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PHARMACEUTICAL QUALITY ASSURANCE

UNIT 1

TOPIC :

- **Quality by design (QbD) :** Definition, overview, elements of QbD program, tools

Quality By Design (QbD)

→ Quality by Design (QbD) is a systematic, scientific, and risk-based approach to pharmaceutical development that ensures predefined product quality through process understanding and control.

→ According to ICH Q8:

- "Quality cannot be tested into products; quality should be built into the product by design."
- QbD focuses on designing and developing pharmaceutical products and manufacturing processes in a way that consistently delivers the desired quality.

Concept of Quality by Design

Quality by Design is based on the principle that product quality should be built into the product from the beginning rather than relying solely on final product testing.

Traditional quality systems mainly depend on testing the finished product, whereas QbD focuses on:

- Understanding the product and process.
- Identifying factors affecting quality.
- Controlling variability.
- Managing risks scientifically.
- Ensuring consistent performance.

Basic Concept

→ Product Understanding + Process Understanding + Risk Management = Quality Product

Objectives of Quality by Design (QbD)

1. Ensure consistent product quality.
2. Improve product safety and efficacy.
3. Reduce manufacturing variability.
4. Minimize product failures and recalls.
5. Increase process understanding.
6. Establish robust manufacturing processes.
7. Facilitate regulatory flexibility.
8. Reduce production costs.
9. Improve manufacturing efficiency.
10. Support continuous improvement.

Need for Quality by Design

- Increasing regulatory expectations.
- Need for robust manufacturing processes.
- Reduction in batch failures.
- Improved product performance.
- Better patient safety.
- Reduced manufacturing costs.
- Faster product development and approval.

Elements of Quality by Design (QbD)

The major elements of QbD include:

1. Quality Target Product Profile (QTPP)
2. Critical Quality Attributes (CQAs)
3. Risk Assessment
4. Design Space
5. Control Strategy
6. Process Analytical Technology (PAT)
7. Continuous Improvement

1. Quality Target Product Profile (QTPP)

→ QTPP is a prospective summary of the quality characteristics of a drug product that should be achieved to ensure desired safety, efficacy, and quality.
→ It serves as the foundation for product development.

Components of QTPP

- Dosage form
- Route of administration
- Strength
- Drug release characteristics
- Stability
- Pharmacokinetic properties
- Appearance

Examples

For a tablet:

- Dosage form: Tablet
- Strength: 500 mg
- Shelf life: 24 months
- Dissolution: More than 85% in 30 minutes

Importance

- Guides formulation development.
- Establishes product goals.
- Helps identify critical quality attributes.

2. Critical Quality Attributes (CQAs)

→ CQAs are physical, chemical, biological, or microbiological properties that must remain within specified limits to ensure product quality.

Examples of CQAs

Physical Attributes

- Hardness
- Friability
- Disintegration time
- Particle size

Chemical Attributes

- Assay
- Purity
- Impurities
- Moisture content

Biological Attributes

- Potency
- Biological activity

Microbiological Attributes

- Sterility
- Microbial limits

Importance

- Ensures safety and efficacy.
- Maintains product consistency.
- Helps identify critical process variables.

3. Risk Assessment (RA)

→ Risk Assessment is a systematic process used to identify, analyze, evaluate, and control risks that may affect product quality.

Steps in Risk Assessment

1. Risk Identification

- Identify potential sources of quality problems.

2. Risk Analysis

- Determine likelihood and severity.

3. Risk Evaluation

- Assess overall risk level.

4. Risk Control

- Implement measures to reduce risk.

5. Risk Review

- Monitor effectiveness of controls.

Importance

- Prevents product failures.
- Improves process reliability.
- Enhances patient safety.

4. Design Space

→ Design Space is the multidimensional combination of input variables and process parameters that have been demonstrated to assure product quality.
→ According to ICH:
→ Working within the approved design space is not considered a regulatory change.

Variables Included

Formulation Variables

- Excipient concentration
- Drug concentration

Process Variables

- Mixing speed
- Granulation time
- Compression force

Importance

- Provides manufacturing flexibility.
- Reduces process variability.
- Ensures consistent product quality.

5. Control Strategy

→ Control Strategy is a planned set of controls designed to ensure that the manufacturing process remains within the approved design space.

Components

Raw Material Controls

- Supplier qualification
- Material testing

Process Controls

- Temperature monitoring
- Pressure control
- Mixing speed control

In-Process Controls

- Weight variation
- Hardness testing

Finished Product Controls

- Assay
- Dissolution
- Stability testing

Importance

- Maintains product quality.
- Prevents deviations.
- Supports regulatory compliance.

6. Process Analytical Technology (PAT)

→ Process Analytical Technology (PAT) is a system for designing, analyzing, and controlling manufacturing processes through real-time measurements.
→ PAT enables continuous monitoring of critical quality and performance attributes.

Objectives of PAT

1. Real-time quality assurance.
2. Better process understanding.
3. Reduction in manufacturing errors.
4. Improved efficiency.
5. Reduced product rejection.

PAT Tools

- Spectroscopy
- Chromatography
- Particle size analyzers
- Moisture analyzers

Advantages

- Immediate detection of deviations.
- Improved product consistency.
- Reduced production costs.
- Enhanced process control.

7. Continuous Improvement

Continuous Improvement is the ongoing effort to improve products, processes, and systems throughout the product lifecycle.

Activities

- Process optimization
- Data analysis
- Corrective actions
- Preventive actions
- Technology upgrades

Benefits

- Better product quality.
- Reduced costs.
- Increased efficiency.
- Improved patient satisfaction.

Advantages of Quality by Design

1. Consistent product quality.
2. Better process understanding.
3. Reduced manufacturing failures.
4. Lower production costs.
5. Improved regulatory compliance.
6. Enhanced patient safety.
7. Greater manufacturing flexibility.
8. Faster regulatory approval.
9. Reduced product recalls.
10. Continuous process improvement.