1. Quality Parable

A giant engine in a factory failed. The factory owners had spoken to several 'experts' but none of them could show the owners how they could solve the problem.

Eventually the owners brought in an old man who had been fixing engines for many years. After inspecting the huge engine for a minute or two, the old man pulled a hammer out of his tool bag and gently tapped on the engine.

Immediately the engine sprung back into life.

A week later the owners of the business received an invoice from the old man for $20,000 USD. Flabbergasted, they wrote to the old man asking him to send through an itemized bill.

The man replied with the itemized bill that said:
- *Tapping with a hammer: $ 10.00.*
- *Knowing where to tap: $ 19,990.00.*

The moral of the story is that, while effort is important, having the experience to know where to put that effort makes all the difference.

2. OPTIM Report # 1

This is OPTIM Report #1 – A deep dive into the topic of "Aligning your Compliance Strategy with 1) Overall Business Strategy, 2) Implementation Tactics, and 3) On-Going Organizational Change.

As a "deep dive", it is an extensive treatment of a complex and therefore often overlooked issue. This following Table of Contents will help you manageably navigate this topic.

Given a Compliance Strategy to comply with FDA and OUS Regulations is important to make sure your Compliance Strategy is aligned with

- Overall Business Strategy,
- Implementation Tactics, and
- On-going Organizational Change.

If any one of these three pillars are minimized or ignored, the chance for long-term sustainable success is hampered.

These three pillars of business are surely not new. However, they are often not fully understood or executed properly to maximize financial returns.

White Paper: Aligning Strategy, Tactics and Organizational Change

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3. Background Definitions

3.1.   A strategy describes the ultimate destination and how an organization is going to get there. In other words, Strategy defines your long-term goals and how you're planning to achieve them. Strategy gives you the path you need toward achieving your organization's mission. [1]

3.2.   Tactics describes the specific action an organization is going to take to accomplish the strategy. Tactics are much more concrete and are often oriented toward smaller steps and a shorter time frame along the way. They involve best practices, specific plans, resources, etc. They may also be called "initiatives." [1]

3.3.   Organizational Change (a.k.a., Change Management) describes the processes, tools and techniques to manage the people to achieve a required strategy. The goal of change is to improve an organization by altering how work is performed. [2]

4. Overview of Strategy vs. Tactics vs. Organizational Change

The famous Chinese military strategist Sun Tzu wrote "The Art of War.", approximately 2,500 years ago. In it, he said,

"Strategy without tactics is the slowest route to victory. Tactics without strategy is the noise before defeat."

OPTIM Associates suggests modifying Sun Tzu's wise insights to include Organizational Change:

"Strategy without tactics and organization change is the slowest route to victory. Tactics without strategy and organizational change is the noise before defeat."

Strategy, Tactics and Organizational Change are not at odds with one another they all work together and have done so for centuries!

One possible reason Sun Tzu didn't explicitly address organizational change is because adapting to organizational changes was absolute. The strategies and implementation tactics were likewise absolute. Any dissenters to new strategies, tactics or change were silenced and/or eliminated.

However, for businesses to succeed in today's environment we must have a deep understanding of the human side of organizational change. This demands we align the company's culture, values, people, and behaviors to encourage the desired results. Strategic plans or the implementation tactics by themselves do not capture the value that is realized. Only by including the sustained, collective actions of employees—at all levels within the organization—who are responsible for designing, executing, and living with the changed environment will the strategy via the tactics succeed.

5. Case Studies

Here are two examples—taken from two Quality Management System (QMS) Remediation Efforts—of how strategy, tactics and organizational change interact that may help differentiate and illustrate the three terms.

5.1.   Case Study #1:

5.1.1.   Compliance Strategy:
During an externally imposed QMS Remediation effort (i.e., Consent Decree), the Compliance Strategy was to return to and maintain compliance with FDA and OUS regulations.

5.1.2.   Overall Business Strategy
The Overall Business Strategy was stated as <u>utilize a knowledgeable third party organization including verified and seasoned technical SME's (Subject Matter Experts)</u> to lift the Consent Decree <u>within 5 years</u>. In this example, the Compliance Strategy was fully aligned with the Overall Business Strategy.

5.1.3.   Implementation Tactics
In order to align the Compliance and Overall Business Strategy, the Implementation Tactics included:
A. Perform a systemic Gap Analysis against existing processes and the regulation.
B. Perform a Root Cause Analysis on the Gaps
C. Modify Quality System procedures and processes based on the Gap Analysis, Root Cause Analysis and Best Practices
D. Demonstrate Effectiveness and Efficiency of modified procedures and processes

5.1.4.   Organizational Change
In order to align Organization Change with Compliance / Overall Business Strategies and Implementation Tactics the organization performed the following:
A. Recognized and Accepted that the entire organization had to change,
B. Developed a Communication Plan for all employees explaining the Compliance and Overall Business Strategies, Implementation Tactics to be used and the new expectations of all employees,
C. Within the Communication Plan, acknowledged that change starts with Executives and that all levels in the organization must change,
D. Within the Communication Plan, outlined the new expectations of all employees and changes to existing roles and responsibilities,
E. Assessed and addressed the corporate values and cultural landscape,
F. Spoke to the "Individual" and personalized the need for change and received unwavering buy-in.

5.1.5.   Results

5.1.5.1.   Compliance Strategy
Both elements of the Compliance Strategy were fully realized. Since the Consent Decree was lifted the company has experienced multiple successful inspections and has a compliant QMS that is successfully being maintained.

5.1.5.2.   Overall Business Strategy
The Overall Business Strategy was fully realized in the projected time frame. Although they experienced extra up-front costs associated with a knowledgeable third party organization including verified and seasoned technical SME's (Subject Matter Experts) the minimal amount and type of procedural rework far outweighed using less expensive non-seasoned contractors.

5.1.5.3.   Implementation Tactics
All the Implementation Tactics were successfully deployed and executed such that the remediated products, processes and procedures successfully demonstrated product safety and efficacy. Additionally, the remediated processes were demonstrated to be effective and more efficient than their predecessors.

5.1.5.4.   Organizational Change:
The amount of Organizational Change was unprecedented. Specifically,

A. The entire organization Recognized and Accepted that they had to change,

B. The Communication Plan was rolled out to all employees explaining the Compliance and Overall Business Strategies, Implementation Tactics to be used and the new expectations of all employees,

C. The Communication Plan, acknowledged that change starts with Executives and that all levels in the organization had to change and were willing to change,

D. The Communication Plan, outlined the new expectations of all employees and changes to existing roles and responsibilities,

E. The Communication Plan clearly assessed and addressed the corporate values and cultural landscape,

F. The Communication Plan, weekly company status e-mails and all ad-hoc communications spoke to the "Individual" and personalized the need for change and received unwavering buy-in. As a result organizational resistance to change was minimized.

5.2.   Case Study #2:

5.2.1.   Compliance Strategy:
During an externally imposed QMS Remediation effort (i.e., Warning Letter), the Compliance Strategy was clearly specified to return to and maintain compliance with FDA and OUS regulations.

5.2.2.   Overall Business Strategy
The Overall Business Strategy <u>utilized a less expensive third party organization including unverified less seasoned technical SME's (Subject Matter Experts)</u> to help lift the Warning Letter <u>within 3 years</u>. In this example, the Compliance Strategy was NOT fully aligned with the Overall Business Strategy and accomplishing the end goal was compromised.

5.2.3.   Implementation Tactics
In order to achieve the Compliance and Overall Business Strategy, the Implementation Tactics included:

    A. Perform a systemic Gap Analysis against existing processes and the regulation,

    B. Perform a Root Cause Analysis on the Gaps,

    C. Modify Quality System procedures and processes based on the Gap Analysis, Root Cause Analysis and Best Practices,

    D. Demonstrate Effectiveness and Efficiency of modified procedures and processes.

5.2.4. Organizational Change

Regarding Organization Change, even with a disconnected Compliance and Overall Business Strategies and compromised Implementation Tactics, a partial Communication Plan was retroactively developed, however some key elements were not addressed and/or reinforced.

    A. There was little recognition and acceptance that the entire organization must change,

    B. The Communication Plan glossed over the disconnects between the Compliance and Overall Business Strategies and did not properly outline the Implementation Tactics nor did it address the new expectations of all employees,

    C. The Communication Plan, did not acknowledge that change starts with Executives and that all levels in the organization must change,

    D. Within the Communication Plan, there was no outline of the new expectations of all employees and changes to their existing roles and responsibilities,

    E. An Assessment of the corporate values and cultural landscape was conducted. However it was heavily tailored to reducing costs of remediation,

    F. The Communication Plan did speak to the "Individual", personalize the need for change and get unwavering buy-in however this was not reinforced when resistance to change surfaced.

5.2.5. Results

5.2.5.1. Compliance Strategy

Since the Warning Letter was lifted in unprecedented time, only part of the Compliance Strategy was successful. The Compliance objective of maintaining regulatory compliance was minimized and therefore now jeopardize the entire organization to a repeat of costly QMS remediation activities.

5.2.5.2. Overall Business Strategy

The Overall Business Strategy was considered successful since the Warning Letter was lifted in an

unprecedented time and revenue / profits were partially restored. However, the disconnect with the Compliance Strategy and potential costs of future QMS Remediation still exists.

5.2.5.3. Implementation Tactics
While proven Implementation Tactics were deployed, their level of rigor and execution were less than successful due to the lack of SME expertise. For example:
A. Only one manufacturing line was remediated to the new processes and procedures while the remaining lines went untouched.
B. Additionally, only one Design History File was remediated to new processes and procedures while the remaining DHF's went untouched.
C. Objective evidence of product safety and efficacy are still in jeopardy.

5.2.5.4. Organizational Change:
Minimal Organizational Change was realized. Specifically,
A. There was little recognition and acceptance that the entire organization must change and they presumably still believe the FDA just didn't understand their business and were being unreasonable.
B. New expectations of all employees including roles and responsibilities were not universally established throughout the company,
C. Executives insulated themselves from changing and were unwilling to "walk the talk" thereby setting a negative example to all employees,
D. The old corporate values and cultural landscape—get the job done at any costs—was maintained,
E. Resistance to change presumably still exists based on individual and/or functional groups comfort level. Specifically, the Complaints Group was unwilling to modify their procedures and practices to align with the Remediated Risk Management Program.

6. Developing Robust Strategies

6.1. "A solid strategy reflects the core values of the organization. Your strategic team should gather input from across the organization to ensure there's alignment between the strategy and each department's priorities. All strategies should be actionable." [1]

6.2. "When creating a robust strategy, focus on the desired end result (the goal). Your strategy is the foundation for all activities within the organization, and how it's crafted will guide decision-making as your teams work to achieve those goals. For example, if a medical device company has a goal to expand market share, its strategy could include offering the most competitive prices and always being in stock of common offerings." [1]

6.3. For example, let's say your organization's overarching mission is to be the market leader in a specific modality. One goal might be to educate physicians and hospital groups about the options available to them with regard to your and your competitors' products. From there, you might decide to implement several marketing tactics and/or internal business efficiency tactics.

6.4. As a result of implementing the tactics the company can begin to measure the success of the strategy using Key Performance Indicators (KPI's). A good KPI uses quantifiable data to answer questions about progress and provides feedback on how to further improve the KPI.

6.5. For example, if your strategy is to reduce customer complaints, a possible KPI might be Quantity of (type of) Complaints per units sold.

6.6. "Remember to set targets that specifically detail your KPIs and break them down into achievable timeframes. If your KPI performance seems to be consistently lagging without much concern, you could try giving targets more weight; some organizations tie KPI performance to incentives like end-of-year bonuses to encourage engagement." [1]

7. Developing Robust Tactics

7.1.   Robust tactics have clear purpose and intent that aids your strategies: both Compliance Strategy and/or your Overall Business Strategy. "It has a finite timeline during which specific activities will be completed and their impacts are measured."[1]

7.2.   A tactic for a medical device company would be to perform a Gap Analysis, Analyze a Design or Manufacturing processes to minimize waste and increase efficiencies which in turn would increase market share and margins all the while maintaining safety, efficacy and regulatory compliance. A medical device company should define the evaluation metrics prior to implementing the tactics to be able to assess their value after implementation.

7.3.   Below are examples how to assess the value of several best practice tactics.

7.3.1.   Gap Analysis might be assessed using an "efficiency factor" or a "regulatory impact". Either one of these factors can be translated into a "most likely" financial cost.

7.3.2.   A Root Cause Analysis might be assessed using an "efficiency factor" as well Cost of Quality and/or Cost of Internal and Cost of External Failures.

7.3.3.   Modification of Quality System procedures and processes should be assessed using an "efficiency factors" or "regulatory impact". Either one of these factors can be translated into a "most likely" financial cost.

7.4.   Viewed together, your tactics will give you the concrete steps you need to track anything relating or tied to your strategy.
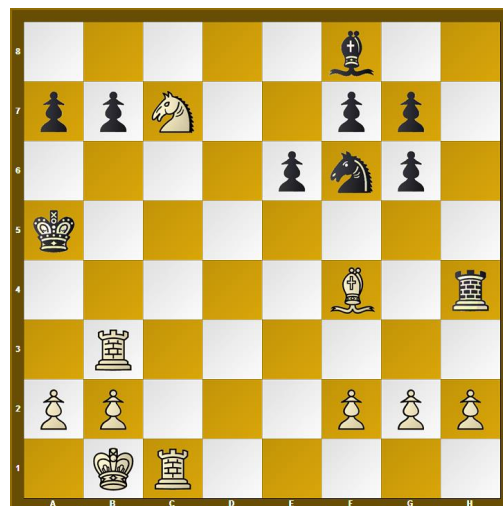
8. Developing Robust Change Management

"Market transparency, labor mobility, global capital flows, and instantaneous communications demand that in almost all companies—from giants down to start-ups—a heightened global competition has concentrated management's collective mind on something that, in the past, it happily avoided: CHANGE. Successful companies develop "a culture that just keeps moving all the time."" [2]

"No single methodology fits every company, but there is a set of practices, tools, and techniques that can be adapted to a variety of situations. What follows is a list of guiding principles for change management. Using these as a systematic, comprehensive framework, executives can understand what to expect, how to manage their own personal change, and how to engage the entire organization in the process." [2]

8.1. Start at the Top

    8.1.1. "Because change is inherently unsettling for people at all levels of an organization, when it is on the horizon, all eyes will turn to the CEO and the leadership team for strength, support, and direction. The leaders themselves must embrace the new approaches first, both to challenge and to motivate the rest of the institution. They must speak with one voice and model the desired behaviors. The executive team also needs to understand that, although its public face may be one of unity, it, too, is composed of individuals who are going through stressful times and need to be supported." [2]

    8.1.2. "Executive teams that work well together are best positioned for success. They are aligned and committed to the direction of change, understand the culture and behaviors the changes intend to introduce, and can model those changes themselves." [2]

    8.1.3. Only after the leadership team demonstrates executive alignment and an unwavering commitment to the necessary changes will the work streams be able to deliver downstream results.

8.2. Involve Every Layer

    8.2.1. "As transformation programs progress from defining strategy and setting targets to design and implementation, they affect different levels of the organization." [2]

    8.2.2. "Change efforts must include plans for identifying leaders throughout the company and pushing responsibility for design and implementation down, so that change "cascades" through the organization." [2]

    8.2.3. "At each layer of the organization, the leaders who are identified and trained must be aligned to the company's vision, equipped to execute their specific mission, and motivated to make change happen." [2]

8.3. Make a Formal Case

    8.3.1. "Individual humans are "inherently rational and will question to what extent change is needed, whether the company is headed in the right direction, and whether they want to commit personally to making change happen." [2]

    8.3.2. "Your employees will look to the leadership for answers. The articulation of a formal case for change and the creation of a written vision statement are invaluable opportunities to create or compel leadership-team alignment." [2]

8.3.3. The formal case should include three basic steps:

8.3.3.1. "First, confront reality and articulate a convincing need for change." [2]

8.3.3.2. "Second, demonstrate faith that the company has a viable future and the leadership to get there." [2]

8.3.3.3. Third, "provide a road map to guide behavior and decision making. Leaders must then customize this message for various internal audiences, describing the pending change in terms that matter to the individuals." [2]

8.4. Address the "Human Side"

8.4.1. "Any significant transformation creates "people issues." New leaders will be asked to step up, jobs will be changed, new skills and capabilities must be developed, and employees will be uncertain and resistant." [2]

8.4.2. "Dealing with these issues on a reactive, case-by-case basis puts speed, morale, and results at risk. A formal approach for managing change—beginning with the leadership team and then engaging key stakeholders and leaders—should be developed early and adapted often as change moves through the organization." [2]

8.4.3. "This demands as much data collection and analysis, planning, and implementation discipline as does a redesign of strategy, systems, or processes. The change-management approach should be fully integrated into program design and decision making, both informing and enabling strategic direction. It should be based on a realistic assessment of the organization's history, readiness, and capacity to change." [2]

8.5. Create Ownership.

8.5.1. "Leaders of large change programs must overperform during the transformation and be the zealots who create a critical mass among the work force in favor of change." [2]

8.5.2. "Creating ownership requires more than mere buy-in or passive agreement that the direction of change is acceptable. It demands ownership by leaders willing to accept responsibility for making change happen in all of the areas they influence or control." [2]

8.5.3. "Ownership is often best created by involving people in identifying problems and crafting solutions. It is reinforced by incentives and rewards." Incentives and rewards can be tangible (e.g., financial compensation) or psychological (e.g., camaraderie and a sense of shared destiny)." [2]

8.6. Develop a Communication Plan

8.6.1. Instead of assuming everyone understands the issues, the need to change and see the new direction as clearly as the Executives and Leaders develop a Communication Plan. This plan should outline and reinforce the core messages through regular and timely methods that is both inspirational, practicable and actionable.

8.6.2. Recognize that internal communications "flow in from the bottom and out from the top and are targeted to provide employees the right information at the right time and to solicit their input and feedback. Often this will require overcommunication through multiple, redundant channels." [2]

8.6.3. The communication plan should outline the methods and frequency of communication including but not limited to company-wide voice mails from the Executive Staff, training sessions, videotapes, newsletters, and town hall meetings that continue through the life of the transformation.

8.7. Assess the Cultural Landscape and Explicitly Address Culture

8.7.1. "Successful change programs pick up speed and intensity as they cascade down, making it critically important that leaders understand and account for culture and behaviors at each level of the organization." [2] Don't make the mistake of assessing culture either too late or not at all.

8.7.2. Performing a "thorough cultural diagnostics can assess organizational readiness to change, bring major problems to the surface, identify conflicts, and define factors that can recognize and influence sources of leadership and resistance." [2]

8.7.3. "These diagnostics identify the core values, beliefs, behaviors, and perceptions that must be taken into account for successful change to occur. They serve as the common baseline for designing essential change elements, such as the new corporate vision, and building the infrastructure and programs needed to drive change". [2]

8.7.4. "Once the culture is understood, it should be addressed as thoroughly as any other area in a change program. Leaders should be explicit about the culture and underlying behaviors that will best support the new way of doing business and find opportunities to model and reward those behaviors." [2]

8.7.5. "This requires developing a baseline, defining an explicit end-state or desired culture, and devising detailed plans to make the transition." [2]

8.7.6. "Company culture is an amalgam of shared history, explicit values and beliefs, and common attitudes and behaviors. Change programs can involve creating a culture in new companies or those built through combining cultures (e.g., mergers or acquisitions), or reinforcing cultures (e.g., long-established companies)." [2]

8.7.7. "Understanding that all companies have a cultural center—the locus of thought, activity, influence, or personal identification—may be an effective way to jump-start culture change." [2]

8.8. Speak to the Individual

8.8.1. "Change is both an institutional journey and a very personal one. People spend many hours each week at work; many think of their colleagues as a second family. Individuals (or teams of individuals) need to know how their work will change, what is expected of them during and after the change program, how they will be measured, and what success or failure will mean for them and those around them." [2]

8.9. Prepare for the Unexpected

8.9.1. "No change program goes completely according to plan. People react in unexpected ways; areas of anticipated resistance fall away; and the external environment shifts." [2]

8.9.2. "Effectively managing change requires continual reassessment of its impact and the organization's willingness and ability to adopt the next wave of transformation. Fed by real data from the field and supported by information and solid decision-making processes, change leaders can then make the adjustments necessary to maintain momentum and drive results." [2]

8.9.3. "Team leaders should be as honest and explicit as possible. People will react to what they see and hear around them and need to be involved in the change process. Highly visible rewards, such as promotion, recognition, and bonuses, should be provided as dramatic reinforcement for embracing change. Sanction or removal of people standing in the way of change will reinforce the institution's commitment." [2]

8.9.4. "Most leaders contemplating change know that people matter. It is all too tempting, however, to dwell on the plans and processes, which don't talk back and don't respond emotionally, rather than face up to the more difficult and more critical human issues. But mastering the "soft" side of change management needn't be a mystery." [2]

9. Summary

It's easy to speak about your strategies, tactics and organizational change as if they're the same thing. They do rely heavily on one another and are definitely intertwined but they should not be viewed as separate concepts.

"Before you implement your strategy, make sure you've got stakeholder buy-in and you've addressed any hesitations. Once you've ironed out concerns and are ready to execute, communicate your strategy across the organization to provide meaning and context around each department's activities."

Once you develop and communicate your strategies, all your teams should know and understand the implementation tactics to be used to accomplish your organizational goals.

And finally, don't forget to actively factor in the capacity of your larger organization to change and adapt to both the strategies and tactics.

If any one of these three pillars are minimized or ignored, the chance for long-term sustainable success is hampered.

10.   About OPTIM Associates, Inc.

OPTIM Associates is a Medical Device consulting company specializing in Quality Systems design, development, execution and remediation for newly developed products as well as existing fielded products. Our specialty runs the entire spectrum from Start-Up QMS and Regulatory Submissions to QMS Remediation assistance due to FDA enforcement actions.
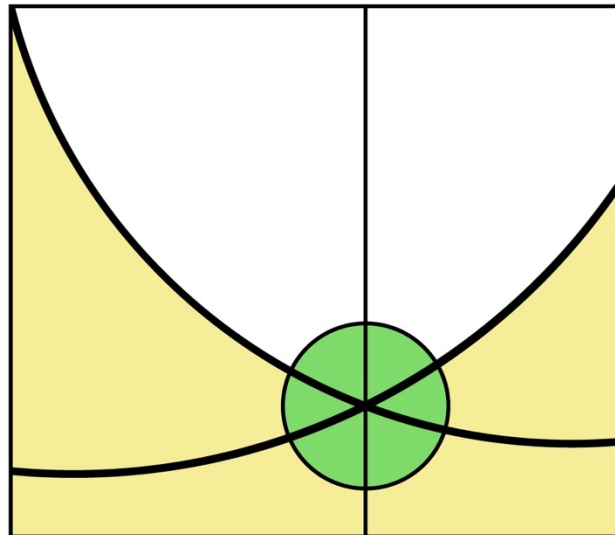
The mission of OPTIM Associates is to provide effective and efficient solutions—with a focus on scalability and sustainability—and deliver highest value and quality for the Medical Device Industry. We actively listen for immediate and underlying causes to offer solutions based on best practices across multiple disciplines. OPTIM Associates ensures our clients receive innovative solutions that address Regulatory Compliance, Overall Business Strategies, Implementation Tactics and Organizational Change for Financial Results.

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