

GMP Training Systems, Inc.

Creators of the GMP Ready-to-Use Training System™

A Time-tested and Classic Approach to Problem Solving and Problem Prevention

David C. Markovitz
President, GMP Training Systems, Inc.

Stuff happens. Problems occur. They must be fixed. Conducting a careful analysis during the problem solving process can lead to problem prevention. This is where the real rewards are. In the FDA regulated industries, a process called CAPA – Corrective and Preventive Action - exists to address this.

FDA expects us to conduct investigations when discrepancies and/or deviations occur. The next step is to apply fixes and permanent changes to prevent the likelihood of the discrepancy or deviation reoccurring.

This article will describe a process for the effective implementation of problem solving and problem prevention actions and how you can integrate this into your GXP training process.

Applying the Scientific Approach

W. Edwards Deming, the renowned quality guru, first

described a process for learning and for improvement or a product, service, or process in his teachings in Japan in 1950. It appeared in the booklet *Elementary Principles of the Statistical Control of Quality*¹.

Deming called it the PDSA Cycle, or Plan-Do-Study-Act Cycle. He referred to it through the remainder of his life (1900 – 1993) as the Shewhart Cycle, as he credits Dr. Walter Shewhart (1891 – 1967) as the developer of this approach.

Deming described PDSA in his book **The New Economics**², thusly.

Step One – PLAN

Somebody has an idea for improvement of a product or process. This is the zero stage, embedded in Step One. It leads to a plan for a test, comparison, or experiment. Step One is the foundation of the entire cycle.

A hasty start may be ineffective, costly, and frustrating. People have a weakness to short-circuit

this step. They may not wait to get into motion, to be active, to look busy, moving into Step Two.

The planning stage may start with a choice between several suggestions. Which one can we test? What may be the result? Compare the possible outcomes of the possible choices.

Of the several suggestions, which one appears to be most promising in terms of new knowledge or profit? The problem may be how to achieve a feasible goal.

Step Two – DO

Carry out the test, comparison, or experiment, preferably on a small scale, according to the layout described in Step One.

Step Three – STUDY

Study the results. Do they correspond with hopes and expectations? If not, what went wrong? Maybe we tricked ourselves in the first place, and should make a fresh start.

Step Four – ACT

Adopt the change, abandon the change, or run through the cycle again, possibly under different environmental conditions, different materials, different people, different rules.

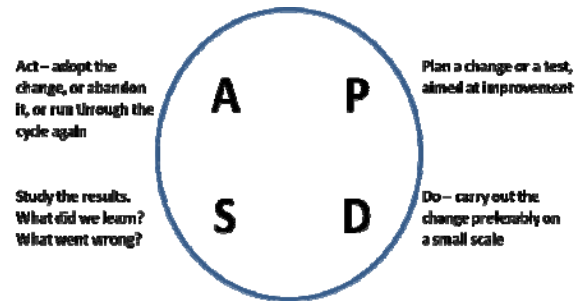


Figure 1 The Shewhart Cycle for Learning and Improvement – the PDSA Cycle.

You may recognize the Shewhart Cycle as the practical application of the scientific method.

Observations – Questions – Hypotheses – Predictions – Experiments – Results – Conclusions.

The beauty of the Shewhart Cycle is in the simplicity of the Four Steps. We'll look at each step in more detail.

A Detailed Look at the Four Steps

In his teachings, Deming would often go on and on about the importance of the zero stage – Planning. As Deming points out, we may start with a choice between several suggestions. Too often people or groups of people come up with an initial idea and try it out.

It is far better to spend more time thinking together to identify several possible routes to consider. It is not unusual to

find that the best solution is not obvious, and may require a meeting or two (or even more) of brainstorming before finding the best approach to try first.

Oftentimes time spent on Planning can reduce the overall length of the project.

Peter Scholtes, in his book **The Leader's Handbook: A Guide to Inspiring Your People and Managing the Daily Workflow**³, says that learning and improvement result from the dynamic interplay between theory and experience.

The entire plan is theory. As it is applied, people will acquire knowledge. Review (or Study) is how people examine how well the theory is working and what needs to be learned so that they can do better.

Here are some details Scholtes suggests to help guide us through the Shewhart Cycle.

Step One – PLAN

1. Start by reviewing various data.
 - Customer data
 - Market data
 - Process data
 - Employee data
 - Previous efforts and results

Required capabilities here are statistical thinking and systems thinking and analysis.

2. Analyze the data, and develop priorities through interactive methods.

Required capabilities include meeting skills, listening skills, and inquiry skills.

3. For each priority – and with ample input and participation – identify all the various interventions, projects, and activities that are necessary and sufficient to accomplish the identified goal.

Required capabilities include systems thinking, improvement strategies, communication skills, meeting skills, inquiry skills, and planning skills.

4. For each priority, assess the risk associated with the potential outcomes. A thorough risk assessment can help prioritize where to start.

Required capabilities include analytical thinking, systems thinking, improvement strategies, communication skills, meeting skills, inquiry skills, and planning skills.

5. Commission the various interventions, projects, and activities, scheduling review dates for each.

Required capabilities here are communication and listening skills.

Step Two – DO

Carry out an intervention, project, or activity on a small and manageable scale. Treat this as a controlled experiment. Collect meaningful data so that it can be easily evaluated.

Required capabilities include neutral observation, listening skills, inquiry skills, and improvement strategies and methodologies.

Step Three – STUDY

Examine and study the data from Step Two.

- Do the results match our theory and expectations?
- What, if anything, new did we learn?
- Do we need to make adjustments and carry out more experiments on a small scale?

- Do we need to discard our theory and start over with a new Plan?

Required capabilities here include meeting skills, listening skills, inquiry skills, and improvement strategies and methodologies.

Step Four – ACT

Here we implement the actions determined in Step Three.

- Yes, the results match our theory and expectations. Let's scale up our efforts until we reach full scale implementation.
- We learned some new things and need to adjust our approach. Let's run through the Four Steps (PDSA) again.
- We learned what didn't work. Time to develop a new theory and plan and run through the Four Steps (PDSA) again.

Required capabilities include systems thinking and statistical thinking and analysis.

There are two important aspects in completing Step Four- ACT.

First, put into place a post implementation monitoring

system. Continue to check the “pulse” of the process over time.

Conducting post implementation monitoring can help in spotting any potential problems before they occur.

Second is in integrating what we have learned into future efforts. Here’s where a well documented project plan comes into play.

In most organizations, people change roles from time to time. Hence the people responsible for a particular process today may be different from those who were responsible before.

A well documented project plan helps organizations avoid making the same mistakes over and over again.

The Learning Organization

Peter Senge, in his book **The Fifth Discipline**⁴, describes the attributes of a Learning Organization. He gives concrete advice on team learning and the art of seeing the forest and the trees.

A particular good piece of advice deals with dialogue and discussion. Senge describes dialogue as a process where complex issues are explored. The goal of dialogue is to go beyond any individual’s understanding.

In discussion, decisions are made. Senge explains that both dialogue and discussion can lead to new courses of action; but actions are often the focus of discussion, whereas new actions emerge as a by-product of dialogue.

An effective team masters movement back and forth between dialogue and discussion. Mastering dialogue and discussion can be very helpful in effectively working through the Shewhart Cycle.

Teaching the Shewhart Cycle in your GMP Training Process

Once you describe the Shewhart Cycle and how it works during a training session, it is very useful to apply it on a practical basis.

A suggestion here is to identify an improvement opportunity from your operation. Find something that is relatively simple to understand by those attending the training session.

Challenge small groups of four or five people to develop a project for improvement using the Shewhart Cycle. You may want to devote an hour or two to this exercise.

Having an experienced and skilled facilitator can help move this process along. Have each small group document their

thinking and actions for each of the four steps.

At the conclusion of the allotted time, have each group present their findings to the entire class. A question and answer period should be a part of this presentation.

This exercise can help participants learn how to apply the Shewhart Cycle and identify potential barriers and roadblocks to effective implementation.

David Markovitz is the Founder and President of GMP Training Systems, Inc., (www.GMPTrainingSystems.com) a top tier provider of GMP training products and services. David can be reached at David@gmptrainingsystems.com and at 714-289-1233.

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¹ Deming, W. Edwards, Elementary Principles of the Statistical Control of Quality, Japan Union of Scientists and Engineers JUSE, 1950, Out of Print

² Deming, W. Edwards, The New Economics for Industry, Government, Education, Massachusetts Institute of Technology, 1994

³ Scholtes, Peter R., The Leader's Handbook: A Guide to Inspiring Your People and Managing the Daily Workflow, McGraw Hill, 1998

⁴ Senge, Peter M., The Fifth Discipline: The Art and Practice of The learning Organization, Doubleday Currency, 1990