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BEING AN EFFECTIVE QA MANAGER IN A COMMERCIAL LABORATORY

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What insights can I share based on my experiences.



- ▶ Skill Set You Will Need to Develop and Refine Over Time to Succeed:
 - ▶ Leadership and the ability to work as a team member.*
 - ▶ Communications: Written and Verbal (learn when to listen and when not to talk)*
 - ▶ Time and Project Management (i.e., planning, prioritizing, multi-tasking and being organized)
 - ▶ Problem Solving and Thinking Out of the Box (share your time when big problems arise)
 - ▶ People Skills (from dealing with the CEO to analysts and with clients and regulatory agencies)
 - ▶ Management (not only of QA and any QA staff but how the laboratory is being managed and how it operates)

NO ONE WAS BORN
A QA MANAGER!

YOU GREW INTO IT
OR WERE THRUST
INTO IT!

- ▶ Ability to speak effectively and present in front of a small or large group of people
- ▶ Willingness to Learn and Grow Professionally (you can always teach an old dog new tricks)
- ▶ Understand IT (LIMS) and how it can help QA
- ▶ Ability to make Decisions (engage others in the decision-making process, especially if it impacts on their operations directly)
- ▶ Ability to stand your ground, but also to forge consensus or reach a compromise
- ▶ Be able to Coach and Teach others (especially new staff). They are the future.
- ▶ Humility, Politeness, Fortitude, Open-mindedness, Enthusiasm, Empathy, Focus and be Personable

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- ▶ It all begins with **LEADERSHIP**. We have all seen the difference between great leadership and poor leadership.
- ▶ *“If the highest person in the organization has 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 to be demonstrated by everyone in QA! Find your personal leadership style and use it daily.
- ▶ Lead from the front. Take the initiative. However, empower others and know when to delegate.
- ▶ Any QA Manager with passion, leadership ability, a vision and good instincts can change a management team and the QMS for the better!
- ▶ Remember, Leadership is contagious.

LEADERSHIP

- ▶ Between QA, management, operations, IT, sales, project management. All departments are important and typically part of the quality management system. If you work in synergy you produce something greater than the sum of its parts.
- ▶ Keep open and effective lines of communication with all laboratory staff and departments to allow working together to meet requirements. **Get out of your office!**
- ▶ QA requirements, just don't tell people what they are, explain them!
- ▶ Be an active listener, seek constructive feedback and welcome pushback. This will give you the other persons perspective.
- ▶ Have an open-door policy.
- ▶ Let others know that no question is a dumb question. Same for ideas.
- ▶ Welcome others to come to you with their problems, concerns and input.
- ▶ Through planning you can create constructive communications.

COMMUNICATIONS

- ▶ Building a Quality Culture*
- ▶ Building Mutual Trust and Earning the Respect of others (ongoing effort)
- ▶ Promoting Accountability and Shared Responsibility for QA across the laboratory
- ▶ Win others over by earning their trust and respect
- ▶ Promote a Systems Based Approach and Integrate the QMS across the laboratory
- ▶ Planning, to prioritize and focus resources and to get buy in.
- ▶ Build in Risk Management and COPQ thinking into the QMS
- ▶ Manage Nonconforming Events (including CA using root cause analysis)
- ▶ Maintain Regulatory, Accreditation and Project Compliance
- ▶ Maintain QA Records (complete, accurate, traceable and retrievable)

QA MANAGER ACTIVITIES

- ▶ Evaluate and Assess (control charts, audits, trend analysis, complaints, data mining)
- ▶ Measure Performance via Quality Metrics and KPIs
- ▶ Monitoring and Management of Nonconforming Events, including building a culture that encourages reporting of such events
- ▶ Be a Change Agent, yet Manage Change <https://asq.org/quality-resources/change-management>
- ▶ Contribute to what concerns others in the organization in ways they don't expect
- ▶ Drive Continuous Improvement <https://asq.org/quality-resources/continuous-improvement>
- ▶ Maintain the QMS, Stay the Course and Deal with Setbacks or other Priorities that Arise
- ▶ Build great Training Systems and Mentor others (e.g. QMS, Regulations, TNI Standard, Risk Management, COPO)
- ▶ Dealing with hurdles and understanding the forces working against your efforts. However, don't be afraid to take risks, that are worth taking.
- ▶ Obtain needed resources to meet your objectives (adequate staff, IT solutions, etc.)
- ▶ Hire good people and treat them like you would like to be treated.

QA MANAGER ACTIVITIES

- ▶ You must 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 and deliver a consistent message. At times be flexible, yet stand firm when you need to, to let others in the organization know your expectations and the direction the culture needs to go.
- ▶ Gain support and commitment for a quality culture throughout the organization (at times given and at times hard won). You will have to be willing to push the envelope.
- ▶ Build a management team that has a common set of values toward Quality
- ▶ Recognize if the culture is highly profit driven, “just get the data out the door” or has a weak quality culture and minimal focus on data integrity.

BUILDING A QUALITY CULTURE

- ▶ You need to work on achieving to the extent possible Organizational Synergy. This is when people and processes merge seamlessly to continuously expand the ability of the organization to deliver products and services to its customers, while maintaining competitiveness. <https://www.socialsynergetics.com/site/org-synergy>
- ▶ Laboratory Operations, IT, Project Management, Quality Assurance, Sales, etc. working to produce something greater than the sum of its parts.
- ▶ Need to break down any walls that see QA and Operations as opposing aspects within the same laboratory. They are both integral and necessary.
- ▶ Help build a laboratory management team that has common values. What is right and wrong, the culture of the organization and underlining principles by which the management team works.
- ▶ QA needs to empower and support others in operations working on improving the laboratory. Help them in unexpected ways.
- ▶ QA needs to be viewed as a go to resource and people they can trust.

RELATIONSHIP BETWEEN QA AND OPERATIONS

- ▶ Different Departments and Managers have different roles and responsibilities for the **business** and thus have a different view of QA importance and its role! That includes the role of QA and the QA Manager.
- ▶ Quality Assurance has compliance pressures to meet regulatory and program requirements, accreditation standards, ethical conduct and business risk mitigation; with primary focus on regulations and compliance.
- ▶ Operations focuses on profits, cost control, production growth, staffing, TAT and keeping the laboratory owners satisfied.
- ▶ Project Management focus on meeting client's needs and obtaining repeat business. Sales want to make sales and deliver what the client needs!
- ▶ There has to be balance between all these business drivers as they are all critical to success in the laboratory business. If you overly emphasize one or two at the cost of another, the laboratory can get out of balance and potentially undermine the business. I have seen where the QA Manager has to actively work to maintain this balance and prevent QA from being underemphasized.

CORNER STONES TO BUSINESS SUCCESS

HOW QA CONTRIBUTES

- ▶ All departments and managers need to understand and support the importance of QA which includes :
 - ▶ Improving Service to the Client
 - ▶ Effective, efficient and having a fully Integrated QMS that meets the needs of the business
 - ▶ Role and Value of Accreditation and Compliance
 - ▶ Need for Control of Nonconforming Work and Systemic Errors that place data quality, the client and laboratory at an unacceptable level of risk and drive up the COPQ
 - ▶ Management of Risk including risk analysis
 - ▶ Need for data the client can **trust** and Data Integrity
 - ▶ Costs and loss of profit to the business due to poor quality (COPQ), and
 - ▶ Need for Continuous Improvement (PDCA)

QA needs independence to be a check.

CORNER STONES TO BUSINESS SUCCESS

HOW QA CONTRIBUTES

- ▶ “QA just needs to do enough to maintain accreditation, everything else is overkill.”
- ▶ Having QA not report to highest manager in laboratory
- ▶ Resist having a corporate QA function for an organization with multiple laboratories or laboratory network
- ▶ Why QA? (had to answer, explain or justify why multiple times to upper management)
- ▶ Get labeled: e.g., QA Zealot, QA Mafia.
- ▶ **Welcome Push Back, it keeps QA honest. You can't just tell them to do it, you need to explain why: it is important, adds value and/or is required. To get buy in.**
- ▶ Most managers will accept and change in time and see how it helps, some will always be a work in progress. Some will be a hopeless cause and hurt the organization.

A QA MANAGER WILL EXPERIENCE PUSH BACK AND RESISTANCE ALONG THE WAY

- ▶ Yes, at times forces in the laboratory may be working against your efforts. It goes with the territory to some extent. “if we had to deal with or document every complaint, we would not get any work done.”
- ▶ Take risks, that are worth taking. Be a change agent where change is warranted and manage that change. Be the go-to-person in your organization! Make your presence felt.
- ▶ Understand office politics and what motivates others. At times know how to be diplomatic, compromise or reach consensus to move forward. Rome was not built in a day.
- ▶ Make every effort to keep the COO, Vice President, and/or Laboratory Director informed and supporting QA. Again, they must communicate and show support for QA efforts.
- ▶ Understand, their day-to-day priorities and pressures are likely not the same as yours.
- ▶ You can, if you wish, just be a survivor and never rock the boat or take the easy route. But where is the fun in that. A QA Manager is too valuable to the organization to be wasted.

A QA MANAGER WILL EXPERIENCE PUSH BACK AND RESISTANCE ALONG THE WAY

- ▶ Stay the course
- ▶ Be driven and passionate about your work
- ▶ Punch through the hurdles
- ▶ Don't be afraid to take risks
- ▶ Open other's eyes to the role and importance of QA to business success
- ▶ Understand that it may be two steps forward and one step back
- ▶ Be flexible and adaptable, as things don't always go as planned.
- ▶ Don't let organizational mediocrity settle in, and remember:

IT'S A NEVER-ENDING JOURNEY

THANK YOU FOR PARTICIPATING!

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Disclaimer: The views and opinions expressed here reflect only those of the author.

ANY QUESTIONS?

SPECIAL THANK YOU TO:
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