

Compliance Basics 3 - Designating a Compliance Officer and Compliance Committee

Introduction

The first article of this series focused on the Elements of an Effective Compliance Programme, largely based on the guidance from the OIG (Office of Inspector General)¹ in the USA. Whilst the guidance is great at stating *what* must happen, it necessarily falls short on *how* it must happen. The second article in this series focused on the first of three preventative elements of an effective compliance programme: “implementing written policies and procedures”. This article focuses on the second preventative element of an effective compliance programme: “designating a compliance officer and compliance committee”. It examines the role of compliance officers and the compliance committee, including what makes a good compliance officer and their likely backgrounds, and proposed membership of the compliance committee.

Before we can look at the appointment of an individual to this important role, we need to examine the role of the compliance officer to pick out the key responsibilities of the role, and to highlight the main skills required. Different organisations include different elements within the role of a compliance officer; some include corporate ethics and / or risk management as well as compliance; others split out the different types of compliance, such as financial, regulatory, and sales and marketing to different teams or individuals. However, there are some basic elements that are always included within the role of a compliance officer regardless of the scope of the role.

The Role of a Compliance Officer

In general, the role of a compliance officer is to implement and manage the compliance programme at whatever level they operate (business unit, function, and / or geography). The compliance officer should also report on progress to the compliance committee and suggest potential improvements to the overall compliance programme. However, possibly the two most important parts of the compliance officer’s role are to be a “trusted advisor” to the head of their business unit (and others), and to “sell” compliance within their organisation.

The term “trusted advisor” was defined by David H. Maister, Charles H. Green and Robert M. Galford in their book published in 2000². They also wrote an article based on the book³ that was primarily aimed at company directors, but has equal relevance for compliance officers. I strongly recommend all compliance officers to at least read the article, and preferably the book. Maister, Green and Galford define the “trust equation” as:

$T = C + R + I / S$, where T is trustworthiness, C is credibility, R is reliability, I is intimacy, and S is self-orientation.

¹ Federal Register Vol.68, No. 86, 5th May 2003, is available to download under “05-05-2003” at <http://www.oig.hhs.gov/compliance/compliance-guidance/index.asp>

² Maister, David H.; Green, Charles H.; Galford, Robert M. (October 2000), “The Trusted Advisor”, The Free Press, ISBN-13 978-0743204149

³ Maister, David H.; Green, Charles H.; Galford, Robert M., “Directors: How to become management’s trusted advisor”, NACD Directorship, October 2000, Vol. 26, Issue 9, p4.

Based on this equation, they also state that everything that the advisor says (credibility) and does (reliability), the feelings they generate in the person being advised (intimacy), and the perception of their motives (self-orientation) will contribute either positively or negatively to their trustworthiness. Thus the ideal compliance officer needs to:

- say the right things,
- do the right things,
- do what they say they will do when they say they will do it,
- build rapport with people, and
- be perceived as serving the needs of the organisation rather their own needs.

The purpose of the compliance officer “selling” compliance to the organisation is so that their colleagues do not automatically think “what can we do to get around compliance”, but rather “what do we need to do to comply”, or even “what more can we do” / “how much further could we take this”. It is essential for compliance officers to understand the challenges faced by their colleagues in the various roles so that they can put the benefits of compliance into terms that their colleagues will readily identify with, and support. This really means that the ideal compliance officer should have broad experience and / or deep knowledge of the overall operation to enable them to find the right triggers to help their colleagues understand.

Alongside these two essential elements of the compliance officer’s role, they will usually be tasked with implementing all the elements of an effective compliance programme (as defined in the OIG guidance) that are relevant to the level at which they operate. For example, the Corporate Compliance Officer (CCO) will usually be tasked with implementing a global mechanism for capturing employee concerns via a reporting helpline, while the compliance officers below the CCO may have no role at all to play in this task, or they may operate the local language version of the helpline.

Looking at those seven elements tells us that good compliance officers also need to be good at:

- Developing and implementing policies, standard operating procedures and guidance, including conducting periodic reviews; this requires knowledge of what must be complied with (laws, regulations, industry codes and company codes) and practical knowledge of what will work and what will not
- Preparing agendas, minutes, reports and papers to enable the compliance committee to function effectively (see below), including highlighting the major issues so that managers can quickly understand the bigger picture; this may also include preparing reports for the directors
- Conducting education and training, including assessing its effectiveness
- Developing effective lines of communication, including encouraging employees to speak up to their supervisors, being available for employees to raise their concerns with, and managing employee reporting helplines
- Conducting or supervising audits and implementing corrective actions / assisting management to implement corrective actions
- Conducting or supervising investigations, including implementing corrective actions / making recommendations to management regarding corrective actions

Finally, whether or not the compliance officer also has responsibility for risk management, they need to be good at managing risks in that they cannot possibly do everything to the same degree, so they

must decide which problems deserve their scarce resources; they must understand which issues present the greatest risks and tackle those first.

Skills and Knowledge of a Good Compliance Officer

Given all that a compliance officer must achieve, they really need a super human set of skills only rarely found in one individual! A good compliance officer must possess:

- A highly developed sense of what is right
- The courage to do the right thing no matter what the consequences
- The gravitas / seniority to be taken seriously by the head of their business unit / the CEO / the board, and people at all levels in the company
- All the attributes in the trust equation (with self-orientation being inversely proportional!)
- Excellent selling skills, including the inter-personal skills to build rapport
- Tenacity to keep asking questions and keep going to the right end point
- Wisdom and judgement to know when they have pushed far enough
- Understanding of the relevant rules (laws, regulations and codes) and practical knowledge of what will work / what will not
- Diplomacy skills
- A sense of altruism to put the company's needs ahead of their own needs (i.e. the opposite of self-orientation)
- Problem-solving analytical skills
- Strong planning skills to enable them to do what they say they will do when they said they would do it
- Attention to detail whilst keeping an eye on the bigger picture
- Leadership and delegation skills
- A great team!

Clearly no one individual will possess all of these skills in the right combination to make the perfect compliance officer, especially as some of them appear to be mutually exclusive, which is why a great compliance officer needs to have a great team that fills in the gaps for them.

Likely Backgrounds of Compliance Officers

In the early days of compliance, most compliance officers came from either a legal or audit background, often because the legal or internal audit teams had been charged with the task of ensuring compliance. Lawyers and auditors can, and do, make good compliance officers, especially as they tend to have high attention to detail and good techniques for problem-solving. However, those with an audit background can sometimes find it difficult to build rapport.

The best compliance officers are those who really understand the mind-set of the people performing the highest risk roles in the organisation, for example sales reps. Those who have been in the role of sales rep and / or sales manager before moving into compliance have a clear advantage in that they understand first-hand the behaviour and mind-set of reps, and they also usually have great selling skills! However, they may be less good at paying attention to detail than their colleagues with an audit or legal background.

People with experience in HR can also make great compliance officers as they tend to be good at building rapport, and they have often been involved in conducting investigations from an HR perspective, thus giving them an advantage in this important requirement of the role.

A good source of compliance officers is the company's fast-track management trainees, who may enter the company within ten years of completing their university degree and gain experience in a wide variety of roles within the organisation to equip them to be future leaders. If you are able to persuade some of these high-flyers to undertake roles in compliance for perhaps a year before moving on to their next role, they can bring a lot of energy and a breadth of experience to the role that is unlikely to be gained from other sources. They also tend to be great at highlighting the key issues as they have been trained to ignore immaterial details. Because they are being trained as future leaders, they have also usually spent some time doing the core roles within the business unit, so they should really understand the issues and the mind-sets involved. Finally, when these high-flyers move into senior management, they can be great advocates for compliance if they have had first-hand experience in compliance roles.

In summary, there really is no typical background for a good compliance officer. I have worked with a number of great compliance officers from different backgrounds. Indeed, most people are surprised when they discover that my own background was in IT before I moved into compliance. What really matters is that the compliance officer must possess the key attributes of:

- a sense of what is right,
- courage,
- gravitas,
- tenacity,
- judgement, and
- rapport-building skills.

Everything else can be learned and / or filled in by having a good team with complementary skills, which is why I would suggest that you look for personality and character rather than background.

Reporting Lines for Compliance Officers

Some companies set up a completely separate compliance function serving all the business units of the company. In this environment, the business unit compliance officers often report upwards into the corporate (or chief) compliance officer. They will also often, but not always, have a dotted reporting line to their business unit head, or the CEO for the corporate compliance officer.

Other companies choose to keep compliance within the business unit with compliance officers reporting to the business unit head, or sometimes to the leader of the compliance committee (if that is someone different). In this arrangement, the compliance officer will often have a dotted reporting line to the corporate compliance officer.

I have worked in both environments with the dotted line reporting as indicated above. Both reporting structures have advantages and disadvantages. Having a separate, dedicated compliance team led by a corporate compliance officer gives a level of focus and a degree of independence to the compliance function and hence the corporate compliance programme, but it can lead to business unit leaders deliberately abdicating, or perhaps misunderstanding, their responsibilities for compliance. Keeping compliance within the business units reinforces the message that ownership of compliance lies with the business units, but it can lead to a lack of focus for the overall compliance programme and may also mean that compliance officers feel somewhat isolated.

In my experience, people will make the structure work, or not work! The compliance officer is often at the heart of a triangle between the business unit, the compliance function, and external bodies such as regulators. A great compliance officer will make these relationships work, regardless of reporting lines, by finding and articulating reasons for everyone to work together for the benefit of patients, since they are the reason for the existence of life science companies.

The Role of the Compliance Committee

The compliance committee is the oversight body for the compliance programme with responsibility for directing the compliance officers to address the appropriate issues. The members of this important committee need to be representative of the business unit as a whole and also senior enough that they have the knowledge and experience to direct the compliance efforts. For these reasons, the ideal compliance committee is the business unit's management team plus the compliance officer (if he or she is not a member of the management team). Ideally, the compliance committee should be led by the business unit head with the compliance officer providing meeting materials as appropriate. Often, the head of finance or medical will be asked to lead the compliance committee for their business unit. While this is not ideal, it can, and often does, work well.

If the business unit leadership team is not the compliance committee, then the next best alternative is to have a subset of the leadership team plus others to ensure adequate representation of the core operations of the business unit. This can often work well, especially where there is a large leadership team for the business. Keeping the compliance committee small can make it more effective as there are fewer people to rely on, so each member must fully engage with all the compliance initiatives.

The agenda for compliance committee meetings will vary depending on which elements are included in the remit of compliance, for example whether or not risk management and corporate ethics are included. However, the focus should be on the major sources of risk for the business unit and / or the company whether or not risk management is included in the remit of compliance, as senior managers will quickly lose patience if the compliance committee is constantly working through tedious details that really do not matter within the overall business context.

Typical agenda items for a compliance committee meeting will include:

- Top few risks for the business unit (if included in the remit of compliance), including any changes since the last meeting / report
- Progress with implementing major elements of the compliance programme, especially any delays that will need members of the compliance committee to take action (although these should never be a surprise in the meeting!)
- Progress with resolving major incidents from previous meetings / reports; an incident can be an instance of non-compliance, a report to the helpline, and / or a "near-miss" depending on the scope and maturity of the compliance programme
- Any new major incidents arising since the last meeting / report
- Items that are likely to cause problems or require action in the future, for example a proposed change to laws, regulations and / or codes that would prohibit or alter some of the core activities of the business unit
- Trends in terms of numbers of incidents arising, resolved and remaining open each quarter / half year / year or other reporting period
- Staffing levels compared with workload, i.e. does the compliance team have enough capacity to cope with the workload

Given that most compliance committees will consist of between eight and twenty people, it is important for the compliance officer to build a core team of trusted advisors to enable them to share issues with a smaller number of people and get their advice regarding which issues to escalate to the compliance committee, plus potential solutions. In my experience, the heads of HR, legal, and medical within a business unit make a very good core advisory team for the compliance officer, as well as adding their personal support to the efforts of the compliance team. You might also want to consider including someone representing the core operations of the business unit to get completely rounded advice.

Whatever the structure of the compliance committee, a great compliance officer will build relationships with all the members based on the trusted advisor model described above. In this way, you will find that your leadership will support your efforts and thus a virtuous cycle will be created and sustained.

The next article in the series will focus on the third preventative element of an effective compliance programme: “conducting effective training and education”, including the differences between training and education, who should be trained in what, when and how that training should be delivered, and keeping training records.

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