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Pre-Qualification and Study-Directed Audits: Differences and Similarities

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Introduction

Many Quality Assurance professionals are involved in either conducting and / or hosting a variety of audits, including pre-qualification and study or project directed audits. Although auditing techniques are generally the same for both types of audits, the scope of the audit may differ depending on if it is a pre-qualification or a study directed audit. There are many other types of audits as well, including for cause audits (i.e. when an audit team assesses potential sources for quality issues), pre-approval inspection (PAI) audits, and quality system audits. However, this article specifically discusses the differences between pre-qualification and study directed audits.

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Pre-Qualification Facility Audit

Performing a pre-qualification facility audit of a prospective vendor, serves several purposes. An onsite audit provides the auditor with the opportunity: 1) to determine whether the facility has quality systems in place required by the applicable regulations; 2) to evaluate whether those systems are adequate; 3) to gain an understanding of the capabilities of the organization and how the facility operates; and 4) to assess overall compliance of the facility to their approved standard operating procedures. The main aim of this type of audit is to determine, with a high degree of confidence, whether the vendor has the capability to provide compliant services and quality data should the vendor's services be retained.

Areas to assess during a pre-qualification facility audit typically include employee training and qualifications, equipment/instrument qualification, calibration and maintenance, computer system validation and change control, information technology procedures such as data backup and logical security, facility maintenance and security, document control, and procedures of the quality assurance unit. Depending on the services the vendor will provide, additional areas may be audited such as the procedures for the bioanalytical department (e.g. method validation and incurred re-analysis). Study or project documentation is not available during a pre-qualification audit. Therefore, study records to demonstrate that some of the procedures, no matter how well they are written, are actually being followed typically will not be available for review due to sponsor confidentiality.

One of the challenges of the pre-qualification audit is the fact that the auditor has a lot of ground to cover in a limited period of time – typically one or two days. The approach used during the audit varies from auditor to auditor, but commonly includes a facility tour, interview with the vendor's staff, review of SOPs and inspection of facility records. The table below shows examples of areas typically inspected, the types of questions an auditor may ask about those areas, and the types of records one may request to confirm that the vendor's SOPs are being followed.

EXAMPLES		
Areas to Audit	**Questions to Ask**	**Records to Inspect**
Employee training	• Does each employee have a job description? • Does each employee have a current CV? • Is there a training matrix? • How is employee competency tested and documented?	Select a couple of employee names from the organizational chart and request their training records.
Equipment / Instrumentation	• How is equipment qualified? • What is the frequency of calibrations/ preventative maintenance? • How is routine and non-routine maintenance documented?	Select a couple of equipment during the lab tour or from an equipment list and request their maintenance record.
Computer Systems	• Are computerized systems used to create, modify and maintain data? Are these systems validated? • What is the validation process? • What is the change control process once the system is validated?	Request the validation documentation and change control for the validated system.

Study-Directed Audits

By contrast, study directed audits have a very different purpose from pre-qualification audits. The main goals of the study directed audit are: 1) to determine whether the study protocol and applicable facility SOPs were followed during the course of the study; 2) to evaluate whether the raw data provides sufficient information to reconstruct the study; and 3) to assess whether the report accurately reflects the raw data.

Again, the auditor needs to use their time effectively in order to achieve the objectives of the audit during the allotted time. A study directed audit is not a repeat of the pre-qualification audit, although some of the areas assessed during a pre-qualification audit may be re-assessed during the time period when the study was conducted, particularly if issues were previously identified during the pre-qualification audit. However, many of the activities performed during the facility audit are not relevant to the study audit and should not be repeated. For instance, it is not necessary to repeat the facility tour or evaluate the validation process for computerized systems, unless changes have been made to the system.

Having said that, keep in mind that there is some overlap between facility and study audits, but the focus is slightly different. Many auditors "follow the sample" during a study audit. Using this approach, one looks at everything the sample "touches" such as the sample receipt, storage and tracking process, instruments and equipment used during the sample preparation/extraction procedure, reagents and solutions used during sample analysis, and reporting of sample results. Using this strategy, instead of asking to see the validation package for the environmental monitoring system which was reviewed during the pre-qualification audit, the auditor may ask to see the calibration certificate for the temperature sensor used to monitor the temperature in the unit where the samples were stored and the temperature record for that unit to ascertain that samples were stored properly. The table below provides additional examples of facility records which may be requested during the audit.

EXAMPLES OF FACILITY RECORDS TO INSPECT DURING A STUDY DIRECTED AUDIT
• Training for the individual who performed the work • Calibration / preventative records for equipment used • Temperature records for units where samples were stored • Reference standard receipt, tracking and storage

The approach used during the study directed audit may include discussions with the responsible scientist, interviews with other scientists who participated in the study, review of the study records to verify compliance with protocol and applicable SOPs, and review of supporting facility records.

Conclusions

In conclusion, techniques for pre-qualification and study audits may be similar, but the focus of the audits is entirely different. Another common element to both types of audits is that effective time management techniques must be employed to assure adequate assessment of the relevant topics to be covered during the audit. Properly identifying the audit scope and focusing the audit on the appropriate topics is a key to efficient use of time and assuring critical areas of concern are adequately addressed.

The Program Committee is looking for volunteers to participate in the meetings and brainstorming sessions for new training-networking ideas relevant to current regulatory guidelines. This would be a conference call and/or helping to put the training sessions together. If you have a knack for event planning this is a perfect group for you. If you are interested in speaking or know of someone that would like to present for the group please contact Manish at the e-mail listed below.

Please Contact: Manish Ranjiktar at vp@nercsqa.org

NERCSQA Mission Statement:

"To serve as a focal point for Quality Assurance "GXP" professionals in the New England Region by establishing a forum for education, training, communication and information exchange among QA professionals in the environmental, pharmaceutical and biotechnology fields of government, private industry, research and academia."

Ging Lee Scholarship

This scholarship is to recognize an individual that has contributed to NERCSQA and to the Quality Assurance profession in general. The scholarship will be used to enhance the education or quality interests of the recipient. The scholarship amount is $2000.00 to be used for attending a national or regional chapter meeting of SQA. Meeting cost, travel, and accommodations are covered it does not include meals or other incidentals. The link for the policy on the scholarship is below.

Ging Lee Memorial Scholarship

Upcoming Training in October: tentative 2 day schedule with GCP training and FDA (former) FDA speaker on current issues.

AH THE GOOD OLE' SUMMERTIME

28th SQI Annual Quality Meeting & College

22 - 27 APRIL 2012

BALANCING THE PAST, PRESENT AND FUTURE

28th SQA Annual Meeting and Quality College

Sunday - Friday, 22 - 27 April 2012

Miami Hyatt Regency

Miami, Florida, USA

Quality College will be held Sunday - Monday, 22 - 23 April 2012 and Friday, 27 April 2012, consisting of full-day and half-day workshops.

The Annual Meeting will be held Tuesday – Thursday, 24 - 26 April 2012. Three days of plenary and concurrent sessions will explore hot topics and the latest regulatory interpretations in the field. Sessions will focus on regulatory-based topics in manufacturing (GMPs), preclinical (GLPs) and clinical (GCPs) research arenas. Other areas of interest include animal health, bioanalysis, biotechnology, computer validation, medical devices, scientific archiving, university issues and much more.