Compliance Basics 2 - Implementing Written Policies and Procedures

Introduction

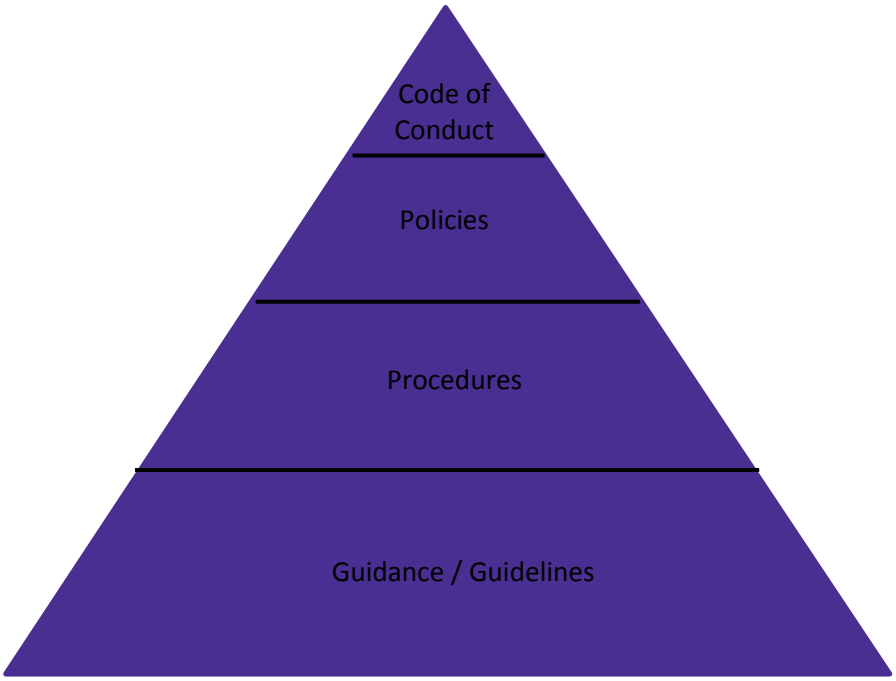
The first article of this series focused on the Elements of an Effective Compliance Programme, largely based on the guidance from the OIG (Office of Inspector General)[1] in the USA. Whilst the guidance is great at stating what must happen, it necessarily falls short on how it must happen. The focus of this article is the first of three preventative elements of an effective compliance programme: "implementing written policies and procedures". This article also touches on the philosophical discussion of rules-based versus values-based cultures.

Differentiating Between the Different Types of Document

In many jurisdictions around the world, it is possible that external authorities imposing sanctions on companies that have not complied with laws, regulations and applicable industry codes will impose reduced sanctions if the company can show that it had an effective Compliance Programme in place at the time of the breach. This is one of many reasons why it makes sense for organisations to pay close attention to their Compliance Programme implementation.

Figure 1 shows how the various types of document build up to a complete set of written policies and procedures that are at the heart of an effective Compliance Programme. The larger pieces of the triangle moving towards the base indicate both an increasing number of documents and an increasing level of content.

Figure 1 – the relationship between the various documents



[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

Codes of Conduct

Most large organisations now have a Code of Conduct, or "company Way" document, that sets out the company's values and basic standards of behaviour expected by its employees, and partner organisations. These range in length from less than ten pages to almost a hundred. Some include worked examples, while others stick to the facts of what is expected. Whatever the style of this document within your organisation, it should cover all the basic behavioural elements that the company expects all its employees and third party organisations to exhibit. Generic statements such as "we obey all relevant laws in all the countries in which we operate" are necessary, but specific statements such as "we do not pay bribes and we do not allow any third party to pay bribes on our behalf" can be much more useful in flagging the specific standards of behaviour that are expected, especially as most employees will not know all the laws in every country in which the company operates.

When determining what to include in the Code of Conduct and what level of detail to go to, it is important to consider both the intended audience and the major risk factors. It should be noted that the primary intended audience is the employees, both of your company, and of third parties who operate on your behalf. However, the secondary audiences should not be neglected. These are all external and will include shareholders and potential shareholders, potential employees, third party organisations who may wish to work your organisation, healthcare professionals, regulators, prosecutors, the media, and anyone else who wants to gain insight into your corporate culture. In addition to the general business risks of anti-competitive behaviour, bribery and corruption, fraud, and so on, particular risks in the life science sector will include anything that could incur an inappropriate risk to human health (and to animal health where applicable), potential breaches of clinical trials legislation, breaches of the relevant GxP[2] regulations, and breaches of codes of sales and marketing practices. The Code of Conduct should also include a commitment to compliance from senior management (preferably the CEO and / or the Chairman) and the expectation that all employees and third parties will comply with the Code of Conduct, policies and procedures.

Whether or not to include worked examples, at all levels of documentation, is a difficult decision. Including them can help to clarify what is meant by a particular point, particularly where the Code of Conduct has not been translated into all the native languages spoken by all the employees and third parties. However, this also makes the document longer, thus taking more time to read, so perhaps not all employees will read all the way to the end if they are included. If worked examples are not included, these can be included in training (see below for more information).

Most of the Codes of Conduct that I have reviewed are fit for purpose, despite their different styles; it is the next layer where things start to go wrong.

Policies, Procedures and Guidance

Some organisations blur the lines between policy, procedure and guidance (or guidelines), often because the people writing the documents do not have a clear enough view of what should be included at each level. Policies should include high level statements of *what* will be done to fulfil the broad requirements of the Code of Conduct. Procedures should include statements of *how* these policy statements will be achieved. Guidance is where any non-mandatory statements regarding both the "*what*" and the "*how*" belong. The two most common mistakes are to include:

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[2] GxP is used as a generic term to include regulations relating to Good Clinical Practices (GCP), Good Distribution Practices (GDP), Good Laboratory Practices (GLP) and Good Manufacturing Practices (GMP). In the US regime, GDP is normally included within GMP, but distribution is separated out in the European regulations.

- too much detail at each level, and
- non-mandatory statements within policies and / or procedures.

Authors of policies and procedures often try to be helpful by including as much detail as possible, which can result in some very long procedures, occasionally reaching one hundred pages or more. Far from being helpful, this level of detail actually increases the risk of non-compliance. Most people faced with a procedure of more than thirty pages will be unable to remember the whole procedure and will also be unable to consistently follow the requirements in that procedure, thus increasing risk. Authors should instead limit their contributions to the absolute minimum of what *must* be done to create consistent results. When offering advice on how to reduce policies and procedures, I often use the example of writing a procedure to make the perfect cup of tea. (I know that I play here to the stereotype of the English enjoying tea each afternoon!) I could write a policy of more than twenty pages on *what* should be done to produce the perfect cup of tea, and a corresponding procedure of over one hundred pages detailing *how* this could be achieved. However, the three most important elements in creating the perfect cup of tea are: boiling water, good quality tea, and adding any extra ingredients (lemon, milk and / or sugar) to the taste of the drinker. Everything else is "nice to have" (or non-mandatory) and belongs in the guidance documentation, if you use guidance.

The area where I have seen most confusion with procedures is where people are using computer systems to record what has happened, or to plan what should happen, especially in manufacturing processes. This is a problematic area because there are often several ways to achieve the same end point within a single system. For example, when using Microsoft Word, a file can be saved by clicking on "File", then "Save". The same end point can be achieved by clicking both the control key (labelled "Ctrl") and the "S" key at the same time. Alternatively, the user could simply click the "save" icon on the shortcut toolbar. If a procedure included the need to save a document at a point in the procedure, it should simply state that the document needed to be saved, not the detail of how to do it, as this can be covered in the guidance document. If the procedure stated that the document should be saved by clicking "File", then "Save", but someone used a different method to save the document that would be a technical breach of the procedure. Although this is a simple example, it illustrates the point that extra, helpful details belong in guidance, not policy or procedure.

The discussion above assumes that there will be separate documents for policies, procedures and guidance. This is the method that I would recommend and the one that most organisations adopt because there may be many procedures covering each policy, and one guidance document, for example how to save files in Microsoft Word, may be referred to by many procedures. However, I have also seen a few good examples where the policy, procedure and guidance were all contained in the same document. This can work well if the policy is stated, and appropriately labelled, at the beginning of the document, or at the beginning of each section, followed by the procedure, which must also be appropriately labelled, and finally followed by guidance, which should be labelled as non-mandatory.

Ownership

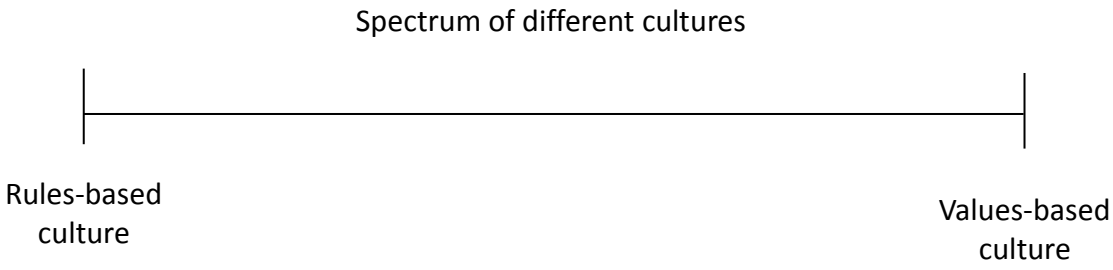
Perhaps one of the most important considerations when writing policies and procedures is to ensure that the right person takes ownership as the author. It is usually best to ensure that a single person is the author of each document, but it often works well to have a team of people writing policies and procedures. This is especially useful for more complex areas where there may be several experts who, together, have a complete picture, but separately would be unable to write the whole document. However, where more than one person is involved in writing a policy or procedure, a

single person must take the role of lead author and that person must have the final authority to decide on the wording. One of the most difficult tasks I have ever undertaken was being a member of a committee charged with writing the policies and procedures for a new Quality Management System (QMS) governing all aspects of Information Technology and Computer Systems Validation for a newly merged company. The committee consisted of around twenty appropriate experts from the two previously separate companies, and was jointly led by one person from each former company. This joint leadership made it very difficult to get final decisions and the committee spent many long hours and even days arguing in circles about the meaning of several individual words, or short phrases. If a single person had been appointed to lead the committee, the task could have been completed in half the time it took, and whilst some people would have had concerns, the end result would still have been fit for purpose.

Rules-Based versus Values-Based Cultures

The points made about the length of policies and procedures bring us to a discussion of "rules-based" versus "values-based" cultures. We can think of a rules-based culture being at one end of a spectrum, with a values-based culture at the other end, and all possible combinations being somewhere in the middle as in Figure 2.

Figure 2 – Spectrum of Different Cultures



In a rules-based culture, usually either everything that is allowed is written down, or everything that is forbidden is written down, and sometimes a mixture of both methods is used. In such a culture, every time some new innovation is introduced, for example the use of SMS text messages to remind patients when to take their medicines, the details of what is, or is not, allowed must be added to the relevant policies and procedures. It is important to ensure that policies and procedures in a rules-based culture include the rules for everything that could possibly be done. Many difficult discussions arise if the rules are unclear, ambiguous, or simply do not cover the elements that are being considered for action. In my experience, people in such a culture can suspend judgement in favour of applying "the letter of the law" (where "law" includes all applicable laws, regulations and industry codes of practice), leading to conversations such as "show me where it is written that this can (or cannot) be done". This is not what most companies intend, especially as many now state within their Codes of Conduct that they comply not only with the letter of the law, but also the intended "spirit" of the law. In a values-based culture, everyone knows and understands the values of the organisation, and preferably also shares them; they do not need to be told what is, or is not, allowed, as they know this from their own internal moral compass. In such a culture, only the bare minimum required by the relevant laws, regulations and industry codes of conduct need to be written down because everyone understands what is required of them. In my view, a values-based culture is the ideal that all organisations ought to be striving for. However, history and human nature teach us that this ideal may not be attainable in our lifetimes, if ever. We only need to look at the history of law-making in most countries around the world to understand that humans have

been writing and re-writing the "rule book" for hundreds, if not thousands, of years and we are yet to achieve the comprehensive listing of all that is, or is not, allowed.

In the next article of this series, I will examine the appointment of compliance officers and setting up a compliance committee, including what makes a good compliance officer and their likely backgrounds.

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In January 2010, Sue established the management consultancy, Sue Egan Associates Limited, specialising in Corporate Governance, Compliance, Risk Management and Change Management. Sue works with clients in various sectors (life sciences companies, charities, a government agency, and other industries) to help them find innovative ways to conduct business ethically and sustainably.