

LIFE SCIENCES

Pharmacovigilance

Qualified person  
Risk management  
Governance  
PV oversight

are you keeping  
up with the  
evolution of the  
QP role?

why

WCI

**“ we have put  
the QP role  
into operation  
and are taking  
it forward ”**

**The journey so far**

Much expectation, and responsibility, has been put on the shoulders of the Qualified Person for Pharmacovigilance (QPPV). The dedication and commitment to the role has, in many organisations, established good oversight of operational processes across pharmacovigilance e.g. QPs have a Detailed Description of the Pharmacovigilance System (DDPS) in place to support the submission process, and operational metrics to ensure Compliance to Regulatory requirements.

However, the role has not been fully defined, and its scope is developing as Regulators are pushing towards more enforcement and focus on proactive safety, which in turn is putting more burdens on the (legal) role of the QP. The role is a continuing evolution, and we recognise that now is the time to ensure compliance with both immediate and expected requirements of the QP.

**What do we see today?**

The publication of Volume 9A – Pharmacovigilance for Medicinal Products for Human Use (April 2007)<sup>1</sup> has certainly made a big impact on the role of the QP.

It has clarified the role and specified the areas for which a QP has oversight responsibility and those for which it has direct responsibility. EU Member States have also focused on the role of the QP, for example by specifying its obligations in national laws.

**Risk Minimisation Plans where we didn't expect them?**

The recent focus on the development of Risk Minimisation Plans (RMPs) for new products in the EU has directly impacted those few products with recent Marketing Authorisation Application (MAA) submissions. Already established products were not covered by this legislation when approved, yet it is being used to control their updates. Where there is a requirement, although not mandatory, to develop RMPs for marketed products, often on a country-by-country basis, the process is very time consuming. Organisations will now need to ensure that these RMPs are being developed adopting the same efficient approach to make certain that messages are consistent across all markets.

Having written these RMPs and given commitments to enhanced PV or risk

minimisation actions in these plans, it is critically important that you are successful in implementing and monitoring the actions, as the agencies consider the approval to be conditional on these commitments. Agencies intend to apply significant fines for failing to adequately implement actions.

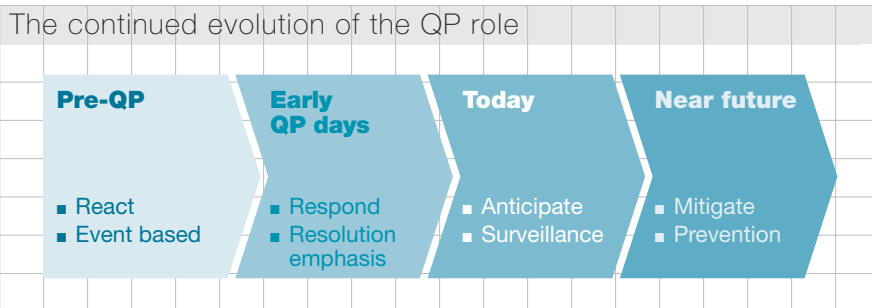
**The growing importance of the QP**

This focus on implementation and effectiveness of risk management actions emphasises the need for the QP to be able to influence functions which have an impact on these actions, which need to be included in defining how the risk minimisation actions will be executed. The QP, in being able to execute the requirements of Volume 9a needs to have the following key attributes:

- influence networks to ensure that the plans are being implemented and tracked
- ensure effective interventions to achieve safety objectives for products
- guarantee agreed actions are carried out by relevant functions

**What next?**

The earlier in the development cycle that potential safety concerns are formalised, the better; enabling the PV organisation to plan for future risk minimisation activities and take early actions to mitigate them before they happen. We see the future expectations of the QP's role focusing on proactive safety. This will require processes in place to ensure visibility of current safety risks across the Product Lifecycle. We believe there will be an expectation to show a success rate in predicting potential safety risks and



“we balance performance and compliance, enabling our clients to be more effective and efficient in drug safety”

“we have defined the future of drug safety and how to get there”

“we understand the evolution of the QP role”

How to be a good QP: Keeping up with the evolution of the QP role



showing that they are mitigated (preferably before a launch or a change in indication or patient population).

**The QP Model for Success**

To rise to the challenge, many factors need to be considered. WCI’s “Model for Success” brings these together to ease the planning and execution of the role.

**Expanding role requires new capabilities**

Being able to achieve these levels of proactive risk management will require the QP to have a much broader reach and interpersonal skills. This requires the appropriate level of involvement and influence on the development of new products, and being able to establish Safety Risk Management as a factor in decision-making to ensure that these needs are adequately incorporated into both planning and budgeting. Achieving this will require early and sustained involvement in development decision-making processes, and a governance structure that ensures the QP is informed and can escalate where necessary to the senior management e.g. Chief Medical Officer or Safety Board. These levels of influence must also reach into in-licensing processes, where the QP requires oversight to ensure safety or operational risks are adequately controlled.

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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)