

It starts with the
1st HABIT
– Be proactive

7 HABITS

*For Highly Effective
Quality Organizations*

Stephen Covey's bestselling book, *The 7 Habits of Highly Effective People*, is perhaps the closest thing to a prescription for success. While it's been nearly two decades since its release, the principles of personal and professional effectiveness still resonate today. Building off his impressive foundation, we offer our insights – based on our many years of working with more than half of the world's leading life sciences companies – on how you can apply the 7 Habits to your quality organization in order to increase effectiveness and drive results.

HABIT 1

Be proactive

Remember the ant and the grasshopper from Aesop's fable? The idle grasshopper takes a vacation while the prudent ant works hard all summer saving food for the months ahead. When winter arrives, the grasshopper grows weak with hunger while the ant enjoys the spoils of preparation. The grasshopper didn't prepare and was forced to face the consequences of his actions. On the other hand, the proactive ant took action to ensure he'd be ready for whatever happened in the future.

When you think about the challenges facing your Quality Organization – from lengthy batch reviews, to fragmented or disparate systems, to paper-based and manual processes – consider the consequences that could arise if these issues are left unaddressed. FDA audits. Warning letters. Consent decrees. Plant closures.

Do you have a strategy for addressing these issues? (Hope is not a strategy.)

By taking a proactive approach you increase compliance, diminish risk and maximize overall quality and efficiency. Forward thinking leads to a level of quality capable of sustaining compliance in a progressive and evolutionary environment. Here are some ways you can do this:

Benchmark against your peers' Key Performance Indicators. Are you working harder to compete?

Collect and analyze data on process bottlenecks. What steps are truly adding value to the process? Are all the steps absolutely necessary to ensure quality?

Look for ways that technology applications can automate and integrate your processes. Do your technology applications interact and share data? Can you remove a laboratory "review step" by introducing a qualified technical interface?

Assess your readiness: If you have the opportunity to fix a problem before an issue arises, will you take it?

HABIT 2

Begin with the end in mind

Imagine the focus and freedom that would be afforded by knowing the end result of your actions. But in our busy lives, with so many competing priorities, we often lose sight of what it is we wanted to achieve in the first place.

To remedy this, Covey asks that we envision what would be said at our funeral, and then consider what we must do to change those eulogies. The lesson? That we have the opportunity – and the ability – to change any course of action if we first envision what we want to accomplish and then use measurable goals to get there.

Now let's consider the two main forces at work on the Quality Organization. One focuses on absolute quality and the other focuses on reaching optimal operational efficiency. Those who view compliance and quality as the clear imperative are often fearful of modernizing their approach and frequently lack an understanding of the market demands necessary to sustain a business. These organizations often wallow in unnecessary paperwork laden with inefficiency. Conversely, organizations with a more pronounced drive toward operational efficiency, often take risks and sacrifice quality assurance in favor of meeting earnings targets or customer demands. (We eventually read about these companies in the newspaper.)

In your role leading a Quality Organization, it's imperative to develop a healthy balance of both. So we challenge you to redefine your end. Set your sights on what you want to accomplish within your role, your organization and your company. If you don't strive for optimal performance, you run the risk of traveling down a path where the end goal is merely survival.

Assess your readiness: Are you willing to lead your organization to the desired point of success?

HABIT 3

Put first things first

Effectively managing time is a constant struggle, both personally and professionally. The key is to prioritize. However, that's easier said than done.

On a daily basis how often do issues suddenly arise that appear more urgent than the last? That's why even after you've defined a set vision and goal, you still need to determine which actions are important versus which are imperative, and then prioritize accordingly.

From a quality perspective, you're committed to getting a safe and effective product to the patient quickly. Perhaps your plan to further this goal includes reducing your cycle times from 120 days to 60 days. Here's how you would apply the third habit to achieve this:

First, review your existing processes and assess any gaps that might exist.

Second, determine ways that you can effectively simplify your product release requirements.

Third, create a phased plan of sequential action items. In this case, it may include organizing your product, people and processes; changing your performance metrics to spur shop floor changes; implementing pull scheduling techniques; applying lean concepts to your ERP system; and optimizing your inventory levels and capacity buffers.

Whatever your plan might be, you need to ensure that you keep focused, and prioritize the items that will help you attain your end goal.

Assess your readiness: Can you adopt a proactive attitude, define exactly what you want to achieve and then prioritize to reach it?

HABIT 4

Think win-win

Tapping into the power of a win-win approach yields amazing results. Often, in our personal lives we apply it subconsciously, seeking the give and take, yin and yang of close one-to-one relationships. Applying this concept professionally, however, can be challenging because the number of interactions multiplies exponentially.

In a pharmaceutical manufacturing environment, competing interests abound. Each role brings forth a unique perspective. To fully appreciate the conflicting viewpoints, let's briefly review a few of these perspectives.

Quality seeks to achieve regulatory compliance and ultimately protect customers. Manufacturing seeks to get the product to the customer as fast as it can while managing cost pressures. Management seeks a solid bottom line with consistent product. Sales seeks assistance meeting customer demands for cost, service and quality.

Because each functional team is so focused on their own needs, they may not realize the dilemmas their actions create for other areas of the company. But in business, as in physics, every action has an equal and opposite reaction – and not always a predictable one.

By focusing on finding mutual benefits that you and your internal stakeholders – manufacturing, supply chain, IT, sales, etc. – desire and embrace, you will find that the barriers of contention and dissension begin to dissolve. Doing so takes time, commitment and open, honest communication, but the effort pays off. Once you collectively determine what you want to achieve and begin to collaborate, synchronization rather than competition occurs, paving the way to reach your organization's common goal.

Assess your readiness: Will you seize a competitive advantage by taking a win-win approach?

HABIT 5

Seek first to understand then be understood

Life moves fast. Faster now than perhaps ever before. Keeping pace pressures us to be reactive instead of proactive. We seek immediate gratification and quick fixes. In the process, we make assumptions. Factor in our need to be understood, and it's not surprising that a lack of communication is endemic in the workplace.

Covey says when two parties are trying to be understood, no one is listening. He calls this the "dialogue of the deaf."

Open communication is critical in every company. But in a life sciences company, with more complex and onerous laws and regulations to contend with, it's even more important. You need to fully understand regulatory commitments, market demands, and capacity requirements. To illustrate this further, let's look at order fulfillment. Manufacturing, packaging and labeling, and regulatory affairs must work together. For example, if packaging and labeling changes occur, you may want to adjust your inventory capacity and scheduling requirements to coincide with regulatory submission and approval timelines. Knowing the challenges each team is facing and addressing them accordingly can help you avoid repackaging and rework. And it can help you get your product to market in a more predictable, more efficient, and more cost-effective manner, as the FDA's Critical Path Initiative recommends.

Before any improvements in your organization can be made, you need to fully understand the challenges each of your functional areas face. Surveys indicate that projects often fail because of misunderstood, misconstrued or miscommunicated user requirements – requirements which are often based on assumptions.

Listen well and listen often. You can identify any issues or problems before they occur and start to create a strategy and process for improvement. Understanding empowers one to be understood.

Assess your readiness: Will your employees approach their challenges differently if they understand the importance of the collective goal?

HABIT 6

Synergize

Innovation is the lifeblood of the life sciences industry. Every day synergy results in new life-saving drugs and therapies.

It sounds relatively simple: work together and results will follow. But applying a synergistic approach is only successful if it's predicated on the previous five habits. You need to be proactive, focus on your end goal, prioritize actions, develop a win-win mentality, listen to and seek to understand all the parties involved...and then collaborate.

Technology is a prime example of the need to synergize. Companies often believe that a new system is the answer to whatever ails them. Like an appliance, they expect to buy it, install it, turn it on and see results. But technology isn't a solution – it's an enabler. There are critical success factors to consider and adopting a team-centric approach is paramount. You need to listen to the needs of the users, identify their issues, incorporate their feedback, and involve everyone in the process. Working together with open, honest and frequent communication is absolutely vital to a project's success. You must create an environment where everyone's input matters.

Does your current team operate synergistically? If not, you might want to align them under a common goal and vision, something specific that they can identify with. Teams with a clear goal in mind often have fewer issues and work together more effectively.

You often see businesses rally together during a new product launch. Everyone in the company is focused on a common goal: bring a safe and effective product to market quickly. So what happens to the teamwork once the product is on the market? The shared objective gives way to each function's own purpose.

Synergy requires a commitment to an idea or solution, an investment of time, open communication and collaboration. By tying performance measurement to cross-functional goals, you can instill teamwork that lasts.

Assess your readiness: Will your business work together more effectively if you redefine function-specific objectives into shared goals?

HABIT 7

Sharpen the saw

Sometimes the obvious eludes us. In the 7th habit, Covey uses the analogy of a woodcutter who saws for several days and becomes less and less productive. The process of cutting dulls the blade, but the woodcutter is so involved in what he's doing that he doesn't think he has time to sharpen the saw.

The moral, of course, is that you have to stop now and again to reassess your effectiveness and make adjustments. Complacency sets you back. To excel, you need to constantly challenge the status quo. Challenge yourself and your own capabilities. Push the envelope. By renewing the four dimensions of your nature – physical, spiritual, mental and social/ emotional – as Covey suggests, you can work more quickly and with less effort.

On a practical level, make sure you're up-to-speed with the most recent guidance documents. Participate in the reviews and provide comments during comment periods. Use risk management tools and challenge old ways of doing things. Seek external advice and assistance for new perspectives.

Now imagine. What happens when you empower others to do the same? Covey says that the same principles that govern our personal quality performance also lead to increased professional and organizational effectiveness. Envision the strides in productivity if your Quality Organization encouraged everyone to sharpen their saw.

Assess your readiness: Will you stop to sharpen your saw in order to unlock your organization's greatest potential?

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Are you ready?

If you're ready to embrace a proactive approach to quality management, Clarkston Consulting can help you take the first step: uncovering your organization's current quality and compliance position.

We've had the pleasure of working with more than half of the world's leading life sciences companies, helping them gain significant quality improvements while ensuring regulatory compliance. Our diagnostic tool provides a comprehensive assessment of both operational efficiency and quality assurance. Beyond a simple gap analysis, it helps companies identify areas for improvement and positions them for operational excellence. Our clients benefit from our deep industry expertise and best practices. We help them achieve reduced cycle times, inventories, downtime and waste, expedited time to market, Right-First-Time batch releases, mitigated risk, enhanced efficiencies and improved profitability.

If you're interested in the success stories from your industry peers, or would like inspiring examples of how they applied Quality by Design and Operational Excellence principles to their Quality Organizations, contact us to learn more.

About Covey

Stephen R. Covey is an internationally respected leadership authority, family expert, teacher, organizational consultant, founder of the former Covey Leadership Center and co-founder and vice chairman of FranklinCovey Co.

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“What could be more fulfilling than putting safe and efficacious therapies into the hands of the patient who needs them? Perhaps knowing you have done so in the quickest, most effective manner possible. Adopt a proactive approach and unleash your potential, as an individual, and within your Quality Organization.”

Paul Allen
Vice President of Life Sciences, Clarkston Consulting

About Clarkston

Clarkston Consulting is a different kind of management and technology consulting firm. We deliver a unique experience for market leaders within the Consumer Products and Life Sciences industries. Considering professionalism, expertise, and value as prerequisites, we take service a step further through our unyielding commitment to the success of people as individuals, both our clients and our employees. By combining integrity, adaptability, and a whatever-it-takes attitude, we have achieved an extremely high rate of referral and repeat business and a client satisfaction rate of 97% over the past five years as measured by the Conference Board.

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