PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1 NOTES

- QUALITY ASSURANCE
- TOTAL QUALITY MANAGEMENT
- ICH GUIDELINES
- QUALITY BY DESIGN
- ISO 9000 & 14000
- NABL ACCREDITATION

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Quality Management System

- QMS is a structured system of procedures and processes designed to ensure that an organization can consistently deliver products or services that meet customer & regulatory requirements.
- QMS is a set of guidelines & procedures in pharmaceutical industry for maintaining the quality & safety of their products & services.
- It is the act of supervising all the activities required for maintaining a desired level of quality.

Concept Of Quality

- According to USFDA, "Quality is a measure of products or services ability to satisfy the customer's demand."
- Quality isn't only about the product being defect-free but also about fitness for use – i.e., how well it performs its intended function.
- In Pharma, quality means ensuring that the drug is safe, effective, pure & consistent throughout its shelf life.

Importance Of Quality

- Ensure safety & effectiveness of the product.
- Maintains uniformity & consistency in each batch.
- Builds customer trust & satisfaction.
- Helps in regulatory compliance (GMP, WHO guidelines etc.)
- Improves product reliability & shelf life.
- Enhances company reputation & market acceptance
- Supports cost controly by preventing rework & failures.

Quality Assurance

- Quality Assurance means making sure that a product is made correctly every time & is safe, effective, & of good quality.
- It focuses on preventing mistakes rather than finding them later.

Objectives Of Quality Assurance

- To ensure good quality of the product
- To make products safe for use
- To maintain same quality in evey batch
- To follow rules & guidelines (GMP)
- To avoid errors & defects

Scope Of Quality Assurance

Quality Assurance covers all steps from start to end:

- Raw Materials Checking
- Manufacturing process
- In- Process controls
- Testing of finished product
- Packaging, storage & distribution
- Proper documentation

Elements Of Quality Assurance

① Good Manufacturing Practices

- GMP are basic rules that ensure products are made in a clean, safe & controlled environment.
- They include:
  - Clean buildings & equipment
  - Proper maintenance of machines
  - Qualified & trained workers
  - Correct manufacturing methods

② Documentation

- Documentation means writing down everything related to manufacturing & testing:
- It includes:
  - Standard Operating Procedures (SOPs)
  - Batch Manufacturing Records (BMR) etc.
- Proper documentation ensures traceability, helps in checking mistakes, & proves that work was done correctly.

③ Quality Control

- Quality Control involves testing & checking raw materials, in-process materials & finished products.
- QC ensures that the product:
  - Meets required standards
  - Is safe & effective

④ Validation

- Validation is the process of providing that machines, methods & processes work properly.
- It confirms that:
  - Equipment gives correct results
  - Manufacturing process produces the same quality product every time.

⑤ Training Of Personnel

- All workers must be properly trained before doing their job.
- Training helps:
  - Workers follow SOPs correctly
  - Reduce human errors
  - Improves overall product quality

⑥ Self - Inspection And Audits

- Self inspection means checking the system regularly to find problems.
- Audits help in:
  - Finding mistakes early
  - Improving the quality system
  - Ensuring compliance with guidelines

Importance Of Quality Assurance

- Prevents poor- quality products
- Protects patient health
- Builds trust in the company
- Reduces wastage & looses

Quality Control

- Quality Control is the part of quality management that checks & tests product to make sure they meet required standards.
- Its main role is to detect errors & defects in raw materials, in process materials, & finished products.

Objective Of Quality Control

- To ensure products meet quality specifications
- To detect defective or substandard materials
- To ensure safety & effectiveness of the product
- To maintain uniformity & consistency
- To support Quality Assurance activities

Scope Of Quality Control

Quality Control covers testing & checking activities such as:

- Testing of raw materials
- In-process testing during manufacturing
- Testing of finished products
- Stability testing
- Environmental monitoring

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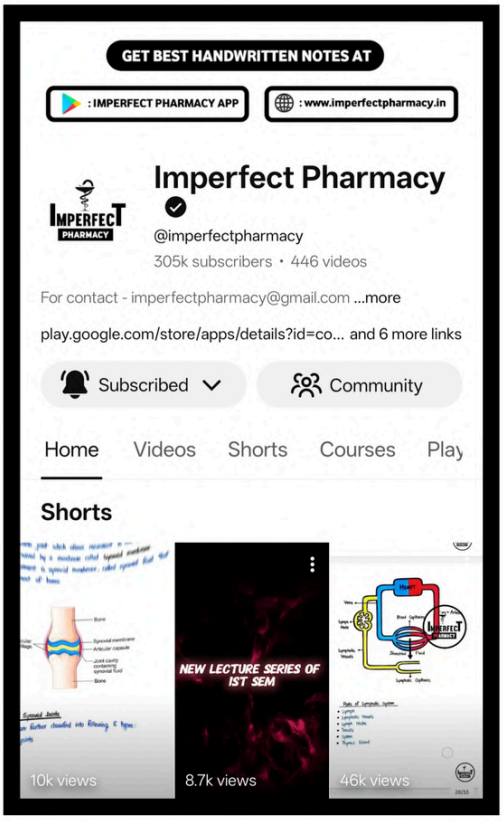

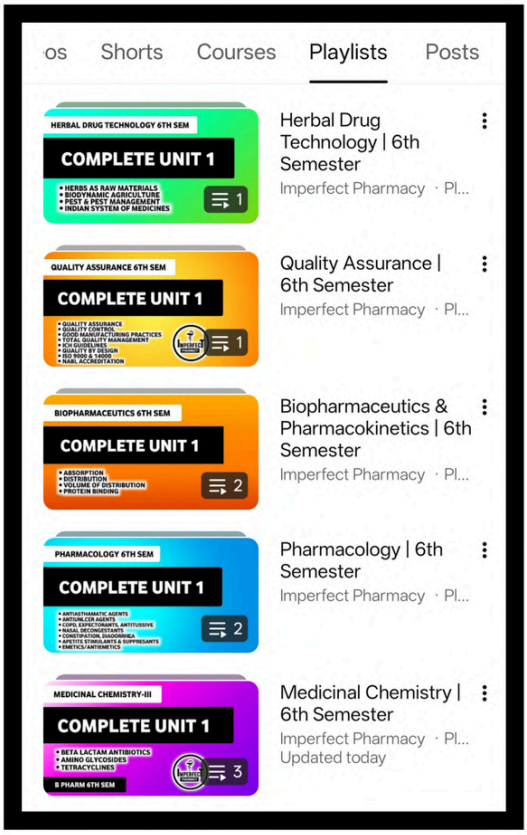

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Elements Of Quality Control

① Raw Material Testing

- All raw materials are tested before use
- Ensures materials meet pharmacopoeial standards
- Prevents use of poor-quality materials

② In-Process Quality Control

- Testing done during manufacturing
- Checks weight variation, hardness, pH, moisture etc.
- Helps in early detection of errors

③ Finished Product Testing

- Final testing before product release
- Ensures product meets specifications for quality, safety & efficacy.
- Only approved products are released to the market.

④ Documentation

- Recording test results & observations
- Includes tests reports & analytical records
- Helps in traceability & audit purpose

Important Of Quality Control

- Prevents release of defective products
- Ensures patient safety
- Maintains product consistency
- Helps in regulatory compliance
- Builds trust in the product

Quality Assurance Vs Quality Control

Quality Assurance (QA)	Quality Control (QC)
• Focuses on process	• Focuses on product
• Prevents mistakes	• Finds mistakes
• Done before & during manufacturing	• Done after or during manufacturing.
• Proactive approach	• Reactive approach
• Concerned with how work is done	• Concerned with what result is obtained
• Includes GMP, SOPs, validation, training	• Includes testing, analysis, inspection
• Responsibility of everyone	• Responsibility of QC department
• Aims to build quality	• Aims to check quality
• Reduces chances of defects	• Detects defects in products

Good Manufacturing Process

- Good Manufacturing Practices (GMPs) are rules & guidelines that ensure medicines & other products are consistently made with good quality, safe & effective for use.
- GMP is a part of Quality Assurance.

Objectives Of GMP

- Ensure products are safe, effective, and of high quality.
- Maintain consistency in every batch
- Prevent contamination, mix-ups & errors
- Ensure compliance with regulatory guidelines
- Build trust among patients & consumers

Elements Of GMP

① Premises & Equipment

- Factory should be clean, well-lit & well-ventilated.
- Equipment should be properly maintained & calibrated.
- Layout should prevent contamination & mix-ups

② Personnel And Training

- Staff should be qualified & trained
- Follow hygiene & safety rules
- Proper supervision & clear responsibilities

③ Raw Materials And Packaging

- Materials should be tested before use.
- Stored in proper conditions
- Prevents use of poor-quality materials.

④ Production Process

- Follow standard operating procedures (SOPs)
- Maintain in-process checks
- Ensure uniformity & consistency

⑤ Quality Control

- Testing of raw materials, in-process samples & finished products.
- Only products meeting specifications are released for sale.

⑥ Documentation

- Maintain records of every step
- Includes batch records, SOPs, equipment logs
- Helps in traceability, audit & investigation

⑦ Storage And Distribution

- Products stored under correct conditions (temperature, humidity)
- Proper labelling & handling during distribution.

Importance Of GMP

- Ensures patient safety
- Maintains product quality & consistency
- Reduces wastage, recalls & legal issues
- Helps in regulatory compliance
- Builds reputation & trust

TOTAL QUALITY MANAGEMENT

- Total - Made up of the whole (or) Complete.
- Quality - Degree of Excellence a product or service provides to the customer in present & future.
- Management - Act, art, or manner of handing, controlling, directing, etc. TQM is the art of manging the whole to achieve excellence.

- TQM requires that the company maintain this quality standard in all aspects of its business. This requires ensuring that things are done right the first time & that defects and waste are eliminated from operations.

OBJECTIVES OF TQM

- To achieve customer satisfaction.
- To ensure continuous improvement in all activities.
- To involve all employees in quality improvement.
- To reduce wastage & defects in processes.
- To enhance efficiency & productivity.
- To maintain long-term success through cosistent quality.

PRINCIPLE OF TQM

- Total Quality Management is built on a set of core principles that help organizations achieve continuous improvement & customer satisfaction.

① Focus On Customer

- The main goal of TQM is to meet or exceed customer expectations.
- Customer satisfaction determines product quality & business sucess.
- Regular feeback helps identify areas for improvement.

② Employee Involvement

- Every employee is responsible for maintaining quality.
- Encourages teamwork, motivation, and participation in decision-making.
- Proper training & empowerment help employees contribute to quality goals.

③ Process Centered

- Quality is achieved by improving the process, not just checking the final product.
- Each step in production is monitored & optimized to prevent errors.
- A controlled process ensures consistent & reliable output.

④ Integrated System

- All department (production, QC, QA, HR, marketing) work together as one system.
- Quality is everyone's resposibility – not limited to a single department.
- Promotes coordination & communication across the organization.

⑤ Strategic And Systematic Approach

- Quality improvement must be planned strategically.
- A clear vision, mission, & quality policy guide the organization.
- Quality objectives are set, implemented, & reviewed systematically.

⑥ Decision-Making Based On Facts

- Decisions should rely on accurate data, not assumptions.
- Statistical tools & quality records help analyze performance & identify issues.
- Data-driven actions improve reliability & reduce defects.

⑦ Communication

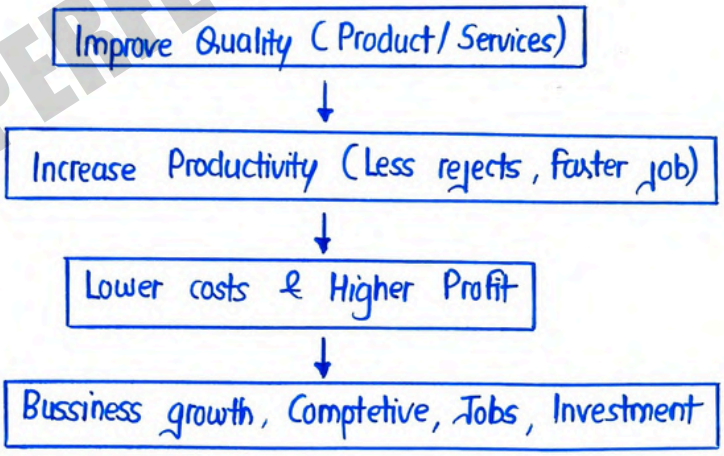
- Open & effective communication ensures that quality goals are understood by all.
- Promotes trust, cooperation & problem-solving among employees.
- Regulars meetings & feeback strengthen teamwork.

⑧ Continuous Improvement

- T&M emphasizes ongoing efforts to improve processes, products & services.
- The aim is to reduce errors, improve efficiently & enhance customer satisfaction.

Effect

- The flowchart below shows the effect of T&M:



Benefits Of TQM

- Improves product quality & reliability.
- Increases customer satisfaction & loyalty.
- Reduces waste, defects & production cost.
- Enhances efficiency & productivity.
- Promotes employee involvement & teamwork.
- Ensures regulatory compliance.
- Improves brand image & market competetiveness
- Leads to long-term success & profitability.

ICH

- ICH stands for "International Council of Harmonisation" of technical requirements for pharmaceuticals for human use.
- It is an international organization that brings together regulatory authorities & pharmaceutical industry to develop common guidelines for any drug development & registration.
- ICH makes common rules for medicines so that same quality, safety & effectiveness standards are followed in all countries.

History & Need Of ICH

- ICH was formed in 1990 by representatives from the regulatory agencies & industries of US, Europe & Japan.
- Initially, it was known as "International Conference of Harmonisation" & Now, it's known as "International Council of Harmonisation".
- The ICH Secretriat (Administrative office) is located in Geneva, Switzerland.
- Before the ICH existed (pre-1990), different countries had different rules for testing drugs.
- If a company wanted to sell a medicine in other countries such as, US, Europe & Japan, they often had to repeat the same expensive tests two-three times just to meet different paperwork requirements.
- The ICH was formed to "hormonize" these rules so that one set of high-quality standards would be accepted everywhere.

Objectives Of ICH

- Harmonize (make same) drug regulations worldwide.
- Ensure quality, safety & efficacy of medicines.
- Reduce unneccessary clinical trials.
- Faster availability of medicines to patients.

MEMBERS IN ICH

- The founding members represents authorities & research based industries in European Union, Japan & USA.

① JAPAN: MHLW (Ministry of Health, Labour & Welfare)
JPMA (Japan Pharmaceutical Manufacturers Association)

② EUROPE: EC (European Commission)
EFPIA (European Federation of Pharmaceutical Industries & Association)

③ USA: FDA (Food & Drug Administration)
PhRMA (Pharmaceutical Reseach & Manufactures of America)

- Additional members include observes such as WHO & regulatory members from countries other than Japan, Europe & USA.

ICH GUIDELINES

ICH Guidelines are divided into 4 main series:

- Q: Quality
- S: Safety
- E: Efficacy
- M: Multidiscipilinary

Quality Guidelines

- The ICH Q-series guidelines deals with the 'Quality' of pharmaceutical products.
- It ensures that a medicine is consistently manufactured, stable, pure & safe for patient use throughout its shelf life.
- These guidelines cover:
  - Raw Materials
  - Manufacturing Process
  - Testing Methods
  - Stability
  - Quality Systems

Objectives Of ICH Q-Series

- To ensure high quality of drugs
- To maintain batch-to-batch consistency
- To control impurities & degradation products
- To establish international quality standards
- To protect patient safety

Quality Guidelines	
Q1A - Q1F	Stability
Q2	Analytical Validation
Q3A - Q3D	Impurities
Q4A - Q4B	Pharmacopoeias
Q5A - Q5E	Quality of Biotechnological Product
Q6A - Q6B	Specifications
Q7	Good Manufacturing Process
Q8	Pharmacopoeial Development
Q9	Quality Risk Management
Q10	Pharmaceutical Quality System
Q11	Development & Manufacture of Drug Substances
Q12	Lifecycle Management
Q13	Continuous Manufacturing of Drug Substances & Drug Products
Q14	Analytical Procedure Development

Q1 - Stability Testing

- Purpose : To study how long a drug remains stable & effective under different conditions

- Includes :
  - Q1A - Stability testing of new drug substances & products
  - Q1B - Photostability (effect of light)
  - Q1C - Stability testing of new dosage forms
  - Q1D - Bracketing & Matrixing designs
  - Q1E - Evaluation of stability data

- Helps in dicding expiry date & storage conditions.

Q2 - Analytical Validation

- Purpose: To ensure analytical test methods are accurate, reliable & reproducible.

- Checks :- Accuracy
  - Precision
  - Specificity
  - Linearity

- Ensures correct testing of drug identity, purity & strength.

Q3 - Impurities

- Purpose: To control harmful impurities in drugs.

- Types :- Q3A : Impurities in drug substances
  - Q3B : Impurities in drug products
  - Q3C : Residual solvents
  - Q3D : Elemental impurities
  - Q3E : Extractables & leachables

- Ensures drugs are safe & free from toxic impurities.

Q4 - Pharmacopoeial Harmonisation

- Purpose: To harmonize standards of different pharmacopoeia like USP, BP, JP, IP.
- Same quality standards accepted in different countries.

Q5 - Quality Of Biotechnological Products

- Purpose: To ensure quality of biological medicines like insulin & vaccines.
- Covers: - Viral safety
  - Stability
  - Cell Substances
  - Manufacturing process
- Important for biotech & biological products.

Q6 - Specifications

- Purpose: To define test procedures & acceptance criteria for drugs.
- Decides what tests to perform & what limits are acceptable.

Q7 - Good Manufacturing Practice (GMP)

- Purpose: To provide GMP guidelines for Active Pharmaceutical Ingredients (APIs).
- Covers:
  - Personnel
  - Equipment
  - Documentation
  - Hygiene
  - Quality Control
- Ensures safe & consistent manufacturing.

Q8 - Pharmaceutical Development (PD)

- Purpose: To develop medicines using Quality by design (QbD) approach.
- Quality is built during development, not checked only at the end.

Q9 - Quality Risk Management

- Purpose: To identify, evaluate, & control risk related to drug quality.
- Helps prevent quality failures & recalls.

Q10 - Pharmaceutical Quality System (PQS)

- Purpose: To maintain quality throughout the entire product life cycle.
- Includes manufacturing, change control & continuous improvement.

Q11 - Development & Manufacture Of Drug Substance

- Purpose: Guidelines for development & manufacture of chemical & biological drug development.

Q12 - Life Cycle Management

- Purpose: To manage post-approval changes in pharmaceutical products.
- Ensures continuous quality after approval.

Q13 - Continuous Manufacturing

- Purpose: Guidelines for continuous manufacturing of drug substances & products
- Improves efficiency & quality consistency.

Q14 - Analytical Procedure Development

- Purpose: Guidelines for developing & improving analytical procedures.
- Supports better analytical validation.

Safety Guidelines

- Safety guidelines ensure that a drug is safe for human use.
- It includes study of toxicity of drugs in animals.
- Check effects on organs, DNA, Cancer risk & reproduction.
- Ensure the drug doesn't cause serious harmful effects.

Efficacy Guidelines

- Efficacy guidelines ensure that a drug works effectively in patients.
- Guide clinical trials in humans
- Include Good Clinical Practice (GCP)
- Study proper dose, effectiveness, & side effects

Multidisciplinary Guidelines

- Multidisciplinary guidelines cover common regulatory topics.
- Provides CTD format for drug submission
- Standardize electronic data & medical terms
- Help smooth communication b/w regulatory authorities & researches

STABILITY TESTING

- Stability means the ability of a drug substance or drug product to remain chemically, physically & therapeutically stable throughout its shelf life when stored under recommened conditions.
- Stability testing checks how long a drug remains good & effective.
- It studies effect of temperature, humidity & light.
- It helps to decide expiry date & storage conditions.

TYPES OF STABILITY TESTING

① LONG-TERM STABILITY STUDY

- Done under normal storage conditions
- Helps to decide shelf life.

② ACCELERATED STABILITY STUDY

- Done under high temperature & humidity
- Predicts long-term stability in short time

③ INTERMEDIATE STABILITY STUDY

- It performed when drug fails under accelerated conditions

Storage Conditions

Study Type	Storage Condition
Long-term	25°C/60 or 30°C/65% RH
Intermediate	30°C/65% RH
Accelerated	40°C/75% RH

Climate Zones

- ICH devides the world into climate zones based on temperature & humidity:

  - Zone I - Temperate
  - Zone II - Mediterranean
  - Zone III - Hot & Dry
  - Zone IV - Hot & Humid

- India belongs to Zone IV

ICH Guidelines For Stability Testing

- ICH provides guidelines for stability testing of pharmaceutical products under Q1 of Q series as follows :

① Q1A - Stability Testing of New Drug Substances & Products

- Used for new drugs
- Drug is stored under different conditions
- Long-term, intermediate & accelerated studies are done
- Helps to fix shelf life & expiry date

② Q1B - Photostability Testing

- Checks effect of light on drug
- Finds whether drug is light sensitive.
- Helps to detect light-protecting packaging.

③ Q1C - Stability Testing for New Dosage Forms

- Used when a new dosage form is made
- Example: Tablet changed to syrup.
- Ensures new dosage form remains stable

④ Q1D - Bracketing & Matrixing

- Used to reduce number of stability tests
- Bracketing tests extreme samples only
- Matrixing tests selected examples
- Saves time & cost

Q1E - Evaluation of Stability Data

- Stability results are analysed
- Helps to calculate expiry dates
- Uses statistical methods

Q1F - Stability Data for Climate Zone III & IV

- Used for Hot & humid countries
- India comes under Zone IV
- Ensures drugs remain stable in Indian climate

IMPORTANCE OF ICH STABILITY GUIDELINES

- Ensures drugs remain safe & effective till expiry.
- Helps regulatory approval
- Prevents product degradation during storage & transport
- Ensures uniforms standards worldwide.

Quality By Design

- The concept of QbD was mentioned in the ICH Q8 guideline, which states that "quality can't be tested into products, i.e., quality should be built in by design".
- Quality by design (QbD) is a systematic, scientific, and risk-based approach to pharmaceutical development that ensures predefined product quality by understanding the process & controlling the variables.

Concept

- QbD focuses on building quality into the product from the beginning, rather than testing it at the end.
- It emphasizes "Quality can't be tested into products, it should be built in.
- It links product performance with process parameters through scientific understanding.

Objectives Of QbD

- To ensure consistent product quality & efficacy.
- To reduce variability in manufacturing.
- To minimize risk of product failure.
- To enhance process understanding & control.
- To facilitate regulatory flexibility & faster approvals.

Elements Of QbD

The following Elements can be included in the study of QbD:

- QTPP
- CQAPs
- Risk Assesment
- Design Space
- Control Strategy
- PAT
- Continuous Improvement

① Quality Target Product Profile (QTPP):

- Describes the intented use, safety, efficacy & quality of the final product.
- Examples: Table strength, dissolution rate, stability, etc.

② Critical Quality Attributes (CQAs):

- Physical, chemical, biological, or microbiological properties that must be within limits for product quality.
- Example: Assay, Content uniformity, hardness, disintegration time.

③ Risk Assesment (RA):

- Identifies & evaluates risks to product quality.
- Tools: FMEA (Failure Mode and Effect Analysis), Ishikawa (Fishbone) diagram, Risk Matrix.

④ Design Space

- The multidimentional combination of input variables (like formulation and process parameters) that ensures product quality.

⑤ Control Strategy

- A set of controls & monitoring parameters to maintain process within design space.
- Includes raw material testing, in-process controls, & end-product testing.

⑥ Process Analytical Technology (PAT):

- A tool used inproduct quality.
- Working within this space is not considered a change by regulatory agencies.
- QbD for real-time monitoring of manufacturing process.
  Ensures consistent product quality without stopping the process.

⑦ Continuous Improvement

- Data from manufacturing is continuosly analyzed for process optimization & innovation.

Steps In QbD Approach

- Define QTPP
- Identify CQAs
- Perform risk assesment
- Design & conduct experiments.
- Establish design space
- Develop control strategy
- Validate & implement continuous improvement.

Benefits Of QbD

- Ensure consistent product quality.
- Improves process understanding.
- Reduces batch failures & variations.
- Provides regulatory flexibility.
- Saves cost & development time.
- Enables effective risk manggement.
- Support continuous improvement.
- Increases patient safety & reliability.

ISO 9000

- ISO 9000 is a series of international standards developed by the International Organization for Standardization (ISO) that provide guidelines & requirements for establishing & maintaining an effective Quality Management System (QMS).
- In industrial pharmacy, ISO 9000 principles are applied to ensure that pharmaceutical products are consistently manufactured and controlled meet quality, safety & efficacy requirements.

Objectives Of ISO 9000

- Ensure consistent product quality
- Improve customer satisfaction
- Establish effective quality management system
- Promote continuous improvement
- Ensure compliance with regulatory requirements
- Encourage evidence-based decision making.

ISO 9000 Family Of Standards

The ISO 9000 series include several related standards:

Standards	Title / Focus
ISO 9000:2015	Fundamentals & vocubalary of QMS
ISO 9000:2015	Requirement for quality management system (certified stadard)
ISO 9004:2018	Guidelines for achieving sustained access through QMS
ISO 19011:2018	Guidelines for auditing management systems

History Of ISO 9000

- Originally published in 1987 by the International Organization for Standardization (ISO).
- Major revisions occured in :
  - 1994 : Focused on preventive actions.
  - 2000 : Combined 9001, 9002, and, 9003 into a sigle standard (ISO 9001).
  - 2008 : Improved clarity & compatibility with ISO 14001.
  - 2015 : Introduced risk-based thinking & leadership focus.
- The ISO 9000 family now includes ISO 9000, 9001, 9004 & 19011 standards.

ISO 9000 Principles

- The ISO 9000 : 2015 & ISO 9001: 2015 standard are based on seven quality management principles that senior management can apply for organizational improvement.

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

① Customer Focus

- The main goal is to meet & exceed customer expectations.
- Satisfied customers ensure long-term success & trust in organization.

② Leadership

- Strong leadership establishes a clear vision & direction.
- It helps align people & processes toward achieving quality objectives.

③ Engagement Of People

- Involving all employees increases motivation & responsibility.
- Everyone contributes to process improvement & product quality.

④ Process Approach

- Managing activities as interrelated processes improves efficiency & consistency.
- It ensures predictable & desired outcomes.

⑤ Improvement

- Continuous improvement is essential for maintaining performance & competetiveness.
- It encourages innovation & adaptation to changes.

⑥ Evidence - Based Decision Making

- Decision should be based on data and analysis, not assumptions.
- This reduces errors & improves effectiveness of actions.

⑦ Relation Management

- Good relationship with suppliers, customers & stakeholders enhance cooperation.
- It supports sustained success & value creation.

Benefits Of Implementing ISO 9000 In Industrial Pharmacy

- Ensures consistent product quality & compliance with GMP.
- Promotes process standardization across departments & facilities.
- Enhances documentation & traceability, aiding regulatory inspections.
- Encourages a quality - oriented organizational culture.
- Provides a framework for continual improvement.
- Faciliates international market access due to globally recognized certification.

ISO 14000

- The ISO 14000 series is a set of international standards developed by International Organization for Standardization (ISO) that focus on Environmental Management System (EMS).
- These standards help organizations minimize negative environmental impacts from their operations, comply with environmental laws & regulations, and persue continuous environmental performance improvement.
- In industrial pharmacy, ISO 14000 provides a structured approach for managing environmental responsibilities — such as waste disposal, energy consumption, chemical handling & pollution control — while maintaining high standards of quality & safety.

Objectives Of 14000 ISO In The Pharmaceutical Industry

- To control & reduce environmental pollution arising from pharmaceutical operations.
- To ensure compliance with national & international environmental regulations.
- To promote efficient use of natural resources & minimize waste.
- To prevent contamination from hazardous chemicals & effluents.
- To demonstrate corporate environmental responsibility & transparency.
- To integrate environmental management into the overall EMS.

ISO 14000 Environmental Standards

ISO Standard	Standard Name/Description
ISO 14001:2015/Amend 1:2024	Environmental Management Systems – Requirements with guidance for use
ISO 14004:2016	General guidelines on implementation
ISO 14005:2019	Guidelines for a flexible approach to phased implementation
ISO 14006:2020	Guidelines for incorporating ecodesign
ISO 14015:2022	Environmental assessments of sites and organizations
ISO 14020:2020	Environmental labels and declarations – General principles
ISO 14024:2018	Type I environmental labelling – Principles and procedures
ISO 14025:2006	Type III environmental declarations – Principles and procedures
ISO 14031:2013	Environmental performance evaluation – Guidelines
ISO 14040:2006	Life cycle assessment – Principles and framework
ISO 14044:2006	Life cycle assessment – Requirements and guidelines
ISO 14046:2014	Water footprint – Principles, requirements and guidelines
ISO 14050:2020	Environmental management – Vocabulary
ISO 14063:2020	Environmental communication – Guidelines and examples
ISO 14064-1:2018	Greenhouse gases – Org. quantification and reporting
ISO 14064-2:2019	Greenhouse gases – Project-level GHG reductions
ISO 14064-3:2019	Greenhouse gases – Verification/validation guidance
ISO 14067:2018	Greenhouse gases – Product carbon footprint

Key Principle Of ISO 14000

- The ISO 14000 series operates on several guiding principles :

① Environmental Policy Commitment - Defining the organization's intent to protect the environment.

② Prevention over Correction - Focusing on preventing pollution rather than reacting to it.

③ Compliance with regulations - Adhering to environment laws & standards.

④ Continuous improvement - Setting & achieving progressively higher environmental goals.

⑤ Stakeholder Involvement - Engaging employees, supplies, customers & communities.

⑥ Documentation & Transparency - Maintaing traceable & auditable environmental records.

Objectives

- Improves environmental performancy by reducing pollution & waste.
- Helps Organization follow environmental laws & regulations.
- Reduces operational costs by saving energy & resources.
- Enhances company image & reputation.
- Promotes sustainable & eco-friendly practices.
- Encourages continuous improvement in environmental management.
- Supports international trade through global recognization.

NABL

- The National Accreditation Board for Testing and Callibration Laboratories (NABL) is an autonomus body under the Quality Council of India (QCI) that provides accreditation to laboratories performing testing, calibration & medical diagnostics in India.
- NABL play a vital role in ensuring that laboratories involved in pharmaceutical industry, calibration of equipment & quality control operate in accordance with international standards for competence & reliability.
- Accredation by NABL signifies that laboratory is technically competent, follows validated methods, and produces accurate, reliable & traceable results.

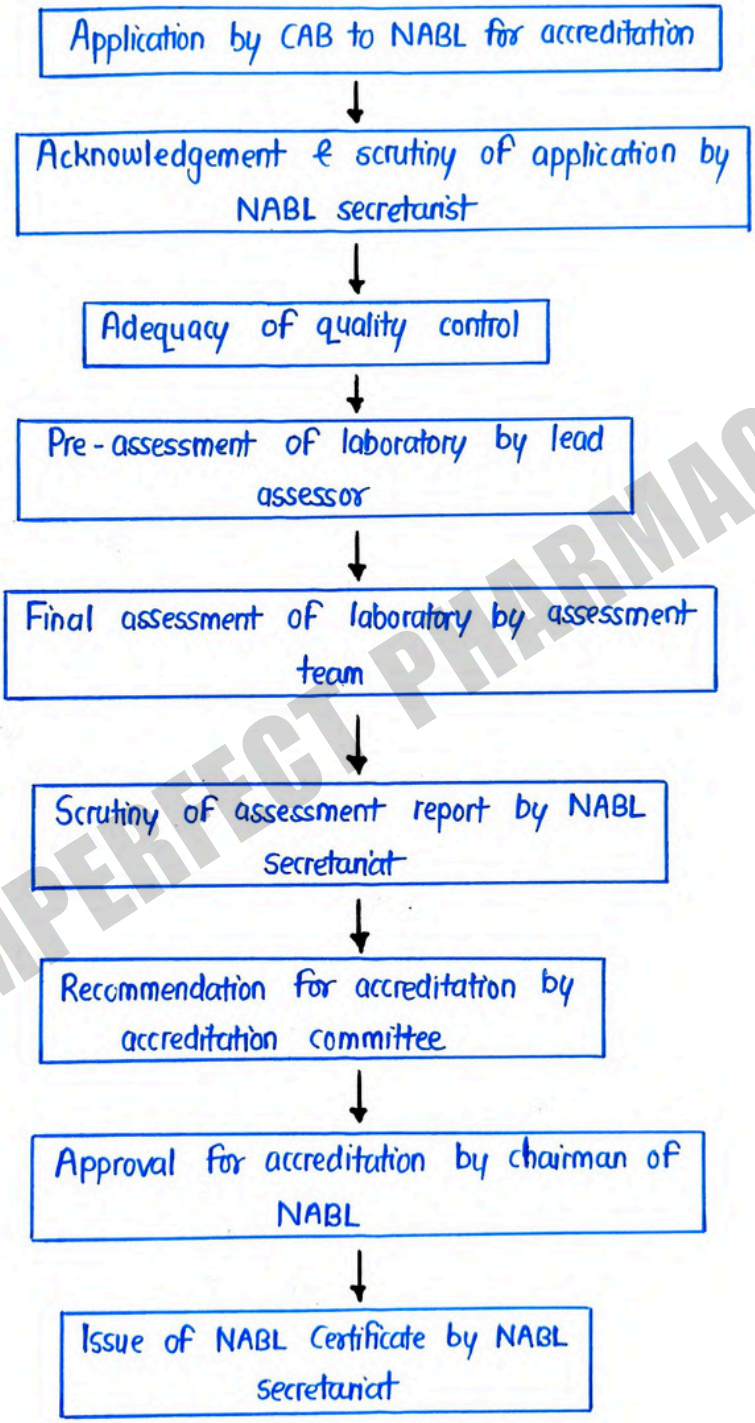
HISTORICAL BACKGROUND

- NABL was established in 1900 under the Department of Science and Technology (DST), Government of India.
  Later, it became a constituent board of the Quality Council of India.
- NABL is a signatory to international mutual recognition arrangements:
  - Asia Pacific Accredetation Cooperation (APAC) MRA
  - International Laboratory Accredetation Cooperation (ILAC) MRA
  - These recognitions make NABL - accredited laboratory results globally accepted.

Objective Of NABL

- To provide a formal recognition system for laboratories that meet international standards of competence.
- To promote quality assurance & technical competence in testing & calibration.
- To ensure data integrity & traceability in laboratory results.
- To enhance acceptance of Indian Laboratory data, globally, minimizing the need for retesting.
- To facilitate regulatory compliance in industries such as pharmaceuticals, food, environment, & healthcare.

NABL Accreditation Process



Benefits Of NABL Accreditation

- Ensures laboratory follows international quality standards.
- Increases reliability & accuracy of test results.
- Builds customer confidence in lab reports.
- Reduces need for re-testing of samples.
- Helps in national & international recognition.
- Improves overall laboratory performance & competence.
- Encourages continuous improvement through regular audits.

THANK YOU

FOR CHOOSING IMPERFECT PHARMACY AS YOUR STUDY PARTNER

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