

# LIFE SCIENCE COMPANIES - ARE YOU HEALTHY?

**It's no secret – the life sciences industry lives in an almost constant state of change.**

Today, change is driven by pressures to institutionalize patient-centricity and value-based care across your business. As can be expected, the quality and regulatory implications of these changes are complex. Patients, legislators, and regulatory bodies are demanding more oversight – meaning the quality and regulatory functions of your business are more critical than ever to your legal, financial, and operational success.

Coupled with more visibility and sensitivity to pricing, these changes are forcing companies across the industry to reassess their organizational ability to adapt and grow. Addressing these external forces requires more than dollars and cents, it requires a healthy organization prepared to not only react but capitalize on these changes.

**So what do we mean by healthy?**

At Clarkston Consulting, we define a healthy life sciences quality and regulatory organization as one where:

- **Quality and regulatory functions are viewed as strategic arms of the business rather than cost centers,**
- **Regulatory requirements are used as tactical levers to drive business growth,**
- **Enterprise-wide quality systems and processes are harmonized to ensure data integrity and enable a more efficient flow of data analytics, and**
- **Management is confident, knowing that the organization has the flexibility to address dynamic market and technology challenges as they arise.**

## HOW CAN CLARKSTON CONSULTING HELP YOU GET HEALTHY?

Clarkston has developed an evidence-based, proven methodology for evaluating organizational health for life sciences quality and regulatory organizations. Utilizing industry benchmarks, best practices, and rising trends, we collaborate to find your strengths and gaps across the functional areas of your business and within your internal and external partners.

Once gaps are identified, we prioritize them, analyze root cause, and develop solutions that fit your goals and objectives while fostering organizational health. From there, we plan, pilot, and implement people, process, and management system changes to establish long-term sustainable success.

We approach this process through four key organizational dimensions.

### 1. ORGANIZATIONAL DESIGN

The architecture of your organization must strategically align with your vision/mission and tactically support business and quality performance objectives. Common questions we explore together related to organizational design include:

- **Are you satisfied with your decision-making response times to quickly address non-compliance? In other words, are you agile enough?**
- **Are you expecting the right leadership performance from your site and quality department leaders?**
- **Do you strike the right balance of breadth and depth for functional quality capabilities and motivational leadership?**

We help you analyze and understand how you've arrived at your current organization and assess how well your quality and regulatory strategies align with each position. Using carefully crafted and measured surveys/interviews, we assess all levels of the organization to evaluate alignment, productivity, and performance opportunities.

## 2. ORGANIZATIONAL EFFECTIVENESS

In the pursuit of effectiveness and efficiency, there must be a balance at every level as both quality of product and speed to market impact outcomes for patients. When regulations and quality standards are not met, harsh consequences follow close behind. But the reverse is true as well – high quality products with long production cycles often lead to product shortages, which end up hurting patients rather than helping.

We work together to assess opportunities for improving the balance between the two through questions such as:

- **Are you trying to “legislate compliance” through SOPs or are you setting up a culture of balanced productivity and compliance?**
- **How do you compare to peer benchmarks and industry improvement trends?**
- **How many strategic and tactical projects are delivered on time and on budget (against expectations)?**
- **How many redo’s do you have within a year, not getting it right the first time (RFT)?**
- **How many extra hours do your employees work because they spend too much time in ineffective meetings?**

Overall, we help you integrate your quality programs to ensure clear accountabilities, responsibilities, and key performance indicators are tied to compensation and job promotions.

## 3. CHANGE ENABLEMENT/TRANSFORMATIONAL SUPPORT

Dynamic changes in the life sciences industry come left, right, and below the belt. New power dynamics are arising, with patients more informed and more empowered to take an active role in their treatment. Innovations in personalized medicine and medical devices (i.e. wearables) are creating challenges in setting and measuring quality metrics and maintaining privacy and security standards in accordance with established regulations (i.e. HIPAA), to name a couple. Add to this an increasingly complex, multi-layered, and global supply chain that requires heightened skills in collaboration and quality oversight across multiple stakeholders.

Some of the challenges we’ll identify and evaluate include:

- **Are executives and senior leadership prepared to drive the necessary types of transformational change?**
- **How are you measuring the impact of the changes and enabling sustainability?**
- **Are 100% of your employees aware of and supportive of the need to adjust to this changing environment? Do they know how to change and why?**
- **How are you measuring behavior change to make sure that you’re on track to deliver against expectations?**

Your organizational and strategic goals serve as the foundation of our change enablement and transformation support methodology. We assess both the size/complexity of the change and your organization’s culture and readiness to sharply focus the scale of the change management effort and support your business objectives. All levels in the organization are engaged to own and drive change today and prepare for change tomorrow.

## 4. TALENT

At the macro level, global industries are facing a shortage of skilled talent, and this is especially true for life sciences quality and regulatory departments. With mergers and acquisitions exerting downward pressure on organization size, it’s more critical than ever to have a strategy in place for obtaining and engaging qualified talent.

Here, we consider the following:

- **Do you have the right team to transform for the future?**
- **How effectively are you managing across your international suppliers, third parties, and outsourced functions when you ultimately own the product quality and patient experience?**
- **How effective are you at managing across multiple generations – are you winning or losing with millennials?**

Together, we assess your end-to-end talent management and succession planning programs against industry best practices and benchmarks. Externally, we also evaluate contract organizations and business partners for strategic and tactical alignment. Taking into consideration everything from reward/compensation to executive coaching, we work together to unlock the potential of your organization’s talent.

## THE INDUSTRY IS AT A CROSSROADS - ARE YOU READY?

There’s no doubt about it – the life sciences industry is in a period rife with challenges. Fortunately, those challenges carry with them just as many opportunities, if not more.

As the industry hurdles forward with innovation and discovery to improve patient health, take the time to drive similar innovation for your organizational health. Meeting the challenges required of this brave new world will require an organization that is healthy, focused, and ready to meet the horizon.