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# Overcoming Hurdles to an Effective and Integrated Quality Management System

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1. Leadership



2. Culture



3. Communication Channels



4. Planning



5. Integrate

# O' the problems we have seen...

**Loss of Accreditation or Recognition** *PT failures* Systematic Errors Rework

Revised Test Reports Customers Leaving

**Holding Times Missed** Unskilled Assessors **Poorly Trained Employees**

Invalid Findings *Get the Work Out the Door Regardless*

Inconsistency in Assessments **Poorly written SOPs**

**No Root Cause Analysis** Superficial Internal Audits

NO Management Commitment Lack of Metrics

Generate Control Charts But Don't Use Them

**Management Reviews That Are A Joke!**

What's Preventive Action? No Quality Culture

**Inadequate Data Review** Sloppy Practices

*Not adhering to SOPs* Inconsistency between ABs



**FRAUD**

While every organization (laboratory or Accrediting Body) is unique and has its own set of dynamics and problems...

What does it take to overcome this?

You all know what it takes!

# Number One: Leadership

- It all begins with **LEADERSHIP**. We have all seen the difference between great leadership and poor leadership.
- *“If the highest person in the organization is not bought in and communicating quality importance, nothing anyone else says in the organization will make it a priority.”*
- Leadership is not: **management by intimidation, my way or hit the highway, if you are not with me then you are against me, how dare you question things, we have always done it that way, do whatever you want I don't care,** or just meet the minimum requirements to be accredited anything else is overkill!
- Leadership needs demonstrated by all involved regardless of position! Find your personal leadership style and use it daily. Leadership is not positional.
- **Any AB Assessor or laboratory QA Manager with passion, leadership ability and a vision can change a management team and the QMS for the better!**

# Number Two: Culture

- You have to work from day one at fostering a culture of quality and continuous improvement that will benefit the success of the organization.
- To do this seize any opportunity to change attitudes and behaviors when you can. **Be proactive!**
- **Set the tone early.** At times be flexible, yet stand firm when you need to, so as to let others in the organization know your expectations and the direction the culture needs to go.
- **Gain support and commitment throughout the organization (at times given and at times hard won).** **You will have to push the envelope.**
- As a necessary change agent, you need to develop the respect and trust of others (only earned).
- **Be a go to person in your organization!** **Make your presence felt.**

# Number Three: Communication Channels

- Create efficient and effective internal and external communication channels. Network within and outside the organization.
- Integrate effective communications channels within QMS elements (e.g., CAPA, Complaints, SOP Review/Revision)
- Establish open lines of communication with staff to allow working together to meet requirements and make improvements.
- Actively seek other's perspectives when a change or decision impacts heavily on them. Welcome push back. It keeps you honest.
- Allow others to come to you with their ideas, problems and concerns.
- Have an open door policy!

# Number Four: Planning

- **Strategic Planning** (Mission, Values, Vision, SWOT, Goals, Measureable Objectives, KPIs, Budget, etc.)
- **Management Review** (continued suitability of the QMS)
- **Annual QA Planning** (tasks, due dates, who's responsible, resources)
- **Tracking, Monitoring and Reporting**
- **Coordinate your Management Review and QA Planning with the Budget Cycle**
- **Ensure resources are available and then utilize them efficiently and effectively to meet your objectives.**
- **Have open and transparent communications on planning efforts!**

# Number Five: Integrate the QMS for Continuous Improvement

- *“Continuous improvement is the name of the game. It happens incrementally over time.”* Manage change.
- Take a systems approach! The QMS is a group of interacting, interrelated and interdependent elements.
- They affect each other in reciprocal manners (back and forth so to speak). When something happens in one it triggers action in another.
- For example: corrective and preventive action (CAPA), Trend analysis and CAPA, data review and corrective action, management review and other elements, audits and continuous improvement, etc.
- I have seen to many times where the elements are stand alone silos and the QMS and organization is vulnerable.



# Number Six: Establish and then Maintain Compliance

- “A quality system implemented only to meet accreditation requirements is doomed to be difficult and often not complied with; it must be implemented to improve efficiency and reliability of the operation.”
- “Design a quality system that allows the organization to continue fine tuning their systems, achieve systematic improvement, while designing a system that works for them.”
- *“ABs should build and maintain the kind of quality system that they expect to see in a laboratory --- which includes effective SOPs, training, corrective action, internal audits, and management reviews.”*
- A well designed and fully functional QMS provides ample opportunity to determine and maintain compliance.
- Always give maintaining compliance with the QMS a high priority!

# Number Seven: Evaluate

- **Audits** – make them value added. They provide a big bang for the buck. Don't squander them. I have seen so many superficial audits by both QA Managers and Assessors.
- **Management Review** – don't allow them to be a paper exercise or have people go down the table and "report." A great opportunity for all of management to contribute to improving the QMS and the organization. That is, evaluate data, brainstorm, multi-voting, gap analysis, action plans.
- **Performance Metrics** – what are they telling you!
- **Trend Analysis** - what are you detecting?
- **CAPAs and Customer Complaints** – what do they tell you about QMS?
- **QA Records** - are they complete, accurate, traceable and retrievable!

# Number Eight: Improvement



- “If you can’t measure it, you can’t improve it.”
- Establish useful and accurate performance metric for your Quality Management System elements. Use these to identify opportunities for improvement.
- Use the results of audits, data analysis, CAPA and the Management Review to identify opportunities for improvement that benefit the organization.
- How can people get better if they are not trained properly and in a learning environment. Have a well defined training program that meets the organizational needs. Training never stops!
- Again, you need the QMS elements in place to be effective and fully functional to allow the chance to improve. Must address material weaknesses or lapses in any QMS element.

# Number Nine: Stay the Course

- Stick to the plans, while adjusting for unexpected priorities.
- Make sure you have good people that actually care about what they are doing and about the success of the QMS and the organization. Whether they do or don't has a lot to do with your leadership. Raise people and the organization up.
- A good team can do miracles. Work on establishing a good management, QA or AB team.
- Those that don't care or are just going through the motions can drag the organization down and perpetuate the wrong type of culture. Try to bring them along, if you can.
- Get others to see the big picture!

# Number Ten: Prepare the Next Generation

- Succession Planning (a must)
- Look for champions and leaders with the right mix of technical, leadership and people skills and mentor them.
- Give them the tools, training and experience they need to be as good as you ever were.
- Let them experience adversity, setbacks and failure.
- Impart knowledge.
- Empower and challenge them.
- Give them a reason to stay!

# Wrap-up

- If you are working on this within your organization, **never let them beat you down.**
- Stay open to new ideas.
- Be driven and stay passionate.
- Punch through the hurdles that stand in the way.
- Don't be afraid to take risks, that are worth taking.
- Open others eyes and win them over.
- Contribute to what concerns them and the organization in ways they don't expect.
- **Be the change agent that your organization needs for an effective and integrated Quality Management System.**

# Thank you and good luck!

*Any questions?*

*I am here all this week.*

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