

# **SNS COLLEGE OF PHARMACY AND HEALTH SCIENCES**

*Affiliated To The Tamil Nadu Dr. MGR Medical University, Chennai*

*Approved by Pharmacy Council of India, New Delhi.*

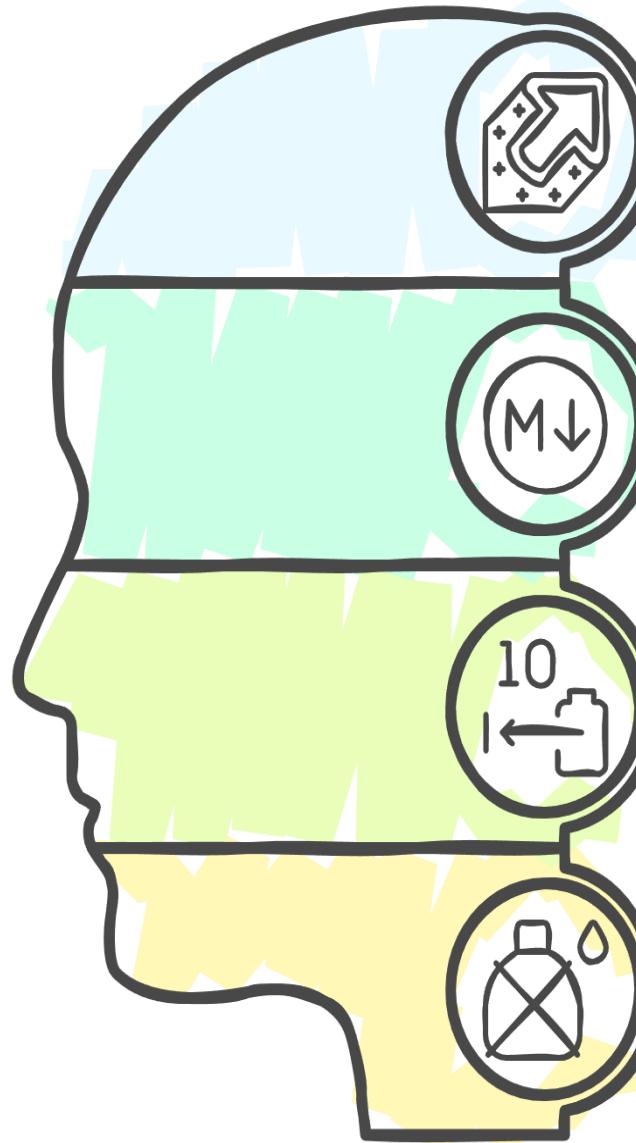
**Coimbatore -641035**



**COURSE NAME: INDUSTRIAL PHARMACY-II**

**(BP 702 T) IV YEAR / I SEM**

**TOPIC: TOTAL QUALITY MANAGEMENT**



## Purpose

Provides guidance on acceptable post-approval changes

## Scope

Applies to changes in manufacturing equipment, process, site, batch size, and composition

## Focus

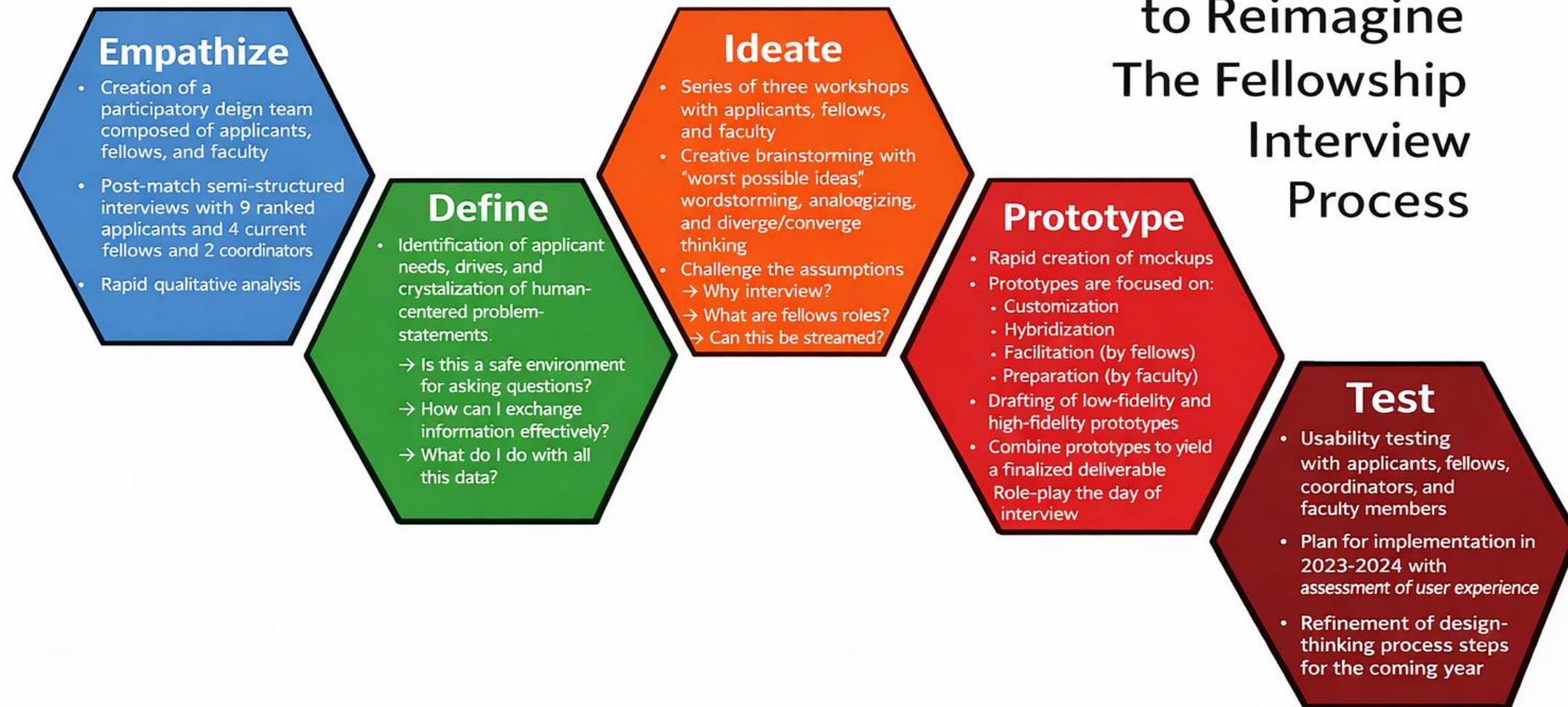
Concentrates on solid oral dosage forms, semi-solids, and liquids

## Exclusions

Excludes sterile and biological products

Made with  Napkin

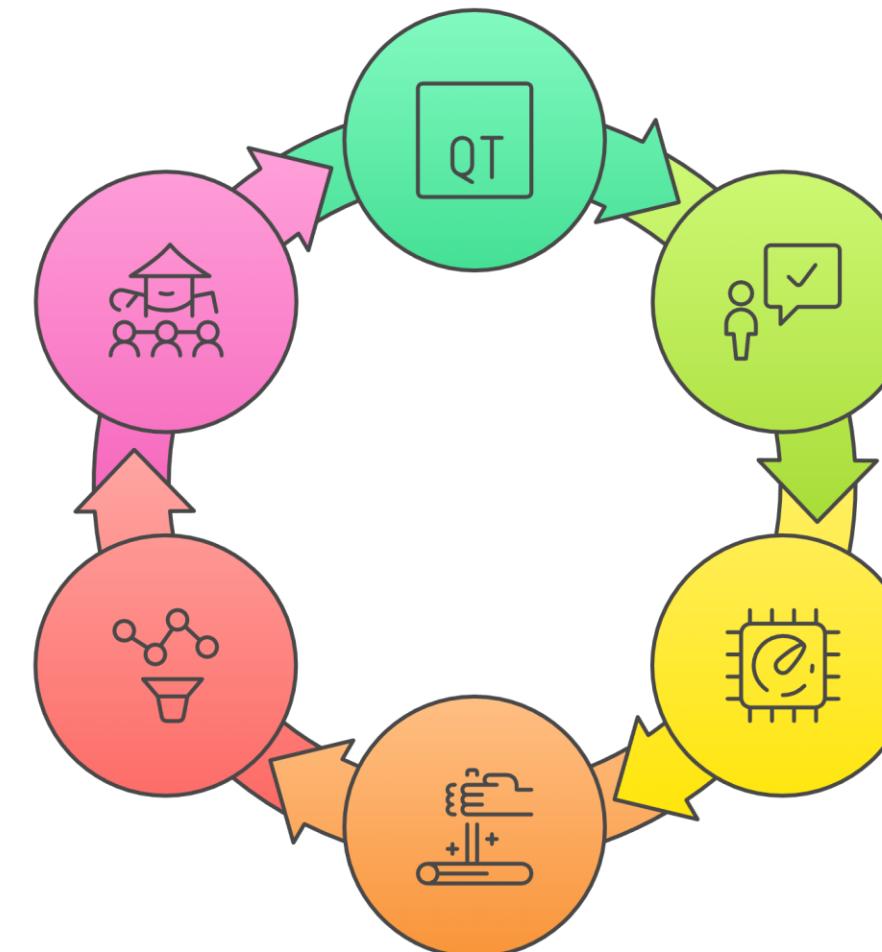
# Using Design-Thinking to Reimagine The Fellowship Interview Process



# Total Quality Management Cycle

## Implement TQM

Initiate TQM practices within the organization.



## Foster Culture

Cultivate a culture of continuous improvement.

## Enhance Services

Offer superior services through improved processes.

## Improve Products

Develop better products through refined processes.

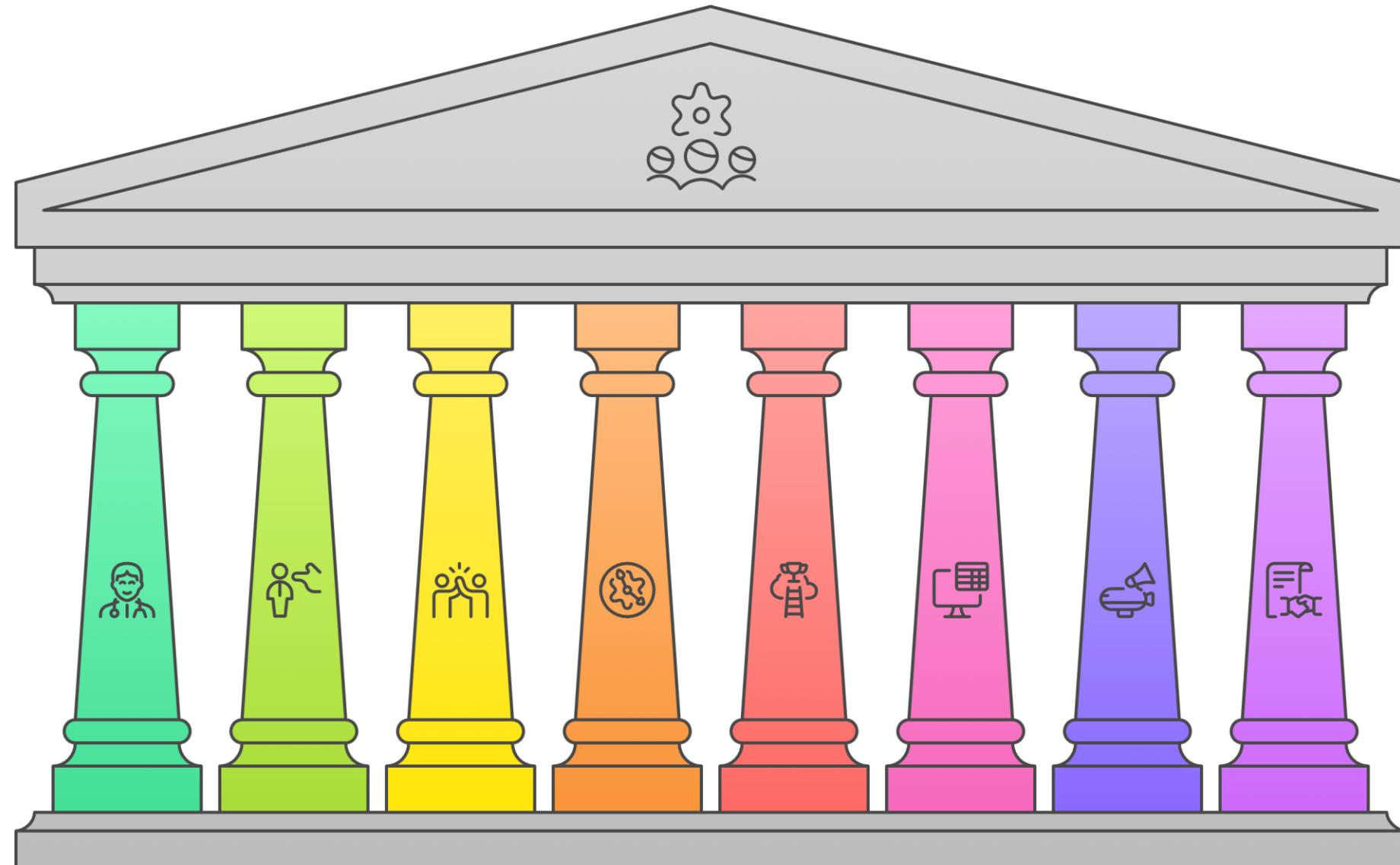
## Gather Feedback

Collect input from stakeholders for improvement.

## Refine Processes

Enhance processes based on feedback.

## Foundations of Total Quality Management



### Customer Focus

Understanding and meeting customer needs and expectations.

### Leadership Involvement

Strong leadership driving and supporting TQM initiatives.

### Employee Empowerment

Empowering employees to participate in quality improvement.

### Process Approach

Managing activities as interconnected processes.

### Continuous Improvement

Commitment to ongoing improvement in all aspects.

### Fact-Based Decision Making

Decisions based on data and analysis.

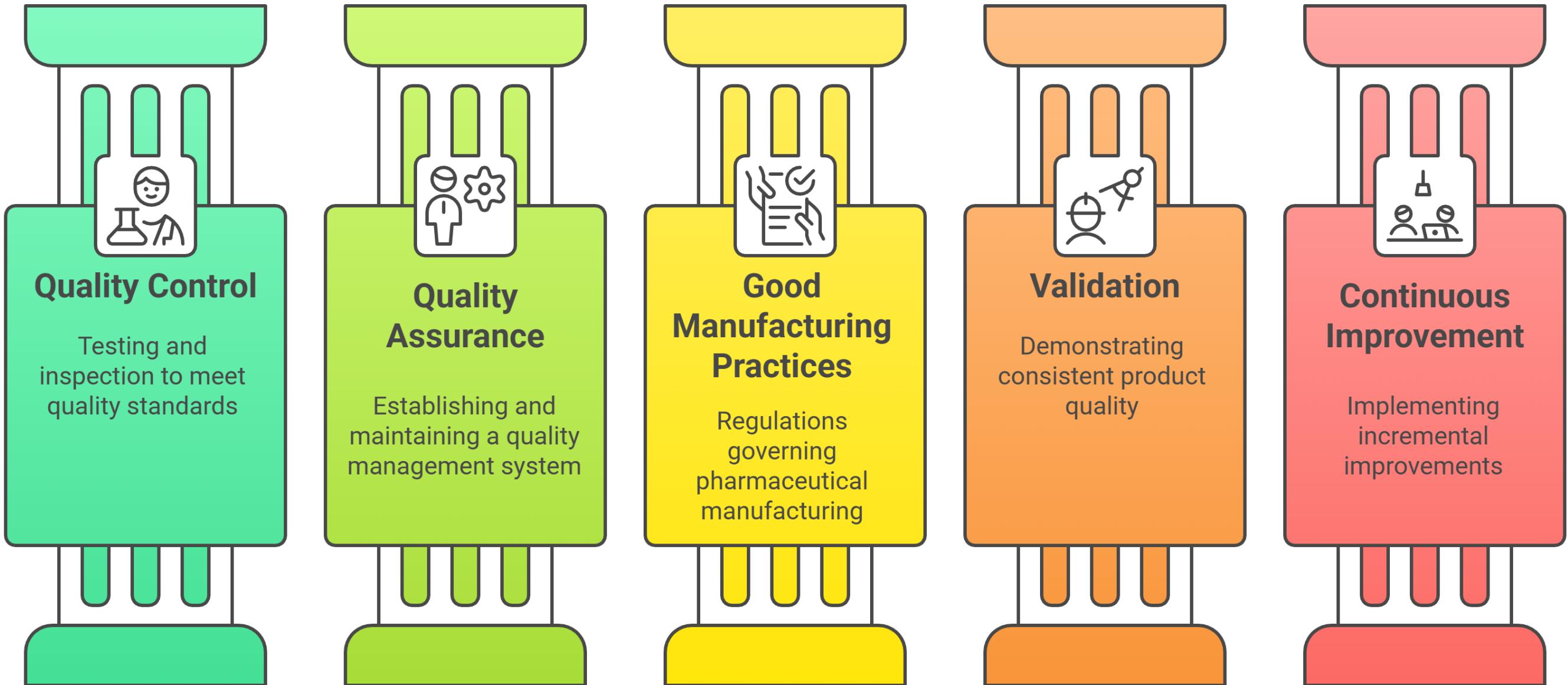
### Communication

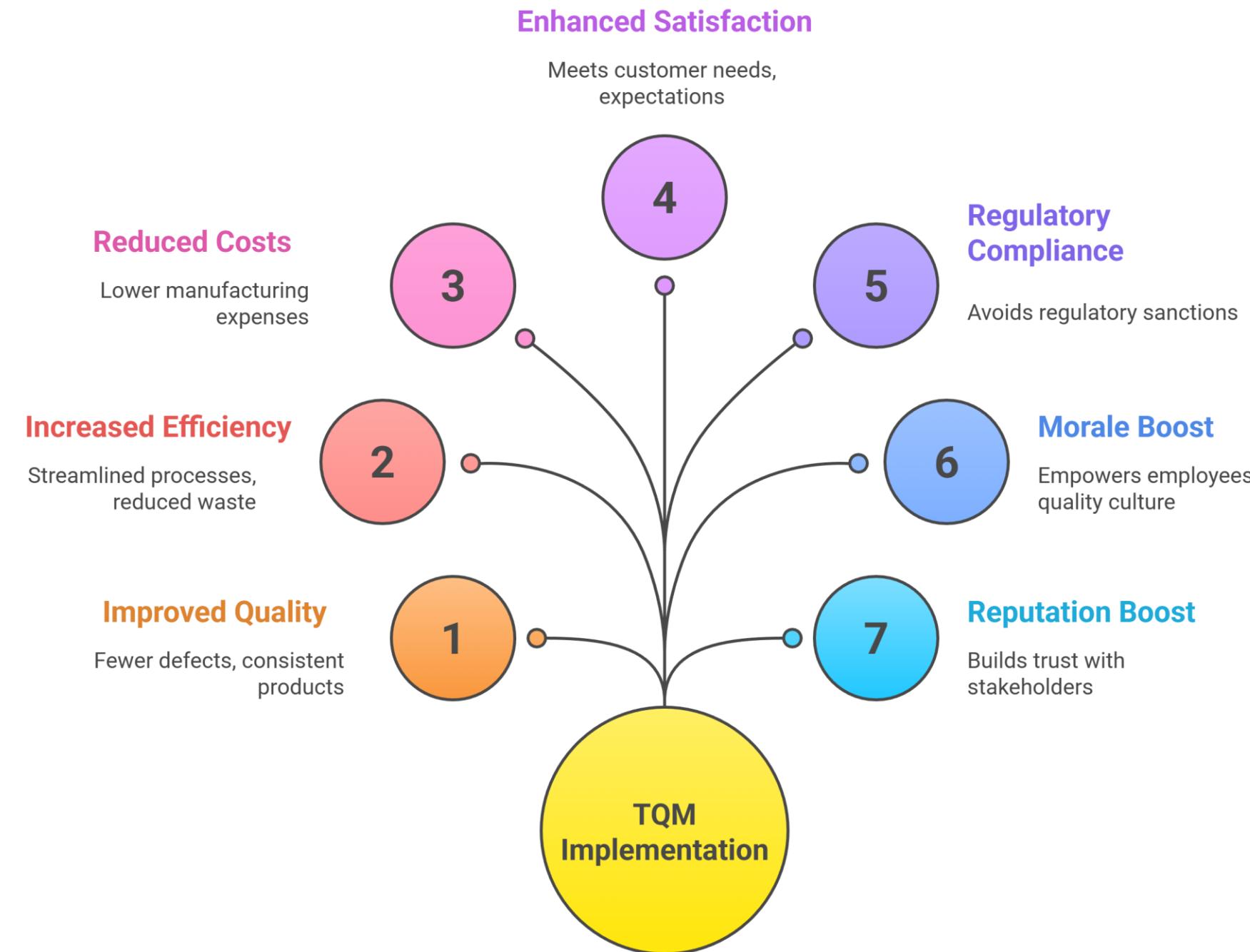
Open and effective communication for coordination.

### Supplier Quality Management

Extending quality principles to suppliers.

# Foundations of Pharmaceutical Quality





# Implementing TQM: Navigating the Hurdles

## Resistance to Change

Employees resist new processes

## Lack of Support

Management commitment is insufficient

## Insufficient Training

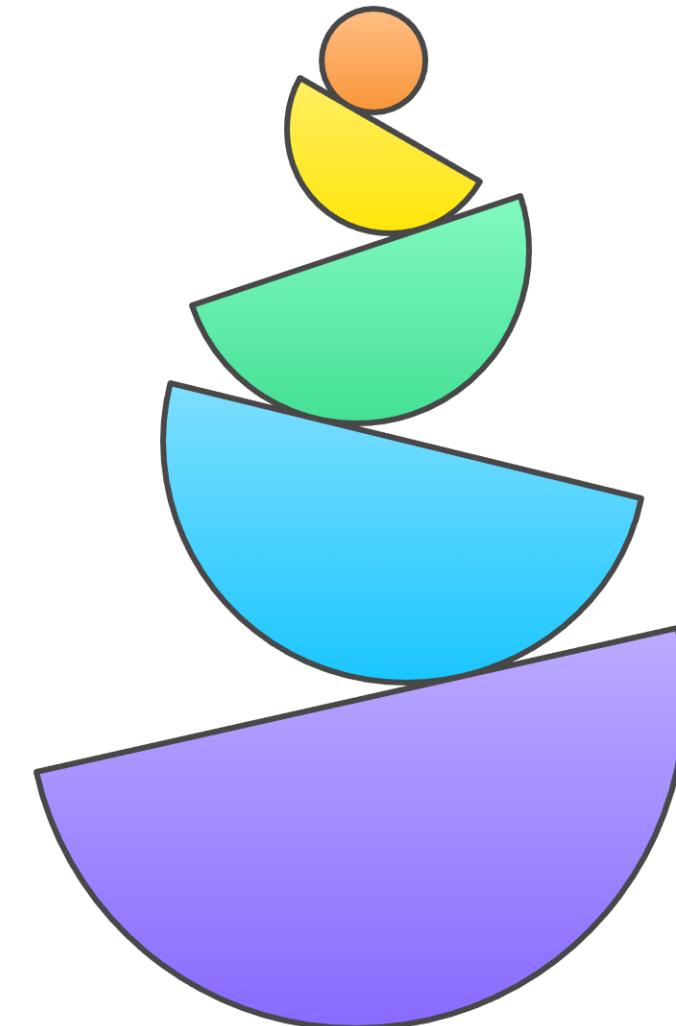
Employees lack TQM knowledge

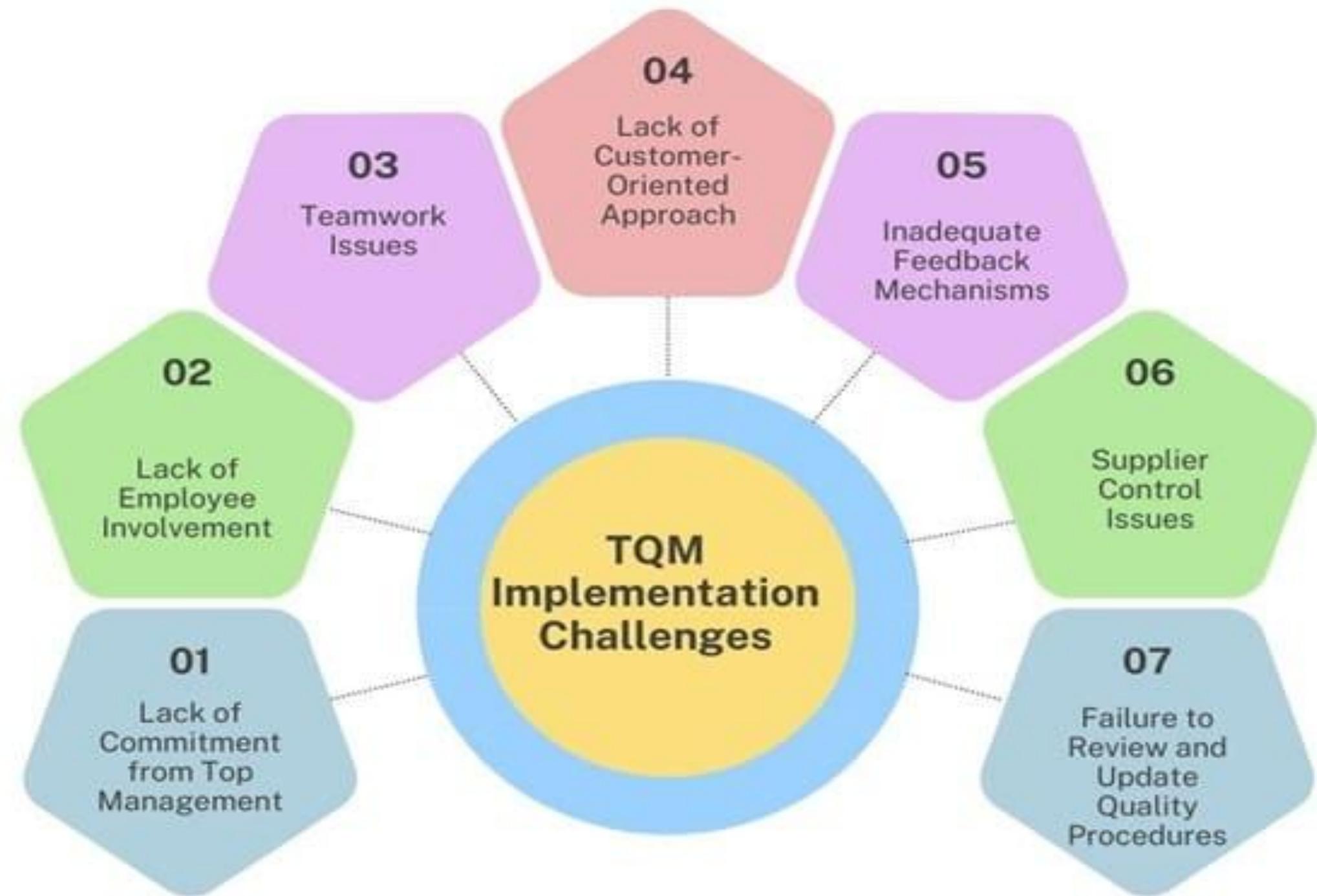
## Resource Constraints

Investment in TQM is limited

## Measurement Difficulty

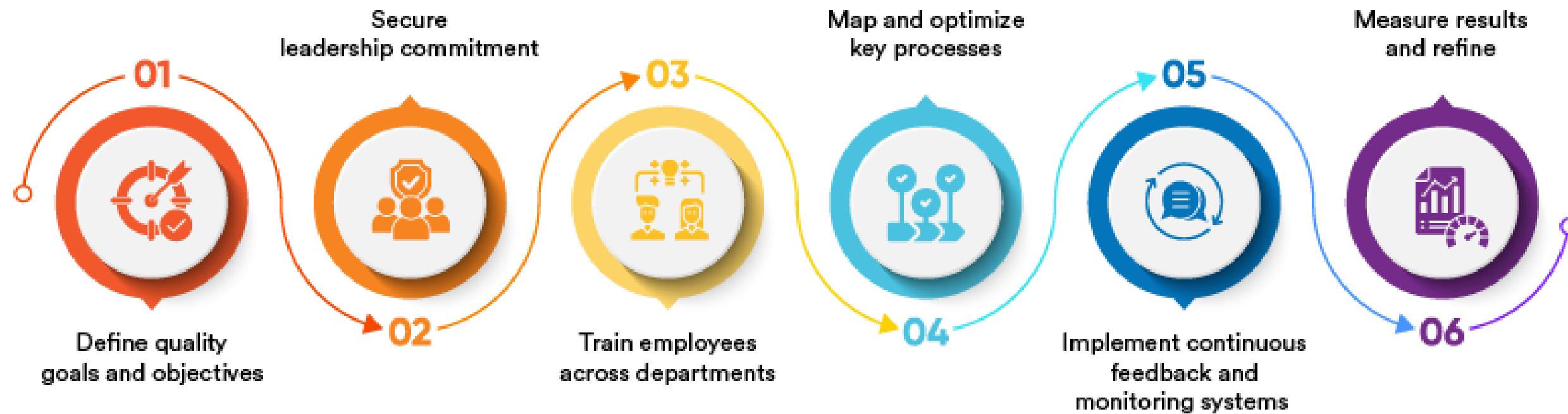
Impact of TQM is hard to gauge



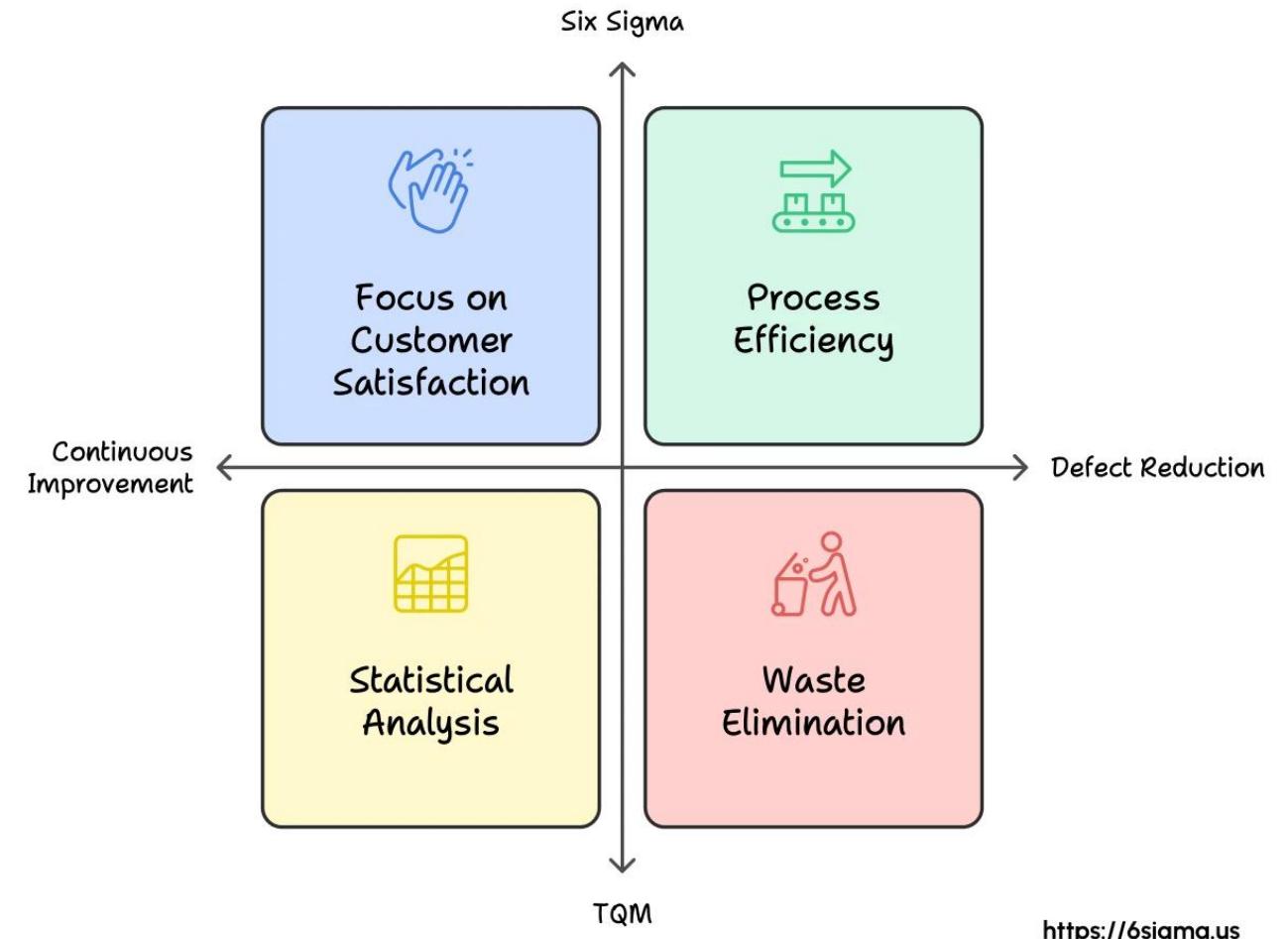


# Principles of Total Quality Management





# Principles of Total Quality Management





# Benefits of Total Quality Management



<https://6sigma.us>



## TOTAL QUALITY MANAGEMENT

# The 4 Pillars



### **Customer Focus**

Meeting and exceeding customer expectations.

### **Continuous Improvement**

Ongoing enhancement of processes and systems.

### **Employee Involvement**

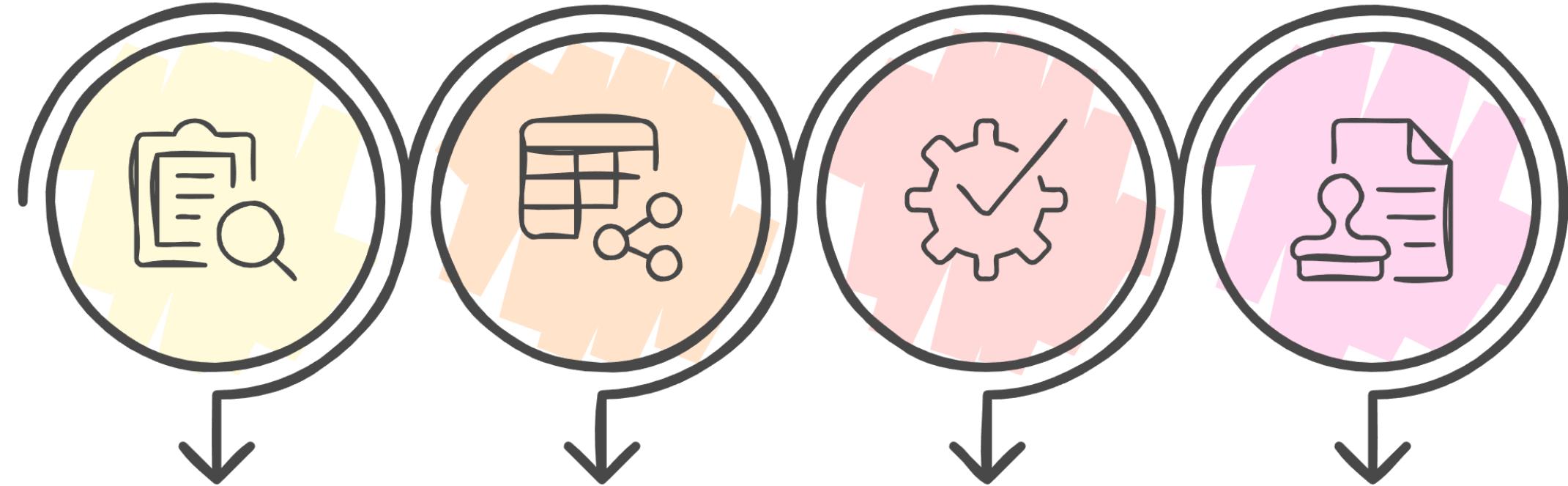
Engaging employees at all levels.

### **Process Approach**

Systematic management of activities and resources.

[www.holistiquetraining.com](http://www.holistiquetraining.com)

# Documentation Requirements



## Change Control

Description, rationale, risk, impact, testing, results, conclusion, signatures.

## Comparative Data

Dissolution, stability, bioequivalence, and analytical data.

## Process Validation

Process performance qualification and continued process verification data.

## Regulatory Submissions

Annual report, CBE-30 supplement, and PAS submissions.

# ASSESSMENT: TOTAL QUALITY MANAGEMENT

- Explain any five advantages of Total Quality Management (TQM).



- How does TQM improve customer satisfaction and organizational performance?



**Assessment**

- Discuss the role of TQM in cost reduction and waste minimization.



# **ASSESSMENT: TOTAL QUALITY MANAGEMENT**

- Explain how employee involvement under TQM leads to continuous improvement.



# **ASSESSMENT: TOTAL QUALITY MANAGEMENT**

**Describe the importance of TQM in achieving competitive advantage in industry**



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- Rao, N. R. (2025). *Evolution of Pharmacy Profession in India*. International Journal of Pharmaceutical Sciences.
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THANK YOU