Quality by Design (QbD)

Current Approach and Its Limitations

- The traditional approach to pharmaceutical manufacturing mainly depends on testing the finished product after manufacturing is complete.
- In this approach, quality is checked at the end of the manufacturing process rather than being built into every manufacturing step.
- This approach is often called the **Quality by Testing (QbT)** approach.

How the Current Approach Works

1. **Manufacturing Process**
   - The medicine is manufactured according to a fixed manufacturing procedure.
   - The process usually remains unchanged unless a major problem occurs.
2. **Finished Product Testing**
   - Samples are collected after manufacturing is completed.
   - The finished product is tested for quality, purity, strength, and other specifications.
3. **Decision**
   - If the product passes all quality tests, it is approved for sale.
   - If the product fails any test, the entire batch may be rejected or reprocessed.

Limitations of the Current Approach

- The approach mainly focuses on detecting defects instead of preventing them.
- Product quality is evaluated only after manufacturing is complete.
- Manufacturing problems may not be identified until the final testing stage.
- A failed batch results in loss of time, raw materials, and manufacturing cost.
- The approach provides limited understanding of how different manufacturing steps affect product quality.
- Process variations may remain unnoticed until product testing is performed.
- It is difficult to continuously improve the manufacturing process because limited scientific knowledge is collected during production.
- Batch rejection increases production costs and delays medicine supply.

Example

- A tablet manufacturing process is completed successfully, but final testing shows that the tablets do not dissolve properly.

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- Since the defect is discovered only after manufacturing is complete, the entire batch may need to be rejected or reprocessed.

Importance

- Understanding the limitations of the traditional approach encouraged the pharmaceutical industry to develop a better-quality system.
- These limitations led to the development of the Quality by Design (QbD) approach.

Why QbD is Required

- Quality by Design is required because medicines must consistently meet quality standards throughout their entire life cycle.
- QbD helps manufacturers understand the relationship between raw materials, manufacturing processes, and final product quality.
- The main goal is to prevent defects rather than detect them after production.

Reasons for Implementing QbD

1. **To Build Quality into the Product**
   - Quality is planned during product development.
   - Every manufacturing step is designed to produce a high-quality product.
2. **To Improve Process Understanding**
   - Manufacturers study how different process parameters affect product quality.
   - Better understanding allows better process control.
3. **To Reduce Manufacturing Variability**
   - QbD identifies the sources of variation in the manufacturing process.
   - Variability is controlled before it affects product quality.
4. **To Improve Patient Safety**
   - Consistent product quality ensures that patients receive safe and effective medicines.
   - The risk of defective products reaching the market is reduced.
5. **To Meet Regulatory Expectations**
   - Regulatory agencies such as the US FDA and ICH encourage the use of QbD.
   - QbD provides scientific evidence that manufacturing processes are well controlled.
6. **To Support Continuous Improvement**
   - Manufacturing processes can be improved without reducing product quality.
   - Continuous monitoring allows manufacturers to identify opportunities for improvement.

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Example

- During tablet manufacturing, scientists determine the ideal compression force that produces tablets with the correct hardness and dissolution rate.
- By controlling this parameter during production, tablet quality remains consistent.

Importance

- QbD improves product quality and manufacturing reliability.
- QbD reduces the chances of manufacturing failures and quality defects.
- QbD supports efficient pharmaceutical development and production.

Advantages of QbD

1. **Improved Product Quality**
   - QbD produces medicines with consistent quality from batch to batch.
   - Products are more likely to meet all quality specifications.
2. **Better Process Understanding**
   - Manufacturers understand how raw materials and manufacturing conditions influence product quality.
   - Better knowledge improves process control.
3. **Reduced Manufacturing Failures**
   - Potential problems are identified early during product development.
   - Defects are prevented before large-scale manufacturing begins.
4. **Lower Production Costs**
   - Fewer rejected batches reduce material loss and manufacturing expenses.
   - Less rework is required during production.
5. **Greater Manufacturing Efficiency**
   - Well-designed manufacturing processes operate more smoothly.
   - Production interruptions become less frequent.
6. **Improved Regulatory Compliance**
   - Scientific evidence supports product quality and process control.
   - Regulatory approval may become more efficient because detailed process knowledge is available.
7. **Continuous Process Improvement**
   - Manufacturers can improve production processes using scientific data.

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- Product quality remains stable while manufacturing efficiency increases.

8. Better Patient Safety

- Patients receive medicines with reliable quality, safety, and effectiveness.
- The risk of quality-related problems is reduced.

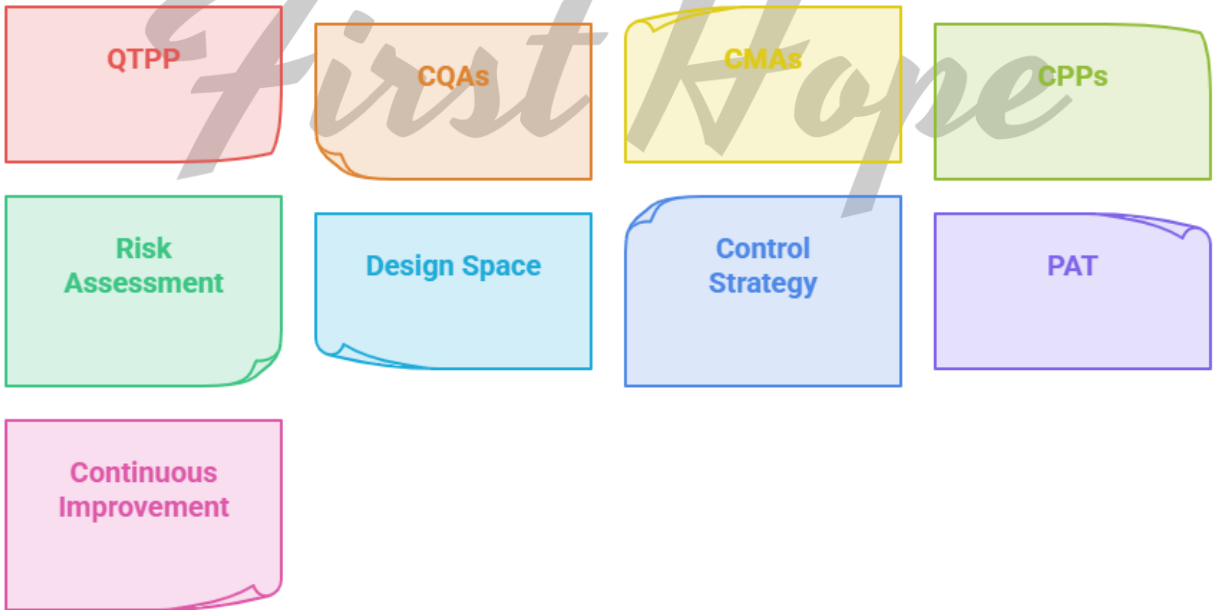
Importance

- QbD improves the overall performance of pharmaceutical manufacturing.
- It benefits both manufacturers and patients by ensuring consistent product quality.
- It supports the production of safe, effective, and reliable medicines.

Elements of QbD

- Quality by Design is based on several important elements that work together to ensure product quality throughout development and manufacturing.
- Each element helps manufacturers understand and control the manufacturing process.

Major Elements of QbD



A. Quality Target Product Profile (QTPP)

- QTPP is a summary of the desired characteristics of the final pharmaceutical product.
- It describes the intended use, dosage form, route of administration, strength, stability, and expected quality of the medicine.
- QTPP serves as the starting point for product development.

B. Critical Quality Attributes (CQAs)

- CQAs are the physical, chemical, biological, or microbiological properties that must remain within acceptable limits.

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- These attributes directly affect the safety, quality, and effectiveness of the medicine.
- Examples include tablet hardness, dissolution rate, drug content, purity, sterility, and moisture content.

C. Critical Material Attributes (CMAs)

- CMAs are the properties of raw materials that can influence product quality.
- These include particle size, purity, moisture content, and flow properties of raw materials.
- Proper control of CMAs helps produce consistent pharmaceutical products.

D. Critical Process Parameters (CPPs)

- CPPs are manufacturing process variables that affect the quality of the finished product.
- Examples include mixing time, mixing speed, compression force, drying temperature, granulation time, and coating temperature.
- CPPs must be carefully monitored and controlled during manufacturing.

E. Risk Assessment

- Risk assessment identifies factors that may affect product quality.
- Scientific tools are used to evaluate the likelihood and impact of manufacturing risks.
- High-risk factors receive greater attention and control during development.

F. Design Space

- Design space is the approved range of material attributes and process parameters within which consistent product quality is achieved.
- Manufacturing can operate anywhere within this range without negatively affecting product quality.
- Working within the design space provides flexibility while maintaining quality.

G. Control Strategy

- A control strategy is a planned system used to maintain consistent product quality throughout manufacturing.
- It includes process controls, equipment monitoring, raw material testing, in-process testing, and finished product testing.
- A well-designed control strategy minimizes process variation.

H. Process Analytical Technology (PAT)

- PAT uses analytical tools to monitor manufacturing processes in real time.
- It helps detect process changes immediately and allows corrective actions before product quality is affected.

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