

To have or not to have an Internal Quality Assurance Program?

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This is probably the question that every QA Manager has to answer daily.

Characteristics of quality include accuracy, immediacy, legibility, durability, attributable, integrity, consistency, and transparency. To achieve quality, established processes must be implemented to standardize methods and to document results of task completion. Strict requirements have been imposed by the Regulatory Authorities on the pharmaceutical industry to ensure that the safety and rights of the subject and the quality of the clinical data are not compromised.

Implementation of an internal QA program provides structure for CRO activities to comply with the requirements. Regular internal auditing ensures compliance to the industry and study specific requirements and assesses the study team's qualifications.

An often overlooked aspect in the implementation process is the active participation of a third party. The third party acts as an objective observer to audit the QA program to ensure compliance with its established processes and that it remains current with the evolving industry requirements.

Key elements in establishing the QA Program infrastructure includes implementation of:

- A master plan describing the program's objectives, scope and infrastructure
- Written procedures in compliance with the applicable industry requirements
- Change control program
- An assessment and training program for employees
- Quality controls based on risk assessment
- Documentation
- Traceability
- Auditing

- Preventive and corrective actions program
- A third party auditor

Like other major organizational changes, the biggest challenges in implementing a QA program would be convincing the employees to become active participants of the change and to ensure that management facilitates the change. Employees may find that participating in the development of and following procedures, attending training sessions, and documenting activities, to be time consuming. Management may regard the implementation of the program as an added expense without the ability to produce a profit. These attitudes could negatively impact the efficiency of the program's implementation and jeopardize its success. This process requires team effort and everyone within the company should recognize its importance.

An additional challenge may be related to the expectations of clients who must realize and accept the additional costs and time required to implement and execute the QA process for projects. The clients must become aware of the QA requirements and accept its importance for the success of their projects.

A proven Quality Assurance program is the guarantee that both the Regulatory Authorities and the clients are looking for when assessing the activities of a CRO. Maintaining an excellent Quality Assurance is a strong statement of a company to demonstrate its commitment to deliver nothing less than quality service.

About the Author:

Marianna Boukas is a graduate of McGill University and recently earned a Certificate in Technical Communication from Concordia University. Her many years of experience in the medical milieu and in academic and pharmaceutical research has evolved into quality assurance. Currently she is the Director of Quality Assurance at JSS Medical Research. Under the tutelage and supervision of compliance specialists she is leading the implementation of the Quality Assurance Program. The compliance specialists audit the JSS Quality Program regularly as an objective third party to ensure compliance.