**UNIT V**

| **Quality Assurance** | **Quality Control** |
|---|---|
| It is a process which deliberate on providing assurance that quality request will be achieved. | QC is a process which deliberates on fulfilling the quality request. |
| A QA aim is to prevent the defect. | A QC aim is to identify and improve the defects. |
| QA is the technique of managing the quality. | QC is method to verify the quality. |
| QA does not involve executing the program. | QC always involves executing the program. |
| All team members are responsible for QA. | Testing team is responsible for QC. |
| QA e.g. Verification. | QC e.g. Validation. |
| QA means Planning for doing a process. | QC Means Action for executing the planned process. |
| Statistical Technique used on QA is known as Statistical Process Control (SPC.) | Statistical Technique used on QC is known as Statistical Quality Control (SPC.) |
| QA makes sure you are doing the right things. | QC makes sure the results of what you've done are what you expected. |
| QA Defines standards and methodologies to followed in order to meet the customer requirements. | QC ensures that the standards are followed while working on the product. |
| QA is the process to create the deliverables. | QC is the process to verify that deliverables. |
| QA is responsible for full software development life cycle. | QC is responsible for **software testing life cycle.** |

- In QA, processes are planned to evade the defects.
- QC agreements with discovery the defects and modifying them while making the product.
- QA detects weakness.
- QC detects defects.
- QA is process oriented
- QC is product oriented.
- QA is failure prevention system.
- QC is failure detection system.

# QUALITY AUDIT

It is the process of systematic examination of a quality system carried out by an internal or external quality auditor or an audit team. It is an important part of organization's quality management system and is a key element in the ISO quality system standard, ISO 9001.

Quality audits are typically performed at predefined time intervals and ensure that the institution has clearly defined internal system monitoring procedures linked to effective action. This can help determine if the organization complies with the defined quality system processes and can involve procedural or results-based assessment criteria.

With the upgrade of the ISO9000 series of standards from the 1994 to 2008 series, the focus of the audits has shifted from purely procedural adherence towards measurement of the actual effectiveness of the Quality Management System (QMS) and the results that have been achieved through the implementation of a QMS.

Audits are an essential management tool to be used for verifying objective evidence of processes, to assess how successfully processes have been implemented, for judging the effectiveness of achieving any defined target levels, to provide evidence concerning reduction and elimination of problem areas. For the benefit of the organization, quality auditing should not only report non-conformances and corrective actions, but also highlight areas of good practice. In this way other departments may share information and amend their working practices as a result, also contributing to continual improvement.

Quality audits can be an integral part of compliance or regulatory requirements. One example is the US Food and Drug Administration, which requires quality auditing to be performed as part of its Quality System Regulation (QSR) for medical devices.

Several countries have adopted quality audits in their higher education system (New Zealand, Australia, Sweden, Finland, Norway and USA) Initiated in the UK, the process of quality audit in the education system focused primarily on procedural issues rather than on the results or the efficiency of a quality system implementation.

Audits can also be used for safety purposes. Evans & Parker (2008) describe auditing as one of the most powerful safety monitoring techniques and 'an effective way to avoid complacency and highlight slowly deteriorating conditions', especially when the auditing focuses not just on compliance but effectiveness.

The processes and tasks that a quality audit involves can be managed using a wide variety of software and self-assessment tools. Some of these relate specifically to quality in terms of fitness for purpose and conformance to standards, while others relate to Quality costs or, more accurately, to the Cost of poor quality. In analyzing quality costs, a cost of quality audit can be applied across any organization rather than just to conventional production or assembly processes

## TYPE OF AUDIT

**1- (INTERNAL AUDIT) FIRST PARTY QUALITY AUDIT** :

When an organization conducts an audit on its own quality system using its own staff / external consultants, the audit is known as first part quality audit or internal quality audit. Important points are: auditing staff must be trained for conducting this exercise and should not bias against the functional department being audited.

**2) SECOND PARTY QUALITY AUDIT (EXTERNAL QUALITY AUDIT):**

The second party quality audit is performed by the purchasing organization upon the supplier organization. The idea here is to have an assessment of the supplier's processes in order to have confidence that the supplier would be able to supply goods or services of an agreed quality level on a sustained basis. Important point is these audits can be performed by the trained personnel of the purchasing organization or an outside agency hired by them.

3) **THIRD PARTY QUALITY AUDIT** (EXTRINSIC AUDIT):

This audit is performed by the certification bodies (ISO registered bodies) on the applicant organization seeking such certification. If these, auditors, after conducting the quality audit on the organization with respect to a standard, find the organization to be worthy enough, the certification is granted to the organization. Third party audits normally results in the disruption of day-to-day activities of the organization being audited during the duration of the audit. Apart from the registered certification bodies, the third part audit may also be conducted by some government departments dealing with environment and pollution, health and safety, atomic energy etc.

## TOTAL QUALITY MANAGEMENT (TQM)

**Total Quality management is defined as a continuous effort by the management as well as employees of a particular organization to ensure long term customer loyalty and customer satisfaction.** It consists of organization-wide efforts to install and make permanent a climate in which an organization continuously improves its ability to deliver high-quality products and services to customers. While there is no widely agreed-upon approach, TQM efforts typically draw heavily on the previously developed tools and techniques of quality control. Remember, one happy and satisfied customer brings ten new customers along with him whereas one disappointed individual will spread bad word of mouth and spoil several of your existing as well as potential customers.

You need to give something extra to your customers to expect loyalty in return. Quality can be measured in terms of durability, reliability, usage and so on. Total quality management is a structured effort by employees to continuously improve the quality of their products and services through proper feedbacks and research. Ensuring superior quality of a product or service is not the responsibility of a single member.

Every individual who receives his/her paycheck from the organization has to contribute equally to design foolproof processes and systems which would eventually ensure superior quality of products and services. Total Quality management is indeed a joint effort of management, staff members, workforce, suppliers in order to meet and exceed customer satisfaction level. You can't just blame one person for not adhering to quality measures. The responsibility lies on the shoulder of everyone who is even remotely associated with the organization.

Total Quality management originated in the manufacturing sector, but can be applied to almost all organizations.Total quality management ensures that every single employee is working towards the improvement of work culture, processes, services, systems and so on to ensure long term success.

Total Quality management can be divided into four categories:

- Plan
- Do
- Check
- Act

Also referred to as PDCA cycle.

**Planning Phase**

Planning is the most crucial phase of total quality management. In this phase employees have to come up with their problems and queries which need to be addressed. They need to come up with the various challenges they face in their day to day operations and also analyze the problem's root cause. Employees are required to do necessary research and collect relevant data which would help them find solutions to all the problems.

**Doing Phase**

In the doing phase, employees develop a solution for the problems defined in planning phase. Strategies are devised and implemented to overcome the challenges faced by employees. The effectiveness of solutions and strategies is also measured in this stage.

**Checking Phase**

Checking phase is the stage where people actually do a comparison analysis of before and after data to confirm the effectiveness of the processes and measure the results.

**Acting Phase**

In this phase employees document their results and prepare themselves to address other problems.

The key concepts in the TQM

- "Quality is defined by customers' requirements."
- "Top management has direct responsibility for quality improvement."
- "Increased quality comes from systematic analysis and improvement of work processes."
- "Quality improvement is a continuous effort and conducted throughout the organization.

## ISO 9000 SERIES

Iso ; It stands for (International Organization For Standardization (**ISO**)

ISO 9000 is a set of international standards on quality management and quality assurance developed to help companies effectively document the quality system elements to be implemented to maintain an efficient quality system. They are not specific to any one industry and can be applied to organizations of any size.

ISO 9000 can help a company satisfy its customers, meet regulatory requirements, and achieve continual improvement. However, it should be considered to be a first step, the base level of a quality system, not a complete guarantee of quality

**ISO 9000 vs. 9001**

ISO 9000 is a series, or family, of standards. ISO 9001 is a standard within the family. The ISO 9000 family of standards also contains an individual standard named ISO 9000. This standard lays out the fundamentals and vocabulary of quality management systems (QMS).

ISO 9000 Series standards

The ISO 9000 family contains these standards:

- ISO 9001:2015: Quality management systems - Requirements
- ISO 9000:2015: Quality management systems - Fundamentals and vocabulary (definitions)
- ISO 9004:2009: Quality management systems – Managing for the sustained success of an organization (continuous improvement)
- ISO 19011:2011: Guidelines for auditing management systems

**ISO 9000 CERTIFICATION**

Individuals and organizations **cannot** be certified to ISO 9000. ISO 9001 is the only standard within the ISO 9000 family to which organizations can certify.

ISO 9000:2000

ISO 9000:2000 refers to the ISO 9000 update released in the year 2000.

The Technical Committee responsible for the ISO 9000 family developed specifications for the ISO 9000:2000 revisions, leading to a significant advancement of the standards and reflecting contemporary concepts of quality management.

The ISO 9000:2000 revision had five goals:

1. Meet stakeholder needs
2. Be usable by all sizes of organizations
3. Be usable by all sectors
4. Be simple and clearly understood
5. Connect quality management system to business processes

## ISO 9000 Principles Of Quality Management

The ISO 9000:2015 and ISO 9001:2015 standards are based on seven quality management principles that senior management can apply for organizational improvement:

### 1. CUSTOMER FOCUS

- Understand the needs of existing and future customers
- Align organizational objectives with customer needs and expectations
- Meet customer requirements
- Measure customer satisfaction
- Manage customer relationships
- Aim to exceed customer expectations

Learn more about the customer experience and customer satisfaction.

### 2. LEADERSHIP

- Establish a vision and direction for the organization
- Set challenging goals
- Model organizational values
- Establish trust
- Equip and empower employees
- Recognize employee contributions

Learn more about leadership and find related resources.

### 3. ENGAGEMENT OF PEOPLE

- Ensure that people's abilities are used and valued
- Make people accountable
- Enable participation in continual improvement
- Evaluate individual performance
- Enable learning and knowledge sharing
- Enable open discussion of problems and constraints

Learn more about employee involvement.

## 4. PROCESS APPROACH

- Manage activities as processes
- Measure the capability of activities
- Identify linkages between activities
- Prioritize improvement opportunities
- Deploy resources effectively

Learn more about a process view of work and see process analysis tools.

## 5. IMPROVEMENT

- Improve organizational performance and capabilities
- Align improvement activities
- Empower people to make improvements
- Measure improvement consistently
- Celebrate improvements

Learn more about approaches to continual improvement.

## 6. EVIDENCE-BASED DECISION MAKING

- Ensure the accessibility of accurate and reliable data
- Use appropriate methods to analyze data
- Make decisions based on analysis
- Balance data analysis with practical experience

See tools for decision making.

## 7. RELATIONSHIP MANAGEMENT

- Identify and select suppliers to manage costs, optimize resources, and create value
- Establish relationships considering both the short and long term
- Share expertise, resources, information, and plans with partners
- Collaborate on improvement and development activities
- Recognize supplier successes

Learn more about supplier quality and see resources related to managing the supply chain.

## WHO GUIDLINE

The **World Health Organization** (**WHO**) is a specialized agency of the United Nations that is concerned with international public health. It was established on 7 April 1948, headquartered in Geneva, Switzerland. The WHO is a member of the United Nations Development Group. Its predecessor, the Health Organization, was an agency of the League of Nations.

The constitution of the World Health Organization had been signed by 61 countries on 22 July 1946, with the first meeting of the World Health Assembly finishing on 24 July 1948. Its current aim include diseases, in particular HIV/AIDS, Ebola, malaria and tuberculosis; the mitigation of the effects of non-communicable diseases; sexual and reproductive health, development, and aging; nutrition, food security and healthy eating; occupational health; substance abuse; and driving the development of reporting, publications, and networking.

The WHO is responsible for the World Health Report, a leading international publication on health, the worldwide World Health Survey, and World Health Day (7 April of every year).

**WHO GUIDLINE**

A WHO guideline is any document containing recommendations about health interventions, whether these are clinical, public health or policy recommendations. A recommendation provides information about what policy-makers, health-care providers or patients should do. It implies a choice between different interventions that have an impact on health and that have implications for the use of resources. Guidelines are recommendations intended to assist providers and recipients of health care and other stakeholders to make informed decisions. WHO has adopted internationally recognized standards and methods for guideline development to ensure that guidelines are free from bias, meet a public health need and are consistent with the following principles. Recommendations are based on a comprehensive and objective assessment of the available evidence.

## RAPID ADVICE GUIDELINES

A rapid advice guideline is produced in response to a public health emergency (such as pandemic influenza) in which WHO is required to provide rapid global leadership and guidance. This type of document needs to be produced within 1–3 months and will be evidence-informed, but it may not be supported by full reviews of the evidence. It will be prepared mainly by the responsible WHO staff members with external consultation and peer review. It must be published with a review-by date that indicates when the guidance will become invalid, or when it will be updated or converted to a standard guideline.

## STANDARD GUIDELINE

A standard guideline is produced in response to a request for guidance in relation to a change in practice or controversy in a single clinical or policy area – such as treatment of postpartum hemorrhage or minimum requirements for safe delivery of HIV care. A standard guideline is not expected to cover the full scope of the condition or public health problem. This guideline will

usually take 9-12 months to complete and should be prepared after consultation on the scope of the guideline and the issue that it covers. It should be supported by systematic reviews of the evidence and one or two meetings of the guideline development group for consultation. A standard guideline may have a specified review-by date depending on the expected rate of change of evidence in the topic area. Most WHO guidelines fall into this category.

## FULL GUIDELINES

A full guideline is one that provides complete coverage of a health topic or disease, such as dengue fever. It would be expected to include recommendations in relation to all aspects of the topic (e.g. surveillance, diagnosis, public health and clinical interventions) and to be fully based on systematic reviews of the evidence for each aspect. These are likely to take 2-3 years to complete, and will require several meetings of a guideline development group. Given the time and expense of producing full guidelines, the need for doing these in WHO needs to be carefully justified.

### COMPILATIONS OF GUIDELINES

A compilation of guidelines contains current recommendations from WHO and other sources, but does not include any new recommendations. Compilations of guidelines are subject to Guidelines Review Committee (GRC) approval. All recommendations included must be current and should be referenced thoroughly and accurately. Producing a compilation of guidelines can be complex and updating may be difficult since individual recommendations may go out of date at different times. 4 WHO Handbook for Guideline Development In principle, all recommendations used in a compilation should be updated by WHO. However, recognizing that WHO resources are limited, this may not be realistic. Members of the guideline development group should discuss and agree on an acceptable level of quality and document their decisions carefully. The GRC recommends using the Appraisal of Guidelines for Research and Evaluation (AGREE) tool to do this.

## DIFFERENT DOCUMENT PREPARED BY QUALITY ASSURANCE

### BMR (BATCH MANUFACTURING RECORD)

A batch manufacturing record is a document designed to provide a complete record of the manufacturing history of a batch of product. The terminology is widely applied within the Pharmaceutical & Chemical industries and is referenced in many of the pharmaceutical and food regulatory agency requirements.

The US Food and Drug administration defines a batch as “a specific quantity of a drug or other material that is intended to have uniform character and quality, within specified limits, and is produced according to a single manufacturing order during the same cycle of manufacture”.

**Batch Manufacturing Records.**

Batch Manufacturing Records are critical documents for ensuring quality and regulatory requirements are achieved. They normally contain information that relates to the following aspects of the manufacture of a batch of product:

| |
|---|
| Dates of start and finish of manufacture. |
| Lists all materials used and amounts of each used. |
| Lists of packaging materials used. |
| Details of the steps completed in the manufacturing process and times of completion. |
| Initials of the person responsible at every stage. |
| Details and results of all in-process checks. |
| Reference to any equipment used. |
| Batch yield and reconciliation. |
| Any deviations. |
| Quality Control information |

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In many cases the Batch Manufacturing Records are written in an instructional format with areas for the operator to fill in processing information.

It is very important to provide the information in the Batch Manufacturing Records where requested.

For certain critical operations, e.g. weighing of raw materials, a second person must check calculations and identity of materials and sign off on the Batch Manufacturing Records.

Each batch has an individual number, written on the Batch Manufacturing Record.

Batch Manufacturing Records must be:

Legible.
Permanent.
Accurate.
Original.
Signed.

**All corrections and deviations must be recorded and signed off in the Batch**


**ManufacturRecords**

## MASTER FORMULA RECORD

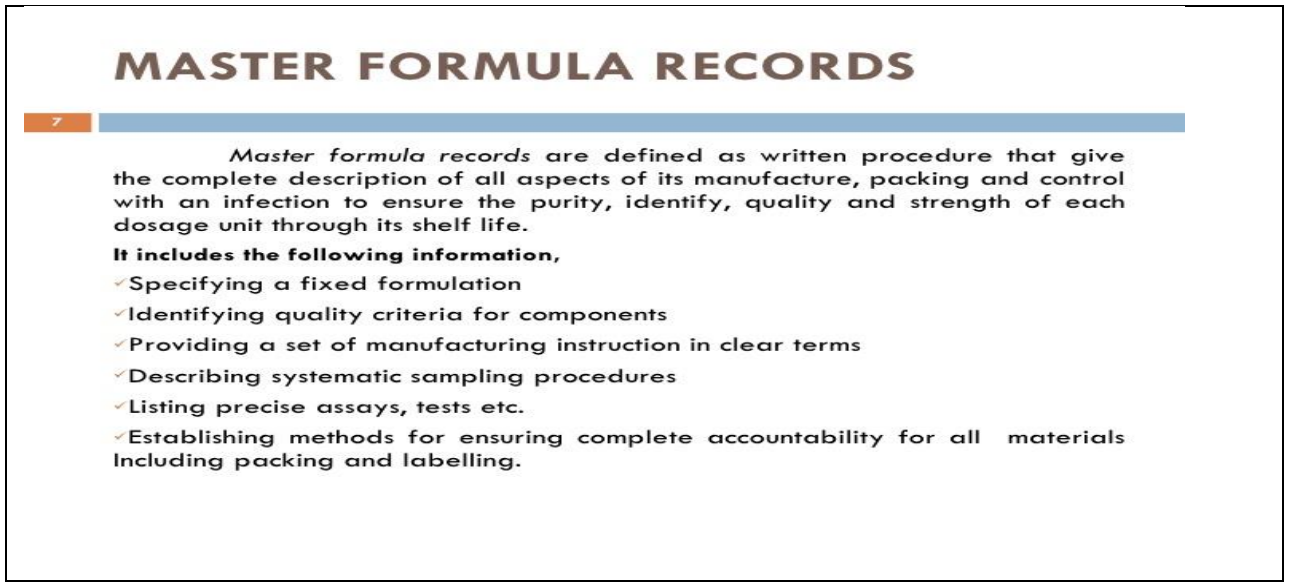
Master Formula Record is that standard manufacturing / packing record which gives complete details of materials used along with their quantities, standard process flow, Area & equipment used, Yield and reconciliation, Instruction & precautions or any other information related to product.

**PROCEDURE**

**Any Master document prepared relating to the plant must include following: -**

- The name of the product together with product reference code relating to its specifications
- The proprietary name of the product along with the generic name, strength of the product and batch size.
- Mention-Name, quantity, and reference number of all the starting materials to be used. Also any substance that may 'disappear' in the course of processing must be mentioned

- The master document must also contain the statement of the expected final yield with the acceptable limits, and of relevant intermediate yields, where ever applicable.
- Include a statement of the processing location and the principal equipment to be used.
- It must include the methods or the reference to the methods, to be used for preparing the critical equipment including cleaning, assembling and calibration.
- Detailed stepwise processing instructions and the time taken for each step must be clearly mentioned.
- The instructions for In-process controls with their limits.
- The requirements for storage conditions of the products, including the container, labeling and special storage conditions wherever applicable must be mentioned.
- Any special precautions to be observed must be included.
- Include Packing details and specimen labels relating to the product




## VALIDATION MASTER PLAN

A Validation Master Plan, also referred to as "VMP", outlines the principles involved in the qualification of a facility, defining the areas and systems to be validated, and provides a written program for achieving and maintaining a qualified facility. A VMP is the foundation for the validation program and should include process validation, facility and utility qualification and validation, equipment qualification, cleaning and computer validation. It is a key document in the GMP (Good manufacturing practice) regulated pharmaceutical industry as it drives a structured approach to validation projects.

Food and Drug Administration inspectors often look at VMPs during audits to see whether or not a facility's validation strategy is well thought-out and organized. A VMP should have logical reasoning for including or excluding every system associated with a validation project based on a risk assessment.

Common topics to be covered in a Validation Master Plan: Introduction, scope, responsibilities, description of facility and design, building and plant Layout, clean rooms and associated controlled environments, storage areas, personnel, personnel and material Flow, water and solid waste handling, infrastructure and utilities, water system, ventilation and air-conditioning system, clean steam, compressed air, gases and vacuum system, list manufacturing equipment, building management systems, products that are planned to be validated, qualification/validation approach, process validation and cleaning validation approach, microbiological monitoring, computer Validation, calibration, maintenance, related SOPs.

**Cleaning validation** is the methodology used to assure that a cleaning process removes residues of the active pharmaceutical ingredients of the product manufactured in a piece of equipment, the cleaning aids utilized in the cleaning process and the microbial attributes.[1] All residues are removed to predetermined levels to ensure the quality of the next product manufactured is not compromised by waste from the previous product and the quality of future products using the equipment, to prevent cross-contamination and as a GMP requirement.

The U.S. Food and Drug Administration (FDA) have strict regulation about the cleaning validation. For example, FDA requires firms to have written general procedures on how cleaning processes will be validated. Also, FDA expects the general validation procedures to address who is responsible for performing and approving the validation study, the acceptance criteria, and when revalidation will be required. FDA also requires firms to conduct the validation studies in accordance with the protocols and to document the results of studies. The valuation of cleaning validation is also regulated strictly, which usually mainly covers the aspects of equipment design, cleaning process written, analytical methods and sampling. Each of these processes has their related strict rules and requirements. Regarding to the establishment of limits, FDA does not intend to set acceptance specifications or methods for determining whether a cleaning process is validated. But some limits that have been mentioned by industry include analytical detection levels such as 10 PPM, biological activity levels such as 1/1000 of the normal therapeutic dose and organoleptic levels.

Cleaning Validation in the context of Active Pharmaceutical Ingredient manufacture may be defined as: "The process of providing documented evidence that the cleaning methods employed within a facility consistently controls potential carryover of product (including intermediates and impurities), cleaning agents and extraneous material into subsequent product to a level which is below predetermined levels".

## CONCEPT OF VALIDATION

**Validation** is a process of establishing documentary evidence demonstrating that a procedure, process, or activity carried out in production or testing maintains the desired level of compliance at all stages. In Pharma Industry it is very important apart from final testing and compliance of product with standard that the process adapted to produce itself must assure that process will consistently produce the expected results.[1] Here the desired results are established in terms of

specifications for outcome of the process. Qualification of systems and equipment is therefore a part of process of validation. It is a requirement of food and drug, pharmaceutical regulating agencies like FDA's good manufacturing practices guidelines. Since a wide variety of procedures, processes, and activities need to be validated, the field of validation is divided into a number of subsections including the following:

- Equipment validation
- Facilities validation
- HVAC system validation
- Cleaning validation
- Process Validation
- Analytical method validation
- Computer system validation
- Packaging validation
- Cold chain validation

Similarly, the activity of qualifying systems and equipment is divided into a number of subsections including the following:

- Design qualification (DQ)
- Component qualification (CQ)
- Installation qualification (IQ)
- Operational qualification (OQ)
- Performance qualification (PQ)

## TYPE OF VALIDATION

A) Prospective validation (or premarket validation)

B) Retrospective validation

C) Concurrent validation

D) Revalidation

### Prospective validation

Establishing documented evidence prior to process implementation that a system does what it proposed to do based on preplanned protocols. This approach to validation is normally undertaken whenever the process for a new formula (or within a new facility) must be validated before routine pharmaceutical production commences. In fact, validation of a process by this approach often leads to transfer of the manufacturing process from the development function to production.

### Retrospective validation

Retrospective validation is used for facilities, processes, and process controls in operation use that have not undergone a formally documented validation process. Validation of these facilities, processes, and process controls is possible using historical data to provide the necessary

documentary evidence that the process is doing what it is believed to do. Therefore, this type of validation is only acceptable for well-established processes and will be inappropriate where there have been recent changes in the composition of product, operating processes, or equipment. This approach is rarely been used today because it's very unlikely that any existing product hasn't been subjected to the Prospective validation process. It is used only for the audit of a validated process.

**Concurrent validation**

Concurrent validation is used for establishing documented evidence that a facility and processes do what they purport to do, based on information generated during actual imputation of the process. This approach involves monitoring of critical processing steps and end product testing of current production, to show that the manufacturing process is in a state of control.

**Revalidation**

Revalidation means repeating the original validation effort or any part of it, and includes investigative review of existing performance data. This approach is essential to maintain the validated status of the plant, equipment, manufacturing processes and computer systems. Possible reasons for starting the revalidation process include:

- The transfer of a product from one plant to another.
- Changes to the product, the plant, the manufacturing process, the cleaning process, or other changes that could affect product quality.
- The necessity of periodic checking of the validation results.
- Significant (usually order of magnitude) increase or decrease in batch size.
- Sequential batches that fail to meet product and process specifications.
- The scope of revalidation procedures depends on the extent of the changes and the effect upon the product.

**VALIDATION PARAMETER**

Various aspects of analytical method validation including:

- Principles of analytical method validation
- Pharmacopoeia methods
- Non-pharmacopoeia methods
- Approaches to analytical method validation
- Characteristics of analytical procedures

- Tests include:
- Identification tests
- Assay of drug substances and pharmaceutical products
- Content of impurities and limit tests for impurities
- Dissolution testing and determination of particle size
- Results should be reliable, accurate and reproducible
- Specifications for materials and products, with standard test methods
- Manufacturer to use "pharmacopoeial specifications and methods", or suitably developed "non-pharmacopoeial specifications and methods" as approved by the national drug regulatory authority
- Use well-characterized reference materials, with documented purity, in the validation study

## PROTOCALL FOR PROCESS VALIDATION

### Design qualification

- The first element of the validation of new facilities, systems or equipment could be design qualification (DQ).
- The compliance of the design with GMP should be demonstrated and documented.

### Installation qualification

- Installation qualification (IQ) should be performed on new or modified facilities, systems and equipment.
- IQ should include, but not be limited to the following:
- (a) installation of equipment, piping, services and instrumentation checked to current engineering drawings and specifications;
- (b) collection and collation of supplier operating and working instructions and maintenance requirements;
- (c) calibration requirements;
- (d) verification of materials of construction. Operational qualification

**. Operational qualification (OQ)**

- It should follow Installation qualification.
- OQ should include, but not be limited to the following:
- (a) tests that have been developed from knowledge of processes, systems and equipment;

- (b) tests to include a condition or a set of conditions encompassing upper and lower operating limits, sometimes referred to as “worst case” conditions.
- The completion of a successful Operational qualification should allow the finalisation of calibration, operating and cleaning procedures, operator training and preventative maintenance requirements. It should permit a formal "release" of the facilities, systems and equipment. Performance qualification
- **Performance qualification**
- (PQ) should follow successful completion of Installation qualification and Operational qualification.
- PQ should include, but not be limited to the following:
- (a) tests, using production materials, qualified substitutes or simulated product, that have been developed from knowledge of the process and the facilities, systems or equipment; 6
- (b) Tests to include a condition or set of conditions encompassing upper and lower operating limits.
- Although PQ is described as a separate activity, it may in some cases be appropriate to perform it in conjunction wit