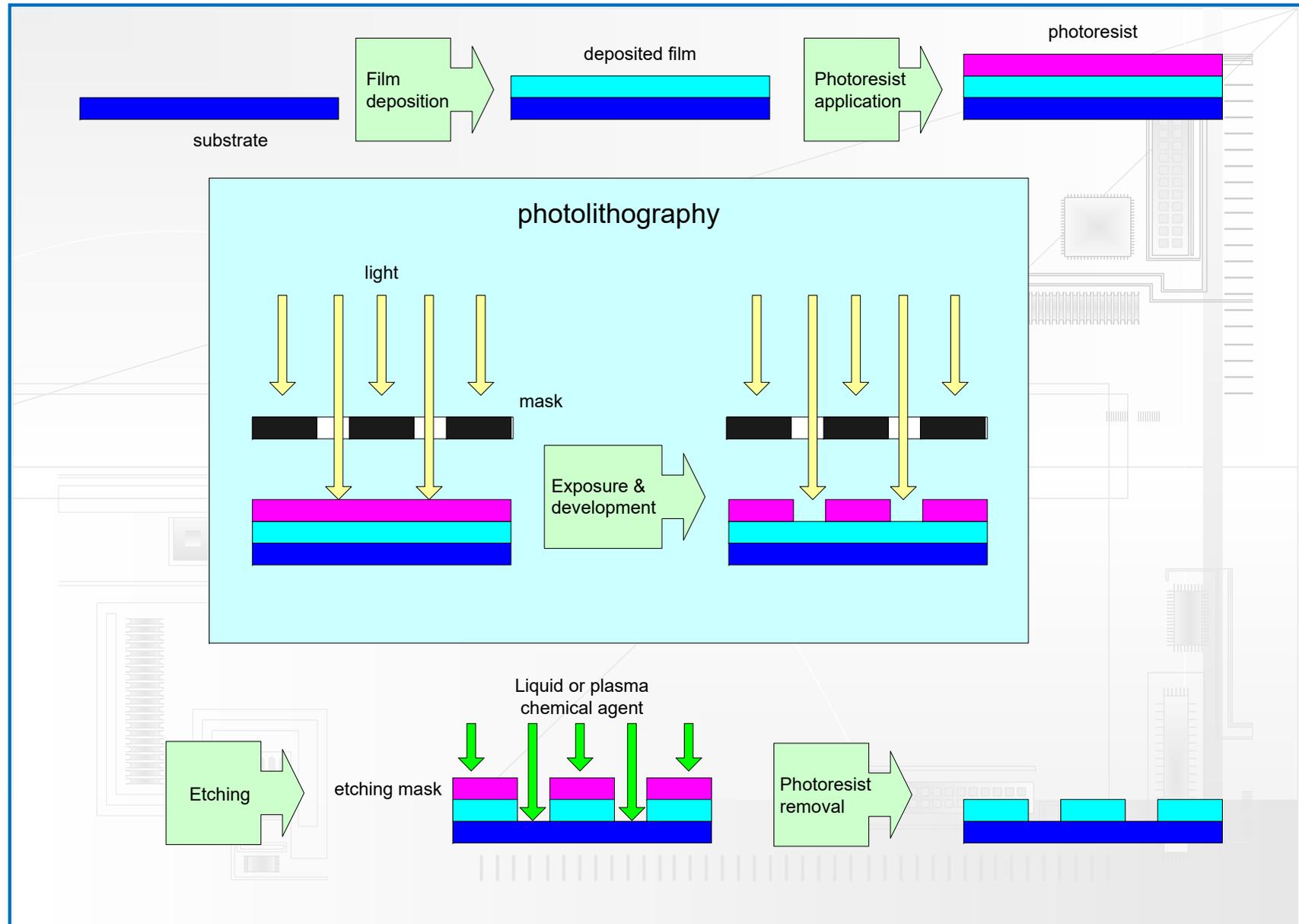


# Tablet manufacturing



[Rogers et al. (2013), Processes, 1, 67]

# Fabrication of integrated circuits: photolithography



# Service processes

- The **conventional process model** can also be used to represent **service processes**
- Example: financial institution that processes automobile loan applications
  - inputs: the loan applications information
    - the customer, his/her credit history, the type of car, its price, the loan amount, etc...
    - controllable factors: type of training that the loan officer receives, the specific rules and policies that the bank imposes, the number of people working as loan officers
    - uncontrollable factors: prevailing interest rates, amount of capital available, and the number of loan applications that require processing
  - output: the number of funded loans that are actually accepted by the applicant, the cycle time, etc...



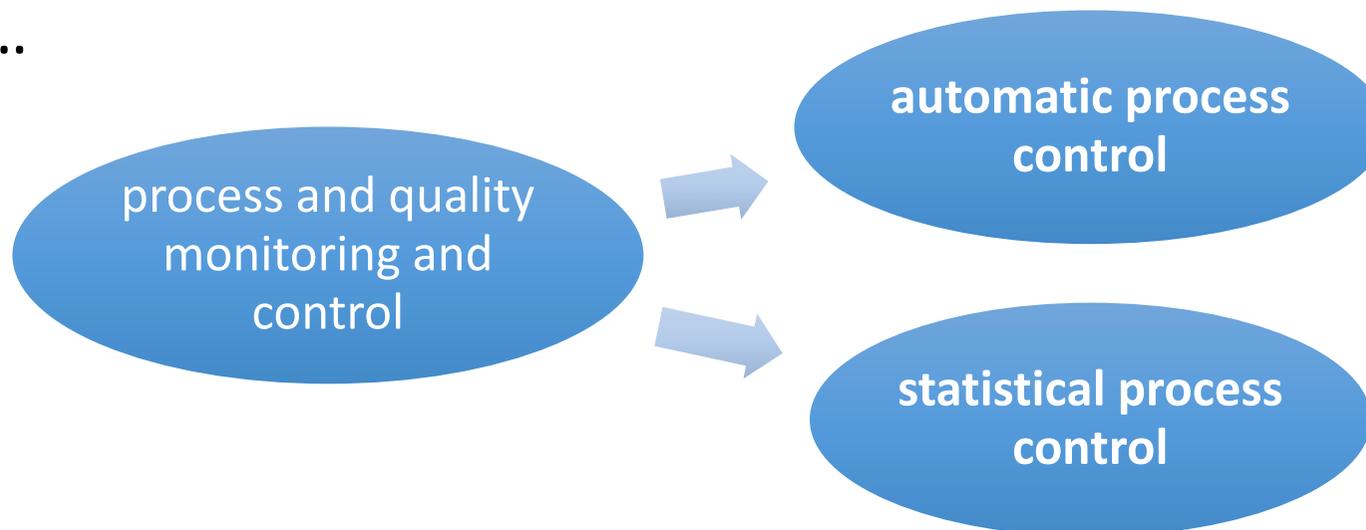
# Requirements for running a process

- A process has to be run **in safe conditions**:
  - far from damaging conditions:
    - operators' life and health
    - environment care
    - integrity of the equipment
- **Quality specifications** have to be met:
  - market requirements are of paramount importance
  - out-of-specifications have to be discarded or reworked
    - increase of the production costs
  - increase manufacturing efficiency
- Production **costs** have to be minimized:
  - economy on raw materials, energy consumption is convenient



# Objectives of process control

- Objectives of process control:
  - safe process
  - satisfy environmental constraints
  - economic benefit:
    - increase productivity
    - maximize profits
    - costs reduction
    - product quality improvement
  - etc...



# Management aspects of the quality improvement

# Management of quality improvement

- Among others, Statistical Process Control and Design of Experiments are the **technical basis for quality control and improvement**
- These techniques must be implemented within the **management system**, which must:
  - organize and direct the overall quality improvement philosophy
  - ensure its deployment in all aspects of the business
- The effective management of quality involves successful execution of three activities:
  - **quality planning**
  - **quality assurance**
  - **quality control and improvement**

# Quality planning

- **Quality planning** is a **strategic activity**, and it is vital to an organization's long-term business success
- Without a **strategic quality plan**, an enormous amount of time, money, and effort will be wasted by the organization dealing with:
  - faulty designs
  - manufacturing defects
  - field failures
  - customer complaints
- Quality planning on a systematic basis is a vital part of this process which involves:
  - identifying customers and costumers' needs (**voice of the customer VOC**)
  - products/services that meet or exceed customer expectations must be developed
  - the 8 dimensions of quality are an important part of this effort
  - determine how these products/services will be realized

# Quality assurance

- **Quality assurance** is the set of activities that ensures:
  - the quality levels of products/services are properly maintained
  - supplier and customer quality issues are properly resolved
- **Documentation** of the quality system is an important component. Quality system documentation involves 4 components:
  1. **policy:**
    - what is to be done and why
  2. **procedures:**
    - focuses on the methods and personnel that will implement policy
  3. **work instructions and specifications:**
    - usually oriented to:
      - products
      - departments
      - tools
      - machines
  4. **records:**
    - a way of documenting the policies, procedures, and work instructions that have been followed
    - used to track specific units or batches of product
    - development, maintenance, and control of documentation are important quality assurance functions
    - vital in providing data for dealing with:
      - customer complaints
      - corrective actions
      - product recalls



# Quality improvement and control

- **Quality control and improvement** involve the set of activities used to ensure that:
  - products and services meet requirements
  - quality improvement on a continuous basis
- The **statistical techniques** such as SPC and DoE are major tools of quality control and improvement (since large variability is a source of poor quality)
- Quality improvement is:
  - often done on a **project-by-project basis**
    - projects should be selected so that they have significant **business impact**
    - projects should be linked with the overall **business goals**
  - involves **teams** led by personnel with specialized knowledge of statistical methods and experience

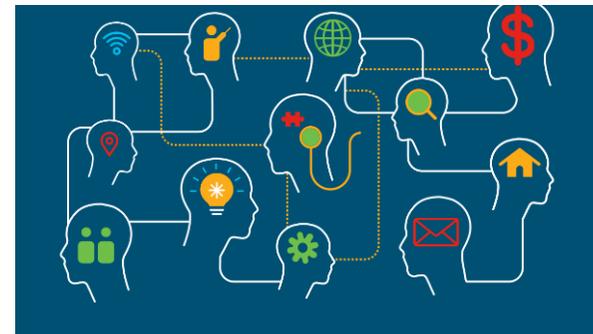
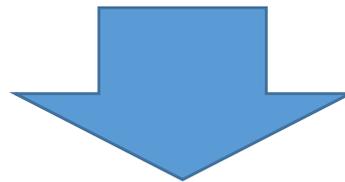
# Quality and productivity improvement

## ■ The philosophy of **Deming's 14 points**:

1. create a constancy of purpose focused on the improvement of products and services
2. adopt a new philosophy that recognizes we are in a different economic era
3. do not rely on mass inspection to “control” quality
4. do not award business to suppliers on the basis of price alone, but also consider quality
5. focus on continuous improvement
6. practice modern training methods and invest in on-the-job training for all employees
7. improve leadership, and practice modern supervision methods
8. drive out fear
9. break down the barriers between functional areas of the business
10. eliminate targets, slogans, and numerical goals for the workforce
11. eliminate numerical quotas and work standards
12. remove the barriers that discourage employees from doing their jobs
13. institute an ongoing program of education for all employees
14. create a structure in top management that will vigorously advocate the first 13 points

# 1. Focus on products/services improvement

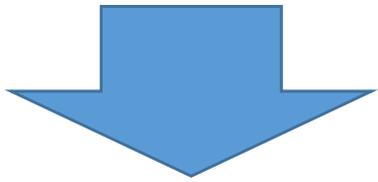
- The organization benefits if you focus on **long-term strategies**:
  - short-term thinking and quarterly business results are not sufficient



- Management should **constantly try to improve** product design and performance
- Invest in **research, development, and innovation**
  - long-term payback to the organization

## 2. Recognizes different economic eras

- The **cost of scrap, rework, and other losses** created by defects is an enormous drain on company resources

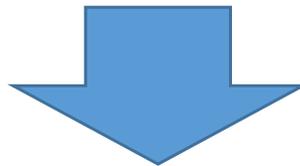


- Reject:
  - poor workmanship
  - defective products
  - bad service, etc...



### 3. Avoid mass inspection quality control

- All inspection usually find out **defects *a posteriori***
  - at that point it is too late
  - the organization has already has paid to produce those defective products
- Inspection typically occurs too late in the process
  - expensive
  - often ineffective



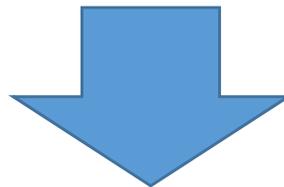
- Quality results from **prevention** of defectives through process

## 4. Consider suppliers quality approach

- The supplier's product price should consider the actual product quality
  - if quality is considered, the lowest bidder frequently is not the low-cost supplier
  - suppliers should be preferred when they:
    - use modern quality improvement methods
    - demonstrate process control and capability



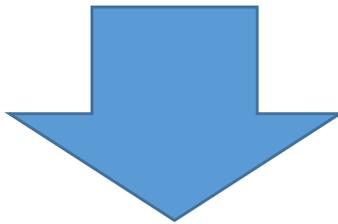
- An antagonistic relationship with suppliers is detrimental



- Build effective, **long-term relationships with suppliers**

# 5. Continuous improvement

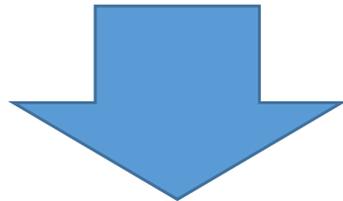
- Constantly try to **improve**:
  - **production**
  - **service system**



- Involve the workforce in these activities
- Make use of science-based methods:
  - statistically based problem-solving tools discussed in this course

## 6. Invest in on-the-job training for employees

- Everyone should be trained in:
  - technical aspects of their job
  - modern methods to improve quality and productivity



- Encourage all employees to practice these methods every day
  - many organizations devote little or no effort to training

## 7. Improve leadership and practice modern supervision

- Supervision should is not merely passive surveillance of workers
- Focus on helping the employees to improve the system in which they work



- Goal of supervision: to **improve the work system and the product**

## 8. Drive out fear

- The economic loss associated with fear is large
  - management can eliminate fear
- Workers should be oriented to be proactive and:
  - ask questions
  - report problems
  - point out barriers to quality and effective production



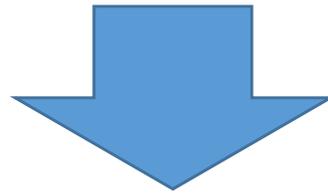
## 9. No barriers between business functional areas

- **Teamwork** among different organizational units and **multi-disciplinary approach** is essential for effective quality and productivity improvement to take place



## 10. Eliminate targets, slogans, and numerical goals for the workforce

- A “zero-defects” target is useless without a **plan** for the achievement of this aim
- Slogans and programs are usually counterproductive



- Work, improve the system and provide information on that



# 11. Eliminate numerical quotas and work standards

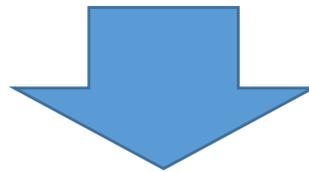
- These standards have historically been set without regard to quality
- Work standards are often symptoms of management's inability:
  - to understand the work process
  - to provide an effective management system focused on improving this process



# 12. Remove the barriers that discourage employees from doing their jobs

## ■ The **workforce**:

- knows the most about their job, the plant, the process, etc...
- usually has valuable ideas about how to make the process work more efficiently
- is an important participant in the business



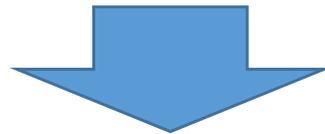
## ■ Management must listen to employees:

- suggestions
- comments
- complaints, etc...



# 13. Program of education for all employees

- Mandatory (in-simple) **education** of statistical techniques for all employees
  - use of the basic SPC problem-solving tools
  - if employees understand their use, they will:
    - look for the causes of poor quality
    - identify process improvements



- Education makes everyone partners in the quality improvement process

# 14. Top management should push on this philosophy

- The very top of the organization must:
  - drive the continuous improvement education and implementation
  - promote the to achievement of improved business results
  - inform everyone that continuous improvement is a common goal

**STRONG EMPHASIS ON ORGANIZATIONAL CHANGE!**



# Deming's 7 deadly management diseases

1. Lack of constancy of purpose
  - Continuous improvement gives assurance to all stakeholders in the enterprise that dividends will continue to grow
2. Emphasis on short-term profits
  - too much emphasis on short-term profits might make the “numbers” look good, but reducing research and development investment, eliminating employees’ training, and not deploying quality improvement activities
3. Evaluation of performance, merit rating, and annual reviews of performance
  - performance evaluation encourage short-term performance, rivalries and fear, and discourage effective teamwork
4. Mobility of top management
  - job hopping determine that a manager spends very little time in the business function and this results in key decisions being made by someone who really does not understand the business
5. Running a company on visible figures alone
  - management by visible figures alone (e.g., number of defects, customer complaints, and quarterly profits) suggests that the really important factors are unknown and unknowable
6. Excessive medical costs
7. Excessive legal damage awards

# Obstacles to success

1. The belief that automation, computers, and new machinery will solve problems
2. Trying to copy existing solutions
3. The “our problems are different” excuse
  - the principles that will solve them are universal
4. Obsolete (business) schools, where graduates have not been taught how to successfully run businesses
5. Poor teaching of statistical methods in industry
6. Reliance on inspection to produce quality
7. Reliance on the “quality control department” to take care of all quality problems
8. Blaming the workforce for problems
9. False starts
  - example: broad teaching of statistical methods without a plan as to how to use them, quality circles, employee suggestion systems
10. The fallacy of zero defects
  - companies fail even though they produce products and services without defects
11. Inadequate testing of prototypes
  - a prototype may be a one-off article, with artificially good dimensions, but without knowledge of **variability**, testing a prototype tells very little
12. “Anyone that comes to help us must understand all about our business.”
  - competent people who know everything about the business may not have any idea on how to improve it
  - new knowledge and ideas must be fused with existing business expertise to bring about change

# Models for quality improvement

- Shewhart cycle
- Juran trilogy
- Total quality control
- Total quality management
- Quality systems and standards
- Malcolm Baldrige National Quality Award
- Six-sigma program
  - DMAIC approach
  - lean manufacturing
- Just-In-Time approach
- Poka-Yoke approach

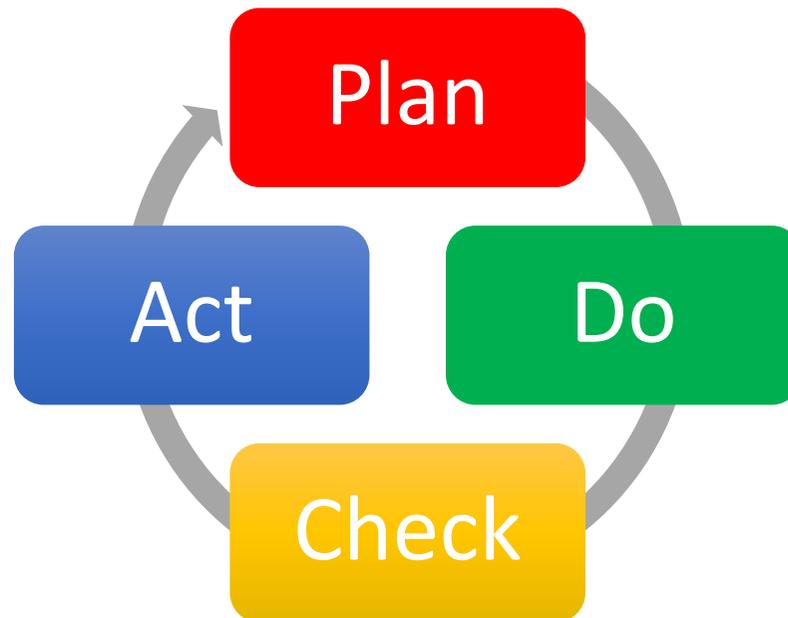
These pioneering approaches stress that:

- quality is an essential **competitive weapon**
- **management** must play a central role in implementing quality improvement
- **statistical methods and techniques** are powerful tools for quality improvement

# Shewhart cycle

## ■ Plan-Do-Check-Act (PDCA) cycle

- a.k.a. PDSA, where S = “study”
- iterative, may require several iterations to solve complex problems
- **Plan**: propose a change aimed at improvement
- **Do**: implement the change, possibly in a pilot scale
- **Check**: analyze the outcomes of the change
- **Act**: adopt the change, if effective; abandon it, if unsuccessful



# Juran trilogy

## ■ Planning:

- identify external customers and determine their needs
- products or services that meet the customer requirements are designed
- the processes for producing these products or services are developed
- performed on a regular basis

## ■ Control:

- employed by the operating forces to ensure that the product/service meets the requirements
- SPC is one of the primary tools of control

## ■ Improvement:

- aims to achieve higher and higher performance and quality levels
- must be on a project-by-project basis
- improvement can either be continuous (i.e., incremental) or by breakthrough:
  - breakthrough improvement is the result of:
    - studying the process
    - identifying a set of changes that result in a large and rapid improvement in performance
  - Designed experiments are an important tool that can be used to achieve breakthrough

# Total quality control

- Company-wide total quality control is concerned with **organizational structure** and a **systems approach** to improving quality
- Feigenbaum proposed a 3-step approach to improving quality:
  - **quality leadership**
  - **quality technology**
    - statistical methods and other technical and engineering methods
  - **organizational commitment**
- Key points of this methodology:
  - it is suggested that much of the technical capability be concentrated in a specialized department
    - this is in contrast to the more modern view that knowledge and use of statistical tools need to be widespread
  - the organizational aspects are important
  - it requires a lot of management commitment to make it work

# Total quality management

- **Total quality management (TQM)** is an organization-wide strategy for implementing and managing quality improvement activities.
  - Deming and Juran philosophy is the focal point, with a broader spectrum of concepts and ideas:
    - participative organizations
    - work culture
    - customer focus
    - supplier quality improvement
    - integration of the quality system with business goals
  - typically, organizations adopting a TQM approach have:
    - **quality councils or high-level teams** that deal with strategic quality initiatives
    - workforce-level teams that focus on routine production or business activities
    - cross-functional teams that address specific quality improvement issues
- TQM has only had moderate success:
  - there is insufficient effort devoted to widespread utilization of the technical tools of variability reduction
  - lack of top-down high-level **management commitment and involvement**
  - inadequate use of statistical methods
  - general as opposed to specific business-results-oriented objectives
  - too much emphasis on widespread **training** as opposed to focused technical **education**
  - regarded it as just another “program” to improve quality:
    - **Zero Defects**
    - **Value Engineering**
    - **Quality is Free**
      - management worked on identifying the cost of non-quality, as the Quality is Free
      - identification of quality costs is very useful, but if associated to the idea about what to do to actually improve many types of complex industrial processes
    - when TQM is wrapped around an ineffective program such as this, disaster is often the result.

# Quality systems and standards

- The **International Standards Organization** (ISO founded in 1946 in Geneva, Switzerland), has developed a series of standards for quality systems.
  - the current version of the standard is known as the ISO 9000 series
    - generic standard, broadly applicable to any type of organization, and it is often used to demonstrate a supplier's ability to control its processes
- The three standards of **ISO 9000** are:
  - ISO 9000:2000 Quality Management System—Fundamentals and Vocabulary
  - ISO 9001:2000 Quality Management System—Requirements
  - ISO 9004:2000 Quality Management System—Guidelines for Performance Improvement
- ISO 9000 is also an American National Standards Institute and an ASQ standard

# ISO 9000

- The **ISO 9001:2000** standard has 8 clauses:
  1. Scope
  2. Normative References
  3. Definitions
  4. **Quality Management Systems**
  5. **Management Responsibility**
  6. **Resource Management**
  7. **Product (or Service) Realization**
- To become certified under the ISO standard a company must:
  - select a **registrar**
  - prepare for a **certification audit** by this registrar
- Preparing for the certification audit involves many activities
  - phase I audit checks the present quality management system against the standard
  - establishing teams to ensure that:
    - all components of the key clause are developed and implemented
    - training of personnel
    - developing applicable documentation
    - developing and installing all new components of the quality system that may be required
  - the certification audit takes place
  - if the company is certified, then periodic **surveillance audits** by the registrar continue (annual or 6-month schedule)

# Example of the ISO 9001:2000 requirements

## ISO 9001:2000 Requirements

### 4.0 Quality Management System

#### 4.1 General Requirements

The organization shall establish, document, implement, and maintain a quality management system and continually improve its effectiveness in accordance with the requirements of the international standard.

#### 4.2 Documentation Requirements

Quality management system documentation will include a quality policy and quality objectives; a quality manual; documented procedures; documents to ensure effective planning, operation, and control of processes; and records required by the international standard.

### 5.0 Management System

#### 5.1 Management Commitment

- a. Communication of meeting customer, statutory, and regulatory requirements
- b. Establishing a quality policy
- c. Establishing quality objectives
- d. Conducting management reviews
- e. Ensuring that resources are available

5.2 Top management shall ensure that customer requirements are determined and are met with the aim of enhancing customer satisfaction.

5.3 Management shall establish a quality policy.

5.4 Management shall ensure that quality objectives shall be established in the quality management system.

5.5 Management shall ensure that responsibilities and authorities are assigned and communicated.

5.6 Management shall review the quality management system at regular intervals.

### 6.0 Resource Management

6.1 The organization shall determine and provide needed resources.

6.2 Workers will be provided necessary education, training, skills, and experience.

6.3 The organization shall determine, provide, and maintain the infrastructure required for the operation of the organization.

6.4 The organization shall determine and manage the work environment for the operation of the organization.

### 7.0 Product or Service Realization

7.1 The organization shall plan and develop processes needed for product or service realization.

7.2 The organization shall determine requirements as specified by customers.

7.3 The organization shall plan and control the design and development for its products or services.

7.4 The organization shall ensure that purchased material or product conforms to specified purchase requirements.

7.5 The organization shall plan and carry out production and service under controlled conditions.

7.6 The organization shall determine the monitoring and measurements to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of products or services to determined requirements.

### 8.0 Measurement, Analysis, and Improvement

8.1 The organization shall plan and implement the monitoring, measurement, analysis, and improvement process for continual improvement and conformity to requirements.

8.2 The organization shall monitor information relating to customer perceptions.

8.3 The organization shall ensure that product that does not conform to requirements is identified and controlled to prevent its unintended use or delivery.

8.4 The organization shall determine, collect, and analyze data to demonstrate the suitability and effectiveness of the quality management system, including

- a. Customer satisfaction
- b. Conformance data
- c. Trend data
- d. Supplier data

8.5 The organization shall continually improve the effectiveness of the quality management system.

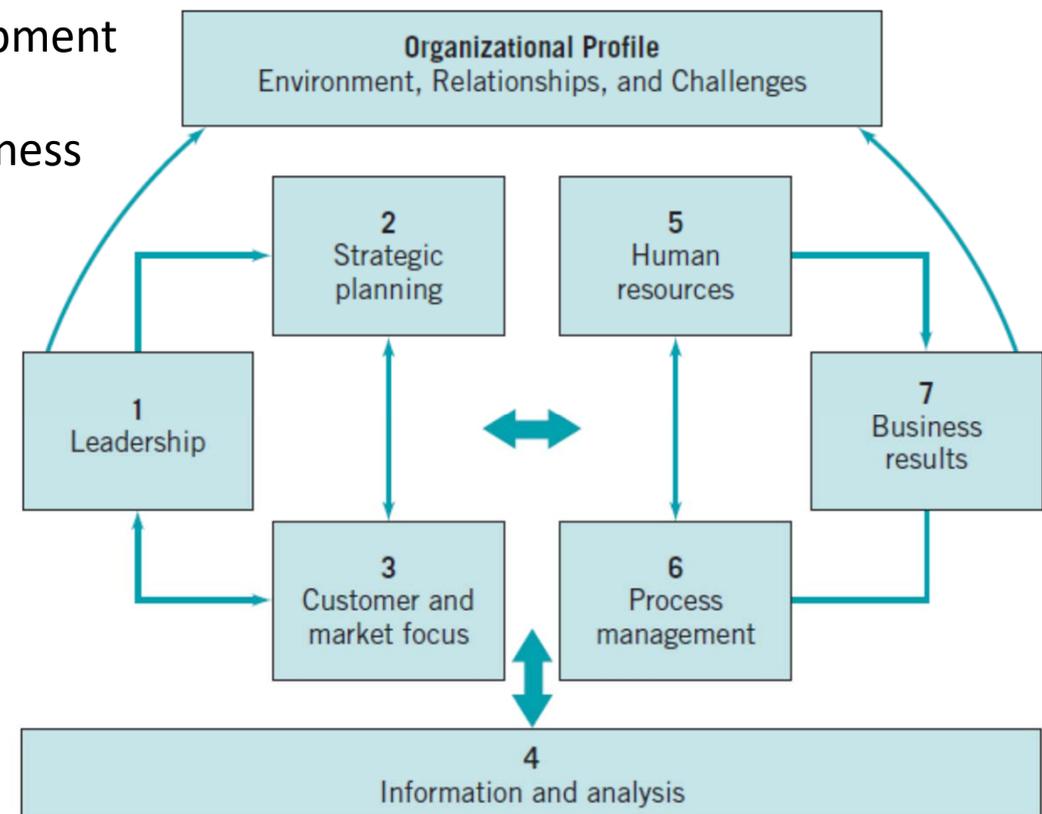
# Limits of ISO 9000

- Focus of ISO 9000 is on **formal documentation** of the quality system
  - **quality assurance** activities.
  - organizations usually must make extensive efforts to bring their documentation into line with the requirements of the standards
- Limits:
  - too much effort devoted to documentation, paperwork, and book-keeping
  - not enough effort to reducing variability and improving processes and products
  - many of the third-party registrars, auditors, and consultants that work in this area are not sufficiently educated or experienced enough in the **technical** tools required for **quality improvement**
    - often unaware of what constitutes modern engineering and statistical practice
    - they concentrate largely on the documentation, record keeping, and paperwork aspects of certification
  - ISO certification does little to prevent poor quality products from being:
    - designed
    - manufactured
    - delivered to the customer
  - it is a \$40 billion annual business worldwide:
    - this money flows to the registrars, auditors, and consultants
      - this amount does not include all of the internal costs incurred by organizations to achieve registration
    - there is no assurance that certification has any real impact on quality
    - many quality engineering authorities believe that ISO certification is largely a waste of effort
- Example: in 1999–2000 there were numerous incidents of rollover accidents involving Ford Explorer vehicles equipped with Bridgestone/Firestone tires
  - nearly 300 deaths in the United States alone attributed to these accidents
  - recall by Bridgestone/Firestone of approximately 6.5 million tires
  - many of the tires involved in these incidents were manufactured at the Bridgestone/Firestone plant in Decatur (Illinois, USA)
  - the Decatur plant was “QS 9000 Certified” and “ISO 14001 Certified” (environmental standard)

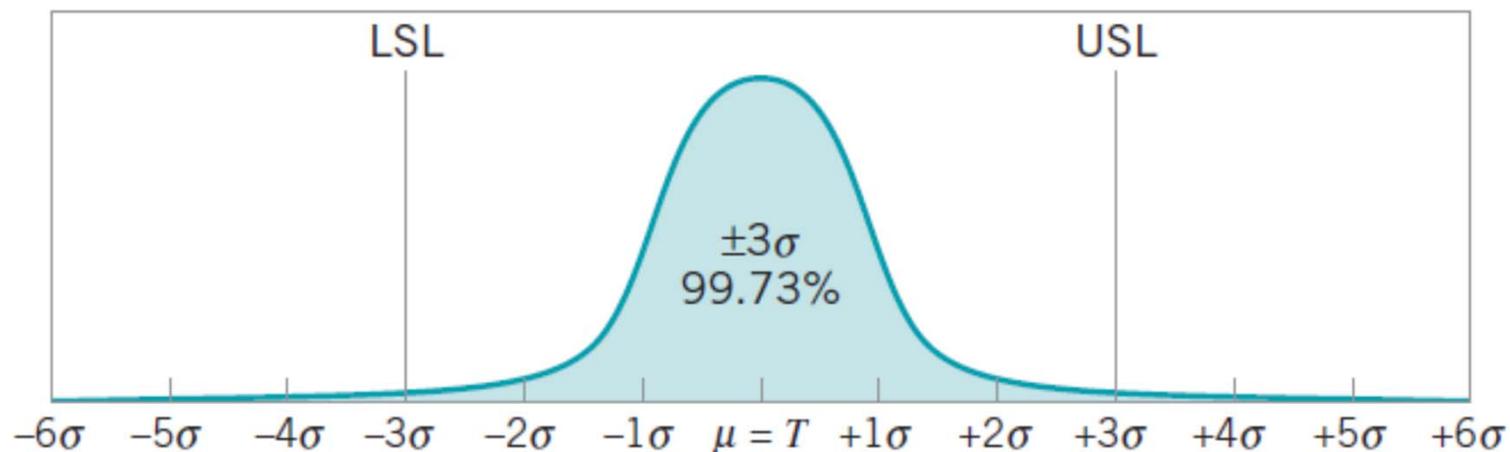


# Malcolm Baldrige National Quality Award

- Annually awarded to recognize U.S. organizations for performance excellence with non-prescriptive criteria
  - to organizations in five categories: manufacturing, service, small business, health care, and education
  - three awards may be given each year in each category
- The criteria are directed towards results in terms of:
  - customer satisfaction and retention
  - market share and new market development
  - product/service quality
  - productivity and operational effectiveness
  - human resources development
  - supplier performance
  - public/corporate citizenship



- The aim of quality control is **reducing variability** in key product quality features
- Example:
  - consider a **normal probability distribution as a model for a quality characteristic**
  - set the **specification limits** at three standard deviations on either side of the mean
    - the probability of producing a product within these specifications is 0.9973
      - 2700 parts per million defective
    - this is referred to as **three-sigma quality performance**



- Suppose to have a product that consists of an assembly of **100 independent components**
  - if all 100 of these components must be nondefective for the product to function satisfactorily with a probability of 0.9973, this means that:  
$$0.9973 \cdot 0.9973 \cdot \dots \cdot 0.9973 = (0.9973)^{100} = 0.7631$$
  - **23.69% of the products produced under three-sigma quality will be defective!**
- Is this acceptable?
  - a fast food service activity for a family of 4 persons involves the assembly of several dozen components
  - a typical automobile has about 100 000 components
  - an airplane has up to 2 000 000 components!



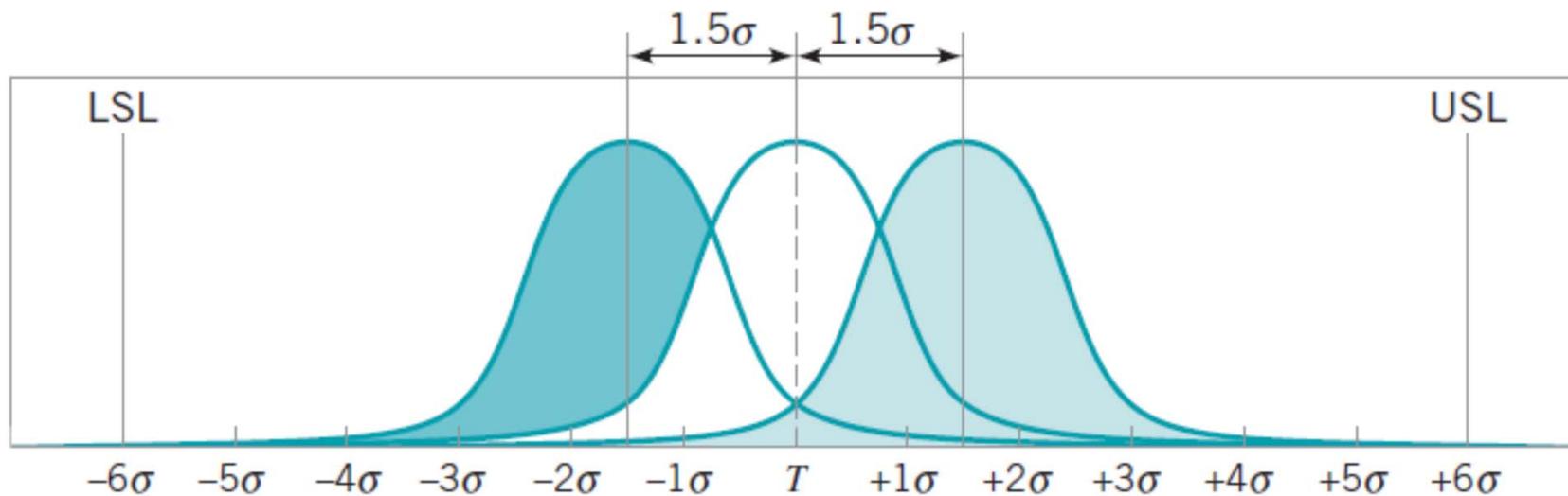
# Six-sigma program

- Products with many components typically have many opportunities for failure or defects to occur
  - Motorola developed the **Six-Sigma program** in the late 1980s  
Focus: reducing variability in key product quality features to **extremely low levels of failure and defects**
  - the specification limits are set at least six standard deviations from the mean
  - only about **2 parts/1 000 000 000 result to be defective**
  - under **six-sigma quality**
  - the probability that any specific unit of the hypothetical product above is non-defective is 0.9999998: much better!!!



# Repercussion of the Six-sigma program

- The six-sigma concept was developed under the assumption that the **process mean was still subject to disturbances that could cause it to shift by as much as 1.5 standard deviations off target**
  - a six-sigma process would produce about **3.4 ppm defective** under this scenario

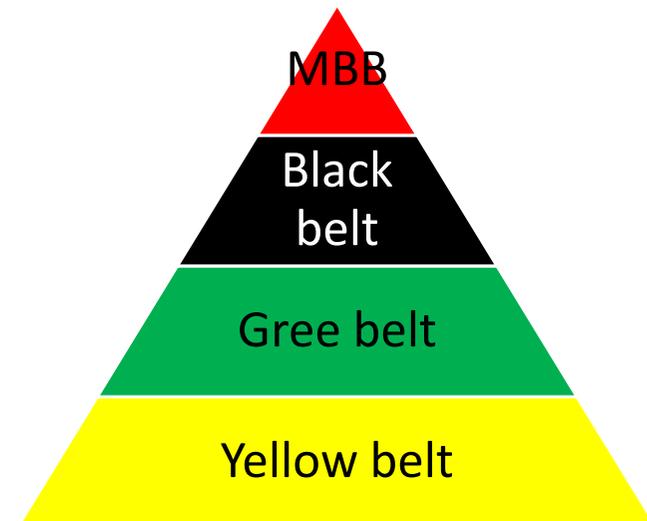


# Limit of the Six-sigma program

- The concept of a six-sigma process is one way to **model quality**
  - it has proven to be a useful way to think about process performance
    - Motorola reduced defectivity by ~1300% in 6 years!!!
  - it is not exactly right
- Process **performance** is not predictable unless the process **behavior** is **stable**
  - when the mean and standard deviation are **constant**
- Unfortunately, processes are usually not truly stable
  - disturbances occur
    - process mean shifts off-target
    - increase in the process standard deviation
    - both
- If the mean is drifting and deviates as much as 1.5 standard deviations off target, a prediction of 3.4 ppm defective may not be very reliable!

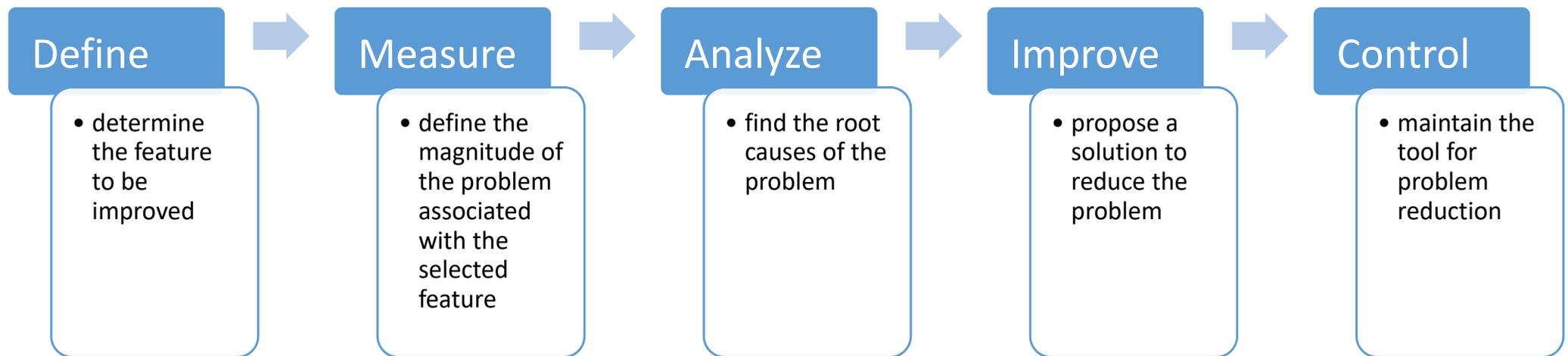
# Improving business performance through Six-sigma

- Nowadays Six-sigma program is a tool to improve **corporate business performance** by both:
  - improving quality
  - reducing costs
- Typical six-sigma projects are 4-6 months in duration are selected for their potential **impact in the business**
- Companies involved in a six-sigma program utilize **trained and specialized individuals** who are team leaders, facilitators, and problem solvers, and lead teams focused on projects that have both quality and business impact:
  - **Yellow belt**
    - aware of Six-sigma principles
  - **Green Belts**
    - use DMAIC and lean manufacturing principles
  - **Black Belts (BB)**
    - full time project leader
  - **Master Black Belts (MBB)**
    - advises on Six-Sigma (2-years experience BB)



# Six-sigma problem solving approach

- **DMAIC** is a 5-step problem solving approach applied in the Six-sigma program



- The DMAIC framework utilizes as basic tools:
  - control charts
  - design of experiments
  - process capability analysis
  - etc...

# Six-sigma and the junk food example...

- A meal served at the fast food with a 99%-good quality independent components:

- hamburger
  - bun
  - meat
  - cheese
  - lettuce
  - onion
  - tomato
  - pickle
  - sauce
- fries
- soda



$$P(\text{single meal is good}) = 0.99^{10} = 0.9044$$

acceptable

- A family of 4 persons @ the fast food

$$P(\text{family meal is good}) = 0.9044^4 = 0.6690$$

not good

- A family of 4 persons @ the fast food once a month (if their heart can stand...)

$$P(\text{single meal is good}) = 0.6690^{12} = 0.0080$$

unacceptable

# Six-sigma generations

- **Generation I** focused on:
  - defect elimination
  - basic variability reduction
- **Generation II** focused on:
  - variability and defect reduction
  - improved business performance through cost reduction
- **Generation III** focused on:
  - creating value throughout the organization and for its stakeholders (owners, employees, customers, suppliers, and society)
    - increasing stock prices and dividends
    - job retention or expansion
    - expanding markets for company products/services
    - developing new products/ services that reach new and broader markets
    - increasing the levels of customer satisfaction

# Examples of Six-sigma tools and applications

- SIX-sigma reduces variability, eliminates defects, and improves business performance in several activities:
  - meeting delivery schedule and accuracy
  - eliminating rework in preparing financial documents
  - proportion of visitors make a purchase through an e-commerce Website
  - minimizing cycle time
  - reducing customer waiting time in service system
  - optimizing payment
  - minimizing lost sales in supply chain management
  - minimizing costs of public accountants, legal services and consultants
  - improving forecasting accuracy and timing
  - improving audit processes
  - closing financial books, improving accuracy of journal entry and posting
  - reducing variability in cash flow
  - improving payroll accuracy
  - improving purchase order accuracy and reducing rework of purchase orders
- A couple of approaches that are typically utilized to these purposes are:
  - **Design For Six-Sigma (DGFSS)**
  - **lean systems**

# Design For Six-Sigma

- Overall business improvement cannot be achieved by focusing on reducing variability in manufacturing alone (**operational six-sigma**)
- **Design for six-sigma** DFSS is an approach for taking the six-sigma philosophy upstream from manufacturing into the technologies for **process/service/product design and development** and its efficient commercialization
  - DFSS is focused on:
    - increasing the sales revenue generated from new products and services
    - finding new applications or opportunities for existing ones
    - in many cases, an important gain is the reduction of development lead time; i.e.:
      - the cycle time to commercialize new technology
      - get the resulting new products to market
  - DFSS makes specific the recognition that every design decision is a **business decision**
    - the cost, manufacturability, and performance of the product are determined during design
    - once a product is designed and released to manufacturing, it is almost impossible to make it better
  - DFSS spans the entire development process from the identification of customer needs to the final launch of the new product/service
    - customer input is obtained through **voice of the customer (VOC)** activities:
      - VOC data are usually obtained by interviews, surveys, interaction, observation of the customer
      - customer needs identification
      - setting priorities based on actual customer requirements
      - determining if it is feasible to meet those needs at a competitive price
    - DFSS is required to focus on customer requirements while simultaneously considering **process capability**
      - matching the capability of the production system and the requirements at each stage of the design process is essential
      - if mismatches between process capability and design requirements are found, resolve the conflicts changing either design or production
- Many of the tools that are used in operational six-sigma are also used in DFSS (e.g., DMAIC)

# Lean systems

- **Lean systems** are designed to **eliminate waste**, where waste means:
  - unnecessarily long cycle times
  - waiting times between value-added work activities
  - rework
  - scrap } often the result of excess variability
- An important metric in lean is the **process cycle efficiency** (PCE), a direct measure of how efficiently the process is converting the work that is in-process into completed products or services:

$$PCE = \frac{\text{value - add time}}{PCT}$$

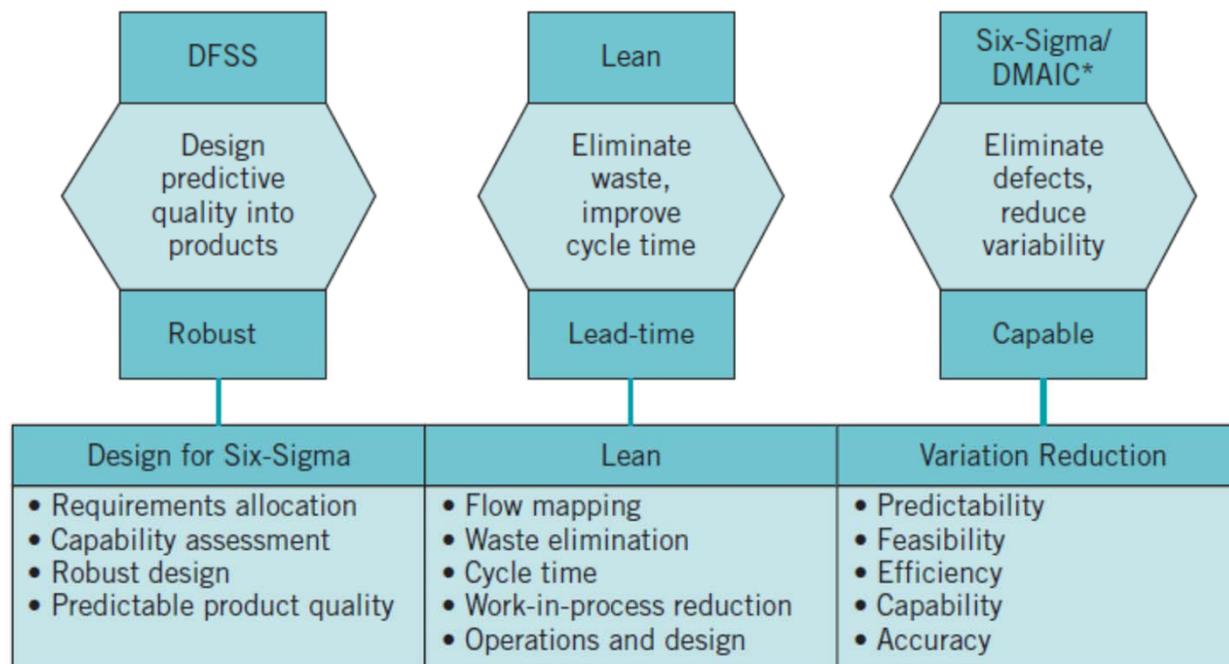
- **value-add time**: amount of time actually spent in the process that transforms the form, fit, or function of the product or service that results in something for which the customer is willing to pay.
- **process cycle time** PCT is related to the amount of work that is in-process through **Little's Law**:

$$PCT = \frac{\text{work - in - process}}{\text{average completion time}}$$

- **average completion rate**: output of a process over a defined time period (i.e., a measure of capacity).
- Lean makes use of many tools of industrial engineering and operations research:
  - **discrete-event simulation**: a computer model of the system is built and used to quantify the impact of changes to the system that improve its performance

# Conclusions on models for quality improvement

- Six-sigma/DMAIC, DFSS, and lean tools:
  - can be used simultaneously and harmoniously in an organization to achieve:
    - high levels of process performance
    - significant business improvement
  - have been successful methodologies
    - management commitment was obtained thanks to:
      - the project-by-project approach
      - the focus on bottom-line business results
    - statistical methods were deployed into the right places in the organization



# Quality and productivity

- Producing high-quality products in the modern industrial environment is not easy
  - rapid evolution of technology
    - when the new technologies are used quickly to exploit competitive advantages, the problems of designing and manufacturing products of superior quality are greatly complicated
  - many new products and services
  - explosion of technology in diverse fields
    - electronics
    - metallurgy
    - ceramics
    - composite materials
    - biotechnology
    - chemical and pharmaceutical sciences, which has resulted in many new products and services
- Too little attention to achieving an optimal process:
  - economy
  - efficiency
  - productivity
  - quality
    - quality improvement is instrumental in:
      - increasing productivity
      - reducing cost

# Quality and productivity

## Vaccines production: an example

### ■ Vaccines production:

- 1000 vials of a vaccine produced per day
  - cost 112€/vial
- 68% are in spec
- 59% can be reworked
  - extra-cost 37€/vial

$$\frac{\text{cost}}{\text{in-spec product}} = \frac{112\text{€}(1000) + 37\text{€}(1-0.68) \cdot 0.59 \cdot 1000}{1000 - (1-0.68)(1-0.59)1000} = 136.954\text{€}$$

### ■ After implementing effective systems for quality control:

- 81% are in spec
- 65% can be reworked

$$\frac{\text{cost}}{\text{in-spec product}} = \frac{112\text{€}(1000) + 37\text{€}(1-0.81) \cdot 0.65 \cdot 1000}{1000 - (1-0.81)(1-0.65)1000} = 124.8736\text{€}$$

### ■ Total saving: 9.12%

# Quality costs

- Financial controls are an important part of business management
  - financial controls involve:
    - comparison of actual and budgeted costs,
    - analysis and action on the differences between actual and budget
- **Quality costs** have emerged as a financial control tool for management
  - quality costs are associated with producing, identifying, avoiding, or repairing products that do not meet requirements
- Many organizations now formally evaluate the cost associated with quality, because of:
  - the **increase in the cost of quality** because of the increase in the complexity of manufactured products due to advances in technology
  - the **awareness of life-cycle costs** (maintenance, spare parts, field failures, etc...)
  - quality engineers and managers effectively communicate quality issues in a way that management understands
- Categories of quality costs:
  - **prevention costs**
  - **appraisal costs**
  - **internal failure costs**
  - **external failure costs**

# Prevention costs

- Costs associated with **efforts in design and manufacturing** that are directed toward the **prevention of nonconformance**:
  - **quality planning and engineering**
    - creation of the overall quality plan
    - inspection plan
    - reliability plan
    - data system
    - activities of the quality-assurance function (manuals, procedures, auditing the system, etc...)
  - **new products review**: quality activities during the development and preproduction stages of new products or designs
    - bid proposals
    - new designs
    - tests to evaluate the performance of new products
  - **product/process design**:
    - design of the product
    - selection of the production processes
  - **process control**: costs to reduce variation and build quality into the product
    - automatic process-control techniques
    - control charts
    - monitoring system of the manufacturing process
  - **burn-in**
    - pre-shipment operation of the product to prevent early-life failures in the field
  - **training**
    - developing, preparing, implementing, operating, and maintaining formal training programs
  - **quality data acquisition and analysis**
    - cost of running the quality data system to acquire data on product and process performance
    - analyzing data to identify problems
    - summarizing and publishing quality information for management

# Appraisal costs

- Costs associated with measuring, evaluating, or auditing products, components, and purchased materials to ensure conformance to the imposed standards
  - **inspection and test of incoming material**
    - inspection and testing of all material
    - receiving inspection and test
    - inspection, test, and evaluation at the vendor's facility
    - periodic audit of the quality-assurance system
  - **product inspection and test**
    - checking the conformance of the product throughout its various stages
    - final acceptance testing
    - packing and shipping checks
    - test in the customer's facilities prior to turning the product over to the customer
    - life testing
    - environmental testing
    - reliability testing
  - **materials and services consumed**
    - material and products consumed in a destructive test/devalued by reliability tests
  - **maintaining accuracy of test equipment**
    - calibration of measuring instruments and equipment

# Internal failure costs

- Internal failure costs are incurred when products, components, materials, and services fail to meet quality requirements, and this failure is discovered prior to delivery of the product to the customer
  - **scrap**
    - loss of labor, material, and overhead of defective product that cannot economically be repaired
  - **rework**
    - corrections of nonconforming units
  - **retest**
    - re-inspection and retesting of products that have undergone rework
  - **failure analysis**
    - cost incurred to determine the causes of product failures
  - **downtime**
    - production line stops because nonconforming supplied raw materials went undiscovered
  - **yield losses**
    - process yields that are lower than might be attainable by improved controls
  - **downgrading**
    - difference between the normal selling price and the selling price of a product that does not meet the customer's requirements (typical of textile, apparel goods, and electronics industries)

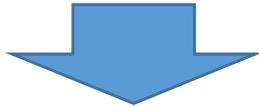
# External failure costs

- Costs of the product does not perform satisfactorily after it is delivered to the customer
  - **complaint adjustment**
    - investigation and adjustment of justified complaints
  - **returned product/material**
    - receipt, handling, and replacement of the nonconforming returned products
  - **warranty charges**
    - service to customers under warranty contracts
  - **liability costs**
    - product liability litigation costs
  - **indirect costs**
    - customer dissatisfaction with the quality level
    - bad customer's attitude toward the company
      - loss of business reputation
      - loss of future business
      - loss of market share

# Analysis and use of the quality costs

- The usefulness of quality costs stems from the **leverage effect**:
  - investments in **prevention and appraisal** have a payoff in reducing expenses in internal and external failures
  - quality costs are:
    - opportunities for improvement rather than scorekeeping tools, but
    - management control tools rather than part of the accounting system
    - tools for avoiding to underestimating the commitment to prevention
- The aim of quality-cost analysis is cost reduction through identification of improvement opportunities
  - this is often done with a **Pareto analysis**
    - identifying quality costs by category (often very difficult)
- Usual method of **reporting quality costs**: ratio (quality-cost/measure of the following activities):
  - hours of direct production labor
  - cost of direct production labor
  - processing costs
  - manufacturing cost
  - sales
  - units of product
- The quality cost figures are often compared with:
  - standards (difficult to be obtained)
  - past performance
- The analysis of quality costs in conjunction with a focused effort on variability reduction has the capability of reducing quality costs by 50% or 60% (if no organized effort has previously existed)
  - however, it is unrealistic to expect it can be reduced to zero
    - in proximity of the zero-quality costs the incremental costs of prevention and appraisal will rise more rapidly than the resulting cost reductions

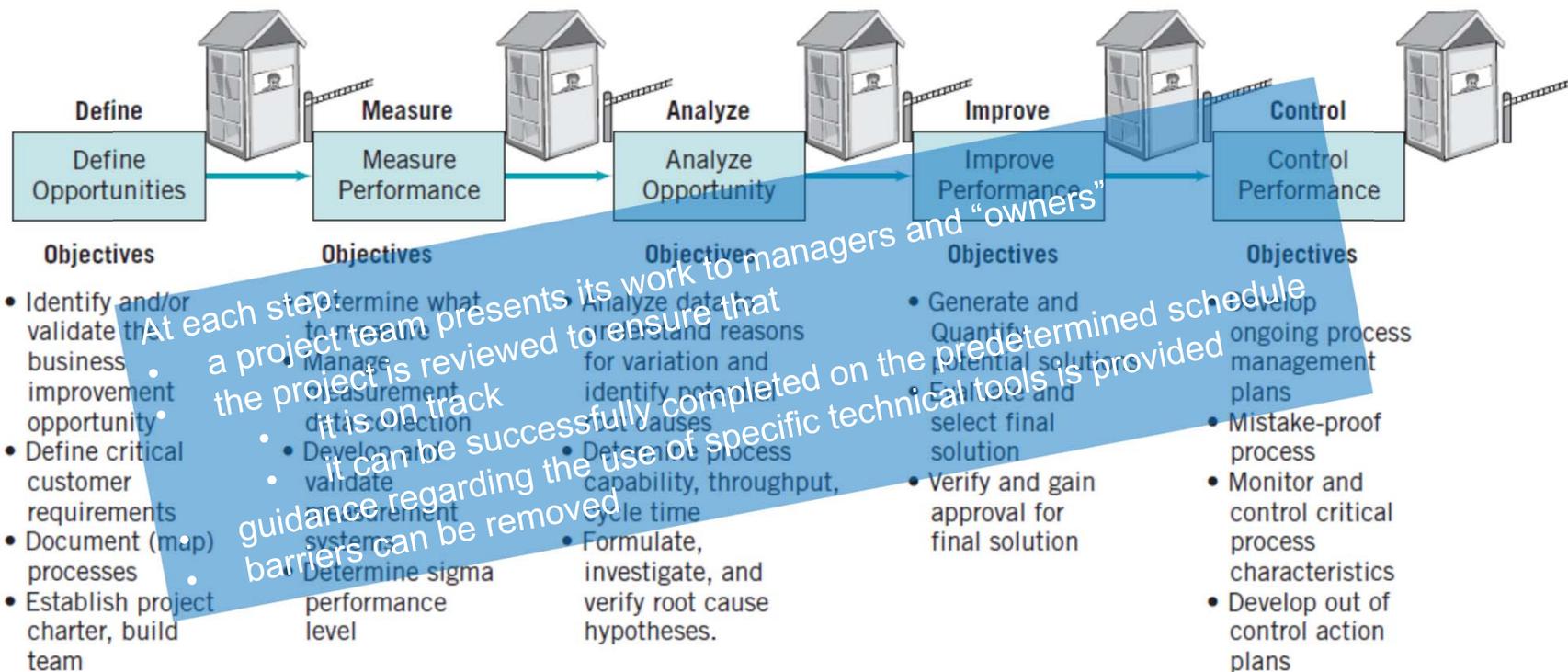
# Legal aspects of quality

- **Liability exposure** of the manufacturer is a major social, market, and economic force:
    - increasing **production volumes**
      - consumerism
      - if the production volume increases more rapidly than the decrease in failure rate, the number of customers who experience failures increases
    - **consumer tolerance** for minor defects and aesthetic problems has decreased considerably
    - **early releases:**
      - the competitiveness of the marketplace forces many manufacturers to introduce new designs before they are fully evaluated and tested
  - **Strict liability**
    - strong responsibility for both manufacturer and merchandiser, also for the ultimate use of that product, not only for its performance
      - **immediate responsiveness to unsatisfactory quality** through product service, repair, replacement of defective product
      - **advertising and promotion** of the product
        - all advertising statements must be supportable by valid company quality or certifications
- 
- Strong **pressure** on manufacturers, distributors, and merchants to develop and maintain a high degree of evidence on the performance and the safety of their products (strong quality-assurance program is needed)
    - quality of the product
    - durability
    - reliability
    - protection from side effects or environmental hazards
    - safety
  - **Regulatory agencies:**
    - law and guidelines

Some details on DMAIC

# DMAIC

- DMAIC is a structured problem-solving procedure widely used in **quality and process improvement**:
  - almost all implementations of Six-sigma use it for **project management and completion**
  - not necessarily formally tied to six-sigma
    - can be used regardless of an organization's use of six-sigma
  - **very general procedure**:
    - applications in lean projects:
      - cycle time reduction
      - throughput improvement
      - waste elimination



- DMAIC is:
  - successful
    - effective use of a relatively small set of tools
  - organized in projects
    - projects should represent a potential **breakthrough** for major improvements in the product or service
    - impact evaluated in terms of financial benefit to the business
      - objective project evaluations.
  - **financial systems integration** is standard practice
- The **value opportunity** of projects must be clearly identified
  - projects must be well aligned with corporate business objectives at all levels
  - the best projects should be considered



- At the **highest (corporate) level** the stockholders, top executives, members of the board of directors, and business analysts who guide investors typically are interested in :
  - return on equity,
  - return on invested capital
  - stock price
  - dividends
  - earnings
  - growth in operating income
  - sales growth
  - generation of new designs, products and patents
  - development of future business leaders
  
- At the business unit or operations level managers and executives are interested in **factory metrics**:
  - yield
  - cycle time and throughput
  - profit and loss optimization
  - customer satisfaction
  - delivery and due-date performance
  - cost reduction
  - safety
  - efficient use of assets
  - new product introduction
  - marketing effectiveness
  - development of people
  - supply chain performance (cost, quality, service)

# Projects selection

- **Project selection** is probably the most important part of the improvement process
  - to be completed within a **reasonable time frame**
  - real impact on key **business metrics**
  - a lot of thought must go into:
    - defining the organization's **key business processes**
    - understanding their interrelationships
    - developing appropriate **performance measures**
- Typical types of projects:
  - **initial projects:** demonstrate the potential success of an overall improvement effort
    - focus on the areas that are full of opportunities
    - driven by current problems
      - issues that are identified by customers
      - no long-term success
  - projects based on **strategic business objectives:**
    - define the key set of critical business processes and the metrics that drive them
    - integrated view of the business
    - identify interfaces among critical business processes
    - risk: projects may be very large, but focusing on narrow aspect of the business
      - reduced organization's overall exposure to the improvement process
      - delayed impact
  - **successful projects:**
    - formal project selection committees
    - regular meetings between customers and the project selection committees to meet the goals
      - projects are strategic and well aligned with corporate metrics
      - some companies use a **dashboard** system to track trends and results

# Numerical evaluation of a project

- Suppose you are operating on a  $4\sigma$  level
  - assuming a 1.5 shift on the mean is allowed this corresponds to 6210 ppm defective
- Objective: achieving the  $6\sigma$  performance (3.4 ppm defective)
- Assuming a criterion of 25% annual improvement in quality, how many years are needed to achieve the goal?

$$3.4 = 6210(1 - 0.25)^x$$

How could it be calculated?

- the number of years to achieve the goal is  $x=26$  years
  - too much...
- if 50% annual improvement is guaranteed the number of years to achieve the goal decreases to 11 years
  - acceptable time horizon
- if 75% annual improvement is guaranteed the number of years to achieve the goal decreases to 5.5 years
  - is it feasible to obtain 75% annual improvement?
  - from the practical point of view, many companies obtained up to 65% annual improvements

# Matlab® solution

- Probability of -4 on a normal probability density function shifted by -1.5 and with standard deviation 1:
  - `normcdf(-4,-1.5,1)`
    - 0.0062
- Probability of -6 on a normal probability density function shifted by -1.5 and with standard deviation 1:
  - `normcdf(-6,-1.5,1)`
    - 3.3977e-6
- Finding the root of a non-linear function in Matlab®
  - `x0=960;`  
`fzero(@(x)(1000*normcdf(-4,-1.5,1)*(1-0.25)^x-1000*normcdf(-6,-1.5,1)),x0)`
    - where x0=960 is the initial guess

# 1. Define step: process charter

- Objectives:
  - identify the project opportunity
  - verify/validate that it represents legitimate breakthrough potential
  - importance for customers and business
- First stage: complete **project charter** (2/4 days):
  - short document (2 pages) with:
    - project description and scope
    - start and completion dates
    - identify the critical-to-quality features of the product/process/service
    - metrics for the success evaluation
    - alignment with corporate goals
    - potential financial benefits
    - milestones
    - team members and leaders
    - required resources

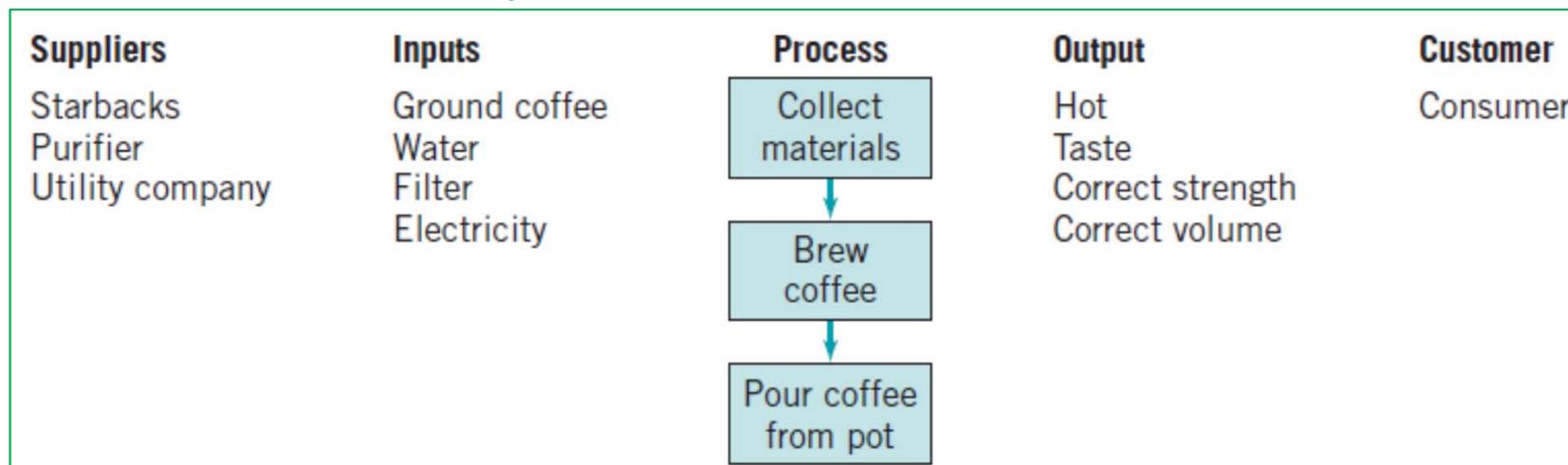
## example

<b>Business Case</b> <ul style="list-style-type: none"><li>• This project supports the business quality goals, namely a) reduce customer resolution cycle time by x% and b) improve customer satisfaction by y%.</li></ul>	<b>Opportunity Statement</b> <ul style="list-style-type: none"><li>• An opportunity exists to close the gap between our customer expectations and our actual performance by reducing the cycle time of the customer return process.</li></ul>																					
<b>Goal Statement</b> <ul style="list-style-type: none"><li>• Reduce the overall response cycle time for returned product from our customers by x% year to year.</li></ul>	<b>Project Scope</b> <ul style="list-style-type: none"><li>• Overall response cycle time is measured from the receipt of a product return to the time that either the customer has the product replaced or the customer is reimbursed.</li></ul>																					
<b>Project Plan</b> <table><tr><td>• Activity</td><td>Start</td><td>End</td></tr><tr><td>Define</td><td>6/04</td><td>6/30</td></tr><tr><td>Measure</td><td>6/18</td><td>7/30</td></tr><tr><td>Analyze</td><td>7/15</td><td>8/30</td></tr><tr><td>Improve</td><td>8/15</td><td>9/30</td></tr><tr><td>Control</td><td>9/15</td><td>10/30</td></tr><tr><td>Track Benefits</td><td>11/01</td><td></td></tr></table>	• Activity	Start	End	Define	6/04	6/30	Measure	6/18	7/30	Analyze	7/15	8/30	Improve	8/15	9/30	Control	9/15	10/30	Track Benefits	11/01		<b>Team</b> <ul style="list-style-type: none"><li>• Team Sponsor</li><li>• Team Leader</li><li>• Team Members</li></ul>
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# 1. Define step: SIPOC diagram

- **SIPOC diagram:** flow chart/value stream map which provides visual detail and facilitate understanding about what needs to be changed in a process:
  - simple overview of the process
  - visualizes basic process information
- SIPOC:
  1. **Suppliers:** those who provide the information, material, or other items for the process
  2. **Input:** information or material provided
  3. **Process:** steps required to accomplish the work
  4. **Output:** product, service, or information sent to the customer
  5. **Customer:** external customer or the next step in the internal business

## example: reduce defects in coffee service



# 1. Define step: action plan and review

- **Action plan:** plan for moving forward:
  - individual work assignments
  - tentative completion dates
  - anticipate the initial ideas on the measure steps
- Define step **review:**
  1. does problem statement focus on symptoms or on causes/solutions?
  2. are all the key stakeholders identified?
  3. what evidence is there to confirm the value opportunity represented by this project?
  4. has the scope of the project been verified (too small, too large)?
  5. has a SIPOC diagram (or other process maps) been completed?
  6. have any barriers to successful completion been ignored?
  7. is the team's action plan for the measure step reasonable?

## 2. Measure step: data collection

- Objective: to **evaluate and understand the current state of the process** through data collection (measures of quality, cost, throughput/cycle time, etc...)
- **Data collation** steps:
  1. develop a list of all of variables (may have been identified at least tentatively during the define step):
    - **key process input variables** (KPIV)
    - **key process output variables** (KPOV)
    - important factors:
      - time spent to perform various work activities
      - time that work spends waiting for additional processing
  2. decide what and how much data to collect:
    - sufficient data to allow for a thorough analysis and understanding of current process performance
    - examine historical records
    - collect data through an observational study
    - it may be necessary to develop appropriate measurement system for recording some specific information
  3. use collected data as the basis for determining the **baseline performance** of the process
  4. evaluate the **capability** of the measurement system (formal gauge capability study: *gauge repeatability and reproducibility, R&R*)
  5. additional activities:
    - divide the process cycle time into value-added and non-value added activities
    - calculate estimates of process cycle efficiency and process cycle time
    - displayed collected data:
      - histograms
      - stem-and-leaf diagrams
      - run charts
      - scatted diagrams
      - Pareto charts

## 2. Measure step: conclusion and review

### ▪ Update the project charter:

- re-examine the project goals and scope
- re-evaluate team makeup
- issues or concerns that may impact project success need to be documented and shared with the owner and sponsor
- make quick, immediate recommendations for improvement

### ▪ Measure step review:

1. comprehensive **process flow chart or value stream map** with identification of:
  - major process steps and activities
  - suppliers and customers
  - areas where queues and work-in-process accumulate
    - queue lengths
    - waiting times
    - work-in-process levels
2. list of **KPIVs and KPOVs**
  - how the KPOVs are related to customer satisfaction and CTQ features
3. **measurement systems capability**
4. assumptions that were made during data collection
5. full understanding on:
  - where that data came from
  - rationale for data collection
  - validity of the measurement systems
  - abundance and redundancy of the data

# 3. Analyze step

## ■ Objective:

- to determine the **cause-and-effect relationships** in the process and the **potential causes** of:
  - defects
  - quality problems
  - customer issues
  - cycle time and throughput problems
  - waste
  - inefficiency
- to understand the different **sources of variability**
  - **common causes**
    - sources of variability that are embedded in the system or process itself
    - removing a common cause of variability usually means changing the process
  - **assignable causes**
    - usually arise from an external source
    - removing an assignable cause usually eliminates the specific problem

# 3. Analyze step: methodologies

- The analyze tools are used with data collected in the measure step
  - to providing clues about potential **causes of the problems** that the process is experiencing
  - to **explore and understand** the relationships between and among process variables
  - to develop **insight** about potential process improvements
  - to identify **opportunities and root causes** to be faced in the improve step
- Methodologies:
  - **Control charts**: to separate common cause variability from assignable cause variability
  - Statistical **hypothesis testing**:
    - to determine if different conditions of operation produce statistically significantly different results
    - to provide information about the accuracy with which parameters of interest have been estimated;
  - **Regression analysis**: to relate outcome variables of interest to independent input variables to be built
  - **Discrete-event computer simulation**: to simulates a process through a computer model
    - to study service and transactional businesses
    - to study scheduling problems in factories in such a way as to improve cycle time and throughput performance
  - **Failure modes and effects analysis (FMEA)**: to prioritize the different potential sources of variability, failures, errors, or defects in a product or process relative to three criteria
    - the likelihood that something will go wrong
    - the ability to detect a failure, defect or error
    - the severity of a failure, defect or error
    - the three scores for each potential source of variability, failure, error or defect are multiplied together to obtain a **risk priority number (RPN)**
      - sources of variability or failures with the highest RPNs are the focus for further process improvement or redesign efforts

# 3. Analyze step: review

- A team approach to consider:
  - to identify opportunities to be targeted for investigation in the improve step
  - to determine if the selected data and analysis methods confirm to effectively impact the desired outcome on the KPOVs and customer CTQs originally focused in the project
  - to find other new opportunities that are not going to be further evaluated
  - to verify if the project is still on track with respect to:
    - time
    - anticipated outcomes
  - to determine possible additional resources

# 4. Improve step

- Objectives:
  - to develop a **solution to the problem**
    - creative thinking about the specific **changes** that can be made in the process to obtain the desired impact on process performance
  - to **pilot test** the solution
    - pilot test are a form of **confirmation experiment** (through an iterative activity)
      - evaluates and documents the solution
      - confirms if the solution attains the project goals.
- Tools:
  - **redesigning the process** through flow charts and/or value stream maps
    - to improve work flow
    - to reduce bottlenecks and work-in-process
  - **mistake-proofing**: designing an operation so that it can be done only one way—the right way
  - designed experiments
    - applied either to actual physical processes or computer simulation models
    - used both for determining
      - which factors influence the outcome of a process
      - the optimal combination of factor settings
- Review:
  - adequate documentation of
    - how the problem solution was obtained
    - alternative solutions
  - complete results of the pilot test (data displays, analysis, experiments, and simulations)
  - plans to implement the pilot test results on a full-scale
    - dealing with any regulatory requirements, personnel concerns, or impact on other business standard practices.
  - analysis of risks of implementing the solution and appropriate risk-management plans

# 5. Control step

- Objectives:
  - to complete all remaining work on the project
  - to hand off the improved process to the process owner along with a **process control plan**
  - to ensure that the gains from the project will be institutionalized
  - to implement the solutions in other similar processes in the business
  - to inform the owner with
    - before and after data on key process metrics
    - operations and training documents
    - updated current process maps
- Methods:
  - **process control plan**: a system for monitoring the solution that has been implemented
    - methods and metrics for periodic auditing:
      - control charts
  - **transition plan**
    - validation check for several months after project completion
    - original results maintained in place and stable so that the
      - ability to respond rapidly to unanticipated failures
    - information on positive financial impact
- Review:
  - to show data illustrating before and after results to demonstrate to be in line with the project charter
  - to implement the process control plan and the monitoring system
  - to complete the information of the process owner
  - to make a summary of lessons learned from the project
  - to list the opportunities that were not pursued in the project to develop future projects
  - to list the opportunities to use the results of the project in other parts of the business

... per sempre a fianco a me!

