Paper SP07

How to Build Compliance Mindset into A Team Habit

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ABSTRACT

Building an efficiently synchronized high-performing programming team is always critically important to a programming group manager. Based on my years of experience in building and leading such teams in global pharmaceutical companies and my current role, I identified 5 critical areas a leader should pay great deal of attention and put effort into when building a high performing team:

1. Building discipline into the team to empower team to perform well at any circumstances, without cutting corners;
2. Building knowledge and skill sets in the team to empower the team with the capability to quickly comprehend tasks at hand and accomplish the tasks with high quality results and speed;
3. Building right process and standards to not only empower the team to accomplish tasks efficiently, also systematically reduce error rate.
4. Building strong collaboration in the team and reducing unhealthy competition, which is especially critical in a global team setting when team members are at multiple locations in different time zones around the world.
5. Building the right group structure to empower the team members to develop their leadership and being accountable for their deliverables.

This paper will be the first of a series of presentations on these critical topics. In this paper, I will only focus on one critical step in building discipline into a team: building compliance mindset into a team habit. As it will build a solid discipline foundation for high performing teams with the attribute of the other 4 areas. This paper will also outline the critical steps to build compliance mindset into a team habit.

INTRODUCTION

Operational globalization is phenomenal these days. It is especially vital in highly regulated pharmaceutical industry. In this global setting, it is impossible for a manager to have close supervision on each team member's daily activities. Thus, it is critical for a team to have the discipline to conduct activities not only with the quality and speed but also compliant with regulations and rules in a consistent manner. Building discipline is the most critical step in building a high-performance team. With discipline built into a team, it will be more efficient and effective to build the knowledge, process, collaboration and team talent.

There is certainly more than one way to effectively build the discipline into a team. For example, we can use the regular 1:1 opportunities and periodic performance review opportunities to provide clear expectation, feedback and coaching; to hold each member accountable and to enforce good behaviors. Those methods can be used simultaneously while using building compliance mindset into a team habit as a driving force.

There are many benefits of using building compliance mindset into a team habit as a pathway to introduce and build discipline. First, compliance is ranked high on a statistical programing manager's priority list, due to the highly regulated business nature of pharmaceutical companies. Second, the activities of many steps in the compliance habit building, such as education, Q&A, compliance checking result reviewing and lesson's learning are team level activities. These activities will also enhance the collaboration. Third, there could also be ripple effects reaching other related line functions. When one team has the compliance mindset built into a habit, the team's experience can be shared with other line functions. Also, the expectation on other line function to follow SOPs can also be shared. When the expectation gets materialized, it can create more harmonization and collaboration between line functions.

STEPS FOR BUILDING COMPLIANCE MINDSET INTO A TEAM HABIT

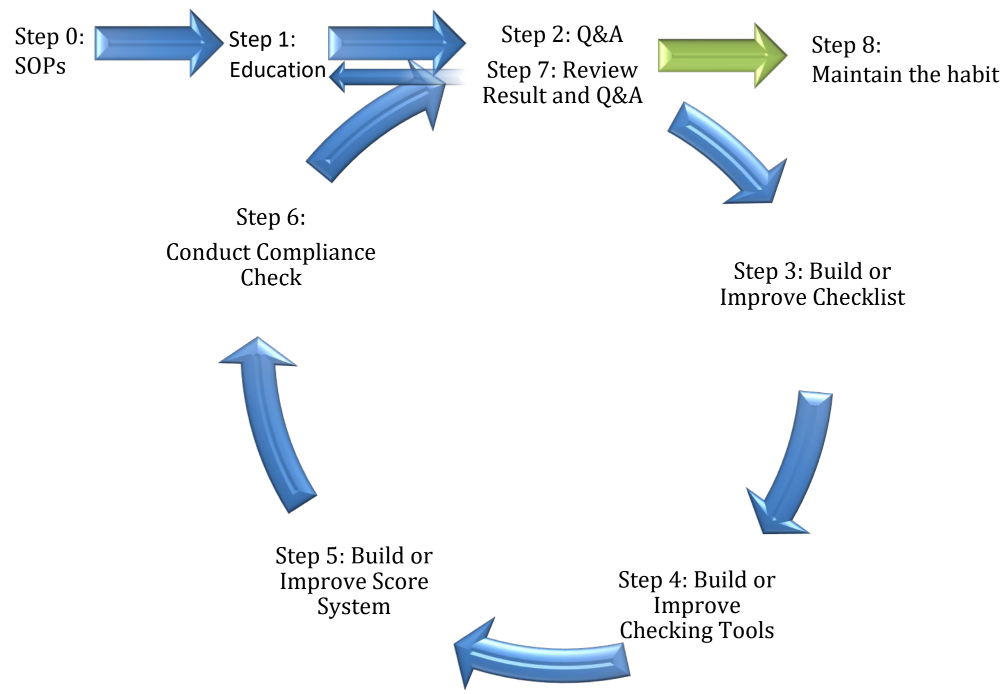

Figure 1

STEP 0: HAVE WELL-CONSTRUCTED SOPS.

SOPs should provide detailed step by step instructions to make sure routine tasks are conducted in a consistent and efficient manner that is compliant with regulatory requirements and guidelines while also reducing the chance of error. Well-constructed SOPs should be up to date, straightforward, clear, and stream-lined. SOP documents should also be consistent, without contradiction or gap.

Although it would be ideal to have well-constructed SOPs ready before we start step 1, we need to understand that there is no perfect SOPs. We can start step 1 with a version of SOPs that are in good shape. Conducting the rest of the steps gives us opportunities to identify potential SOP improvement needs. The collected feedback on the SOP should be shared with a standards team to support future SOP improvement strategies.

STEP 1: EDUCATE THE TEAM ON THE SOPS.

The first step is to have all the team members educated on their role within the critical SOPs. For team members who took the training a while ago, a refresh training is necessary.

Requesting team members to read the SOPs typically doesn't result in deep understanding.

A better approach is hosting discussion sections for team members to bring in their questions from study and following SOPs. With discussion and reading related section of SOP during the meeting, teams can reach right answers on most questions.

There will be questions that people cannot reach agreement on the right answer after discussion. Those questions are likely related to which actions are considered as being compliant to SOPs for a specific step and which actions are not. Those questions should be collected for further clarification for standard group.

During the discussion, people will also provide feedback on desired SOP improvement on certain process defined in current SOPs for efficiency and SOP consistency reasons. A portion of the feedback might come from efficiency point of view. However, people might not realize that specific process is necessary to ensure the essential documentation as the compliance evidence or to ensure the quality consistency. In this situation, the manager should clearly explain to the team the reason and why it should be strictly followed. There definitely will also be legitimate feedbacks that can truly increase the productivity consistently and systematically, or close the gaps or inconsistency among different SOP documents. For this type of feedback, the manager should acknowledge the excellent feedback and collect those feedback to share with standard team for the future SOP improvement.

STEP 2. CONDUCT SOP AND COMPLIANCE Q&A SECTION FOR THE TEAM.

Manager should take all unanswered questions to standard team and discuss with them the questions one by one to compile the best answer for the question. It is critical that the manager explains the specific scenarios generating the questions to help standard team to have a clear understanding where the question comes from and to be able to provide the specific and relevant answers.

The manager should conduct the Q&A sections with the team again to share those answers to make sure everyone has a deep understanding of current SOPs.

STEP 3. COMPILE OR IMPROVE A CHECKLIST FOR THE COMPLIANCE.

SOPs are like traffic laws. No matter how well all the rules are defined and how well people are educated, without police patrolling the streets, the rules will be broken left and right for speed or convenience. Thus, it is necessary to conduct compliance check regularly. The primary goal of the check is not to punish the offender. Rather, manager should use the finding to identify the weak spot, further educate the team on how to improve compliance. With that in mind, a checklist should be constructed with items clear to understand and clear to check.

If there is already a checklist available at company level for documentation purpose, it could be a good place to start. A checklist for documentation purpose normally has items in a very general term to keep the check list in a very concise format. When we do actual check, the general terms must be translated into precise executable action items.

For example, for the documentation purpose, you might have an item as "All output, programs, requirements, and validation documentation are complete and stored as defined in departmental process", the executable action items should be split into following executable action items

1. All ADaM data setup programs documented in the Program Development and Validation Tracker are developed in the pgmsetup folder;

2. All TFL programs documented in the Program Development and Validation Tracker are developed in the pgmanal folder;

3. All protocol specific macros documented in the Program Development and Validation Tracker are developed in the macrolib\protocol-macros folder.

4. All developed SAS programs should have corresponding outputs, logs, and listings. Every log/listing associated with the output datasets/TLFs should have consistent time stamps.

5. Developer Testing are completed for all the programs with program validation category value number 1, 2, 3, 4.

6. Validation for Protocol Specific programs are completed. validation process executed have later time stamps than those of develop process.

Step 4. Develop or improve tools for the team to conduct the check themselves.

As it is very challenging to check all the action items manually, we need to develop tools that can be utilized for two purposes. 1. For the trial programmers to do self-checking to ensure the compliance and quality; 2. for the compliance SME to do the periodical checking.

The team should be involved in the tool development and testing. It is also an educational opportunity for them to get familiar with SOP requirements.

Step 5. Develop or improve a score system on the compliance checking and inform the team of the coming independent compliance check

In order to give the team an intuitive picture on how well they are conducting their activities on compliance, we can develop a score card for checking the deliverable compliance. Most of our programmers are highly educated, many of them even have advanced degrees. Their brains have been trained for decades to get excited for a competitively high score. A well-designed score system can be really motivative to encourage compliance.

At beginning, we should identify the key items in the check list developed in step 4 to help the team get critical compliance done in a consistent way. We can also use the opportunity to improve our checklist and checking tools.

Step 6. Conduct independent compliance check on deliverables finished in the previous quarter

When we first start, we should check all the deliverables completed in the previous quarter using the tools and score system developed in step 4 and 5 to accumulate enough information on team's compliance stats, as well as to help the team building the compliance habit.

Before checking, we should give team a heads-up for them to complete all the necessary steps, as a little bit nudging can sure help building the right habit.

Step 7. Share compliance checking results.

Once the step 6 is done, the results need to be shared with each deliverable team to evaluate what correction action should be taken based on company SOPs. If there is a serious deviation from the SOP, we should work with standard team to assess whether there is any CAPA action need to be taken to remedy the deviation and act accordingly.

The compliance check results, including the scores, areas the team have done well and areas the team needs to improve should be summarized and then shared with the team. As the purpose of sharing is to further educate the team on the compliance and discuss the improvement, the summarized information should be shared in a confidential format without revealing the study number and programmer name to avoid the feeling of public humiliation and to encourage open discussion.

We can also use this opportunity to discuss with team on the best practice we can follow or the tools we can develop or improve that can help the team improve compliance, efficiency and reduce deviation.

This learning and teaching could also be considered as the step 2 of next round of education and checking. When it is necessary, we can also go back to step 1 to both refresh our knowledge and further enhance the understanding of the SOPs.

Repeat the cycles until the team compliance score reaches and stays at a high level.

Step 8, stable stage, maintain the habit.

When the team can consistently maintain the compliance score at a high level for a few quarters, we know the team habit of being compliant with SOP is well established. We might also find the team's performance is also improved significantly at the same time. Once the team reach the stable stage, only periodical and selective compliance checking is needed to make sure the habit is well maintained and to identify potential issues.

CONCLUSION

With meticulous planning and execution, we can build compliance and discipline into a team habit following appropriate steps. With the discipline of doing the right thing at the right time, team will start to develop the drive to learn, to collaborate and to build the tools for improvement. Along the way, we can identify talent and build up the leadership structure within the team. All these will lead to a high performing global team.

RECOMMENDED READING

The ONE Thing: The Surprisingly Simple Truth Behind Extraordinary Results by Gary Keller and Jay Papasan
The Power of Habit: Why We Do What We Do in Life and Business by Charles Duhigg
Nudge: Improving Decisions About Health, Wealth, and Happiness by Richard H. Thaler and Cass R. Sunstein

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