Risk-Based Auditing

ClinAudits LLC

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Background

Effective auditing of clinical, manufacturing and laboratory processes, systems, and practices is imperative as it ensures not only that quality standards are met, but that the requirements for human safety are upheld. The use of risk- based auditing maintains these same objectives while making the auditing process more efficient and effective.

In recent years, the need for risk-based auditing has become apparent. The FDA has concluded that modern quality systems coupled with effective risk management practices mitigates potential risks, resulting in shorter and fewer FDA inspections (1).

As the need to manage risks within the pharmaceutical, biotechnology, tissue engineering and medical device industries increase, it places pressure on these industries to identify the areas that pose the greatest risks.

Managing risks through risk-based auditing plays a central role in maintaining the integrity of the auditing process by allowing for higher quality audits in a shorter period of time. ClinAudits believes that risk-based auditing complements its mission of providing high quality compliance auditing.

What is Risk-Based Auditing?

Risks are defined as circumstances that threaten organizational objectives. Internal processes can manage these risks.

Risk-based auditing (RBA) evaluates risk factors relating to internal processes to determine whether these internal processes are managing risk at acceptable levels. This approach seeks to improve the quality and effectiveness of audits by determining the areas of risk requiring attention. These areas include data that are most significant to the organization, concentrating on the objectives rather than the controls. The emphasis is placed on the synergies of the overall systems in addition to the individual systems in place.

The auditor, when conducting an audit, is responsible for understanding the entity and its environment to appropriately identify and assess risks. Once these are established, the auditor can respond to the identified risk and determine if current processes sufficiently manage risk.

(1) "Guidance for Industry: Quality Systems Approach to Pharmaceutical cGMP Regulations." *Food and Drug Administration*. September 2006. Web. Retrieved March 2016 at http://www.fda.gov/

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Risk-Based Auditing Versus Traditional Compliance-based Auditing

Risk-based auditing and traditional compliance-based auditing are both necessary auditing approaches that serve different purposes.

Risk-Based Auditing	Traditional Compliance-Based Auditing
Evaluates risks	Evaluates compliance
Identifies risks associated with achieving quality objectives	Identifies breaches of procedural adherence
Identifies operational inefficiencies leading to higher risks	Identifies noncompliance with governmental authority regulations
Proactive	Reactive

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Risk-Based Auditing Versus Traditional Compliance-based Auditing

Traditional Compliance-Based Auditing

Traditional compliance-based auditing (TCBA) is a documentation review to ensure that controls and procedures meet governmental authority requirements, in addition to providing assurance that activities have been performed properly. TCBA is a gap analysis between the governmental authority requirements and operational procedures. Any non-compliant results afford the company the opportunity to rectify their procedures.

Significant drawbacks of TCBA are that it does not challenge the rules, and it provides little to no room for judgment. While traditional auditing ensures SOPs are compliant with governmental authority regulations, it does not necessarily mean that the SOPs are effective.

Risk-Based Auditing

Risk-based auditing is a progressive approach that can be applied to any function. It focuses on higher risk activities that are of significance to the organization. By concentrating on company objectives and threats to those objectives rather than just controls, it is often more efficient than TCBA. It is also more comprehensive than TCBA by emphasizing a broader system view rather than individual system views. Furthermore, RBA identifies where accountability could be blurred, such as where interfaces between functions occur.

When and Why RBA Should Be Considered

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A range of factors should be considered prior to conducting risk based audits:

- The complexity of the risks.
- The goal or purpose of the service being audited, which can determine what risks are most relevant and the degree of severity for each risk in question.
- The geography of the service or program being audited, due to regional variations of regulatory standards.
- The level of experience of vendors and investigators.
- The level of use of information technology for document management systems, training systems, compliant systems, and the quantity of data.
- The relative safety of a drug/device, particularly considering if there is no prior experience in human clinical trials.
- The stage of the study, considering studies in later stages often have additional risks emerge during the course of the study.

RBA Across Various Audit Types

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Risk-based auditing can be applied to GMP, GCP, GLP, or GTP auditing once the areas of risk for the organization are identified and prioritized. RBA can be performed efficiently to audit some of the following audit types: clinical operations of the organization, data management, drug safety, training modules, investigator sites, and vendor/service providers within a short period of time based on priorities set forth by the client.

Preparing for Risk-Based Auditing

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In general, to prepare for an RBA audit, there is prospective identification of critical data and processes. These can include factors that threaten the quality of the drug, may pose problems in getting the drug approved by a governmental authority, the protection of human subjects, or the integrity of the data. Risk identification identifies the types of activities to be audited and the data to be collected. It also considers the range of potential risks inherent in these activities so as to best classify the overall risks in the system.

The RBA process considers the risks that apply first and foremost to the critical data and processes to ensure that these risks are sufficiently mitigated. Other ways in which risks are prioritized include the likelihood of risks occurring, the impact of such errors on quality, safety and integrity, and the extent to which such errors are detectable.

The risk assessment part of the discovery audit process results in the development of an audit plan, which specifies the risks that should be addressed by the audit and the critical parameters to be assessed. It may be decided that some risks are better managed through other activities rather than auditing, or that some areas are better serviced by traditional compliance-based auditing over RBA.

Benefits of Risk-Based Auditing

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Risk-based auditing is a proactive approach to identify serious risks that may jeopardize an organization's ability to achieve their objectives. Risk-based auditing focuses on areas of identified risks, prioritize the risk (high, medium, low) and suggest effective ways to mitigate them. Risk-based auditing also provides an opportunity for clients to identify and map out risks if they have not done so earlier. While both risk-based auditing and traditional auditing are necessary auditing approaches, risk-based auditing provides the clients several benefits that are not maximized in the traditional approach.

For risk-based auditing, auditors are required to understand both the program goals beforehand and the system environment as a whole, which allows efficient allocation and utilization of resources. With a focused agenda for auditors, risk-based auditing framework enables effective auditing within a short timeframe with strategically aligned effective deliverables for the clients going beyond compliance.

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