



**Whitepaper**

# COMPLACENT OR COMPLIANT?

An introduction to compliance and the role of the Responsible Person (RP) and Qualified Person (QP) within the Pharmaceutical Industry

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## Complacent or Compliant?

In most lavatories in the work-place there are printed signs reminding everyone to wash their hands before leaving. It's a simple rule, an obvious guideline that we should all follow, especially in any industry processing food or manufacturing medicine. However, it is estimated that nearly 50% of us simply don't wash our hands regularly or fail to hand wash properly. Basic hygiene is a simple matter of common sense, in the pharmaceutical industry it is a matter of compliance and yet we apparently seem not to follow this rule all of the time.

If we can be lazy about something so fundamental, can we be sure that we are following other laws, regulations and guidelines? Maybe our failure to do so is because we fail to see why we are being asked to comply. It's obvious why we should wash our hands, but is it so obvious why we need to follow a particular operational procedure or use a particular computer system or check printed labels on materials for errors in content and accuracy?

In May 1999 the drug Vioxx was launched by the pharmaceutical company Merck and Co. It was an effective treatment for conditions affecting the joints of the body such as arthritis and osteoarthritis. Vioxx very rapidly gained widespread acceptance in the market because it was - unlike other similar drugs - not only an affective anti-inflammatory (essential in reducing soreness in the joints) but it had the added bonus of being well tolerated by the stomach, which other treatments were not.

Worldwide there were soon over 80 million people using Vioxx. That is an impressive market share for a new drug. However, on 30<sup>th</sup> September 2004, just over five years after its launch, Merck and Co voluntarily withdrew the product from the market amidst concerns that it was contributing to heart attack and stroke among long-term users. By 2008 there were over 30,000 law suits filed against Merck and Co in American courts because of these potential side-effects.

In the year before its withdrawal, Merck and Co had made some \$2.5 billion from the sale of Vioxx. But by 2007 Merck announced that it had reserved \$970 million to pay for Vioxx related legal expenses and had set aside a staggering \$4.85 billion dollars for legal claims from citizens within the United States of America. That is an amazing turn-around in fortunes.

Exactly what went wrong in the Vioxx case? It is still open to debate. A 2005 report suggested that – while senior management had acted in good faith over the launch of the drug – there may have been some degree of confusion and misunderstanding among the sales team as to the exact nature of the clinical safety of the product. Although Merck and Co did win many of the legal cases in court, such a human and financial disaster had enormous repercussions. And the impact is not only felt by its managers and shareholders, but also by their patients.

Vioxx is just one example of several similar disasters in the past. Understandably the modern pharmaceutical industry has a very strong desire to avoid similar catastrophes. So today the pharmaceutical industry is one of the most publically regulated and self-regulated bodies in existence.

## The consequences for being complacent

Compliance regulations are designed to prevent some of transgressions of which some companies were once guilty – such as:

- The payment of ghost writers to publish material in medical journals, allegedly written by academics and doctors but actually designed to endorse and promote certain products.
- The covering up of dangerous side effects in order to get a product to market.
- The selling of medicines to patients who didn't need them in order to maximise sales.
- The bribing of doctors and hospitals to purchase more expensive medicines or favour a particular product.
- The falsification of sales figures to avoid taxation and make more profit at the tax payers' expense.
- The mismanagement of production processes leading to contamination during manufacturing or storage of medicine.
- The distribution of medicines to those who were not eligible to receive them.

Fortunately, such wrongdoing is now largely confined to the history books. Today, compliance with the regulations that govern the pharmaceutical industry worldwide is of the utmost importance. It is universally accepted by all employees, suppliers and contractors. No wonder, because such compliance is absolutely vital as it can be a matter of life and death.

Failure to comply with today's established high standards of ethics, marketing, manufacture and research can result in human tragedy. But it can also initiate costly legal actions which can end up in compensation claims that can lead to the downfall of companies. In some cases failure to comply can even lead to charges of manslaughter against individual directors and company managers.

That's why no employee, supplier or contractor can be complacent about complying with such regulations. They must make it their business to become familiar with the industry's regulations and to stay familiar with them - in particular how they apply to their own areas of expertise.

Remember, non-compliance could lose you your job. Worse still, you could even end up in jail!

## Being compliant

No one will expect a new-comer to the pharmaceutical industry to fully understand the sometimes complex requirements of the industry's regulations. But it is everyone's duty to understand all of the aspects of compliance that affect their role within the company.

Acquiring understanding is not enough in itself. It is each individual's responsibility to follow the regulations carefully and accurately. They are there for a purpose. Once they have been pointed out and explained it is their responsibility to stick to them. And that also applies to a free lance contractor or an occasional supplier,

The stakes are high as governments worldwide have the power to:

- Impose fines on individuals and companies,
- Sue companies or individuals, or even to
- Take over the management of the business.

Today, audits are taken at all stages of the supply chain and can be used to prove that there has been a failure to follow the rules. It is quite possible that an identified compliance failure revealed during an audit could even lead to the bankruptcy and closure of a company.

Therefore, complying with the regulations is not some one-off test. Compliance is not merely a matter of attending an induction course and occasionally flicking through

the latest regulations with half an eye. Understanding the need to comply with regulations is an on-going and serious responsibility, which has to be treated seriously. As the world around us is constantly changing, compliance needs to be monitored regularly and requires a degree of self-discipline and self-awareness from every employee and contractor.

Everyone in the pharmaceutical industry should periodically ask themselves if they are still complying with current laws, regulations and rules. Have they checked them since they first learnt about them? Do they still follow the guidelines or have they begun to take short-cuts?

It is your responsibility to be informed and to comply with regulations as they affect you, because if every individual takes personal responsibility the corporation as a whole will be a better and safer industry.

Pharmaceutical organisations offer training related to basic hygiene, safety and operational procedures. Attendance at these sessions and the passing of any subsequent tests are recorded. This is in order to provide assurance to internal and external auditors that all personnel are properly trained and compliant aware. This procedure is essential to the security and future of the company and these audits ensure that the laws, regulations and guidelines linked to compliance are implemented and applied. Just as importantly, such audits identify any failures in compliance so that action can be taken to remedy and repair them. Make sure you attend all training sessions, their importance cannot be over-estimated.

## Introducing the Responsible Person (RP) and Qualified Person (QP)

There will always be sudden problems or unexpected difficulties or complex choices in any supply chain process. Sometimes such issues are beyond our scope of expertise. Fortunately, help is on hand if we are in any doubt about any aspect of compliance. In those circumstances we should turn to the Responsible Person and Qualified Person for advice and guidance.

The Responsible Person (or RP) protects patients against potential hazards caused by poor distribution practices.

The primary focus of the RP will be on auditing the implemented Supply Chain processes that covers the following areas of expertise:

- Product labelling
- Product storage
- Product distribution

As the title suggests, this individual will act as being responsible for the welfare of the patient as soon as the manufacturing process has been completed. The RP must ensure that medicine is handled by those properly trained according to guidelines stated in approved Standard Operational Procedures (also referred to as SOP's). It is important that the RP has the authority to enforce that the SOP's are followed to the letter. That also implies that the RP has unlimited access to all areas within the company to offer the opportunity to monitor the execution of the instructions as described in the SOP's.

Obviously, the RP must acquire a personal understanding of the working of the medicine sold to the patients.

Apart from the RP, also the Qualified Person (or QP) has been introduced into the pharmaceutical industry to safeguard the company against error and failures in compliance that may lead to illegal actions exposing the company to charges of negligence or putting the patient in danger.

It is the QP's responsibility to certify batches of product before they reach the market-place. As such they have skills, experience and knowledge that include not only manufacturing processes, company policies and strategies but the wider implications of regulations and legal compliance. It is clear that the QP's responsibility overshadows those assigned to the RP.

The QP will be involved in every step of the supply chain from procurement of raw materials and manufacture of the product, to its distribution.

To summarise, both RP and QP are instrumental to protect the company, employees, shareholders and patients against malpractice when handling medicine throughout the Supply Chain process. While the RP emphasises on the storage and distribution of medicine, the QP also keeps a very close eye on the manufacturing process.

QP's can be spotted throughout the entire company, but tend to spend most of their time at manufacturing plants. RP's would normally only surface at distribution centres.

Although the RP and QP are employed by the company, it is a legal requirement that they need to act independently. Therefore their primary focus relate to patient safety and compliance before taking into account company policy.

They will ensure that:

- Processes and procedures are documented and comply with the required standards and regulations.
- The products that are physically delivered to the distributor match the documentation that goes with them.
- Ensures that information made available to the patient is accurate and complete.

As a contractor, supplier or new employee you should consider the RP and QP as the most senior point of reference and advice regarding compliance. It is in your interest to understand their role and to follow their guidance and recommendations.

The RP and QP are there for a purpose – don't be afraid to approach them and discuss any issue or difficulty.

## Final thoughts

Everyone within the pharmaceutical industry needs to become and remain COMPLIANCE AWARE. Regulations are meant to be followed. Regulations save lives. Regulation secures the future of the industry.

Therefore:

- Always ask for advice and help concerning regulatory matters
- Attend training when it is offered
- Learn all the rules and regulations that apply to your job

Regulations are ongoing and can never be ignored – keep abreast of them  
Never allow yourself to become 'complacent about compliance'.

This document is only a very brief guide to the importance of compliance within the pharmaceutical industry. New employees and contractors are advised to consult with their line managers, RP's or QP's for further information.

Remember that there is never room for complacency in the matter of compliance. The stakes are just too high!

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