

Introduction

The role of auditors can vary between different organisations. In some companies there are very large QA teams who specialise in specific types of audits and work with a small, select group of people. In other companies just one or two auditors work across the whole organisation in large multi-cultural teams. QA can also work with a range of vendors, CROs and sponsors and regularly interact with other auditors and regulatory inspectors.

QA have a high profile role within all organisations, reporting to senior management, influencing processes and strategies and as such their ability to communicate effectively and build quality connections despite all these challenges is vital.

In today's environment with the increasing struggle to both survive and achieve, QA must take a more active role in adding value to the organisation they work for. With increasing numbers of global trials and many more virtual interactions it is vitally important that QA's approach is more proactive and they maintain high level visibility. This will allow for important organisational connections to be built allowing QA to proactively be involved in key stages to avoid risk of non-compliance, legal issues or risk to reputation allowing for strong financial and business continuity.

Quality Connections

If we look at the operational teams and our suppliers/vendors they are responsible for every day ensuring that their data is of the highest quality. Employees need to be made aware of their contribution and their importance in achieving acceptable quality levels. They need to work with their management teams to define their processes/SOPs. This is an ongoing dynamic process. Operational teams need to respond positively and in a timely manner to QA, respond to CAPAs and various improvement initiatives as well as not repeating errors time after time.

Management plays a significant role by defining and implementing quality strategies working closely with QA in this process. Staff training and performance are key to clinical research success and developing their teams approach to quality through organisational structure, definition of roles and responsibilities and by providing adequate resources to conduct quality trials. They work with their teams and QA to develop SOPs and procedures to maintain the quality of the work for which they are responsible for. Management need to schedule and perform ongoing effectiveness checks to prevent stagnation in performance.

The CEO describes the quality consciousness of the organisation by working with QA and senior management to define quality objectives and top level policies and business strategies.

Finally, the quality link between and across the whole organisation is QA and the Quality Management System as listed in the Diagram below.



Communication Barriers for QA Teams

The main question to ask is 'are people really listening to QA?' With QA's significant role in the organisation and influence with senior management it is easy to understand the cautious approach to QA. People would prefer for us to leave them alone and not burden them further when they already have plenty to do. The organisation may need some persuasion to understand the beliefs, values and visions from QA. Misunderstandings need to be avoided and clarified immediately as they arise.

QA often work remotely and this can further complicate communication. Cultural diversity, the inability to observe body language and the difficulty in building a rapport can obstruct the flow of good communication.

The Key to Good Communications for QA Teams

This is our suggestion as to the 4 Cs of Good Communication:

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| CLARITY | This is usually something QA is good at! We need to be clear in what we say. Have we provided the correct information with necessary references? |
| COMPLETENESS | Or timeliness. This is QA's ability to deliver the right message on time. |
| CONFIRMATION | QA need to make sure that people have all the information they need and know how to respond to QA or address the issue they are facing. Have QA interacted with all necessary departments? |
| CONSIDERATION | It is important to keep the right people informed, but not to over burden them. It is also vital that QA listen to the organisation and interact with them proactively. |

Effective Auditor Interactions during Routine Audits

All routine audits involve a high level of interaction this is usually conducted formally between QA and the audit teams and auditees at various stages of the audit process. Initial contact is made as a formal request to audit and make available documents and personnel.

During an audit ongoing communication occurs between the auditors and the auditees and perhaps their line managers or other departments, as necessary. The scope of the audit has of course been carefully defined in the audit plan, but it may be necessary to change direction and if so this information needs to be shared with relevant people. Audits involve detailed questioning and an auditor must be able to interact and obtain information from people effectively.

Being aware of cultural differences and being polite and showing patience and understanding. The auditor needs to build a rapport and fairly quickly, but still needs to remain objective. 'Please' and 'Thank you' work well with most people.

During the closeout meeting we usually present the most critical findings first. However, there may be some good processes or well maintained documents that we can comment on. It is always good to praise someone when a job has been done well. If possible interruptions and contradictions should be avoided during the closeout meeting, by this stage the auditees should be aware of how the audit has gone and what they can expect. No one reacts well to nasty surprises.

The audit team also need to keep closely connected with periodic exchanges of information, discussions about audit progress and there may be a need to reassess work between the audit team members.

Communication is a two way process, it is not just about asking the right questions (usually short and open in format), but by showing an interest in people and listening and by putting nervous people at their ease will help the communication flow.

Directed Audits & Importance of Quality Connections

Directed audits require the utilisation of very experienced auditors to ensure 'no stone is left unturned'. This auditor is under a great deal of pressure, and it is important that they do not feel intimidated by the task.

Diplomacy, persuasion and tactful questioning which are key characteristics for all auditors are essential in order to assess the situation accurately. The difficulty faced is understanding the honest error and difference of opinion compared to concealment and intent to deceive.

Normal auditing is not aimed at the individual but the process, however, when we are looking at fraud cases the integrity of the individual is most definitely under scrutiny and therefore the auditor must always remain calm and professional.

Once we have our emotions under control, we cannot account for the actions and responses for those we are auditing.

All possible avenues need to be explored prior to the onsite auditing phase, including the 'surprise audit' which may be called for in specific situations, e.g., for sites that will not confirm an audit date or appear to be hostile or uncommunicative in setting up or discussing the audit.

During planning, discussions with study team members will also need to be more in depth when you are embarking on a directed audit. Communication has to be open, and selected members of staff and management need to be kept informed. Good communication is vital.

Once at the site, communication with suspected fraudsters will now be face to face. Very careful questioning is conducted, and responses written as they have been provided based on evidence and not opinion. Interviews are even more important than with routine audits; specific questions planned for the investigator and other staff. You need to establish what has happened directly from those involved. One auditor cannot accurately perform the interviews and fully documenting responses simultaneously, so it is common for two auditors to be needed.

It is sometimes helpful to conduct separate interviews and then compare and contrast the answers given to ferret out the truth.

Once 'evidence' has been obtained the personnel involved need to be carefully but directly challenged on the facts that have been identified. Questions need to be asked and an explanation needs to be elicited. This is perhaps the most difficult time for everybody and you should not be surprised if the staff you are questioning walk out of a room, call in a complaint regarding your interruption or unprofessionalism or you are asked to leave. This is especially relevant in cases where there is significant fraudulent data uncovered at the site. In some cases, dependent upon the extent of scientific misconduct discovered at a site, legal counsel may be present. Whatever happens, the auditor needs to remain professional and to try and maintain the flow of communication.

The close out meeting is usually a time to discuss and present your findings with openness and frankness, but this may not happen. If the evidence and questioning stage have not gone well or if you have reason to believe that the site may destroy vital evidence, then this meeting is more of a formality.

You will need to know how you will approach this meeting in advance.

Sometimes further follow up is going to be required with other study team members, statistical analysis may need to be conducted and sponsors will need to be notified (if they have not already been informed). It must be remembered that any fraud investigation needs to be conducted in such a way to protect the person making the allegations to the extent possible and the person against whom they are made. Sometimes, even with the best efforts to protect confidentiality, the site may be able to figure out who is the whistleblower by the type of questions being asked or the documentation be reviewed. If the allegations are not substantiated, or are found to be untrue, there must be a process in place to remove all details from files and restore any damage done to reputations.¹

The audit report should be written as a priority when you return from the audit to document the evidence you have obtained and the significance of these findings stressed along with any regulatory reporting requirements to the sponsor and ethics committee.²

QA Communication Techniques: Signs of Effective and Ineffective Communication

You know your communication system is effective when:

- The individual departments have defined performance metrics
- Correction of gaps results in reduction in gap between desired and actual performance matrices
- Early reporting to QA is encouraged by managers
- QA is viewed by stakeholders as more than just an independent consultation or audit for the company for risk management, governance and overall accountability.
- Stakeholders should understand that a good quality communication system protects them against outcomes (findings) that could have a negative impact for the company.
- Company voluntarily makes corrections because they see the benefits of compliance and timely preventative actions
- Company takes responsibility to determine root cause of non-compliance issues

Signs of ineffective communication include:

- Stakeholder's acknowledgement of non-compliance without addressing corrective and preventative action
- Lack of clarity in their communication to QA
- Shopping for answers in consulting with QA
- Departments providing incomplete details on issues
- Not escalating noncompliance issues to QA when discovered
- Throwing up obstacles for planned QA audits of agreed upon risk assessments for company

QA Communication Techniques: Do's and Don'ts

- Encourage open communication system for discussion of audit findings & feedback
- Report findings based on quality risk matrix, benchmarking & performance data
- Provide company training on areas of weakness, i.e., resolving audit findings, early detection of issues and reporting to QA, mock inspections & best practices sharing
- Promote/actively participate in continuous process improvement initiatives within company as open feedback mechanism for improvement
- Conduct a Gap Analysis within your company to determine where there is disconnects between perceptions (what is suppose to happen) to what actually happened (reality) to close the gaps
- Develop a risk assessment model to rank the gaps uncovered into high, medium and low priority

Helpful Hint: By determining priority, this will highlight the areas that should be investigated first. The order of priority should not preclude being able to allocate resources and attention needed to address an identified issue.

- Use of unclear communication that results in cultural barriers – language, perception, translation
- Complex organisation results in not getting to the key individuals responsible for overall decision
- Not considering the effect communication will have on management of projects, i.e. time, billable services, adequate resources
- Responding emotionally rather than based on facts
- Supplying too much information at one time
- Not asking the important follow-up questions to identify the gap which include (based on ISO 9001:2001):
 - Systematic questions
 - Management questions
 - Resource questions
 - Realisation questions
 - Analytical questions
- Not turning the identified gaps into action statements to formulate remedial action to minimize impact and facilitate resolution

Summary

Auditors need to possess excellent communication and interaction skills in order to succeed and advance in the ever changing, multi-cultural and highly regulated business of clinical research. They are required to use their extensive skills in almost every situation they encounter. Auditors must create an image of adding value to the organisation and not just being trouble shooters/inspectors. They need to possess strong listening and interpersonal skills and to a certain extent they need to be aware of body language triggered from asking specific questions which illicit unusual display of behavior; although this skill must be carefully utilised.

The importance of having the right people and the processes to be successful requires a successful quality connection. Without this, people and processes are not aligned. QA can add valuable contributions to aid the success of the organisation. The QA team can be seen as a link or a bridge across the organisation in the way they relate to and work with operational teams, management and the top decision makers.

References

- Barrett J. *Conduct of an inquiry into alleged misconduct. Fraud and Misconduct in Biomedical Research*, 4th Edition, 16: 260-273.
- Horne B, Dodsworth N., *Fraud and Misconduct, Quassar*, September 2011.