The “Tone at the Top”: Can It Mitigate C-Suite Personal Liability?

Gregory V. Page
Mark A. Waring
Geoffrey R. Kaiser
Kevin Cornish
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GREGORY V. PAGE, PHD*
MARK A. WARING**
GEOFFREY R. KAISER, ESQ.***
KEVIN CORNISH****

I. INTRODUCTION

What keeps life science chief executives up at night? Growth, erosion of competitive advantage, market position, meeting quarterly financial projections, public financial filings and auditor attestations, product safety/quality, shareholder return, board meetings and government regulatory actions, to name a few.

While all of these issues have the potential to cause sleepless nights (or months), executives and board members typically do not have an appropriate level of understanding of their personal liability regarding non-compliance with government regulations. Federal focus on certain regulations and laws has resulted in recent actions against companies and executives. This is creating an expectation within government and private circles that executives and boards actively set the tone concerning company focus and resources dedicated to compliance and product quality in their organizations. Many executives and boards of directors do not have an adequate basis of understanding and appreciation of their personal responsibilities within these laws, regulations, interpretations and expectations and the personal exposure that non-compliance can create.

The Food and Drug Administration (FDA) has been under great public and government scrutiny related to recent cases of pharmaceutical contamination and/or perceived product failures.1 There is great pressure being put on FDA to use all resources available to better ensure public safety and force industry compliance.2 FDA has always had the ability and authority to hold any/all corporate officers (CxOs) and board members personally liable and accountable for the actions of their organizations, both in a civil and criminal context.3 FDA’s authority to hold company executives liable vicariously for all actions taken by company employees comes primarily from the Food, Drug and Cosmetic Act (FDCA)4 and is further supported by a Supreme Court ruling from 1975 known as the Park Doctrine5 in which the High Court reaffirmed its prior ruling in United States v. Dotterweich.6 Dotterweich held that all corporate employees who have “a responsible share in the furtherance of the transaction which the statute outlaws” may be held criminally liable even in the absence of any consciousness of

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4 21 U.S.C. §§ 331(a), 333(a).
The concept of “responsible share,” moreover, is exceptionally broad. The FDCA is interpreted by the courts and applied by federal prosecutors as a “strict liability” statute, meaning that senior executives can be held criminally responsible for non-compliant actions related to the release of misbranded and adulterated products, even if they had no direct knowledge of those activities. In *Park*, the Supreme Court ruled FDA had the power to charge executives who had the authority to prevent adulteration or misbranding, even if they were unaware that misbranded or poor quality products were being sold. The rationale underlying these cases, as declared in *Park*, is that it is proper to hold criminally accountable “the persons whose failure to exercise the authority and supervisory responsibility reposed in them by the business organization resulted in the violation complaint of.” Furthermore, in a clear signal to senior corporate executives that maintaining an effective global compliance program is a necessity, and not a luxury, the Supreme Court in *Park* commented: “the (FDCA) imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur.”

Proactive and highly public commitment and integration of compliance activities and resources at executive and board levels is becoming both an expectation of government agencies and a business imperative to manage company and personal risk as well as mitigate the organizational impact of regulatory actions. However, potential risks associated with regulatory actions by government agencies typically do not proactively garner an executive or board group’s time, attention and resources. Rather, such efforts come to fruition when the company is under some type of inquiry, investigation or action by a state or federal agency such as the United States Department of Justice (DOJ), FDA, and the Office of Inspector General (OIG) for Health and Human Services (HHS) at which time the ability to proactively mitigate company and personal risk is past. Life sciences companies are slowly changing this approach in light of the volume and significance of many public government inquiries and investigations into the business operations of the industry.

In order to help establish a baseline compliance knowledge level, a CxO executive and/or board member should be prepared to provide answers to the following questions that are typically posed by federal regulators or enforcement agencies:

- Can you provide documentation as to management and the board’s understanding of key compliance needs, issues and integration within company efforts related to perceived product quality risk areas?
- Can you provide documentary evidence that your organization has an effective quality management system in place that complies with federal regulations for the manufacture of your products?
- Can you provide documentation demonstrating regular communications concerning compliance from the CEO to the company and the Board to company executives as an integral part of your management communication plan?
- Can you provide documentation demonstrating CxO and/or board level management of issues your company has identified with quality and compliance risks, and the status of remedial efforts?
- Does your company’s resource management plan address quality and compliance management in the same way it supports and funds research and development (R&D) and marketing efforts?

To further highlight the pressure upon FDA from Congress and the public to better address safety issues associated with drugs and devices a report last year was
issued by a panel of outside advisers to the agency which said American lives were in danger because FDA did not have the money, the staff or the scientific expertise to protect them. In a recent speech, FDA Commissioner, Dr. Andrew von Eschenbach, acknowledged that FDA “may fail in its mission to protect and promote the health of every American.” The Senate passed a budget resolution in March 2008, that would make FDA’s allocated budget excluding user fees $375 million greater in 2009 than this year. The recently issued FDA Amendments Act of 2007 (FDAAA) gives FDA additional powers to impose civil penalties for violations. Congress’s push to expand FDA staffing and budget levels gives the agency additional impetus to actively flex it’s muscles in terms of protecting public safety.

II. BACKGROUND

Warning letters are almost always addressed to the chief executive officer (CEO) and usually state that FDA holds the senior executives responsible for all non-compliant activities conducted by the company they run. A recent warning letter to a major medical device manufacturer specifically addressed this responsibility:

As president of the company, you have executive responsibility to assure that all devices manufactured or contract manufactured by you or your facilities comply with the Quality System regulation, Title 21, Code of Federal Regulations (CFR), Part 820. The Quality System regulation requires each manufacturer to establish and maintain a quality system that is appropriate for the specific medical device(s) designed and manufactured. Further, management with executive responsibility and the management representative(s) are responsible for ensuring that the quality system requirements are effectively established and effectively maintained. We consider you and the management located at corporate headquarters office listed at the above address to be the highest management individuals in your organization, and therefore, the most responsible and accountable for the actions of all the other corporate manufacturing sites including, but not limited to, those listed above.

FDA defines a product as “adulterated” if it is produced under conditions that do not meet current good manufacturing practice (cGMP) or quality system regulations (QSRs). Taken under its strictest interpretation, manufacturers that fail to meet federal quality regulations during the production of a drug or medical device may be, by definition, producing an adulterated product that is illegal to sell or distribute to the consuming public. Many warning letters are written to reflect this interpretation, which is stated clearly in the following excerpts:

The purpose of this letter is to apprise top management of the observations made at your facilities and to remind you of your responsibility to assure all facilities are in compliance with the Act and all pertinent regulations. FDA is concerned with the breadth and scope of the specific violations noted in this letter and the inspectional observations noted on the form FDA-483s which we believe are symptomatic of serious underlying problems in your firm’s manufacturing and quality systems. These inspections revealed that your devices are adulterated under section 501(h) of the Act, in that the methods used in, or the facilities or controls used for, the design, manufacturing, packing, storage, or installation are not in conformance with the CGMP requirements for medical devices which are set forth in the Quality System (QS) regulation, as specified in 21 CFR 820. The FDA inspections found systemic violations in the quality management system.
employed to ensure the safety and effectiveness of your device that recurred at several of your facilities.¹⁰

Our inspection revealed that your devices are adulterated within the meaning of section 501(h) of the Act [21 U.S.C. § 351(h)], in that the methods used in, or the facilities or controls used for, their manufacture, packing, storage, or installation are not in conformity with the CGMP requirements of the Quality System (QS) regulation found at Title 21, Code of Federal Regulations, (21 CFR) Part 820.¹¹

A product is misbranded if, among other things, its labeling is “false or misleading in any particular or lacks adequate directions for use.”¹² Pharmaceutical products promoted by manufacturers for medical indications not approved by FDA as safe and effective have been deemed misbranded under the FDCA.¹³ This type of conduct sometimes referred to as “off-label marketing,” has been at the center of some of the largest pharmaceutical investigations conducted by FDA and DOJ in recent years, including the Purdue Pharma case discussed below.

Misbranding can occur, not only by promoting a drug or device for indications not approved by FDA, but also by permitting a defective device to enter the stream of commerce. This is not merely a theoretical concern. One need only consider the DOJ’s pending investigation of former device manufacturer Nichols Institute Diagnostics (NID), a subsidiary of Quest Diagnostics, for issues arising from alleged quality problems with NID’s parathyroid hormone test kits to understand the possible implications of a manufacturing process that does not produce products that perform as expected.¹⁴ If quality control problems at the factory cause the performance characteristics of a medical device to vary materially from the performance characteristics represented in the labeling for that device, then the labeling may be false and misleading, and the device “misbranded” within the meaning of the FDCA¹⁵ in the eyes of government agencies. To the extent public health is implicated by such misbranding or company employees choose not to inform anyone of the problem until it is uncovered by a third party, it is that much more likely to draw the ire of regulators and the DOJ. As in the off-label marketing context, senior executives may be held criminally liable for such misbranding, irrespective of whether they were aware of the problems that caused the misbranded condition of the device. All this highlights the importance of maintaining rigorous controls and oversight of the manufacturing process, and moving proactively to correct and, if necessary, disclose problems concerning product quality as such efforts and information are the only proactive methods of mitigation available.

III. CURRENT STATUS & ISSUES

A. Domestic Operations

The agency’s changing views on personal executive liability has been voiced by FDA representatives and agency watchers at several recent conferences and is evidenced by highly visible agency actions in recent years.

¹⁰ Cordis Cardiology, FDA Warning letter April 1, 2004.
¹¹ Medtronic, Inc. FDA Warning letter (July 3, 2007).
¹³ 21 U.S.C. §§ 331(a), 352(f).
¹⁵ 21 U.S.C. §§ 331(a), 352(a).
<table>
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<th>Company</th>
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| Advanced Bionics        | In 2008, FDA alleged the company had significant cGMP violations, including shipping a recalled product as well as illegally shipping hearing aids between January 2005 and July 2006. FDA further accused Advanced Bionics of shipping (and subsequently implanting into patients) two hearing aids containing a component from an unapproved vendor, after the March 2006 recall.  
(A Boston Scientific subsidiary at the time)                                                                 | The FDA is seeking fines from Advanced Bionics and its president. The company will pay a civil penalty of $1.1 million, and the president/CEO, Jeffery Greiner will pay $75,000.                                                                 |
| NuMED                   | In 2007 NuMED and its president pled guilty to distributing cardiac stents without FDA premarket approval. If FDA approves the stent after completion of the Johns Hopkins trial, the defendants must furnish it to providers for five years at no charge.  
(In 2007 NuMED and its president pled guilty to distributing cardiac stents without FDA premarket approval.)                                                                 | The company had to pay a criminal fine of $2.3 million and an additional $2.3 million to Johns Hopkins to fund a clinical trial. Additional loses as a result of supplying 5 years of free product. Negotiations with the government are ongoing. |
| Purdue Pharma           | In 2007, Purdue Pharma and three executives were sentenced and fined for the deceptive marketing of OxyContin, a painkiller that reaped billions for the company. The company had long argued it should not be held responsible for what happens when its painkiller is abused.  
(In 2007, Purdue Pharma and three executives were sentenced and fined for the deceptive marketing of OxyContin, a painkiller that reaped billions for the company.)                                                                 | The CEO, Chief Legal Counsel and Director of Medical Affairs agreed to pay personal fines totaling $34.5 million, serve three years probation and perform 400 hours of community service.  
Purdue agreed to pay an additional $600 million in fines.                                                                 |
| AbTox                   | In 2006, ex-CEO sentenced and fined for selling products that caused blindness. US Attorneys accused company executives of knowingly selling sterilization equipment that caused blindness in 18 people undergoing eye surgery. The devices were sold to hospitals for about $100,000 each, they noted.  
(In 2006, ex-CEO sentenced and fined for selling products that caused blindness. US Attorneys accused company executives of knowingly selling sterilization equipment that caused blindness in 18 people undergoing eye surgery.)                                                                 | CEO sentenced to 10 years in prison and ordered to pay $17.2 million in restitution. The CEO and another executives were previously convicted of wire and mail fraud, selling an adulterated or misbranded device and conspiracy to defraud FDA |

1  Amended Administrative Complaint for Civil Penalties, FDA Docket: 2007H-0433 Advanced Bionics, LLC, 12740 San Fernando Road Sylmar, California and Jeffrey H. Greiner, an individual, (Mar. 17, 2007).
2  Knight Ridder, TRIBUNE BUSINESS NEWS, (Feb. 24, 2007).
3  THE ROANOKE TIMES, VA, (July 21, 2007).
4  FDA NEWS DEVICE Daily Bulletin, (Friday, Sept. 15, 2006).
In the case of Purdue Pharma, in addition to the $34.5 million in personal fines, Purdue Frederick, the parent company, pled guilty to a felony of misbranding with the intent to defraud. The company is required to pay the remaining $600 million in fines and forfeitures. The fine is one of the largest ever assessed against a pharmaceutical company and also the first time that company executives were sentenced to a crime under this statute. In asking the presiding judge to accept the plea agreement, Assistant U.S. Attorney Randy Ramseyer said the “unprecedented” convictions will force the entire industry to be more vigilant in guarding against prescription drug abuse. “By pleading guilty, they are admitting that doing nothing is not good enough,” Ramseyer said. “They should have done something.”

Not only were the convictions based solely on the executives’ positions of responsibility, there was also no evidence to link the misbranding to rampant abuse of OxyContin. The judge stated “I do not doubt that many of our fellow citizens, with only a passing knowledge of this case gleaned from the headlines, will deem it inappropriate that no jail time is imposed, it bothers me, too.” However, the judge said it would be improper to send someone to jail for something they did not actually do.

Historically, FDA’s best and most visible method for demonstrating that it is actively responding to calls for an increased focus on safety is to make examples of violators and to follow very well plowed methods by other government offices such as the OIG for HHS. If, in fact, FDA is seriously perceived to be unable to meet its statutory mandate for protecting the public health, it is a given that the agency’s inspectional and enforcement activities should increase dramatically. Those enforcement activities will likely include more direct actions against corporate executives similar to those seen in the Purdue case.

B. Multi-nationals and Internationally Outsourced Operations

The real and immediate question facing global manufacturers is “How much can we or should we rely upon representations of developing country’s facilities, regulators, quality control/assurance procedures and industrial infrastructure to manufacture our company’s products and/or components?” The realities of global cost and commerce almost mandates use of such cost management approaches yet the word wide risks associated with recent incidents and historical track records significantly raises the importance of this question. The increasing trend to outsource the manufacture of both active ingredients and finished goods is driven by two factors. Firstly, the opportunity to increase margins by lowering production costs. Secondly, gaining access to the enormous growing markets of increasingly affluent consumers in developing economies has the potential to increase product demand base significantly. Both are valid objectives but both have and will continue to increase exposure of corporations to quality related problems. Reliance of 3rd party and/or partner company quality/compliance representations can be viewed as border line abdication of what is expected by way of company (and by inference executive and board) commitment and involvement in compliance and quality risk management.

Lower product costs in developing nations is most often tied to the low cost of labor, lack of adequate environmental protection controls, lack of government

16 Lab Business Week via IncRx.com, (June 3, 2007).
17 THE ROANOKE TIMES, VA, (July 21, 2007), Purdue Executives handed Hefty Fine.
18 Id.
oversight/reporting and inability of the industrial infrastructure to support high quality, highly regulated manufacturing processes. If a pharmaceutical manufacturer wishes to produce U.S. drugs under these challenging conditions, and based upon recent FDA leadership comments and the agency’s focus on safety above all else, it falls upon the manufacturer to ensure that the proper oversight, controls and documentation are put into place and not rely on 3rd party/partner company representations. Once those risk control costs are added onto the balance sheet, the overall opportunity of a 3rd world manufacturing operation becomes potentially less attractive and certainly much less assured. In addition the negative consequences associated with product/brand risk become part of the calculation when a high visibility problem (such as heparin contamination) with a foreign manufactured drug or device arises. A recent statement by FDA confirmed that cost is often the driver for manufacturing in developing nations saying “it suspected that the additive (oversulphated chondroitin sulphate) was put into regular heparin stock to keep costs down.”

IV. INDUSTRY RESPONSES

To survive and grow, big Life Science corporations need a global presence and the market opportunities in India, China and South America are simply too large to be ignored. Continued R&D investments by companies like GlaxoSmithKline (GSK) and Merck in India’s Ranbaxy laboratories (Ranbaxy stands to earn up to $100 million in milestone payments from the GSK agreement alone) and Pfizer’s 2005 investment in China and it’s plans to invest $300 million in Korea coupled with aggressive Chinese R&D investment plans by AstraZeneca, Novartis and Eli Lily simply re-enforce the reality of a global economy. A similar trend can be seen in the clinical trials as well, as evidenced by a recent Financial Times report which stated that 274 registered clinical trails were being conducted in China alone, with a similar number already underway in India. In fact, FDA has proposed changes to the legislation designed to “update the standards for the acceptance of non-investigational new drug foreign studies and to help ensure the quality and integrity of data obtained from such studies.”

Under these conditions the corporation might expect to be more closely scrutinized by western regulators, but do the regulators have the resources to get the job done? The Government Accountability Office (GAO) estimated that a significant gap in funding for overseas inspections currently exists. The GAO said FDA needs $70 million annually to inspect all overseas facilities every two years but FDA has allocated only $11 million for all foreign inspections in Fiscal Year 2008. When an agency such as FDA lacks appropriate resources to proactively oversee companies and meet its obligations, enforcement agencies such as the OIG and DOJ are assured to use their tools, resources and budgets to force industry movement toward proactive policing and investment through prosecution. Those prosecution efforts are likely to focus on both the company and individual executive management personnel. In April 2008, FDA’s newly appointed Center for Drug Evaluation and Research (CDER) Director, Janet Woodcock, M.D. told a Senate panel that companies need to be held accountable for the quality of their drugs and active pharmaceutical in-

Ingredients (API). FDA will never have sufficient resources to be “the quality-control unit of the world,” and drug makers will have to assume more responsibility for the quality of their products. She added that FDA needs more authority to pursue violators in the pharmaceutical supply chain. “The FDA or any other regulator cannot test quality into products, and we cannot inspect quality into products.”

“The FDA must have the tools to hold all these parties accountable,” she said. In addition, Dr Woodcock told the panel that much of the USA’s pharmaceutical process has moved overseas in the last 15 years, with finished medicines then being imported back into the country, and that elements of generic drugs can be produced in as many as 15 different facilities. The FDA of “the last century” is not constructed to regulate the volume of medicines and foods which are now produced abroad, she said, adding that while the agency’s responsibilities have soared, inspection resources have dropped.

Congress may want FDA to focus funding and resources toward more foreign inspections by the agency, but does the agency itself? In multiple appearances before congressional committees, Commissioner Andrew von Eschenbach initially declined to seek more money for foreign inspections, although in an apparent change of direction in his May 5, 2008 budget letter to the Congressional sub-committee on Labor, HHS, Education and Related agencies, he did request $13.2 million (and 37 FTEs) to increase foreign medical product facility inspections and increased FDA’s foreign geographic presence. However, these dollar amounts still fall far below the GAO estimates.

The risks associated with foreign manufacturing increase further when one adds in the lack of Intellectual Property protection and counterfeit drug production already well documented in many developing areas of the world. A report by the Times of India suggests that between 5 percent to as much as 20 percent of the drugs sold in that country are counterfeit and the Indian government is currently conducting a study to better define the extent of the problem. Brazil’s generics industry has often trampled over U.S. and International patents. As recently as last year (2007), its government threatened to invoke compulsory licensing (a legal mechanism that, in effect, legitimizes by-passing existing patent protection) to force foreign drug firms into offering huge discounts. In Thailand the government has invoked compulsory licensing for some drugs.

Regardless of potential increases in short term profitability, the decision to enter into manufacturing agreements with non-U.S., non-European based manufacturers, located in developing areas of the globe, can become a critical strategic initiative with potentially catastrophic implications and should not be taken lightly. If executives and their boards see value in the third world marketplace and are prepared to stay for the long haul, they need to commit the dollars and U.S./EU resources needed to bring the proposed site(s) up to global quality and safety standards.

V. CONCLUSION

Although the agency has not traditionally pursued personal assets of industry executives, the current political climate coupled with a disgruntled consuming public’s negative opinion provides a “perfect storm” scenario leading to the filing of both civil and criminal charges against executives of companies in violation

21 Janet Woodcock, M.D., FDA Needs Help to Monitor Drugs, but Industry is Equally Accountable, PHARMTECH.COM, (Apr 30, 2008).
22 American Association for the Advancement of Science, Center for Science, Technology and Congress, (June 2008).
of federal quality and safety statutes. These violations could be documented by something as simple as a 483 citation or may be based in the contents of a warning letter, consent decree, Corporate Integrity Agreement (CIA) or Deferred Prosecution Agreement (DPA).

It is in the best personal and corporate interests of any Life Sciences executive with open 483 citations to be aware of the cited issues and the status of the corrective actions. If the company is working under the restraints of a warning letter or other serious regulatory action, senior executives and board members should be able to demonstrate active involvement in a very visible, management oversight role to ensure the issues are transparent and the solutions are both appropriate and attainable. The issues cited in any regulatory agency actions are serious by definition and should not be considered to be only a Quality Assurance or Regulatory Affairs departmental problem. Corporate cultures that continue to frame their compliance programs within these outdated operational models can quickly and easily see these compliance deficiencies explode into serious multi-level business problems that impact market capitalization and production capacity and may very well cripple an organization’s ability to continue to exist as a functioning business. Senior executives must take ownership, set the corporate tone for compliance and act decisively at the first signs of government agency interest.

Given the Supreme Court’s admonition to those “who execute the corporate mission” that they have a “primary duty to implement measures that will insure that violations will not occur” (Park, at 672), the more evidence a company can produce demonstrating that it has a compliance program in which CxO and board members play an active role with demonstrable participation and awareness, the better positioned the company’s executives will be in arguing that it would be fundamentally unfair to penalize them, civilly or criminally, for the isolated derelictions of lower level employees. This alone should provide the impetus needed to have executive level visibility and involvement in addressing non-compliance issues and implementing compliance programs and initiatives.

A. What Can Executives do to Help Mitigate These Risks?

The most critical action that can be taken by C-suite executive and corporate board members is to become actively involved in addressing and managing the compliance issues cited by regulators. This is often referred to as setting “The Tone at the Top” and although many CxO’s view this as the consultant’s mantra; it is none the less, true. The resources and actions required to effectively manage almost any non-compliance situation and associated governmental actions can be addressed through visible executive involvement and active leadership in the following areas:

1. Active Attention Is Required

The Purdue case makes it is clear that to be perceived as addressing problems in a reactive mode is simply inadequate as a company policy. It is an obligation of the board and C-suite executives to actively seek out and remediate non-compliance issues across their entire organization. The fact that any single executive could not possibly know all the intricacies of compliance within a large, multi-national organization is immaterial. In an approach that has many analogies to the Sarbanes
Oxley mandates enacted earlier this decade, executives that have the authority to act also have the obligation to act. Historically, the quality and regulatory functions are often viewed as overhead and may be one of the first places executives look to cut costs, but that can no longer be the case. Clearly the repercussions of inaction, or even of inattention, can be a serious, short-sighted and costly exercise. Senior executive must be able to demonstrate pro-active involvement & visibility. Executives must seek out, evaluate and respond to external compliance evaluations covering all aspects of their business operations. In addition to retention of professional service teams with deep pharmaceutical expertise, many large multi-nationals are expanding the roles of their compliance, risk management and Internal Audit (IA) groups to begin to examine and evaluate compliance activities. Although this has traditionally been the purview of quality and regulatory departments, bringing the critical evaluative view of hard nosed, financially focused auditors to review compliance programs is a tremendously useful tool. Such an integrated team will often require external training, oversight and program development support yet the benefits to the organization as a whole, can be multifold.

Use of multi-departmental resources such as compliance, risk management and IA can greatly facilitate reporting of risk management efforts to senior executives in a meaningful and concise fashion. Gains can be made by compliance integration of overlapping activities and resources among these areas by working to combine reporting of company risk issues and efforts in a meaningful, “dashboard” format allowing executives and boards to review, understand and act on key issues quickly and meaningfully. Such a tool also provides an “at a glance” tracking/reporting mechanism regarding the status of key initiatives and programs and facilitates a commonality of understanding and purpose between management and the board. Crucial in reporting is measurement of progress and consistent achievement of positive gains. Such dashboard reports are key in monitoring and tracking gains.

The increased evaluative rigor required to explain compliance activities to professionals who are not well versed in “typical” compliance actions and methods, such as IA personnel will lead to improved transparency and understanding of all quality and compliance functions. Quality Program management will benefit by having to explain compliance programs and issues to auditors who have no real background or experience in Life Science compliance. This type of review forces the quality program owners to critically evaluate the foundations upon which their programs are built. Using an integrated risk management approach (in which all known risks are defined, categorized, evaluated and dispositioned) will result in questions being asked that have never been asked before and will demand documentation that is both clear and accurate to support compliance status claims. If quality can get through an integrated compliance, risk management and IA review, they should be well prepared for any government regulator.

2. Monitoring, Assessment and Remediation Oversight

Executive boards should review and approve a compliance dashboard report at every board of directors meeting. These reviews do not need to be extensive or time consuming if there are no surprises to report and existing remedial actions and programs are on track as documented in project plans and prior commitments.
to governmental agencies. Discussion is only required if new issues arise, program
corrections are needed or unexpected problems have been discovered.

In addition to quarterly reviews, executive sponsors should also commit dol-
lars and resources to support compliance functions. The proactive examination
and resolution of potential compliance problems can save significant remedial
costs and protect brands and revenue. Many companies with little or no exposure
to the impact that regulatory actions can have on day to day business operations
are at a great disadvantage in today’s harsh regulatory climate. Executives should
consider compliance activities, training requirements and enforcement/remediation
activities as a critical aspect of annual performance reviews. In particular, board
members should actively search for industry trends and issues and ensure that the
Chief Compliance Officer or Chief Quality Officer is tasked with evaluating and
reporting on the internal status of industry hot-points and ensure that the company
takes actions on any documented deficiencies.

3. Communication

In order to help set the “tone at the top,” compliance messages and communica-
tion from the C-suite and board should be a regular and expected occurrence. A
compliance message from the CEO or board should not be viewed as an event or
anything out of the ordinary. In many organizations, such communication is often
the predecessor of government legal action and other “bad news.” This should never
be the case. Executives should strive to keep employees and other management
personnel informed as to current compliance status, ongoing initiatives, pending
or existing issues and the need for continual improvement. The goal here is to try
to get buy-in and awareness around the criticality of compliance at all levels of the
organization. Executive communication from the board and C-suite level should
be simple, concise and clear. It is still the task of the quality group to drive home
the detailed messages, and communications around specific issues but compliance
messages from senior executive help set the foundations.

In many cases it is corporate cultural issues that lead to compliance problems.
Company executives that place more emphasis on quarterly production numbers and
financial performance while minimizing or downplaying the quality departments'
autonomy and authority run a much greater risk of setting the wrong “tone at the
top.” This environment inevitably leads to a culture where the quality assurance
role becomes one of policing problems rather than ensuring the manufacture and
sale of safe and effective products. Although there is a natural reluctance to spend
capital on proactively seeking out, documenting and correcting compliance issues
on an internal basis, the era of management simply reactively responding to non-
compliance citations has long since passed. Setting the correct “tone at top” is a
critical first step to establishing a corporate culture of compliance and transparency
that today’s regulatory environment demands.

In conclusion, the actions, documentation and remediation efforts resulting
from both internal and external compliance review programs can be invaluable if
a company is found to be non-compliant is some area of its business operations.
Both regulators and prosecutors continually comment on the mitigating nature
of being able to demonstrate that C-suite executives are pro-active, involved and
responsive to compliance program activities. It is a sad truth that no matter how
good any compliance program is, compliance is a complex business and non-com-
pliant activities can and do occur. In today’s regulatory environment, attention to quality and compliance is not just something mandated for those companies found to be non-compliant, but rather a basic cost of doing business. Executives and their boards are likely to significantly minimize the risk of penalties and other punitive actions resulting from non-compliance citations if they can demonstrate their active involvement with and support of compliance initiatives.