

LIFE SCIENCES

Risk Management

Regulatory compliance  
Risk management  
Risk-based approach

manage risk,  
manage the  
regulator

why

wci

**“ we have a proven  
approach to  
safety compliance  
risk management  
which embraces  
regulatory  
guidelines and  
requirements ”**

### Why this is important

Risk Management is the smart route to safety and to well-aimed investment. In the increasingly competitive life sciences sector spotting potential risks before they become a danger to the patient is a must and has just been enforced by new regulations (e.g. Volume 9a). So how can life science companies both manage risk and manage the regulator?

The traditional approach of pure compliance to regulations using a typically paper heavy system will probably keep you on the right side of the regulators – but, will it help you to improve your processes? The public demands a demonstrable increase in safety. No wonder the regulators are looking for a new approach!

The traditional approach does not increase safety, so much as encourage risk. Nor does it deliver better or faster drug development – which ought to be one of the required outputs. The defect of the traditional approach is that, though it uses immense resources, it addresses the letter but not the spirit of regulations. Yet the opportunities are there.

Shareholders are most likely to agree. They do not want to see their shares crashing when somebody dies and the perpetrators get off. Get caught putting profits before patient safety and nobody will trust you again. And trust is an issue that is right at the core of life sciences – and once lost, trust is nearly impossible to recover.

### Flexibility

The stakeholders seem to have a shared interest in a more flexible and sophisticated regulatory process. The industry must be ever aware of ALL its stakeholders. That includes patients – patients whose lives are being saved now and patients yet to be saved. When everyone can see the point of a change, the law – patent, regulation – will follow. As a patient we want remedies that are effective, free of side effects, cheap and simple to use. In that order. The more serious our illness, the more important effectiveness becomes.

The new, outcome-focused approach where you are accountable for your Serious Adverse Events (SAEs) whether technically compliant or not, is welcome in principle, but it needs to be backed by a systematic methodology. That methodology is, without question, Risk Management and its accompanying Information Technology, the smarter route to fewer Adverse Events (AEs), safe drugs and well aimed investment. But it is easy to do it superficially, endangering public safety. So regulators fear life science companies will use it as a short cut to compliance. What it requires as a regulation tool is involvement and understanding from professional level regulators rather than administration level bureaucrats. We should be comfortable with that.

Risk Management has been around for a long time in regulated industries, for example the aerospace industry, so is it not time the life science industry took action? The risk

management techniques and methodologies exist and are well proven. Correctly implemented and leveraging a structured framework will ensure compliance to the regulations and, at the same time, improve the processes and, therefore, contribute to an increase in patient safety.

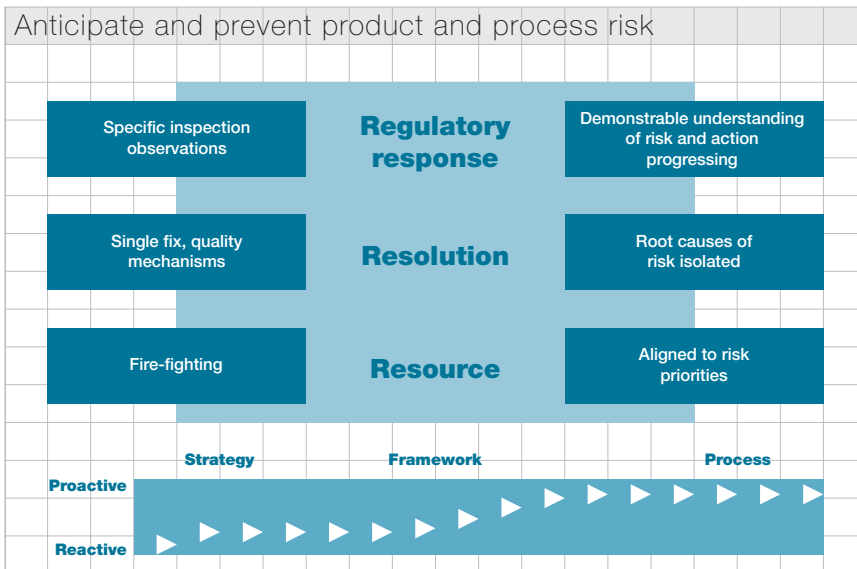
### Reporting

As regulators concede more flexibility they will seek to influence R&D portfolios by providing incentives for those needed but currently non-viable projects. Today, a bad compliance report damages both trust and value. A satisfactory report does nothing for the share price. But a good one excites no interest. What if a good inspection result could raise corporate value? What if the regulator got involved in the company's plans as well as its near completed projects? Focus on that common interest. What if, in consequence, the report could cite specifics – for example ‘an exemplary use of risk management techniques, focusing care where it is most needed’, ‘an investment in patient safety 20% above the industry average?’ It is coming, we have little doubt. And when it does, though bad reports will still damage the company, good reports will boost it – because the investors would sense better returns from lower levels of risk. Why not double patent length when people are crying out for a remedy that is not currently viable? Offer regulatory approval very early as soon as the most likely treatments are identified, before major trials? Sound risky? That has already happened!

**“we configure our risk management framework to align with the objectives of the business”**

**“we understand cross industry best practices and apply to a life science context”**

**“we have a structured framework that ensures compliance to the regulations whilst improving processes”**



There is no bucking this trend; it is risk management for everybody. It is no longer only a matter of investing defensively to prevent human and public relations disasters. A shift of perspective is under way that will ensure the Risk Management input is essential to good business decisions. Regulators will need to adopt Risk Management principles to focus their own energies and efforts. Their involvement, closer but more co-operative than ever before, will protect the public not only from today's risks but tomorrow's too – by providing life science companies

with the incentives (positive reports, early approvals, more flexible and risk assessed regimes) to invest in what is going to be important.

A risk-based approach to compliance is on its way. The burden would be enduring. But it will be well worth it: the benefits are there for the taking. As detailed in the above diagram, the strategy must ensure the ability to both anticipate and mitigate risk; providing a formalised and transparent evaluation and communication process and accountability for all functions involved

in decision making. This must include clear decision escalation criteria and a crisis management policy for high impact issues requiring fast track action. This finally will help to move a reactive risk management strategy towards a proactive strategy.

### **Future prospects**

Ten years on, a risk-based approach, varying the regime with the situation, will be the norm from companies and regulators alike. As they promote Risk Management in life science companies, regulators will rapidly adopt what they advocate. They will concentrate their attention where it will have the biggest pay-off in public safety and health – or lose all credibility. So the regulator's new role, more important and much more useful than before, influencing the approach to the future rather than identifying the unadmitted errors of the past, will protect us from risks of today's medicines AND from the risk of not having the right medicines in the future. Regulatory incentives will give life science companies the encouragement to invest in future need, reducing the very real risk of ignoring important, unmet needs that, as things stand, offer no commercial pay-off. Public Good and Private Profit: it is a win-win situation at last!



**Simplify what you do  
to assure compliance and  
boost performance**



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**For further information:**

Europe: +44 (0) 2392 268133

USA: +1 212 792 4267

[info@wcigroup.com](mailto:info@wcigroup.com)

[www.wcigroup.com](http://www.wcigroup.com)