



# Plan-Do-Check-Act: A tool for continual improvement

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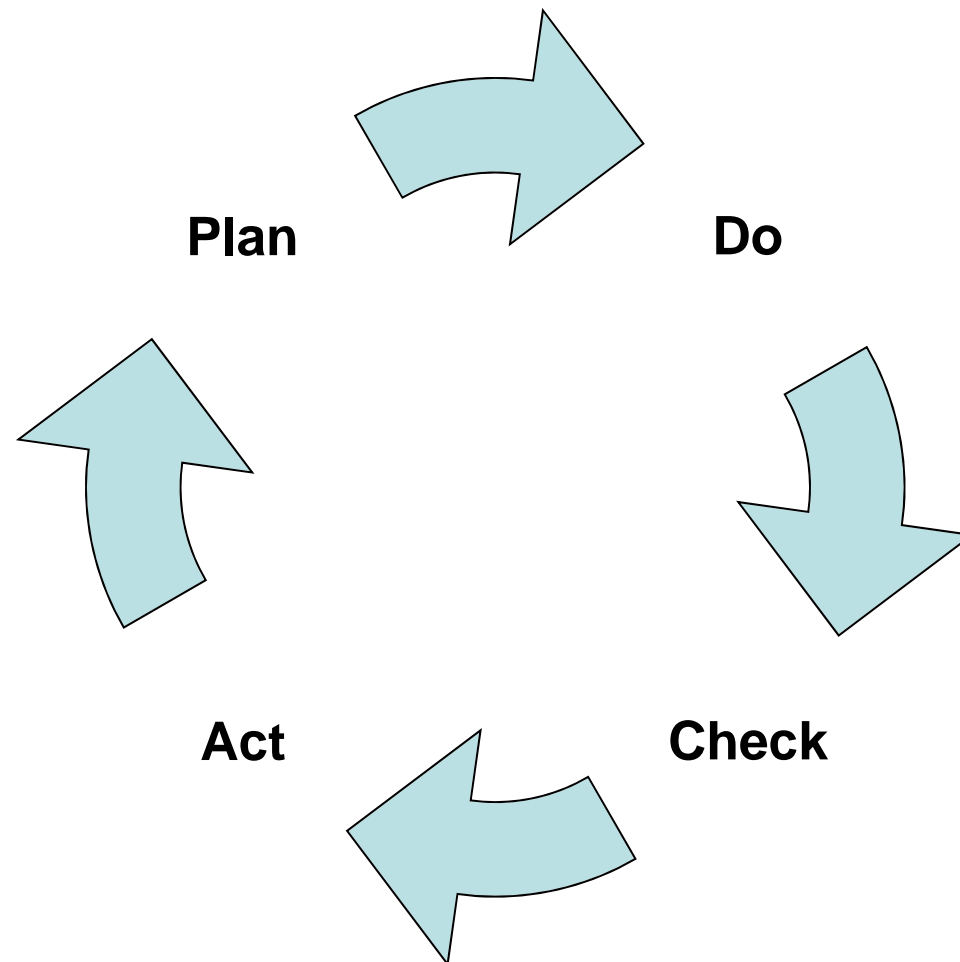


# Objectives

- Overview of PDCA
- Considerations when employing PDCA
- Example – Precedent Tracking System
- Practice use of PDCA for organizational opportunity



# Plan-Do-Check-Act Cycle Model





# History

- Used to develop a plan for improvement
- Developed by Walter Shewart – general process improvement model
- Adapted by W. Edwards Demming (Plan-Do-Study-Act) – emphasize role of learning improvement activities



# Process steps in PDCA

Plan	Do	Check	Act
<ul style="list-style-type: none"><li>a. Study the situation.</li><li>b. Determine what needs to be done.</li><li>c. Develop a plan and measurement process for what needs to be done.</li></ul>	Implement the plan.	<ul style="list-style-type: none"><li>a. Determine whether the plan worked.</li><li>b. Study the results.</li></ul>	<ul style="list-style-type: none"><li>a. If it worked, standardize the change.</li><li>b. If it didn't, try something else.</li><li>c. Continue the cycle.</li></ul>



# Questions for Consideration

- Did the action produce the desired results?
- Were any problems created?
- Was the action worth the investment (cost, time, etc.)?
- Should the plan be modified?
- Do procedures or processes need to change?
- Should the project be taken to completion?
- Does the scope need to be expanded or narrowed?
- Does the cycle need to be started over?



## Example:

# Precedent Tracking System

**Objective:** Establish a process for documenting and sharing OPS CMC decisions (i.e., precedents), and to improve – when appropriate – consistency in decision making while allowing for change when justified.

**Definition:** A “precedent” is a decision that does not follow existing guidance, standards, or previous decisions, or is a decision regarding new (not previously existing) technology based on a new (not previously existing) standard or rationale.



# Plan

- a. Study the situation – inconsistent awareness of precedent setting decisions
- b. Determine what needs to be done – develop process to capture and share precedent setting decisions
- c. Develop a plan and measurement process for what needs to be done – develop a precedent tracking system; and track precedent topic areas and capture customer feedback





# Do

- Implement the plan –
  - Identify subject matter experts who understand the technical and regulatory needs
  - Identity group to develop solution – could include IT
  - Define a precedent under the regulatory framework and quality system requirement
  - Identify the precedent documentation requirements such as application, dosage form, guidance, policy, deviations in practice

(continued)



# Do

- (Continued)
  - Collect sample precedents to build knowledge base and add value for users
  - Develop method to capture feedback on inconsistencies, for example, establishing a Precedents Review Board

# Check

- a. Determine whether the plan worked – Review the number of precedents identified and the quality of the information including data elements and quality characteristics; review information on feedback regarding inconsistencies
- b. Study the results – Should new guidances be developed; should policies be revised; should templates be changed; evaluate usefulness to review staff



# In-progress

- Established definition
- Developed prototype IT solution
- Developed intermediate IT solution
- Identified sample precedents