Unit-1

∵ Quality Assurance & Quality Management Concepts :

∴ Quality management System -

It is defined as a management technique used for communicating to employees what is required to produce the desired quality of products & services & to influence employee actions to complete tasks according to the quality specification.

Components -

It has 4 main components :

- Quality planning
- Quality assurance
- Quality Control
- Quality Improvement.

Purpose -

It is to ensure every time a process is performed, the same information, methods, skills & controls are used & applied in a consistent manner.

Principle -

There are 7 Quality Management Principle are :

- QMP 1 - Customer focus
- QMP 2 - Leadership
- QMP 3 - Engagement of people
- QMP 4 - Process approach
- QMP 5 - Improvement
- QMP 6 - Evidence-based decision making
- QMP 7 - Relationship management.

∴ Quality Control & Quality Assurance –

Definition –

→ **Quality** : Quality is define as 'the degree of Excellence'.
(OR)
Quality is defined as "an inherent characteristics, property or attribute".

→ **Quality Assurance** :
ISO 9000 defines as "a part of quality management focussed on providing confidence that quality requirements will be fulfilled".

→ **Quality Control** :
ISO 9000 defines as "a part of quality management focussed on fulfilling quality requirements".

Difference between Quality Assurance & Quality Control –

Terms	Quality Assurance	Quality Control
Definition	ISO 9000 defines as "a part of quality management focussed on providing confidence that quality requirements will be fulfilled".	ISO 9000 defines as "a part of quality management focussed on fulfilling quality requirements."

	QA	QC
Focus	QA is a proactive quality process which aims to prevent defects in the process used to make the product.	QC is a reactive process to identify and address the defects in the finished products.
Goal	To improve development & test processes to reduce defects when the product is being developed.	To identify defects in a developed product before it's released.
How	QA activities and quality management systems & the assessment of its adequacy & conformance audits of the system.	QC test & eliminates sources of quality problems through tools & equipment so that customer's requirement are continually met.
What	Prevention of quality problems through planned & systematic activities including documentation.	The activities are used to achieve & maintain the product quality, process & service.
Responsibility	Everyone on the team involved in developing the product is responsible for quality assurance.	Quality control is usually the responsibility of a specific team that tests the product for defects.
Example	Verification is an example of QA.	Validation is an example of QC.

Techniques	Statistical tools & Techniques can be applied in both QA & QC. When they are applied to processes (process input & operational parameters), they are called Statistical Process Control (SPC) & comes under the QA.	When statistical tools & techniques are applied to finished products (process outputs), they are called as Statistical Quality Control (SQC) & come under QC.
As a tool	QA is a managerial tool.	QC is a corrective tool.
Orientation	QA is a process oriented.	QC is a product oriented.

∴ Good Manufacturing Practices (GMP) –
GMP is a set of regulation, codes & guidelines for the manufacture of drug products, medical devices in vivo & in-vitro diagnostic products & foods.

Objective –
The main aim of GMP is to consistently produce high quality medicines that meet the international standards required for responsibly managed healthcare. Processes used in manufacture are carefully controlled & any changes to the process must be evaluated.

Components-

There are 5 key elements which are often referred as the 5 P's of GMP -

- People
- Premises
- Processes
- Products
- Procedures

And if all 5 are done well, there is a sixth P i.e. Profit.

General Requirement -

- Avoid risks & possibilities of mix-up at all stages of mfg, labelling pkg, testing.
- AHUs, comfort of the personnel working & regular monitoring of temp. & humidity, particle count, DOP testing, etc.
- Proper drainage system which prevents backflow. Avoid open channels & if provided must be able to clean & disinfect.

Building & facilities -

(1) Design & construction features.
(2) Lighting
(3) Ventilation, air filteration, air heating & cooling
(4) Plumbing
(5) Sewage & refuse
(6) Washing & toilet facilities
(7) Sanitation
(8) Maintenance.

Principles of GMP -

(1) Design & construct the facilities & equipment properly.
(2) Follow written procedure & instruction.
(3) Document work.
(4) validation work.
(5) Monitor facilities & equipment.
(6) Write step by step operating procedures & work on instruction.
(7) Design, develop & demonstrate job competence.
(8) Protect against contamination.
(9) Control components & product related processes.
(10) Conduct planned & periodic audits.

GMP Category -

(i) **Sale -**
no distributor & no importer shall sell a drug unless it has been fabricated, packaged, labelled, tested & stored.

(ii) **Premises & Equipments -**
- Permits effective cleaning.
- Prevents contaminations.
- Orderly condition
- Good state of repair.

(iii) **Personnel -**
- Appropriate education, training & experience.
- Sufficient no. of people
- Receive GMP training.

(iv) Sanitation:-
- Sanitation program to prevent contamination.
- Limit the sources and types of contamination:
  → Cleaning procedures for facilities & equipment.
  → Pest control
  → Environmental monitoring.

(v) Raw material, Packaging material & Finished product testing:-
- Each lot or batch of raw material is tested:
  → To confirm the identity of raw material.
  → To provide assurance that quality of the drug in dosage.
- Samples of incoming materials are collected & tested before use.
- Approved test methods & specification are used.
- Results must conform to specification for release for use or sale
- Transportation & storage records.

(vi) Manufacturing Control:-
- Written procedures are established & followed master formulae, manufacturing order & packaging order.
- Critical processes are validated.
- 2nd person verification of activities.
- Self-inspection programmed.

(vii) Quality Control department:-
Quality control responsibilities are:
- Testing of bulk components prior to use by production.
- Testing of finished products prior to release for sale.

- Stability program.
- Review batch records, labels.
- Release product based on QC test results.
- Training auditing.
- Customer complaints.

(viii) **Records -**
- Document all GMP activities.
- Use good documentation practices.
- Records must be readily available.

(ix) **Good documentation Practices -**
Documentation must be:
- Permanent (Blue or Black) ink.
- legible, clear, concise
- Accurate
- Timely Complete.

(x) **Samples -**
Retain samples of each lot of raw material & finished product for specified period of time.

(xi) **Stability -**
- Establish the length of time in which the product meets all specification.
- Monitor the drug for this period of time.

(xii) **Stability Products -**
Packaged in separate enclosed area by trained personnel using method to ensure stability.

Importance of GMP -

- A poor quality medicine may contain toxic substances that have been unintentionally added.
- A medicine that contains little or none of the claimed ingredient will not have the intended therapeutic effect.

Uses of GMP -

- GMP in Solid dosage form.
- GMP in Semisolid dosage form.
- GMP in liquid orals
- GMP in Parenteral products.
- GMP in Ayurvedic medicines.
- GMP in Bio-technological products.
- GMP in Neutraceutical & cosmeceuticals.
- GMP in Homeopathic medicine.

Risks -

- Unexpected contamination of products, causing damage to health or even death.
- Incorrect labels on containers, which could mean the patients receive the wrong medicine.
- Insufficient or too much active ingredient, resulting in ineffective treatment or adverse effects.

Difference between GMP & cGMP -

GMP	cGMP
• GMP without validation terminology its a GMP.	GMP with validation terminology its a GMP.
• GMP refers to good manufacturing practices that are guideline followed by over 100 countries	cGMP refers to current good manufacturing practices that need to be adhered to by participating countries.
• GMP applies to pharmaceutical & healthcare products & helps to maintain high standards in these products.	cGMP is to remind accepting countries that all guideline must be followed with latest & current product processes.
• Cost-friendly to implement.	More expensive to implement.
• Much broader & it goes deeper into complaints, book keeping, personnel & labeling practices.	Applicable in selected scenarios directly related to the manufacturings processes only.
• Lower quality assurance.	More reliable in quality assurance.
• The acquisition of the GMP guideline & requirements is much easier as they are more general.	Requirement are less acquirable than GMP.

:: Total Quality Management (TQM) :

Definition -

Total - Consisting of the whole.

Quality - degree of quality offered by a product or service.

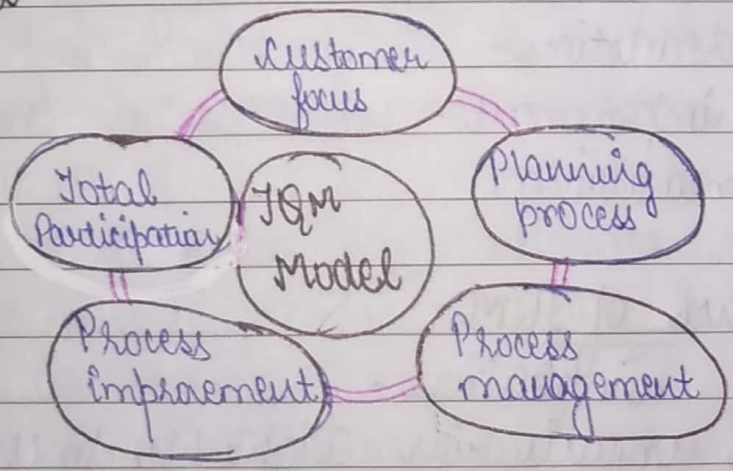
Management - practice, art or planning, command, management.

TQM is the art of handling the whole to achieve perfection.

(or)

An integrated organisational effort to improve the product quality at every level is referred to as Total Quality management.

TQM Model -



6 Cs of TQM -

- Control
- Committment
- Culture
- Customer focus
- Cooperation
- Continuous Improvement

Objectives of TQM -

- To meet customer requirements.
- Success & development of organization
- Improvement of quality Continuously
- To stimulate the employees in becoming increasingly Competent & creative.
- Development of the relationship b/w employees in the organization at all stages of transparency & Confidence.

Characteristic of TQM -

- Committed management
- Adopting & Communicating
- Closer customer relation
- Increased training
- Open organization
- Employee empowerment
- Flexible Reduction.
- Process improvements.
- Process measuring.

Significance of TQM -

- Encourage innovation.
- Makes the organisation adaptable to change.
- Motivates people for the better quality.
- Integrates the business arising out of a common purpose.
- Provide the organisation with a valuable & distinctive Competitive edge.

Elements of TQM -

There are 8 key elements of TQM. These elements can be divided into 4 groups according to their function:

(i) Foundation : Ethics, Integrity, Trust
(ii) Building Bricks : Training, Teamwork, Leadership
(iii) Binding Mortal : Communication
(iv) Roof : Recognition

→ Ethics - It is the discipline related to good & bad deeds under any situation.
Ethics teach two-faceted subject are organisation ethics & individual ethics.

organisation ethics establish a business code of ethics that set up guidelines that all employees are to adhere in the performance of their work.

Individual ethics refers to the personal wrong or rights.

→ Integrity - It refers some characteristics traits like honesty, morals, values, fairness & adherence to the fact & sincerity.
These characteristics define, "what internal or external customers expect & what they deserve to receive".

→ Trust - It is the by-product of integrity & ethical conduct & builds the framework of TQM.
Trust ensures participation of all the members & allow empowerment that influences pride ownership & commitment for the task to be performed.

→ **Training** - It makes employees more productive.
Training enables employees to implement TQM effectively within their department & also make them indispensable resources.

→ **Teamwork** - For a successful business, teamwork is a key element of TQM. Teamwork provides quicker & better solv" to problems in business.
A team provides permanent improvement in processes & operations.

→ **Leadership** - It is the most important element in TQM that can be seen everywhere in an organisation. Leadership provides a direction to the entire process of TQM.

→ **Communication** - It is defined as a common understanding of idea between the sender & receiver.
It acts as a vital link between all elements of TQM. It binds everything together, Starting from foundation to roof of TQM.

→ **Recognition** - It is the final element of TQM.
It is the most important factor which act as a catalyst & drives employees to work hard as a team & deliver their labour cost.
Every individual is hungry for appreciation and recognition.

Philosophy of TQM-

→ **Quality circle :** It is also known as work improvement. It is defined as a small group of employees who voluntarily meet at regular times so that they can identify, analyse, solve quality & other problems related to their work environment or organisation.

→ **Customer Focus :** Goal is to identify & meet customer needs.

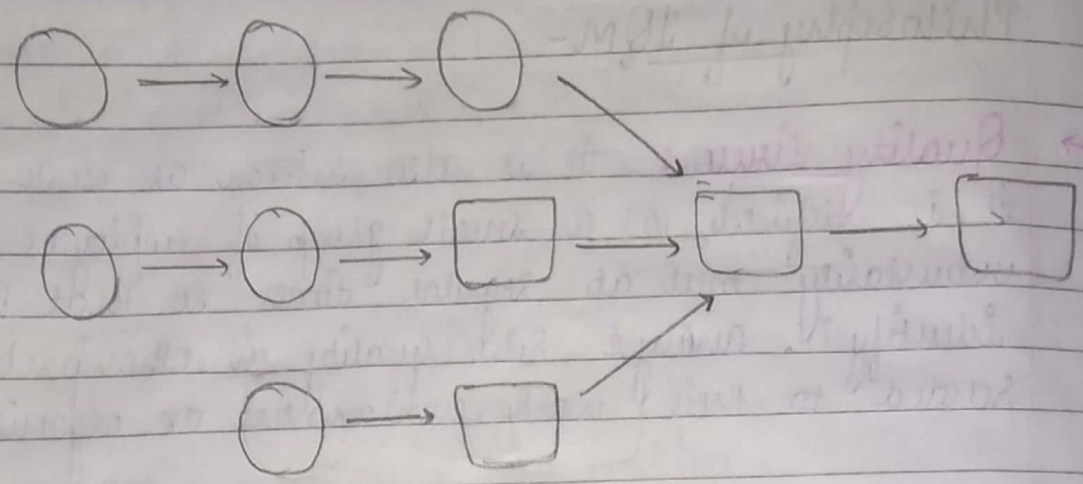
Application -
- Partnership.
- Service relationship with internal customers.
- Customer driven standard.
- Never compromise quality.

→ **Employees Empowerment :** Employees are expected to seek out, identify & correct quality problems.

Application -
- Training
- Excellence team
- Measurement & recognition
- Suggestion scheme.

There are 7 different Quality tools, which are also called 7 tools of quality control:

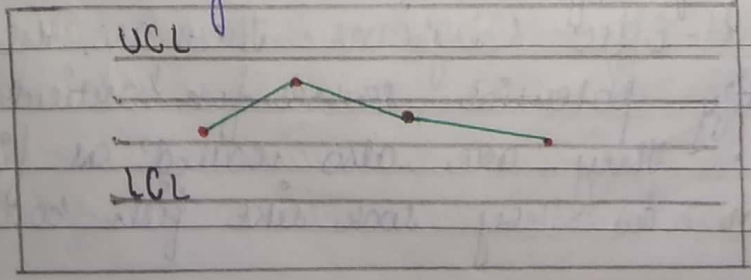
(a) **Flow Charts** - These are schematic diagram of the sequence of steps involved in a process. Flowchart provides a visual tool that can be easily used & understood.



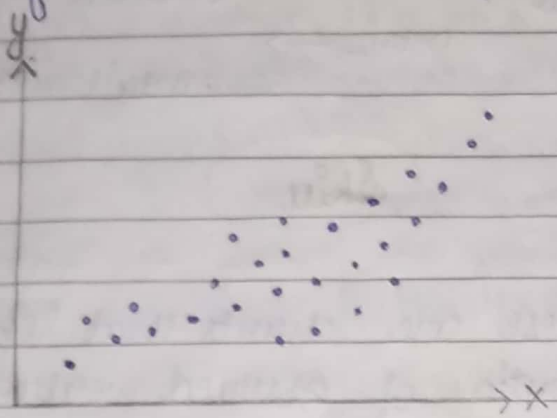
(b) Check lists - These are the lists of common defects & the no. of observed occurences of these defect. Checklist is a simple & effective fact-finding tool using which the worker collects specific information regarding the observed defects.

Defect Type	No. of Defects	Total
Broken zipper	1 1 1	3
Ripped material	1 1 1 1 1 1 1	7
Missing buttons	1 1 1	3
Faded colours	1 1	2

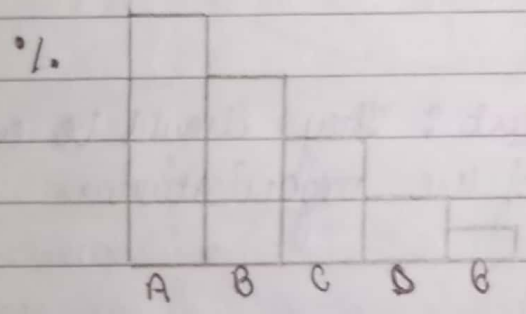
(c) Control charts - These important quality control tools are charts used for evaluating whether or not a process is working with in the expectation related to some measured value such as weight, width or volume.



(d) Scatter Diagram - These are the graphs that represent the relationship between two variables. Scatter diagram are used to detect the amount of correlation or the degree of linear relationship between two variables.

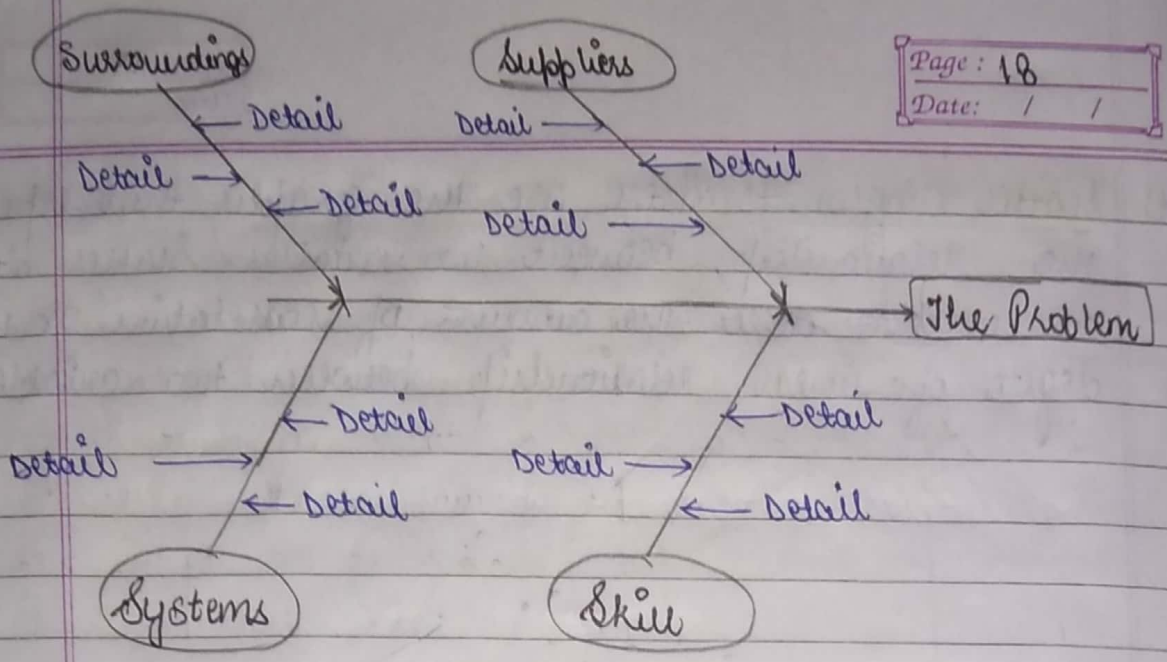


(e) Pareto Analysis - It is a technique used for identifying quality problems based on their degree of importance.

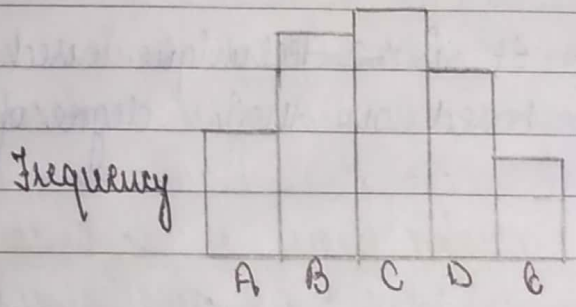


Quality problems

(f) Cause-and-Effect Diagram - These are charts used to identify potential causes for particular quality problems. They are also termed as Fishbone diagram as they look like fish bones.



(g) Histograms - These are charts that represent the frequency distribution of observed values of a variable.



→ Continuous Improvement : They should be a permanent objective of the organisation.

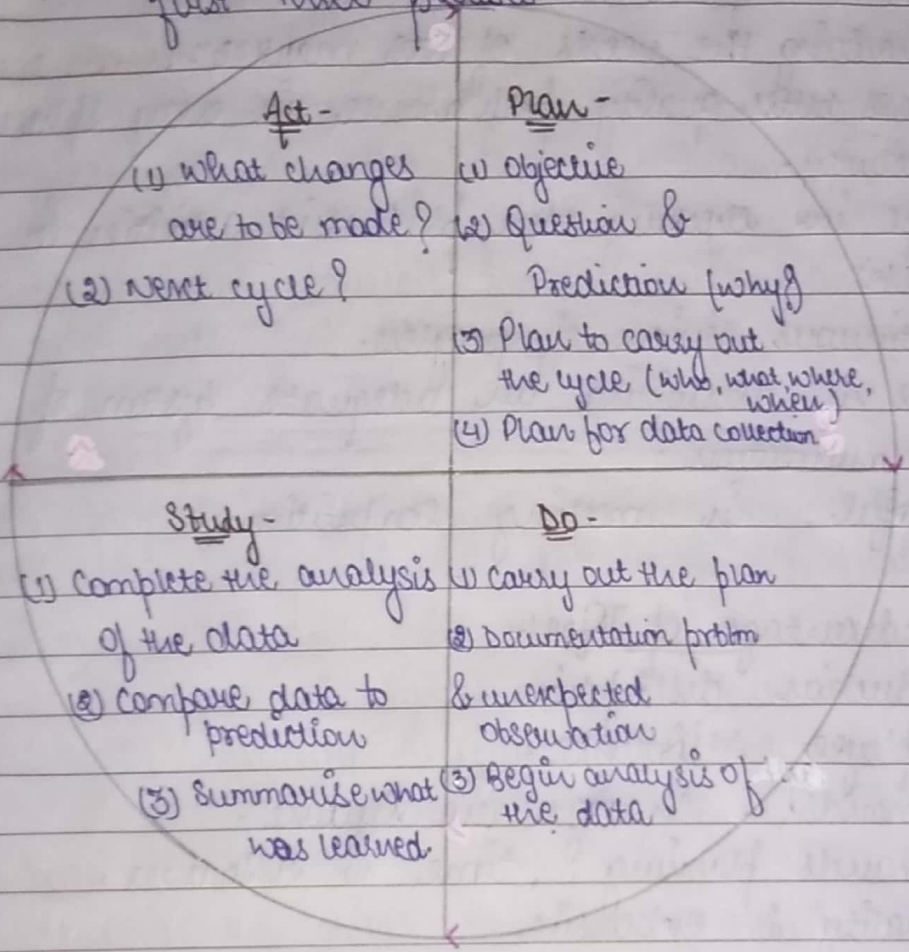
Applications -

- Systematic measurement
- Excellence team
- Cross functional process management
- Attain, maintain & improve standards.

(a) The Plan-Do-Study-Act (PDSA) cycle -

(1) Plan - It is carry out the project plan.
(2) Do - It is implement the plan (Do) & collect data
(3) Study - It is to study the data collected.

(4) Act - It is to act depending on the results of the first three phases.



(5) Benchmarking -

- Benchmarking is the practice of comparing business processes & performance metrics to industry best practices from other companies.
- Dimensions typically measured are quality, time & cost.
- It is also known as Best practice benchmarking or Process Benchmarking.
- It is a process of measuring the performance of a company's process against business considered to be "Best in class".
- The point of benchmarking is to identify internal opportunities for improvement.

Advantages of TQM-

(1) Lower Production cost.
(2) Emphasizing the needs of the market.
(3) Assures better quality performance in every sphere of activity.
(4) Helps in checking non-productive activities & waste.
(5) Continuous review of progress.
(6) Helps in developing an adequate system of communication.
(7) Helpful in meeting competition.

Disadvantage of TQM-

(1) Production disruption.
(2) Employee resistance.
(3) Demands a change in culture.
(4) Demands planning, time & resources.
(5) Quality is expensive
(6) Takes years to show result.
(7) Discourages creativity.
(8) Not Quick-fix solution.

ICH Guideline:

Full Form -

Old - International conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.

New - International Council for Harmonization of Technical Requirements for Pharmaceutical for Human use.

Definition -

ICH is a joint initiative of regulatoss & re-search based industry of Europe, Japan & USA which involve scientific & technical discussion regarding the testing procedure & their evaluation to ensure safety, quality & efficacy of the medicine.

Purpose -

(i) Increasing the global harmonic of technical requirements to ensure the production of safe, reliable & high quality medicines.
(ii) To promote public health.
(iii) To harmonize technical requirements for registration or marketing approval.
(iv) To minimize replication in human clinical trials.
(v) To minimize the use of animal testing without compromising safety & effectiveness of drug.
(vi) The most secure & cost-effective way to create & track pharmacokinetics.

Participants of ICH -

- The six parties of ICH represent the regulatory bodies & research based industry in the 3 regions : Europe, Japan, USA.

Region	Regulatory bodies	Research based industry
Japan	(MHLW) - Ministry of Health labour & welfare	(JPMA) - Japan Pharmaceutical manufacturer Association
Europe	(EU) - European union	(EFPIA) - European Federation of pharmaceutical industries & Association
USA	(FDA) - Food & Drug administration	(PhRMA) - Pharmaceutical Research & manufacture of America.

- ICH observer have been allied with ICH process from starting to till now - ICH committee i.e. WHO, Health Canada, (EFTA) - European Free trade Association.

Process of Harmonization -

Each harmonisation action is started with a concept paper which includes a short summary of the proposal.

After approval of concept paper the ICH task & support the relations of EWG or IWG.

The ICH harmonisation activities are categorised as -
(1) Formal ICH procedure.
(2) Question & Answer procedure.
(3) Revision procedure.
(4) Maintenance procedure.

→ Formal ICH Procedure :
An formal ICH procedure is started with the steering committee's approval of a concept paper & business plan.

Steps -

Consensus Building
↓
Confirmation of Six-party unanimity on the Technical document
↓
Regulatory Consultation
↓
Appraisal of an ICH Harmonized Tripartite Guideline
↓
Implementing ICH process.

→ Question & Answer procedure :
The Q & A procedure is followed when additional guidance is required to help interpreting certain ICH guidelines & ensure uniform implementation in & outside the ICH regions.

→ **Revision Procedure:**

The revision procedure is compiled either when the scientific / technical content of an existing ICH guideline is invalid or when a new data is to be added with no amendments to the existing ICH guideline needed.

→ **Maintenance Procedure:**

The maintenance procedure is applicable only for alterations to the QSC guideline on impurities: residual solvents. This process is used when new information is to be added or the technical content is invalid.

Overview of QSEM -

ICH guidelines are mainly categorised into 4 types:

(i) **Quality Guideline (Q):** Those relating to chemical & pharmaceutical quality assurance.
(Stability Testing, Impurity Testing)

(ii) **Safety Guideline (S):** Those relating to in-vitro & in-vivo pre-clinical studies.
(Carcinogenicity testing, Genotoxicity testing)

(iii) **Efficacy Guideline (E):** Those relating to clinical studies in human subject.
(Dose response studies, Good clinical practices).

(iv) Multidisciplinary Guideline (M): These are cross-cutting topics which donot fit uniquely into one of the above categories. (MedDRA, ESRI, M3, CTD, M5)

Q-Series

Q_1 → Stability (Q_{1A}-Q_{1F})
Q_{1A}: Stability testing for new substances & products.
Q_{1B}: Photosensitivity testing of new drug substance & product
Q_{1C}: Stability testing of new dosage form.
Q_{1D}: Bracketing & matrixing design for stability of testing of new drug substance & products.
Q_{1E}: Evaluation of stability data.
Q_{1F}: Stability data package for registration application in climatic zone III & IV.

Q_2 → Validation of analytical procedure.

Q_3 → Impurities (Q_{3A}-Q_{3D})
Q_{3A}: Impurities in new drug substances.
Q_{3B}: Impurities in new drug products.
Q_{3C}: Impurities - guideline for residual solvent.
Q_{3D}: Impurities - guideline for elemental impurities

Q_4 → Pharmacopoeias (Q_{4A}-Q_{4B})
Q_{4A}: Pharmacopoeial harmonization
Q_{4B}: Evaluation & recommendation of pharmacopoeial texts for use in the ICH regions.

Q_5 → Quality of Biotechnology product (Q_{5A} - Q_{5E})

Q_{5A}: Viral safety evaluation of biotechnology products derived from cell lines of human or animal origin

Q_{5B}: Analysis of expression construct in cells for production of r-DNA derived protein products.

Q_{5C}: Stability testing of biotechnological products.

Q_{5D}: Derivation & characterisation of cell substrates used for production of biological products.

Q_{5E}: Comparatability of Biotechnological products subject to change in their manufacture process.

Q_6 → Specification (Q_{6A} - Q_{6B})

Q_{6A}: Test procedures & acceptance criteria of new drug substances & new drug products chemical.

Q_{6B}: Test procedures & acceptance criteria of biotechnological products.

Q_7 → Good Manufacturing Practice (GMP)

Q_8 → Pharmaceutical development

Q_9 → Quality Risk management (QRM)

Q_{10} → Pharmaceutical Quality System (PQS)

Q_{11} → Development & manufacturing of drug substance

Q_{12} → life cycle management.

ICH Stability Testing Guidelines –

Stability studies include testing of those features of a drug substance that may change during storage & influence quality, safety & efficacy.

→ **Climatic Zones for Stability Testing :**

- For stability testing, the world has been divided into 4 zones depending on the environmental condition to which the pharmaceutical products are subjected during storage.
- These conditions have been derived based on the MAT (mean annual temperature) & relative humidity data in these four regions.

Climatic Zone	Climate	Regions	MAT/Mean annual Partial water vapour pressure	Long-term Testing Condition
I	Temperate	United Kingdom, Northern Europe, Russia & United States	≤15°C / ≤11 hPa	21°C / 45% RH
II	Subtropical & Mediterranean	Japan & Southern Europe	>15-22°C / >11-16 hPa	25°C / 60% RH
III	Hot & Dry	Iraq & India	>22°C / ≤15 / >22°C / >15-27 hPa	30°C / 45% RH
IVa	Hot & Humid	Iran & Egypt	>22°C / >27 hPa	30°C / 65% RH
IVb	Hot & very Humid	Brazil & Singapore		30°C / 65% RH

→ **Protocol for Stability Testing :**

The protocol for stability testing is an essential requirement before starting the stability testing & it is a written document containing the key component of a regulated & well - controlled stability study.

There are some protocols which are used for stability testing :

(a) Batches.
(b) Container & closures
(c) Orientation of storage of containers
(d) Sampling time points.
(e) Bracketing & Matrixing
(f) Sampling Plan
(g) Stratification Plan
(h) Test storage condition
(i) Test parameter
(j) Acceptance Criteria.

Page: 85
Date: / /

Quality by Design:

Definition -
A systematic approach for development of pharmaceutical products that begins with predefined objectives & emphasizes product & process understanding & process control based on sound science & quality risk management is defined as Quality by Design.

Overview -
The concept of QbD was developed by Dr. Joseph M. Juran, who believed that quality must be designed into a product & most quality problems are related to the way in which a product was designed.

Intended use, Safety & efficacy

↓

Define quality target product profile

↓

Design formulation & process

↓

Identify critical material attributes & critical process parameters

↓

Control materials & process.

Elements of Qbd program -

(1) **Process Parameter** : This is any input operational parameter of system or unit operation (flow rate) & process state variable (temperature, pressure).

(2) **Control Strategy** : It is defined as a planned set of control derived from current product & process understanding that assures process performance & product quality.

(3) **Design space** : It is defined as the multidimensional combination & interaction of input variables (eg- material attributes) & process parameter established to provide quality assurance.

(4) **Critical Quality Attributes (CQAs)** : It is defined as a physical, chemical, biological or microbiological property or characteristic that should be with in a appropriate limit, range or distribution to ensure the desired product Quality

(5) **Quality Target product profile (QTPP)** : It is defined as a prospective summary of the quality characteristics of a drug product that ideally will be achieved to ensure the desired quality taking into account safety & efficacy of the drug product.

Tools -

(a) Prior knowledge : Prior knowledge is the exclusive information, understanding or skill that applicant acquire through previous studies.

(b) Design of Experiments (DOE) : It is a structured & organised method of determining relationship between the factors influencing process outputs.

(c) Process Analytical Technology (PAT) : It is defined as a system for designing, analysing & controlling manufacturing through measurements during processing of CQAs of raw & in-process materials & processes to ensure the final product quality.

(d) Risk Management Methodology : It is defined as a systematic process for the assessment, control, communication & review of risks to the quality of the drug product across the product lifecycle.

ISO 9000 & ISO 14000 –

→ ISO:

- ISO is 'International organisation for Standardization'.
- It is a non-governmental organization established in 1946 in Geneva, Switzerland.
- It is derived from Greek word 'isos' means 'equal'.
- ISO is the world's largest developer of standards.
- ISO's is the development of technical document.
- ISO Standards are useful to the whole society as they contribute in the development, manufacturing & supply of products & services which are more efficient, safer & cleaner.

Role of ISO –

- ISO makes trade between countries easier & fairer.
- ISO provides governments with a technical base for health, safety & environmental legislation.
- ISO helps in transferring technology to developing countries.
- ISO standards ensure safety & quality of products & services to customers & other users.

→ ISO 9000:

- ISO 9000 is a set of international standards on quality management & quality assurance.
- It assures high quality development of software.
- ISO 9000 helps a company to satisfy its customers, meet regulatory requirements & achieve constant improvement.

- It provides a base level of a quality system.
- It was originally published in 1987 by the ISO.

ISO 9000 Series -

ISO 9000 : Quality management system of fundamentals.
ISO 9001 : Quality management system of requirement
ISO 9002 : For external quality assurance purpose.
ISO 9003 : Quality system model for quality assurance in final inspection.
ISO 9004 : Quality management system for guideline of performance improvement.

Objectives of ISO 9000 -

- Achieve, maintain & seek to continuously improvement in product quality.
- Improve the quality of operation.
- Provide confidence to internal management.
- Provide confidence to customers
- Provide confidence that quality system requirements are fulfilled.

Benefits of ISO 9000 -

- Increased marketability.
- Improved customer service
- Reduced operational expenses
- Better management control
- Increased customer satisfaction
- Improved internal communication
- Reduction of product-liability risk.
- Improved health, safety & reduction of waste.
- Enhanced product quality & reliability at a reasonable price.

Elements of ISO9000 -

(i) Management Responsibilities
(ii) Quality System
(iii) Contract review
(iv) Design control
(v) Document & data control
(vi) Purchasing
(vii) Control of customer supplied product
(viii) Product identification & traceability
(ix) Process control

(x) Inspection & testing
(xi) Control of inspection, measuring & test equipment
(xii) Inspection & test status
(xiii) Control of non-conforming product
(xiv) Corrective & preventive action.
(xv) Handling, Storage, packaging, preservation & delivery
(xvi) Control of quality records.
(xvii) Internal quality ...
(xviii) Training
(xix) Servicing
(xx) Statistical Techniques.

Steps for registration of ISO 9000 -

→ Requirements for Registration of ISO 9000:

- Company review
- Refine
- Map function
  : Process Control
  : Inspection
  : Purchasing
  : Training
  : Packaging
  : Delivery
- Must reregistered in every 3 years
- Helpful for companies that donot currently have a quality management.

→ Steps in obtaining ISO 9000 Certification:

➤ Get top management -

- Top management considers ISO 9000 registration
- Quality Steering Committee meets to evaluate process
- Committee informs top management of ISO 9000 costs, schedule, etc
- Top management commits to persue ISO 9000 registration

➤ Train Personnel -

- Hold basic quality & ISO 9000 training for all employees.
- Select & train personnel to be internal auditor.

➤ Prepare quality manual policy -
- Study & understand ISO 9000 requirements as they apply to your company.
- Write company vision & mission statements.
- Write basic quality Policy manual outline.
- Complete first draft of Quality Policy manual.
- Send copy of manual to customer desiring ISO 9000 compliance.

➤ Prepare operating Procedure -
- Define responsibilities using Quality manual as a guide.
- Have those responsibilities for function outline their procedure.
- Interview managers & fine-tune procedures.
- Compare operating procedures with Quality manual for consistency.

➤ Hold Internal Audit -
- Hold internal audit of ISO 9000 manual vs. ISO 9000 compliance
- Implement corrective action items from audit.

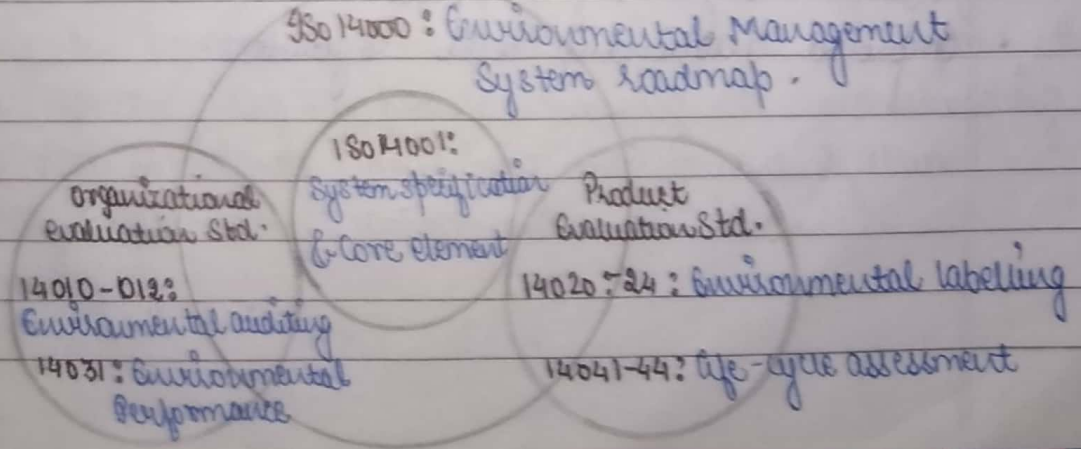
➤ Select registar -
- Research registrars & their cost
- Qualify possible registrars.
- Select third party registrars.

Page: 87
Date: / /

➤ Go through registration process -
- Apply for registration & audits
- Hold pre-assessment audit
- Take any needed corrective action
- Have ISO 9000 registration audit
- Take any needed corrective action
- Re-audit as needed
- Take any needed corrective action

➤ Obtain ISO 9000 registration -
- This verifies that you operate your business in compliance to the ISO 9000 requirements.

→ ISO 14000:
- ISO 14000 is a series of international environmental management standard, guides, & technical reports.
- ISO 14000 provides a systematic way of managing an organization's environmental affairs.
- ISO 14000 focuses on continual improvement of the system.
- First published in 1996 by the ISO.
- The series is divided into 2 separate areas:
(i) Organizational evaluation Standards.
(ii) Product Standards evaluation.



ISO 14000 Series -

ISO 14001 : System Specification & elemental core.
ISO 14004 : General guidelines on principles, system & supporting techniques.
ISO 14010 : General principles of Environmental Auditing
ISO 14020 : Environmental labelling
ISO 14031 : Environmental performance evaluation
ISO 14040 : life cycle assessment
ISO 14050 : vocabulary
ISO 14063 : Environmental Communication
ISO 14064 : Greenhouse gases

Benefits of ISO 14000 -

- lower management cost
- lower disposal cost
- Reduced energy consumptions
- Increased productivity
- Auditing & Report Saving
- Increased compliance
- Enhanced export potential
- meet supplies needs.
- Reduced regulatory exposures
- Improved relationship with regulators.

Elements of ISO 14000 :-

- Environmental policy
- Planning
- Implementation
- Study & Correct
- Management Review
- Continuous Improvement.

Steps for Registration :-

▶ **Step 1 : Plan well -:**
Any organization who wishes to be ISO certified needs serious planning & prep" to ensure that effort, money & time is not wasted. Take time to re-assess your business processes. Check & review all significant data & documents.

▶ **Step 2 : Review the ISO 14001:2015 Standard -:**
Be equipped by getting familiar with the entire ISO 14001: 2015 certification process. Identify legal requirements. Define the EMS scope & procedures.

▶ **Step 3 : Disseminate & Train -:**
It is important that all employees know what goals you are trying to achieve & the process involved to improve the EMS. Next step is to provide training & understanding the ISO standards, developing management system, dealing with non-conformances & so on.

- Step 4 : Perform Internal Audits -:
The best way to evaluate if the EMS is effective is to perform internal audits & self-assessments. Use digital ISO 14001 checklists to assist with documenting & tracking the improvement of your processes.

- Step 5 : Get Certified -:
Choose a notable third-party certification body that will come in to assess the EMS process for adherence with the ISO 14001 : 2015 requirements.

NABL Accreditation :-

- NABL is "National Accreditation Board for Testing & Calibration Laboratories"
- Accreditation is a formal recognition, authorisation & registration of a laboratory that has demonstrated its capability, competence & credibility to perform the tasks it claims to be able to do.
- NABL has been established with the objective of providing government, Industry Association & industry in general with a scheme of Conformity Assessment Body's (CAB) Accreditation which involves third-party assessment of the Technical competence of testing.
- NABL is an autonomous body under the Department of Science & Technology (DST) government of India & registered under the Societies Act.
- NABL accredited laboratories linked with International bodies like Asia Pacific laboratory Accreditation Cooperation (APLAC) & International laboratory Accreditation Cooperation (ILAC) & thus got international recognition.
- The international Standard currently followed by NABL is ISO 15189, which is specific for medical laboratories.

Scope of NABL Accreditation :-

(1) Testing laboratories : Biological, Electronics, Fluid-flow, Mechanical, chemical, Electrical, Non-Destructive Testing, Radiological, Thermal Forensic.
(2) Proficiency testing Providers
(3) Reference material producers.

(4) Calibration laboratories : Electro-Technical, Mechanical Fluid flow, Thermal & optical Radiological

(5) Medical laboratories : Microbiology & Serology, clinical biochemistry, histopathology, cytopathology, clinical pathology, Haematology & Immunohaematology, genetics & nuclear medicine (in-vitro test only)

Benefits of NABL Accreditation :-

- Due to accreditation status, customer confidence in testing & calibration reports issued by the laboratory has increased.
- Due to enhanced customer confidence & satisfaction, the business of laboratory has been increased.
- Accreditation provide better control over the laboratory operation.
- Laboratories get feedback about their technical capability & quality assurance system.
- NABL accreditation results in time & money saving as the need for the re-testing of the products is reduced or eliminated.

Procedure of NABL Accreditation :-

(1) **Application for NABL Accreditation :** The laboratory that desires to get NABL accreditation submits an application in the prescribed form along with its quality manual & prescribed form.

(2) Acknowledgement of Application : The NABL secretariat, on receiving the application in the prescribed format, issues an acknowledgement & assigns a unique ID no. to it.

(3) Review by lead Assessor : The NABL Secretariat appoints a lead assessor to evaluate the application & quality manual & submit it report to NABL secretariat.

(4) Pre-Assessment : The lead assessor visits the laboratory for a pre-assessment of the degree of vigilance of the laboratory for evaluating any non-conformity in the implementation of the quality system & for determining the no. of assessors required, key location to be visited, etc.

(5) Assessment : NABL makes an assessment team including the lead assessor, technical assessor or expert & an observer, after consulting the laboratory that has applied for NABL accreditation.

(6) Scrutiny of Assessment Report : The NABL Secretariat examines the assessment report.

(7) Accreditation Committee : This Committee examines the assessment report & also the report of the laboratory has submitted regarding the corrective actions taken by it.

(8) Issue of Accreditation Certificate : If the recommendation of the accreditation committee is positive, the laboratory is granted accreditations & is also issued an accreditation certificate by NABL.