

Practical Next Steps

Addressing Opportunities
– Case Study

Case Study

Objective: You are tasked to develop a system to establish if a product is considered a medicinal product, medical device, cosmetic or health supplements in your agency.

Your system shall ensure the following:

- (i) consistency in the decision making process while allowing for change when justified
- (ii) documentation and implementation of the decision
- (iii) feedback channel from customers to facilitate continual refinement of the system, when appropriate

Process steps in PDCA

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