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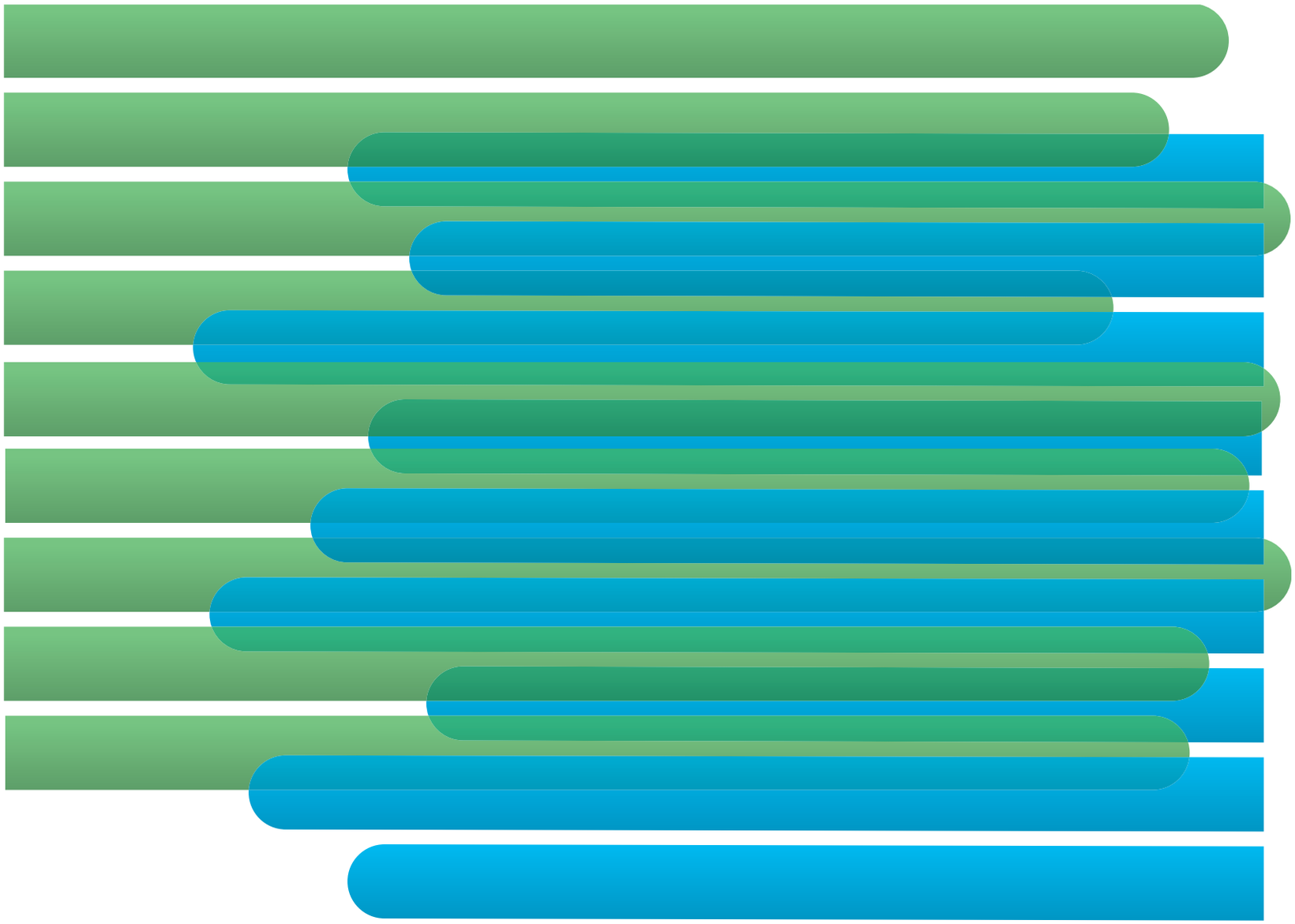
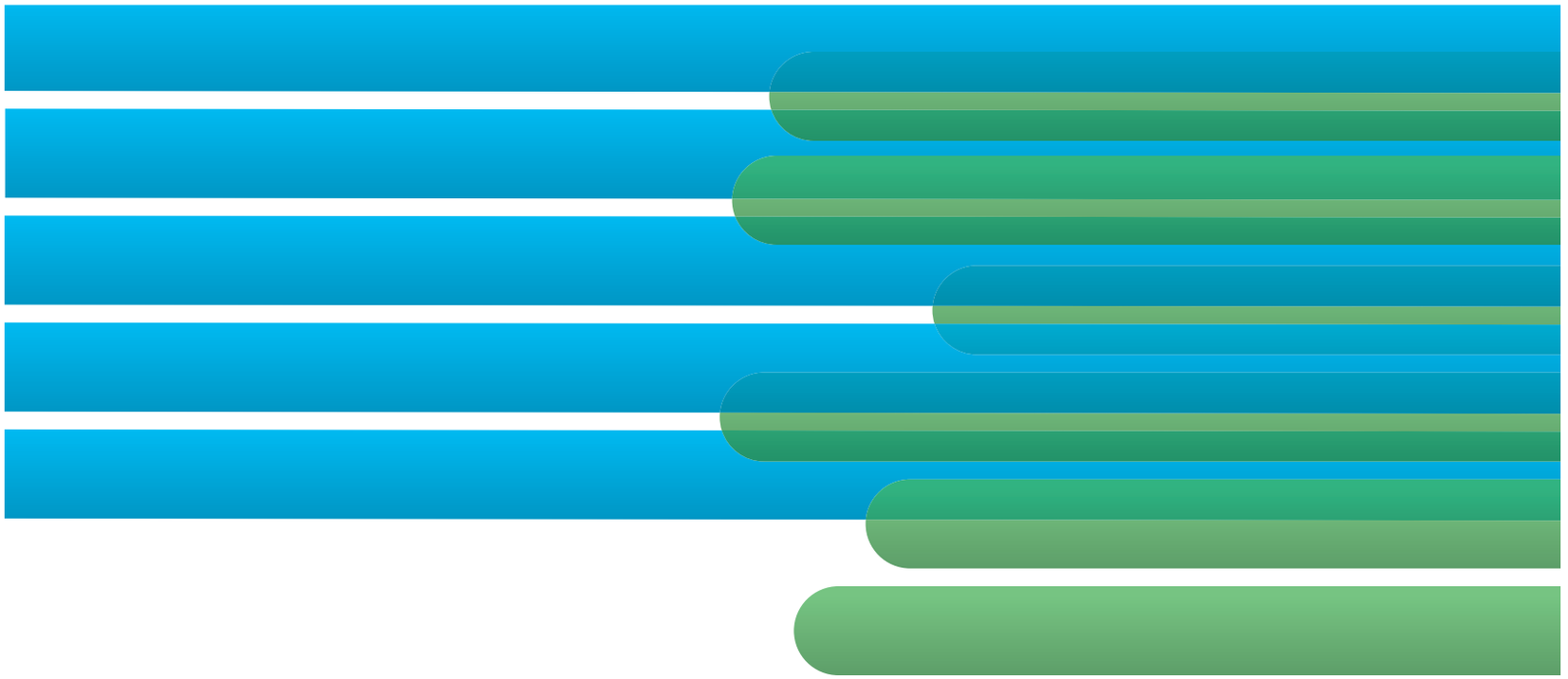


MAKING THE CASE:

The Imperative for Life Sciences Companies to Integrate Corporate Compliance and Quality Compliance



In its simplest form, quality is about making sure that the products offered by a company are safe, effective, and meet the requirements of the prevailing regulations around good manufacturing methods.

Corporate Compliance is about making sure that the company operates in a safe, effective manner and by doing so creates loyal, satisfied customers who want to continue doing business with the company.

Despite the simularities of objectives, most life sciences companies treat Corporate Compliance and Quality Compliance (“Quality”) as separate disciplines, and provide limited opportunities for natural synergies to flourish. However, for a life sciences company to be competitive and sustainable in this era of increasing regulatory complexity crossing traditional national boundaries this must change; Corporate Compliance and Quality Compliance must become an integrated team that works together seamlessly.

STARTING FROM THE BEGINNING

As life sciences Corporate Compliance and Quality professionals struggle to explain what value they bring to the company, over time they unwittingly have made it more complicated and difficult to understand for the average business owner and senior executive. Therefore, it seems logical to start at the beginning and simplify things.

At their roots, Corporate Compliance and Quality Compliance are about managing risk to the company; risk that can bring negative outcomes and hurt the company's overall success and profitability. Where they differ, is in the scope of the risks being addressed.

The life sciences Corporate Compliance Officer's focus involves oversight of all legal and compliance risks facing the company; not just those pertaining to quality.[1] Within his or her purview are a number of risks including, but not limited to: intellectual property protection (a part of legal risk), financial controls, pharmacovigilence, and safety.

Originally defined by the Federal Sentencing Guidelines to be an umbrella-like risk mitigation structure, Corporate Compliance functions have evolved over time in such a manner that many Compliance programs limit their scope to the traditional ethics space (e.g., Code of Conduct), or commercial bribery risks (e.g., off-label promotion, transparency and anti-kickback).

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[1] *See* Leslie R. Caldwell, *Remarks delivered at the Compliance Week Conference*, (May 19, 2015) (http://bty.io/OzYgt) ("In designing compliance programs, companies would be wise to examine all of their lines of business – including those not subject to regulation – and determine where specific risks are and how best to control or mitigate them.")

FIGURE 1: COMPLIANCE OFFICER'S FOCUS

As Figure 2 illustrates, the head of Quality's focus, on the other hand, is much narrower, encompassing those regulations, systems and process that pertain to product quality (e.g., current Good Manufacturing Practices (cGMP), quality risk management, product safety, regulatory compliance).

FIGURE 2: COMPLIANCE/QUALITY REMIT

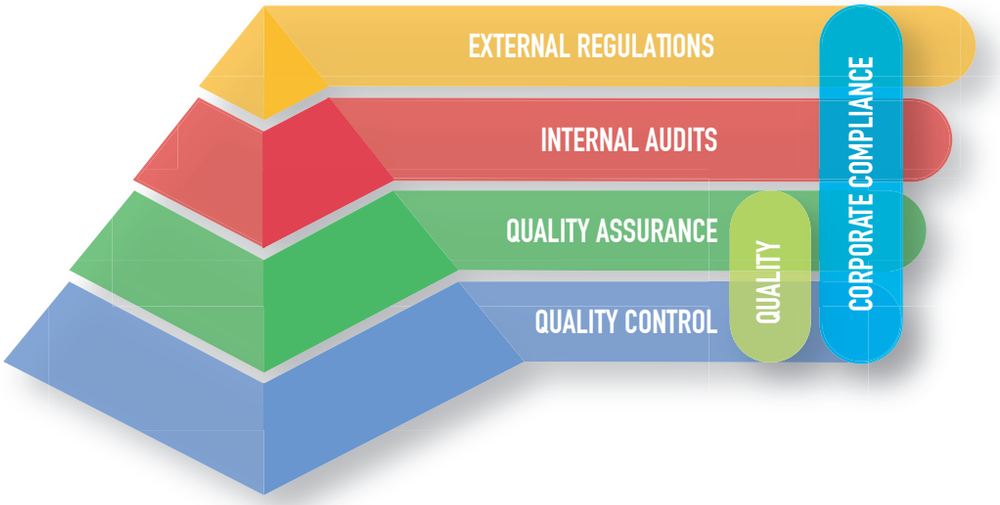
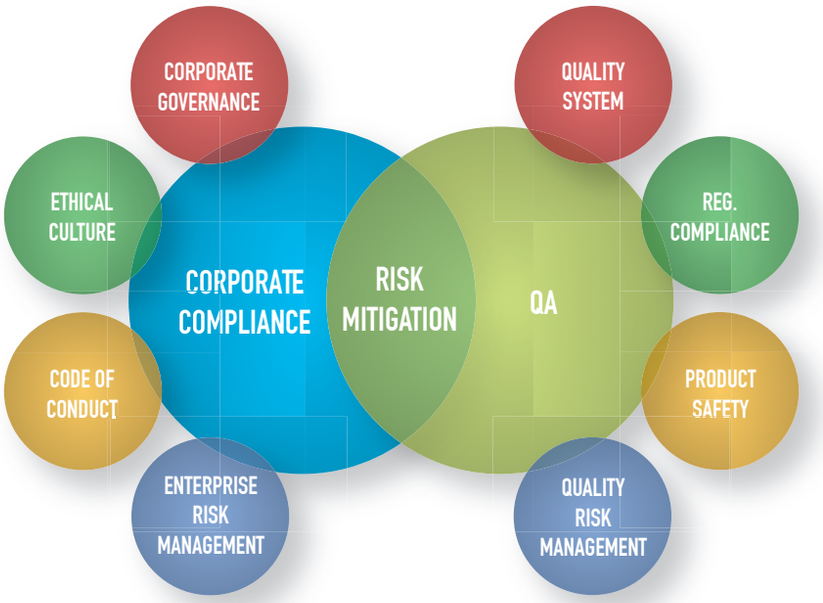


FIGURE 3: COMPLIANCE/QUALITY OVERLAP



Given the fact that Corporate Compliance and Quality can overlap (see Figure 3 above), but often do not, it is little wonder that life sciences senior executives are confused.

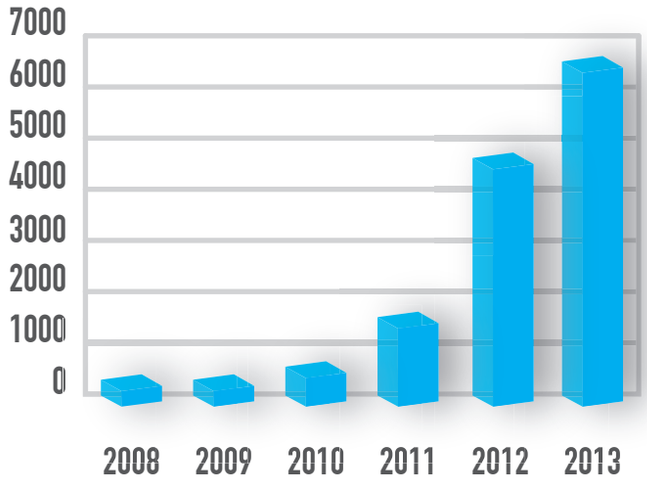
THE REGULATORS' POSITION

While the Corporate Compliance and Quality functions have been evolving as described above, Food and Drug Administration ("FDA") has been making the case for quality in the life sciences. This formal program goes beyond the traditional quality initiatives stressing that compliance with the quality regulations and requirements is merely the baseline. From the FDA's perspective, companies need to strive for more than simple compliance.

The Officer of Inspector General ("OIG") also has been making similar efforts in areas under its jurisdiction. For the OIG, the push has been for companies to institute truly "effective" compliance programs; programs that reasonably detect and prevent non-compliance. Like the case for quality, the OIG takes the same position as the FDA; simple compliance is not enough.

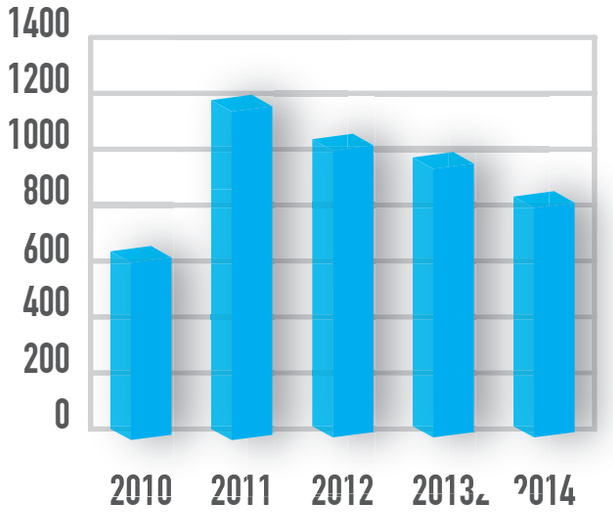
Despite both the OIG's and FDA's efforts, incidents of non-compliance continue to rise as Figures 4 and 5 illustrate.

FIGURE 4: FDA WARNING LETTERS
FISCAL YEARS 2008–2013



This is an exponential rise, which continues year on year as the FDA's enforcement actions are applied with increasing vigor. Source: http://www.fda.gov/downloads/ICECI/EnforcementActions/LICM384647.pdf

FIGURE 5: FEDERAL CRIMINAL HEALTHCARE FRAUD PROSECUTIONS
FISCAL YEARS 2010–2014



Fraud prosecutions mirror the FDA enforcement trends particularly for foreign manufacturers. Source: HHS & DOJ Annual Reports on Healthcare Fraud and Abuse Control Program

So what needs to change?

The continued rise in non-compliance incidents clearly demonstrates that something needs to change. We believe that the "something" is the need for Corporate Compliance and Quality to become an integrated overlapping team that works together seamlessly.

However, this is easier said than done. Doing so involves changing culture, habits, behaviors and ways of working that may have developed over years or even decades, and which until now have served the company and its employees reasonably well. In this highly mobile, highly connected, highly regulated world, stakeholders no longer will patronize firms that do not have quality and compliance as a primary focus.

So what does it take to achieve an integrated Corporate Compliance/ Quality team?

We believe that achieving an integrated team requires three (3) primary things:

1. Securing commitment:

Without organizational commitment, any initiative, especially one this complex is doomed from the outset. However, the necessary commitment is not only required from senior management (often referred to as the "tone from the top"), but also from middle management and the junior staff. Senior management commitment alone is not a guarantee of success as others in the management chain can block or derail an initiative they do not support. A focus on leadership principles an grass roots initiatives should be a foundational requirement to help assure change management success.

2. Speaking the same language:

Another common problem area is the failure to communicate. At its heart, effective communication requires a common language with common definitions. For example, what does "risk" mean? Is it just risks to product quality or does it include overall customer satisfaction as well? Standard definitions are crucial to achieve a common understanding. This needs to be a component of a whole culture change management process which should involve "grass roots" initiatives to propel change virally. Process excellence is a good way to propel this.

3. Identifying combined compliance/quality expertise:

In order for the integration to succeed, it requires project leadership to be facile in both Corporate Compliance and Quality. Without experience and expertise in both areas, it is easy to miss the opportunities for natural synergies as well as potential roadblocks, and for the project leadership to be "written off" for being out of touch. It is very important to key into a "can-do" mindset to achieve this and cascade the drive to success using common principles and ultimate goals.

While the principals are easily articulated, they are challenging, and time consuming to implement. Therefore, if life sciences companies wish to reamin sustainable, they are going to need to begin this journey as soon as possible, or risk being obsolete in the near term.

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