



# Hello!

***I am Xiaohui Wang***

With 19 years of project and people management experience; am passionate about improving team performance and efficiency; have lifelong curiosity for knowledge

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# How to Build Compliance Mindset into A Team Habit



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## High Performing Team



### Discipline

Empowers team to perform well at any circumstances, without cutting corners

### Knowledge & Skill

Empowers the team with the capability to quickly comprehend and accomplish the tasks with high quality results and speed

### Process & standards

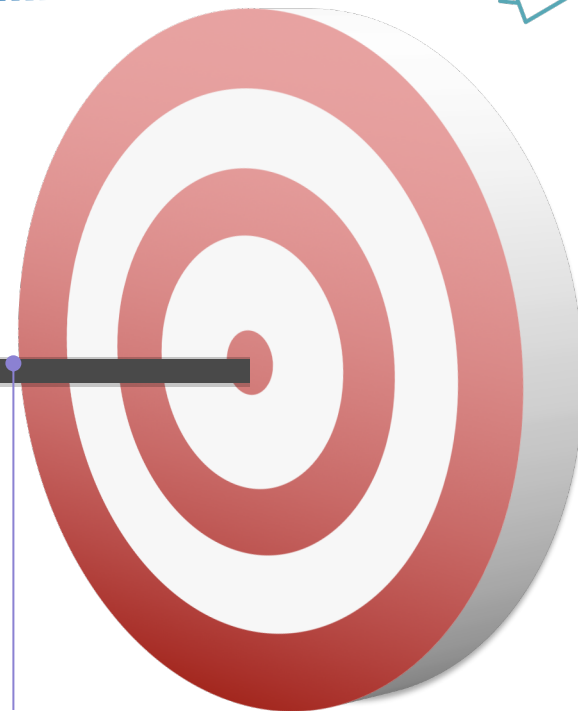
Empowers the team to accomplish tasks efficiently, also systematically reduce error rate.

### Collaboration

Accelerates the high performance team building in all areas.

### Right Group Structure

Empowers the team members to develop their leadership and to be accountable for their deliverables





## Discipline

### Why it is so important

- Global team; members should be able to perform independently
- Highly regulated industry

### How to build team discipline

- Build compliance mindset into a team habit
- Regular 1:1 and team meetings to provide the feedback
- Hold each team member accountable





## Steps For Building Compliance Mindset Into A Team Habit

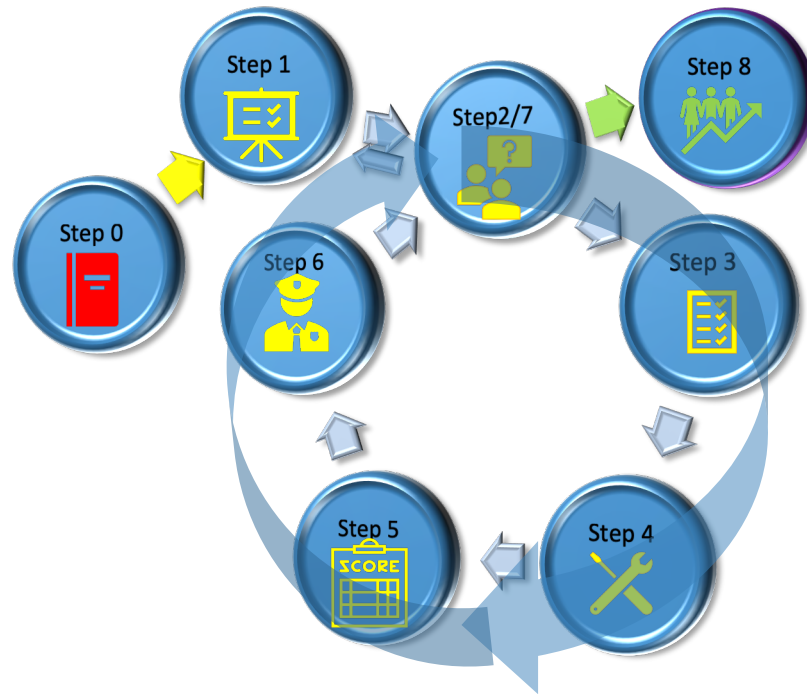
Step 0 : SOP

Step 1 : Education

Step 2 : Q&A

Step 3 : Build or Improve Checklist

Step 4 : Build or Improve Checking Tools



Step 5 : Build or Improve Score System

Step 6 : Conduct Compliance Check

Step 7 : Review Result and Q&A

Step 8 : Maintain the habit

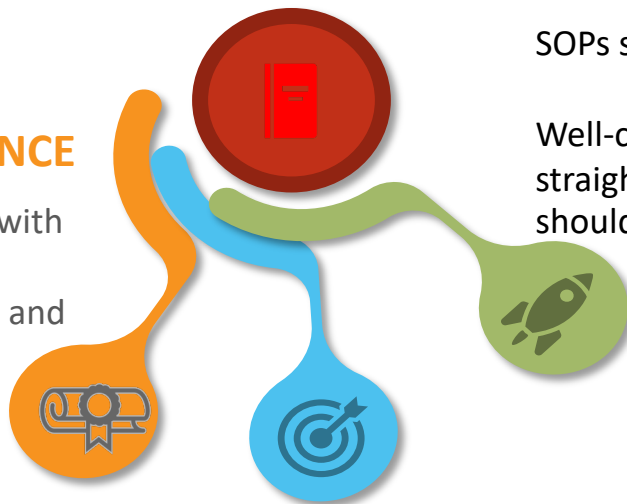


## STEP 0: HAVE WELL-CONSTRUCTED SOPS

### ☉ Purpose of SOPs

#### ENFORCE COMPLAINECE

Compliance with regulatory requirement and guidelines.



#### INCREASE ACCURACY

Well defined SOPs can reduce chance of error

#### SOP

SOPs should provide detailed step by step instructions.

Well-constructed SOPs should be up to date, straightforward, clear, and stream-lined. SOP documents should also be consistent, without contradiction or gap.

#### IMPROVE EFFICIENCY

Well defined SOPs make the process consistency possible, which is the foundation of standardization to improve efficiency



## STEP 1: EDUCATE THE TEAM ON THE SOPs

- Self-study the SOPs
- Bring questions to guided group discussion

### Misunderstanding

With discussion, team can reach the right understanding on the majority of questions

### If team cannot reach agreement

Collect the question to discuss with standard team for the right answer

### Efficiency focus, missing compliance reason

Manager explains why the step is necessary for the compliance reason

### Identified SOP gap

Manager collect the feedback and share with standard team for future improvement





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

- Manager should discuss with standard team the collected questions to compile the best answer for the question

Questions should be discussed one by one.

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 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 have a deep understanding of current SOPs



## STEP 3: COMPILE OR IMPROVE A CHECKLIST FOR THE COMPLIANCE

**Compliance checklist should be concise and specific in order to conduct the compliance check**

**Example:** “All output, programs, requirements, and validation documentation are complete and stored as defined in departmental process”



Build compliance mindset into team habit

Conduct regular compliance check

Compliance checklist (Key points)

Compliance checklist (Detailed)

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

- Macros or other tools can be developed based on the detailed checklist
  - For programmers to check their deliverable and improve their process
  - For SME to conduct the compliance checking
  
- Tool development and UAT should involve the team
  - To provide input
  - To further improve the understanding of SOPs
  - To be mentally ready for the compliance checking



## **STEP 5. Develop or improve a score system on the compliance checking + inform the team of the coming independent compliance check**

- A Score system can be developed for compliance check
  - Can reflect the status and progress of compliance
  - Can motivate team members to improve compliance



## **STEP 6. Conduct independent compliance check on deliverables quarterly**

- Check the compliance of all the deliverables of previous quarter using the tools and score system developed in step 4 and 5
  - Before the first time check, give the team a head up
  - Continue improve the tools and score system



## STEP 7. Share compliance checking results and conduct Q&A



### Share result with individual project team

- 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.
- Discuss the future improvement plan



### Share with entire team summarized results

- Including the scores, areas the team have done well and areas the team needs to improve, in confidential format without study numbers and programmer names
- Have the Q&A to further educate the team on SOPs, clarify new questions
- Get input on area for improvement on checklist, tools, and score system

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.



## STEP 8. Maintain the habit in a stable stage

- Consistent compliance score at a high level for a few quarters means the team habit of being compliant with SOP is established.
- Team's performance is also improved significantly at the same time.
- Still needs periodical and selective compliance checking 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. With all these we can build a high performing global team.



## Recommended readings

- **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*



## Credits

Special thanks to all the people who made this presentation possible:

All the colleagues have been working with me all these years building remarkable teams

All the managers and mentors giving me inspirations and guidance

Amy Gillespie and Greg Zhou's honest and valuable feedback and comments on the paper



**Thanks!**

**Any questions ?**

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