



# The Cost of Quality

Nicky Dodsworth and Sherri Hubby at Premier Research Group Ltd explain how, as pharma companies and CROs take action to tighten their processes, quality is often the first area to be cut for high utilisation of non-billable activities

In the clinical trial industry, we are all aware of applying best practice considerations and their effects on overall timelines, cost effectiveness and quality. However, the three are not synonymous and sometimes compromise is required. Stakeholders within the companies frequently view quality assurance (QA) as an overhead or a 'nice to have'. But those of us who have worked in QA are aware of the impact on the organisation if quality is not taken seriously. We work in an increasingly regulated industry where we endeavour to maintain compliance. Without quality, the cost to the organisation can be enormous; this can include the risk of regulatory non-compliance, legal issues, disgrace or reputation, and the possible associated financial and business continuity risks. In today's volatile environment with the increasing struggle for survival, QA must take a more active role, adding extra value to our organisations.

has been a very time consuming, costly and often repetitive process for all concerned. Until recently it was believed that no alternative to this way of working could be realistically achieved.

## THE FUTURE ROLE OF QA

Undoubtedly, some of the responsibilities of the QA group will remain the same. The role of QA in ensuring the organisation is 'inspection ready' – the oversight and assurance to senior management that the organisation is performing as it should, without any unwelcome surprises – is still going to be a key requirement. However, the way that QA performs these tasks will need to be reassessed in order to provide added value to the organisation.

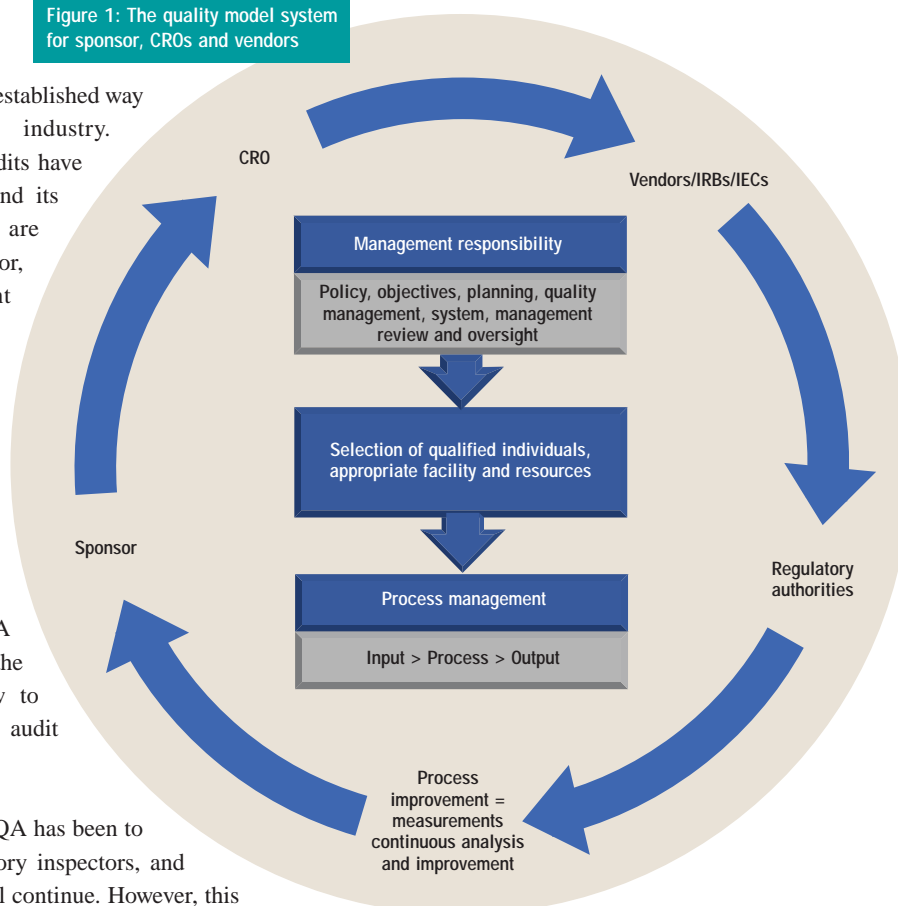
## THE ROLE OF QA IN THE PAST

First, it may be useful to look at the established way QA has worked within the industry. Traditionally, many face-to-face audits have been conducted involving travel and its associated costs. While these are interesting and exciting to the auditor, and can provide important information, the costs in both time and money spent needs to be considered against the benefits to an organisation.

QA has and will continue to operate in an independent way; however, the role of QA, which historically may have been isolated, should be addressed in the future. QA has tended to be more 'reactive' to the needs of the organisation in how to assess and respond to issues and audit findings.

One of the significant functions of QA has been to interface with auditors and regulatory inspectors, and this is undoubtedly a role which will continue. However, this

Figure 1: The quality model system for sponsor, CROs and vendors



The current economic impact requires a more proactive approach from QA, looking at reaching more people within the company in terms of time, cost and overall QA exposure. This means that QA involvement within a company should start at the lowest level possible, such as being involved in study start-ups, process improvement committees, and encouraging early reporting of non-compliance issues to ensure processes are in place before the issue rises in criticality.

Many routine audits can be performed ‘virtually’ where data can be reviewed remotely through the use of newer technologies such as video conferencing, eCRFs and eTMFs. There will still be the need for some face-to-face audits, for example in the case of ‘for cause’ audits and initial process audits, where in-person interviews often play a key step to establishing rapport and getting to the root cause of issues.

Another major role of QA that has undergone an evolution is the way training is rolled out within organisations; especially with the considerations of many companies that have a global presence in the market place. Instead of travelling to specific locations, training presentations can be recorded and implemented through web conferencing and documentation of training can be maintained in electronic training systems. This method is extremely effective when presenting lessons learned on past quality issues, and offers the ability to address questions via live chat sessions with all participants.

We are now starting to experience joint audits and regulatory inspections. EMA-FDA inspections have recently started and this approach will probably lead to other inspectorates conducting similar inspections. Several sponsor companies who have affiliate companies are also starting to conduct joint audits of their vendors. These are positive methods and will not only lead to a more standardised attitude, but will be a time- and cost-effective way of conducting these vital assessments.

Another growing trend is the conduct of office or affiliate company audits and questionnaires. These are driving forces to aid with standardisation across the whole group. Recently acquired companies need to be harmonised and integrated into the organisation within specific timeframes while causing minimum disruption to services.

### IMPLEMENTING A PROACTIVE QUALITY SOLUTION APPROACH

One trend that can provide upfront information on the quality of the organisation is to complete assessment

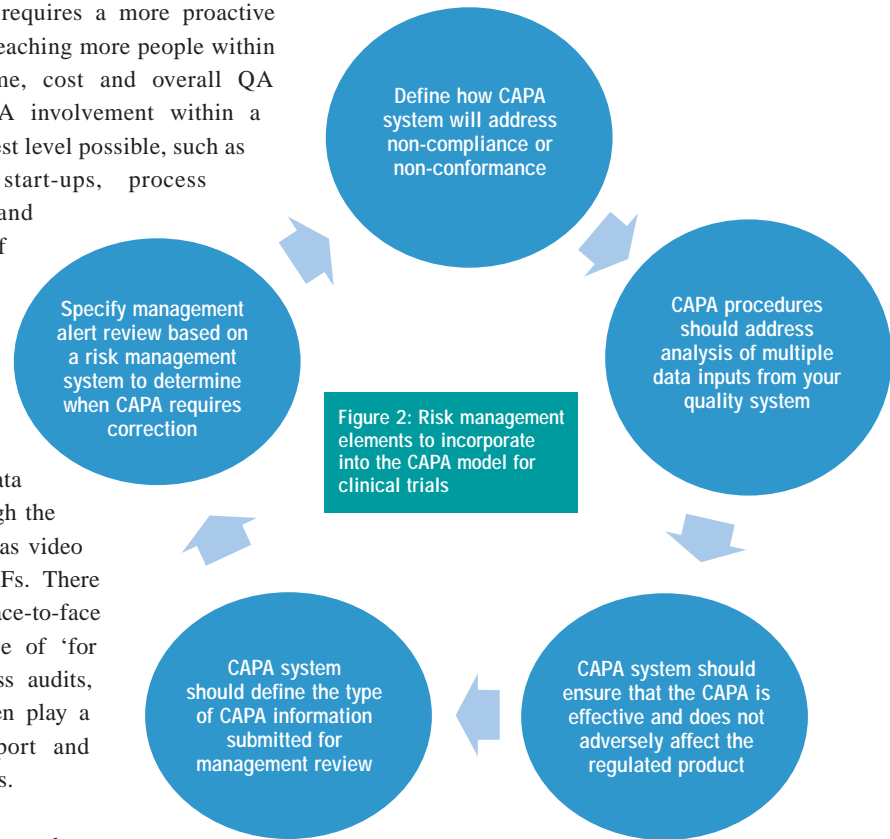


Figure 2: Risk management elements to incorporate into the CAPA model for clinical trials

questionnaires as the initial point of determining whether appropriate quality assurance and quality controls are in place to give you confidence in using a vendor. These assessments normally contain ‘trigger-point’ questions. Questions that are answered with a ‘no’ or ‘not applicable’ should be further probed as this may indicate that a particular process in place could be an indicator of potential issues or limited capabilities.

QA has traditionally been involved in vendor selection and assessment, but another ‘value enhanced’ role is to involve QA in the longer-term oversight. The standard two-yearly audits can be waived by involving QA in ongoing assessments. Working with operations to ‘weed out’ poorly performing vendors early in a process is advantageous. Equally, to be able to work with a few key vendors who consistently perform well will benefit everyone.

We can also learn from the FDA model used for premarket application (PMA) review and apply this internally to our own quality system as well as managing risk for medicinal product use (1,2). Applying the FDA model to the continuous process improvement and ISO standards, we can see that in order to have a successful quality model, open and early dialogue is required between all involved parties, from the sponsor/CRO designee and vendors that are delegated work, to the ethics committee and regulatory authorities (see Figure 1) (1).

In addition, FDA’s Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff could be incorporated into an internal corrective

and preventative action (CAPA) model for all clinical trials (see Figure 2) (2).

## CONCLUSION

QA has a unique role of seeing the 'bigger picture' and being able to analyse issues for any major repercussions across the organisation. QA requires a high level of visibility within the organisation to make an impact on processes, efficiencies and quality improvement throughout the whole group. In times of change, it is good to take stock and re-think how to improve. There is an interesting future ahead as QA will play a more significant role within organisations, enhancing business process efficiency to allow businesses to meet their ever demanding objectives.

## References

1. **Managing the Risks from Medical Product Use: Creating a Risk Management Framework Report to the FDA Commissioner From the Task Force on Risk Management, US Department of Health and Human Services, Food and Drug Administration, May 1999**
2. **Quality System Information for Certain Premarket Application Reviews; Guidance for Industry and FDA Staff; US Department Of Health and Human Services, Food and Drug Administration; Center for Devices and**

Radiological Health (CDRH) in conjunction with the Center for Biologics Evaluation and Research (CBER), document issued on 3 February, 2003

## About the authors



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