QUALITY MANAGEMENT SYSTEM

CONTENTS:

❖ Quality Management System & Certifications:

- ✓ Concept of Quality
- ✓ Total Quality Management
- ✓ Quality by Design (QBD)
- ✓ Six Sigma Concepts
- ✓ Out of Specifications (OOS)
- ✓ Change Control
- ✓ Introduction to ISO 9000 series of quality systems standards
- ✓ ISO 14000
- ✓ NABL
- ✓ GLP

❖ QUALITY MANAGEMENT SYSTEMS :

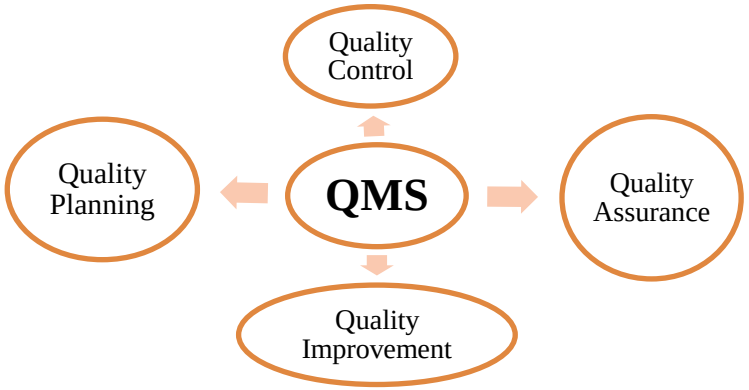


Fig.1 (Quality Management System)

- Quality Control: maintain standard
- Quality Assurance: Maintain desired level of quality
- Quality Planning: To determine the important factors for project & figuring out cost
- Quality Improvement: Documenting their contribution

➢ OBJECTIVE OF QMS:

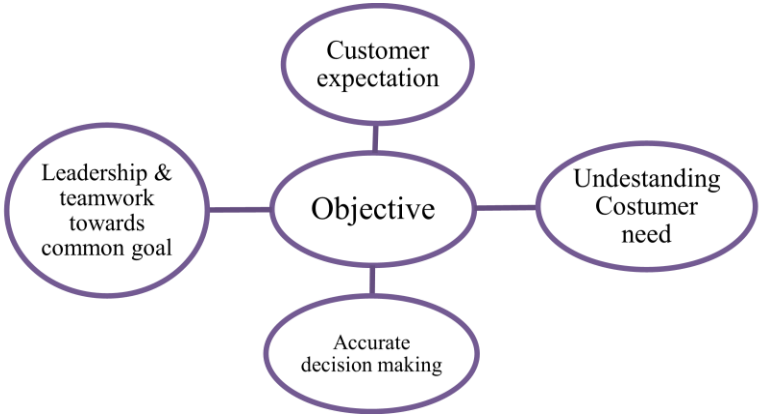


Fig.2 Objective of QMS

CONCEPT OF QUALITY:

- Totality of the features & characteristics of product or service.
- Ability to satisfy stated or implied need.

Fig.3 (Concept of Quality)

❖ TOTAL QUALITY MANAGEMENT:

- ➢ Customer – Oriented Process
- ➢ Continuous improvement of business operation

Principle of total quality management:

- Produce quality work
- Focus on customer
- Employee involvement
- Continuous improvement

➢ MODEL OF TOTAL QUALITY MANAGEMENT:

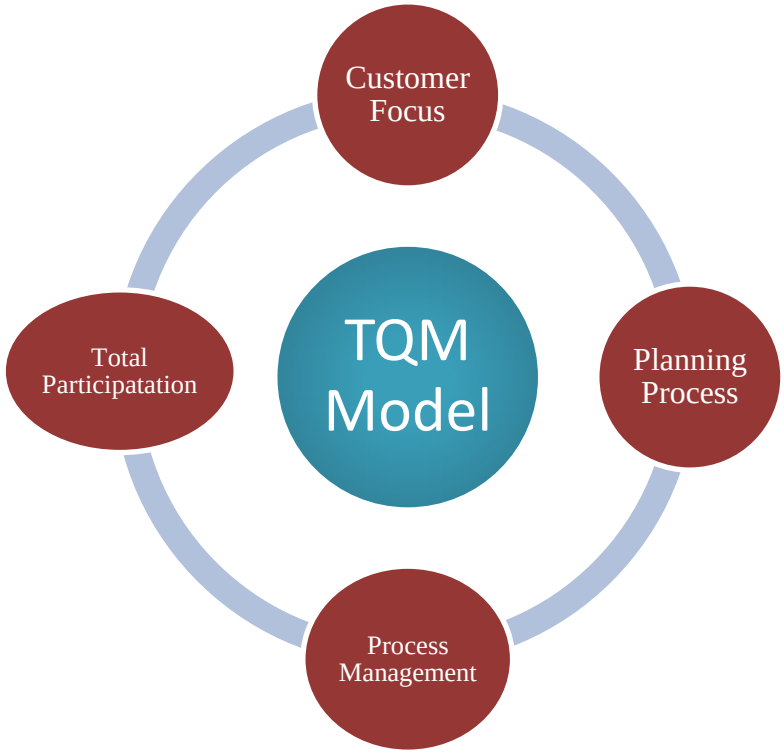


Fig.4 TQM Model

➢ BENEFITS OF TOTAL QUALITY MANAGEMENT:

- Strengthened competitive position
- Higher productivity
- Enhance market image
- Elimination of defect & waste
- Higher profitability
- Reduced cost & better cost management
- Time required to develop new innovation, and a reputation as a quality
- Makes the company adopt more readily to changes
- Makes the company more sensitive to customer needs
- Improve access to global markets, higher customer retention level
- Performance which will meet or exceed customer expectation

➢ Element of Total Quality Management:

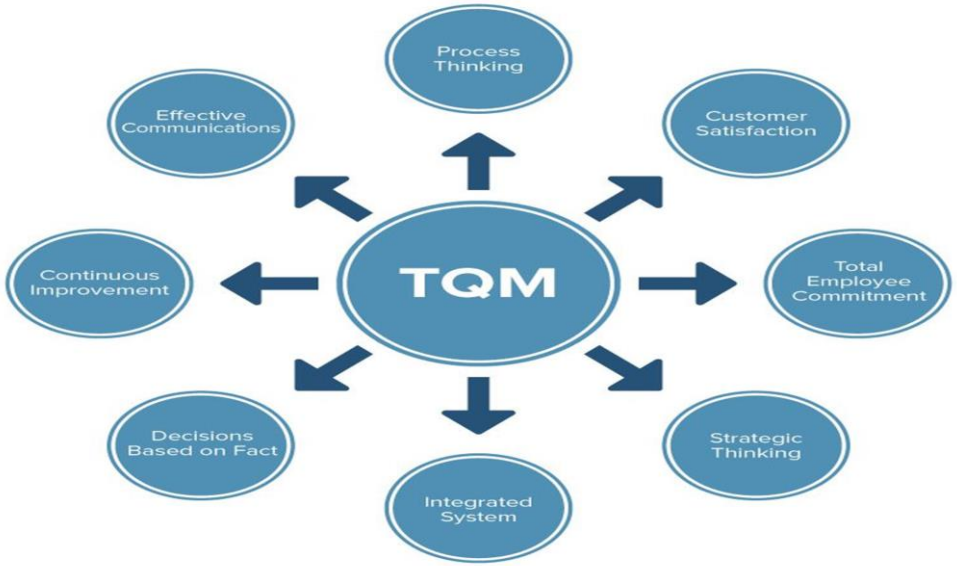


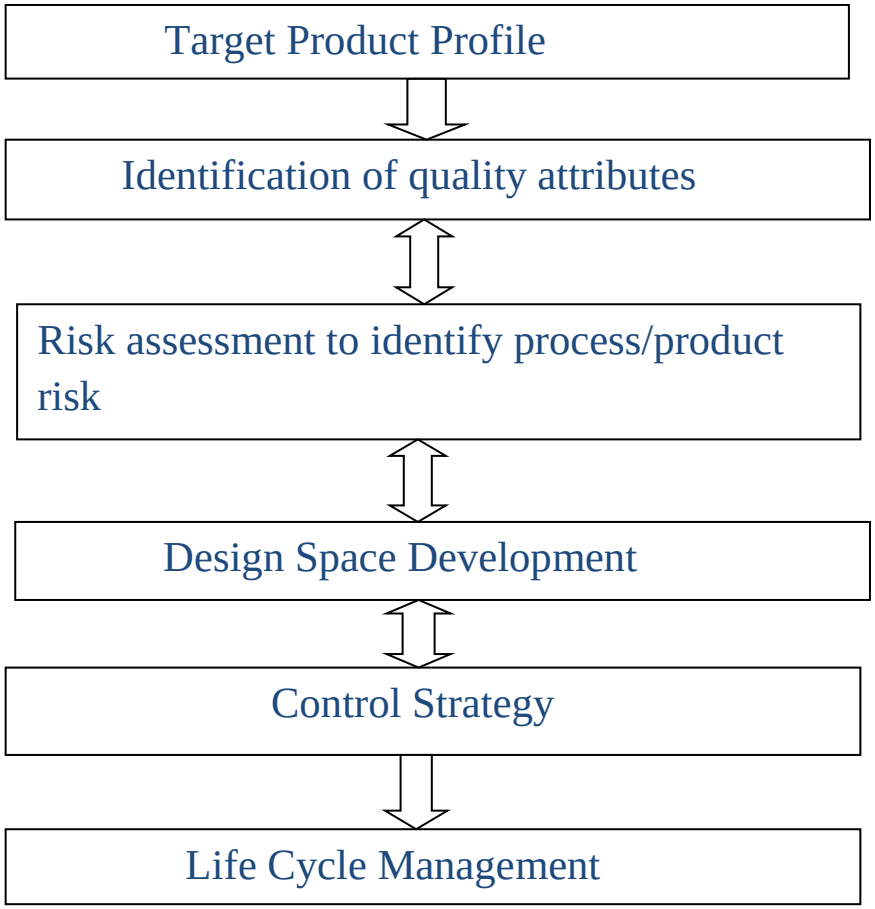
Fig.5 Element of TQM

❖ QUALITY BY DESIGN:

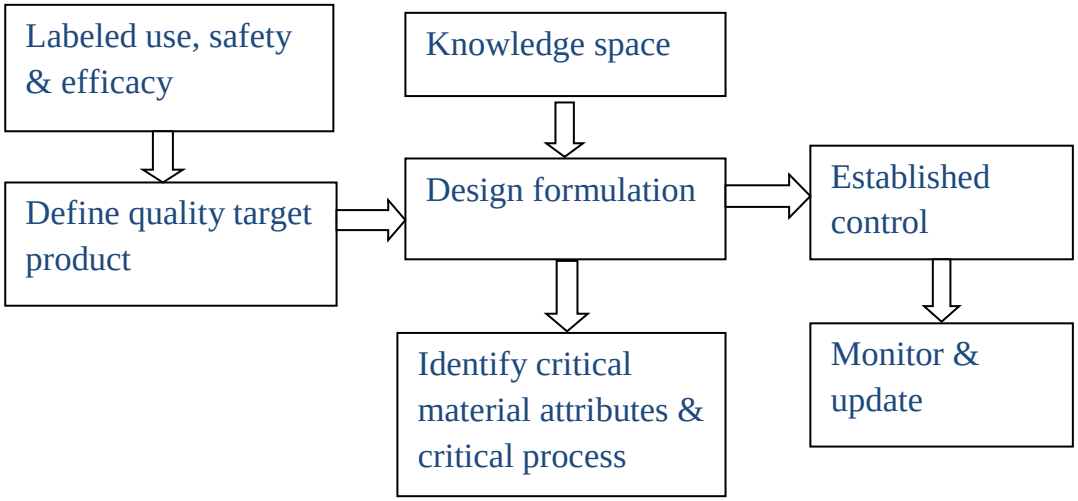
Systematic approach to development-

- Begins with predefine objective
- Emphasizes products
- Process understanding
- Process control
- Based on sound sciences &quality risk management

➢ KEY ASPECTS OF QUALITY BY DESIGN:



➢ PROCESS OF QUALITY BY DESIGN :



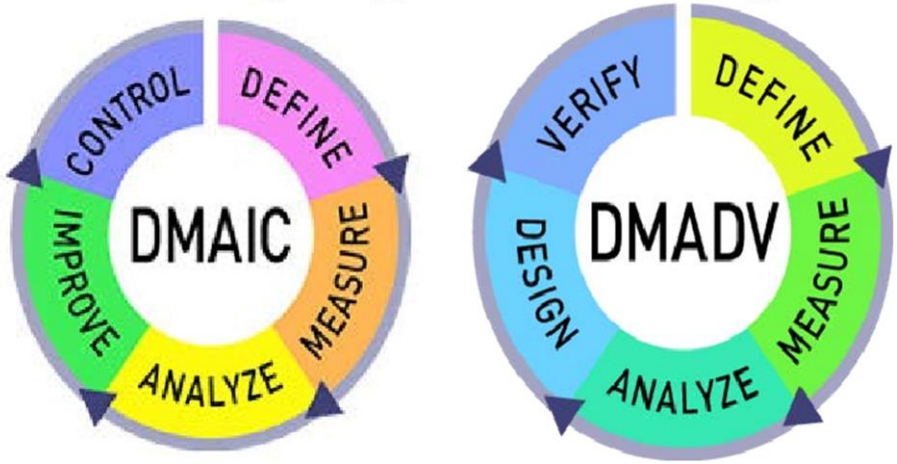
➢ ADVANTAGES:

- Benefits to industry
- Better understanding of the process
- Less batch failure
- Better development decision
- Less intense regulatory over sight & less post approval submission
- More efficient technology transfer to manufacturing
- Build scientific knowledge base for all products
- Empowerment of technical staff
- Risk based approach & identification
- Avoid regulatory compliance problem
- Greater regulatoryconfidence of robust products
- Efficient,agile , flexible system
- Better innovation due to the ability to improve processes without resubmission to the FDA when remaining in the design space

❖ SIX SIGMA CONCEPT :

- Business statistical strategy
- Identifying defect &removing manufacturing defects
- Improve quality

DPMO level through the application of the DMAIC approach.



➢ SIX SIGMA OBJECTIVES:

❖ Overall business improvement:

Six sigma methodology focuses on business improvement. Beyond reducing the number of defect present in any given numberof products.

❖ Remedy defect /variability:

Any business seeking improved number must reduced the number of defective product or services products.

❖ Reduced costs:

Reduced cost equal increase profits.

❖ Improve cycle time:

Any reduction in the amount of time it takes to produce a product or perform a service means money saved, both in maintenance costs& personnel wages.

➢ FOCUS OF SIX SIGMA:

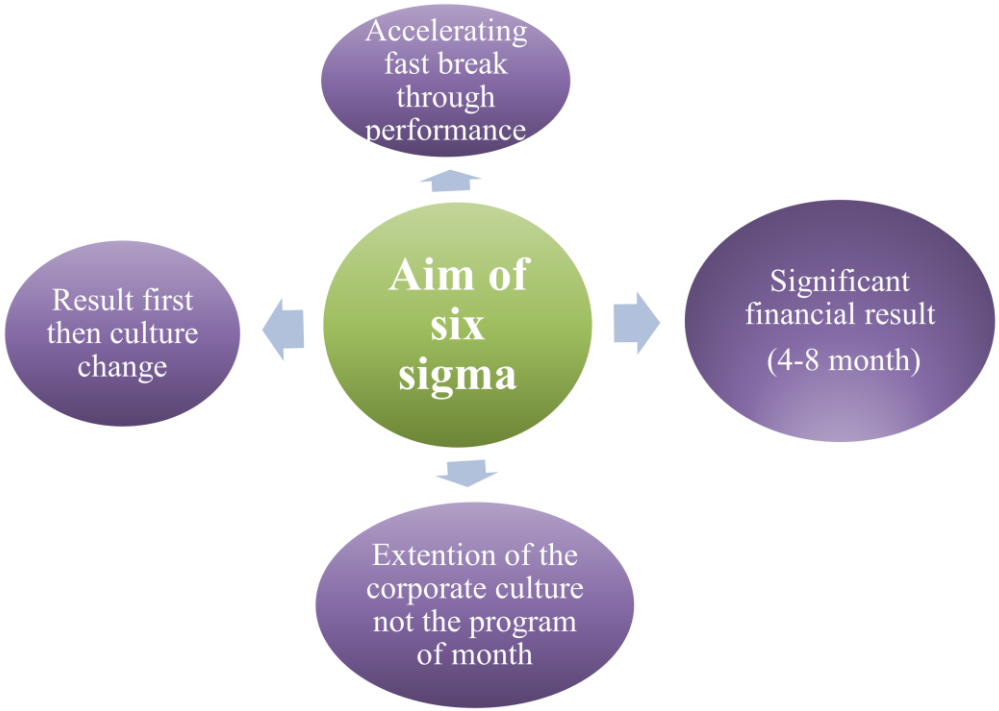


Fig.6 Aim of Six Sigma

➢ ELEMENTS OF SIX SIGMA:

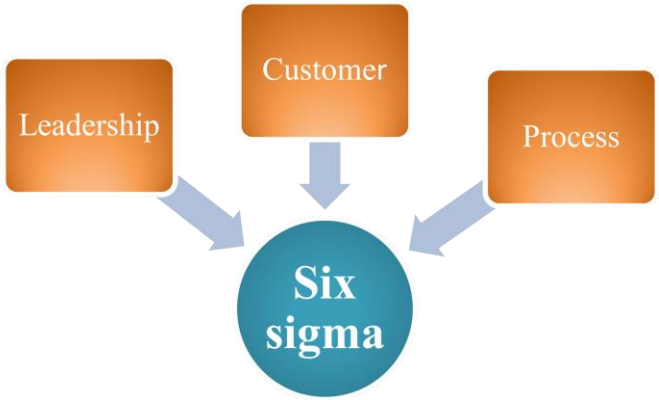
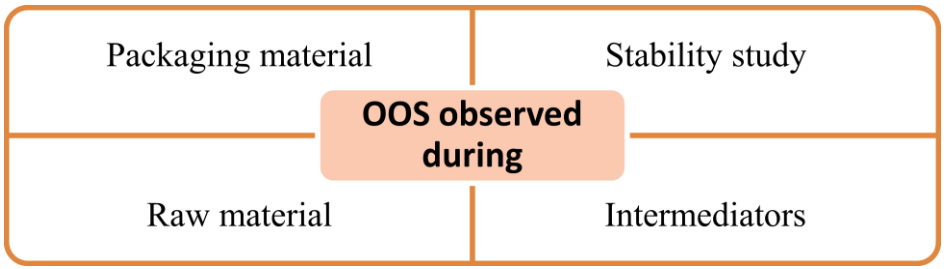


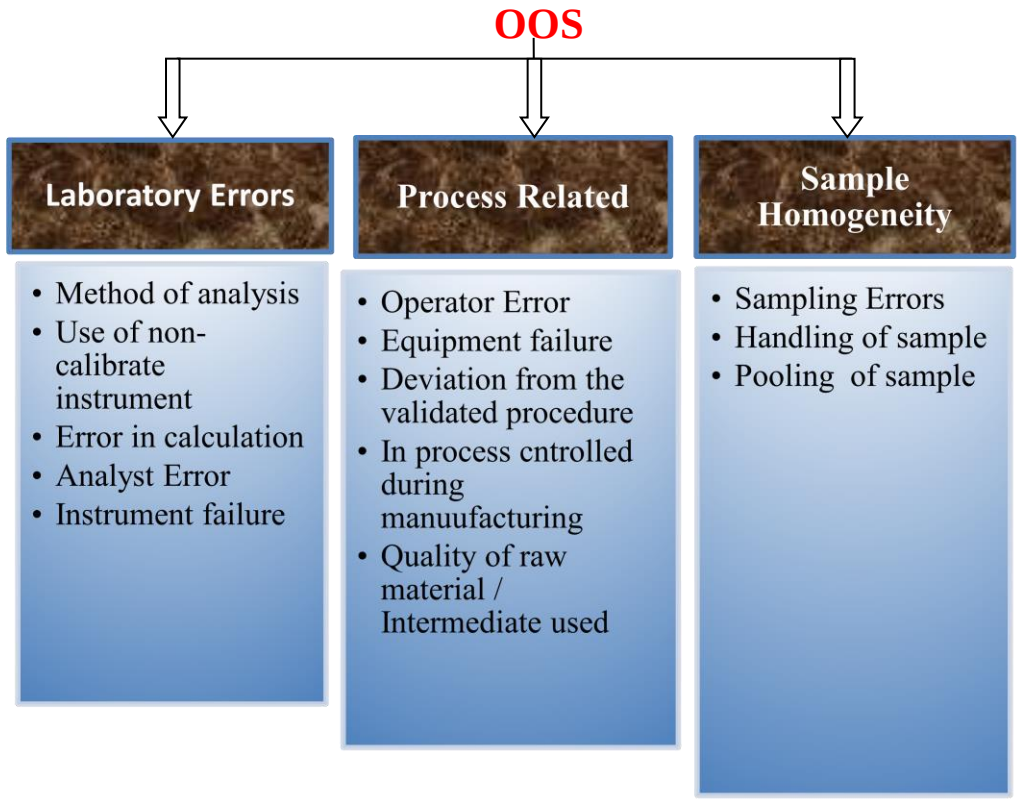
Fig.7 Element of Six Sigma

❖ OUT OF SPECIFICATION :

- The result obtained out of define test limit is called Out Of Specification.(OOS)
- Drug is not meeting documented standard.



➢ OOS FOUND DUE TO :



❖ CHANGE CONTROL:

Change control is a quality tool & management to maintain & keep the record of all changes as a history, changes can be related facility, documentation, system, equipment, instrument, procedure, layouts & products etc.

➢ CHANGE MANAGEMENT PROCESS:

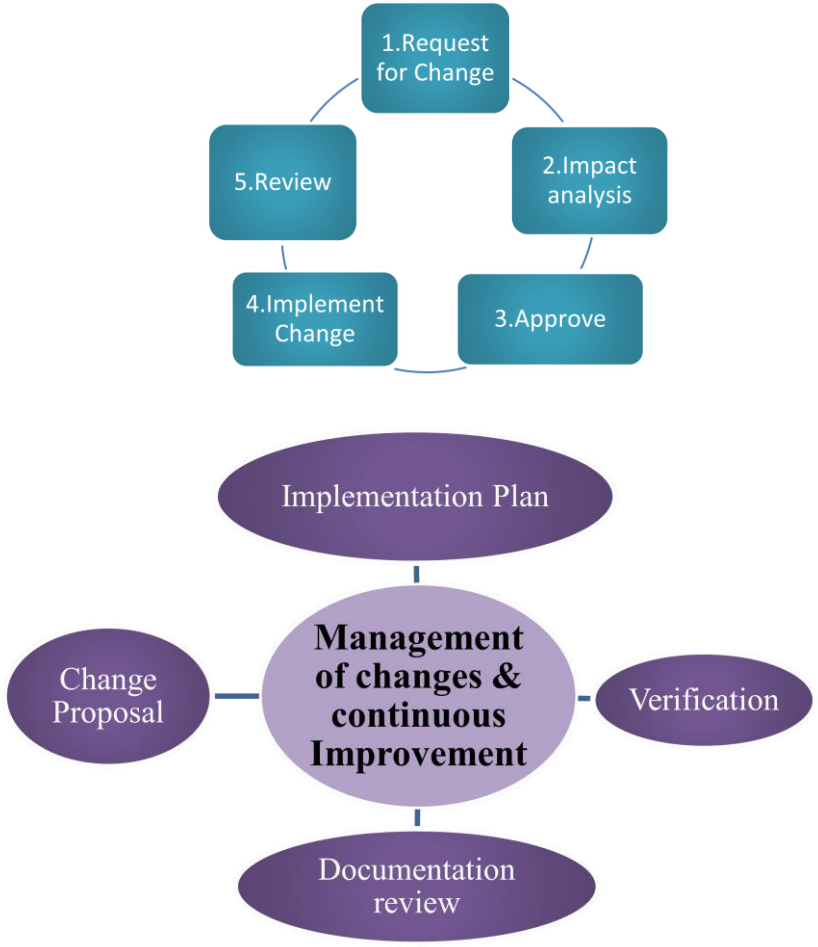


Fig.8 Change Management Process

➢ IMPORTANCE OF CHANGE CONTROL:

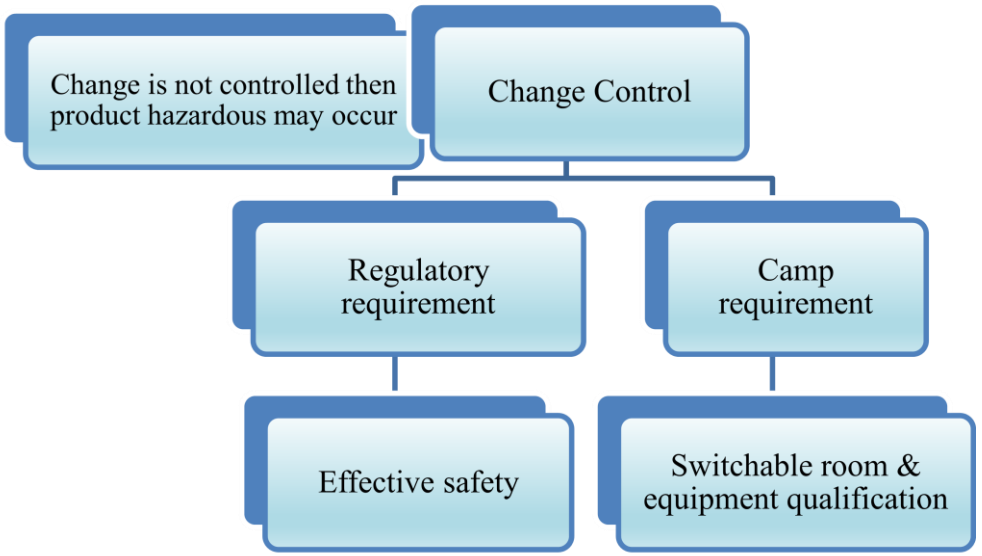


Fig.9 Importance of change control

❖ INTRODUCTION TO ISO 9000 SERIES OF QUALITY SYSTEM STANDARD:

ISO 9000 is series of standard development and published by the ISO that defines establish and maintain an effective quality assurance system for manufacturing and service industries.

- ❖ International organization for standardization.
- ❖ Series of quality management system standard.
- ❖ Provide guidance & tools for companies & organisation.
- ❖ To ensure that their product & services consistently meet costomer's requirement.
- ❖ For consistant improvement in quality.

Fig.10 QMS Principle

➢ ADVANTAGES OF ISO 9000:

- ❖ Increase marketability.
- ❖ Reduced operational expenses.
- ❖ Better management control.
- ❖ Increase customer satisfaction.
- ❖ Improve internal communication.
- ❖ Improve customer service.
- ❖ Attractiveness to investor.

❖ ISO 14000:

- ✓ Provides practical tools to manage the environmental responsibilities of companies & organisation.
- ✓ Standard is related to Envirnmental Management System.(EMS)

➢ FEATURES:

1. Minimum harmful effect on environment.
2. Continuous improvement to achieve the desired performance.

ISO 14000 is divided in two parts:

1. Organizational evaluation standards.
2. Product evaluation standards

Fig.11 Environmental management ISO 14000

➢ ISO 14000 POLICY:

- ✓ Prevention of pollution.
- ✓ Continual environmental improvement.
- ✓ Applicable in size & scope.
- ✓ Available to the public.
- ✓ Commitment to comply with environmental laws & regulation.

➢ PRINCIPLE OF ISO-14000 PDCA MODEL:

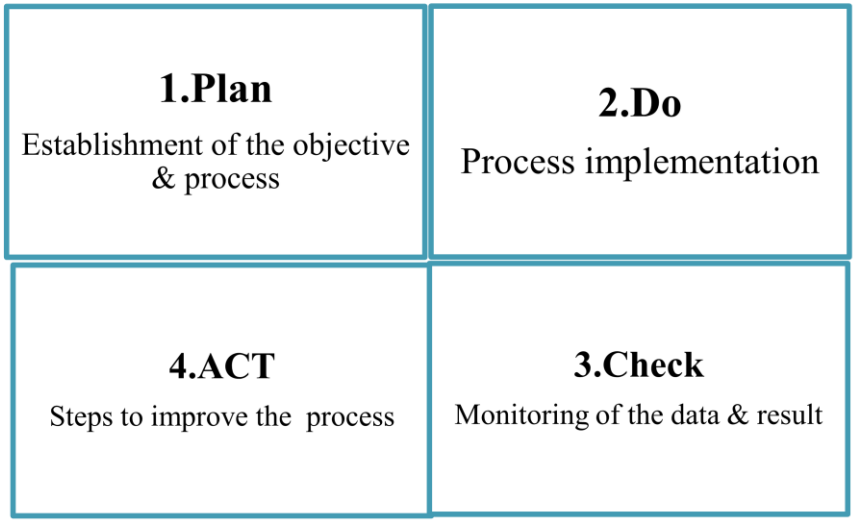


Fig. 12 Principle of ISO 14000 PDCA Model

➢ ISO 14000 CERTIFICATION PROCESS:

- ❖ Preliminary assessment.
- ❖ Document review.
- ❖ Initial assessment.
- ❖ Main assessment.
- ❖ Certification/registration.
- ❖ Surveillance.

➢ BENEFITS OF ISO 14000:

- Better conformance to environmental regulations
- Greater marketability
- Better use of resources
- Higher quality goods and services
- Increased levels of safety
- Improved image and increased profits

❖ National Accreditation Board for Testing and Calibration Laboratories (NABL):

- ❖ NABL is autonomous constitute.
- ❖ It is providing accreditation to the government, industry etc.

➢ NABL & ISO PRINCIPLE:

- ✓ Accreditation Systems: ISO/IEC 17011 (2017) (Conformity assessment-requirements for accreditation bodies accrediting conformity assessment bodies).
- ✓ Testing and Calibration Laboratories: ISO/IEC 17025 (2005) and ISO/IEC 17025 (2017) (General requirements for the competence of testing and calibration laboratories).
- ✓ Medical Laboratories: ISO 15189 (2012) (Medical laboratories-requirements for quality and competence).
- ✓ RMP (Reference Material Producers): ISO 17034 (2016) (General requirements for the competence of reference material producers.

SCOPE OF NABL ACCREDITATION

Testing Laboratories	Calibration Laboratories	Medical Laboratories	Medical imaging conformity assesment bodies	Proficiency testing providers	Reference material producers
•Biological •Chemical •Electrical •Electronics •Fluid flow •Mechanical •Non destructive testing •Photometry •Radiological •Forensic	•Electro technical •Mechanical •Fluid Flow •Thermal optical •Radiological •Medical devices	•Clinical biochemistry •Clinical pathology •Haematology & immunochemical •Histopathology •Cytopathology	• Fluoroscopy • Computed tomography • Ultrasound • Colour doppler • MRI	• Testing • Calibration • Medical • Inspection	• Chemical composition • Physical properties • Engineering properties • Miscellaneous properties

➢ NABL VISION:

To be the world leading accreditation body and to enhance stakeholders confidence in its services

➢ NABL MISSION:

To strengthen the accreditation system accepted across the globe by providing high quality, value driven service, fostering APLAC/ILAC MRA, empanelling competent assessors, creating awareness among the stake holders, initiating new programs supporting accreditation activities and pursuing organizational excellence.

➢ ADVANTAGES OF NABL:

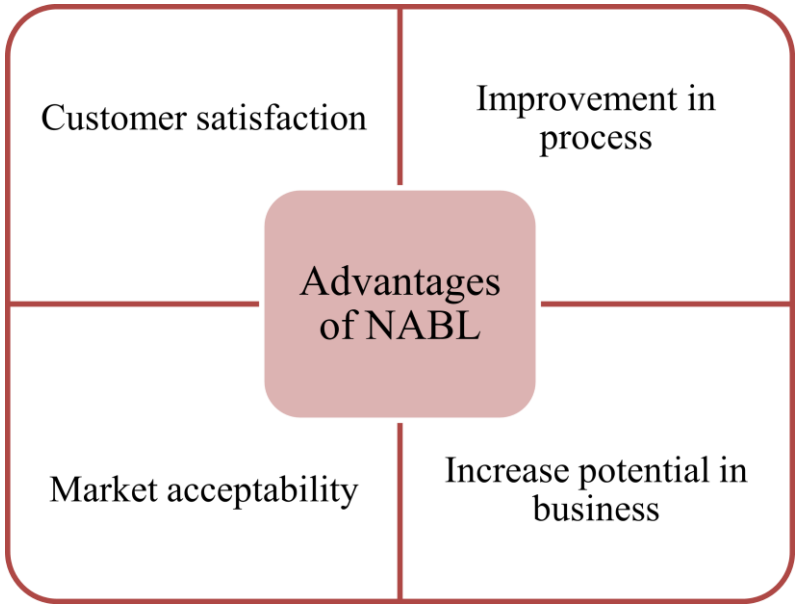


Fig. 13 Advantages of NABL

BENIFITS OF ACCREDITATION:

- Increased confidence in testing /calibration reports issue by laboratory
- Better control of laboratory operation
- Saving in terms of time and money due to reduction of elimination of the need for retesting of product
- Customers can search and identify the laboratories accredited by NABL for their specific requirement
- Potential increase in business due to enhance customer confidence

COMPLAINTS:

- NABL is open to receiving complaints for any of the activity performed by its official assessors, accreditation committee member and the accredited CABs.
- The details provided in NABL 132 “procedure for dealing with complaints”
- NABL is open to appeals from the CABs against its decision
- The details are provided in NABL 134 “procedure for dealing with appeals against adverse decision taken by NABL”

NABL CAN PROVIDE ACCRIDITATION:

- Private or government laboratory
- Small operation to large multi filed laboratory
- Site facility, temporary filed and mobile laboratory

GLP- GOOD LABORATORY PRACTICE:

Good laboratory practice is the FDA regulation

OBJECTIVE:

- Make sure data is traceable
- Promote international acceptance of test
- Adopt good and safe operating procedure and recording system
- Prevent the human error in the performance of the job
- Prevent equipment error in the measurement
- Improve efficient performance of the job
- Prevent unsafe and hazardous acts which could affects individual and /or properly

PURPOSE OF GLP:

- GLP is to certify that every step of the analysis is valid or not
- To promote the development of quality test data
- Avoid repetition of study
- Obtained reliable and reproducible data
- Shorten the registration time of the drug
- Obtained comparable data between countries
- GLPs have heavy emphasis on data recording, Record and specimen retention
- Assure the quality and integrity of data submitted to FDA in support of the safety of regulatory product

WHY WAS GLP CREATED?

- In the early 70sFDA became aware of cases o poor laboratory practice all over the united state
- Data generation without conduct of study
- Falsification of the laboratory work
- Replacement of dead animal and the fabrication of the test result
- They discovered a lot of fraudulent activities and a lot of poor lab practice
- Example of some of these poor lab practices found where
  - ✓ Equipment not been calibrated to the standard form, therefore giving wrong measurement
  - ✓ Inadequate test system
  - ✓ Incorrect or in accurate account of actual lab study

STANDARD OPERATING PROCEDURE:

- Routine inspection, cleaning, maintenance, testing and calibration
- Action to be taken in response to equipments failure
- Keeping record, reporting, storage, mixing and retrieval of data
- Definition of raw data
- Analytical method

HOW TO PRACTICE THE GLP?

- General provision facilities
- equipment
- Testing facilities operation
- Test and control articles
- Record and reports
- Protocol for and conduct of study
- Organization and personnel

Fig.14 GLP principle

BASIC ELEMENTS IN GLP:

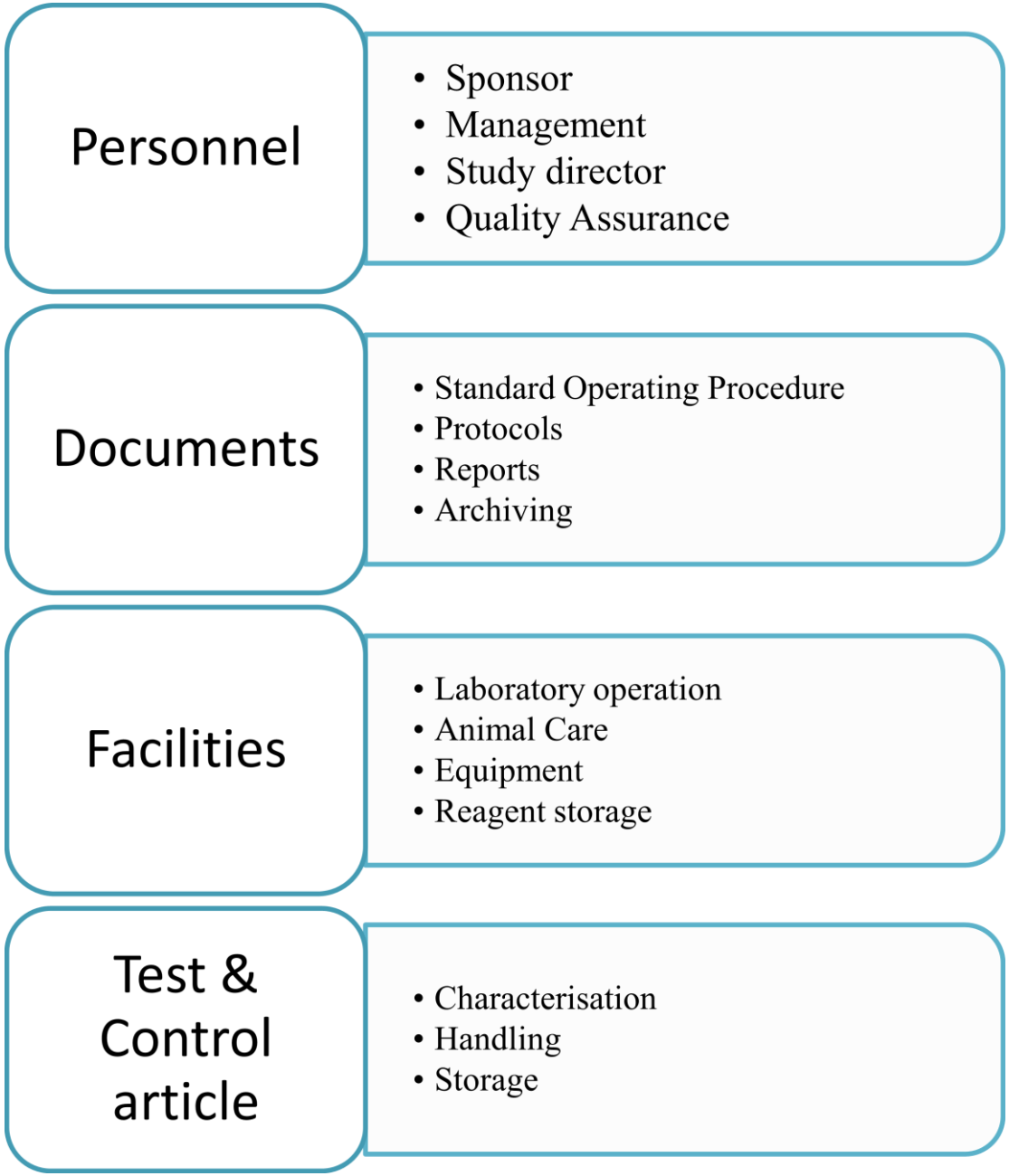


Fig. 15 Basic elements in GLP

GOALS OF GLP:

- To make life difficult for study personnel
- To ensure accountability
- To ensure ability to reconstruct the study

ADVANTAGES OF GLP:

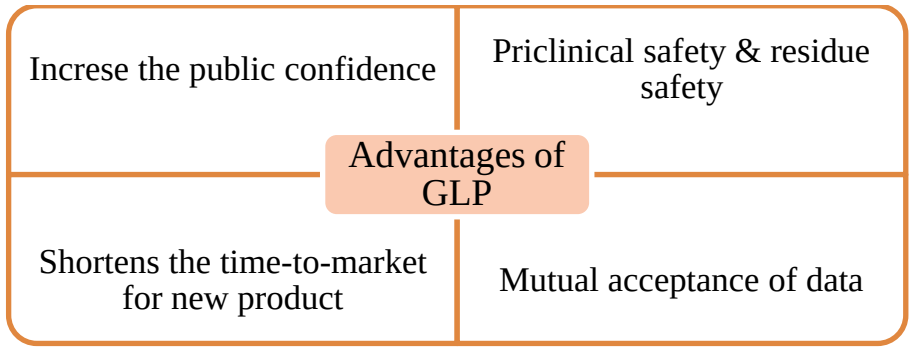


Fig.16 Advantages of GLP

DISADVANTAGES OF GLP:

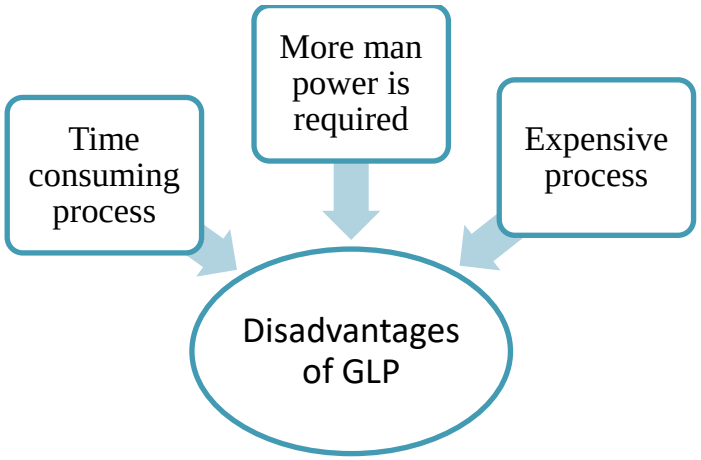


Fig.17 Disadvantages of GLP

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