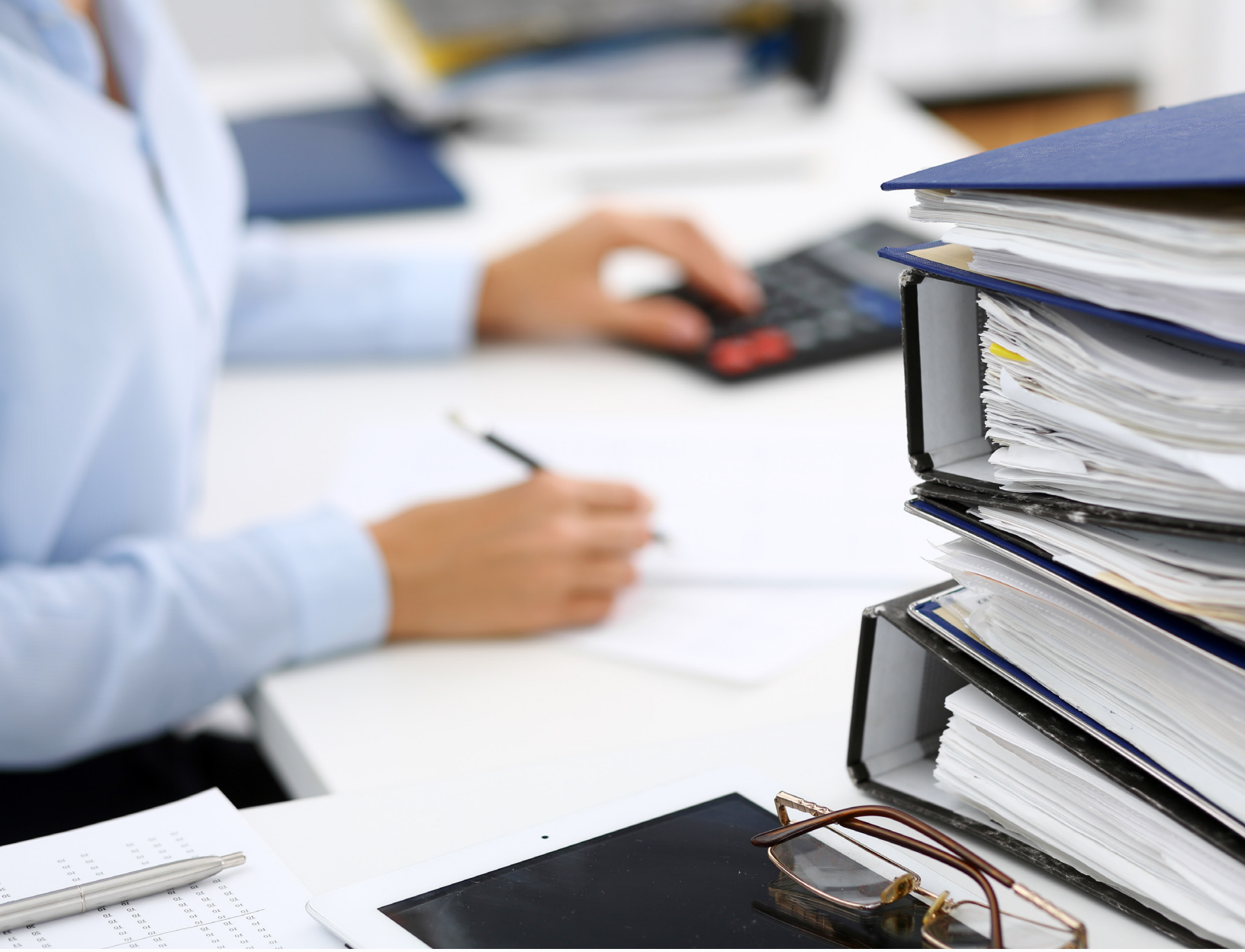

Is Your Backroom Audit Ready?

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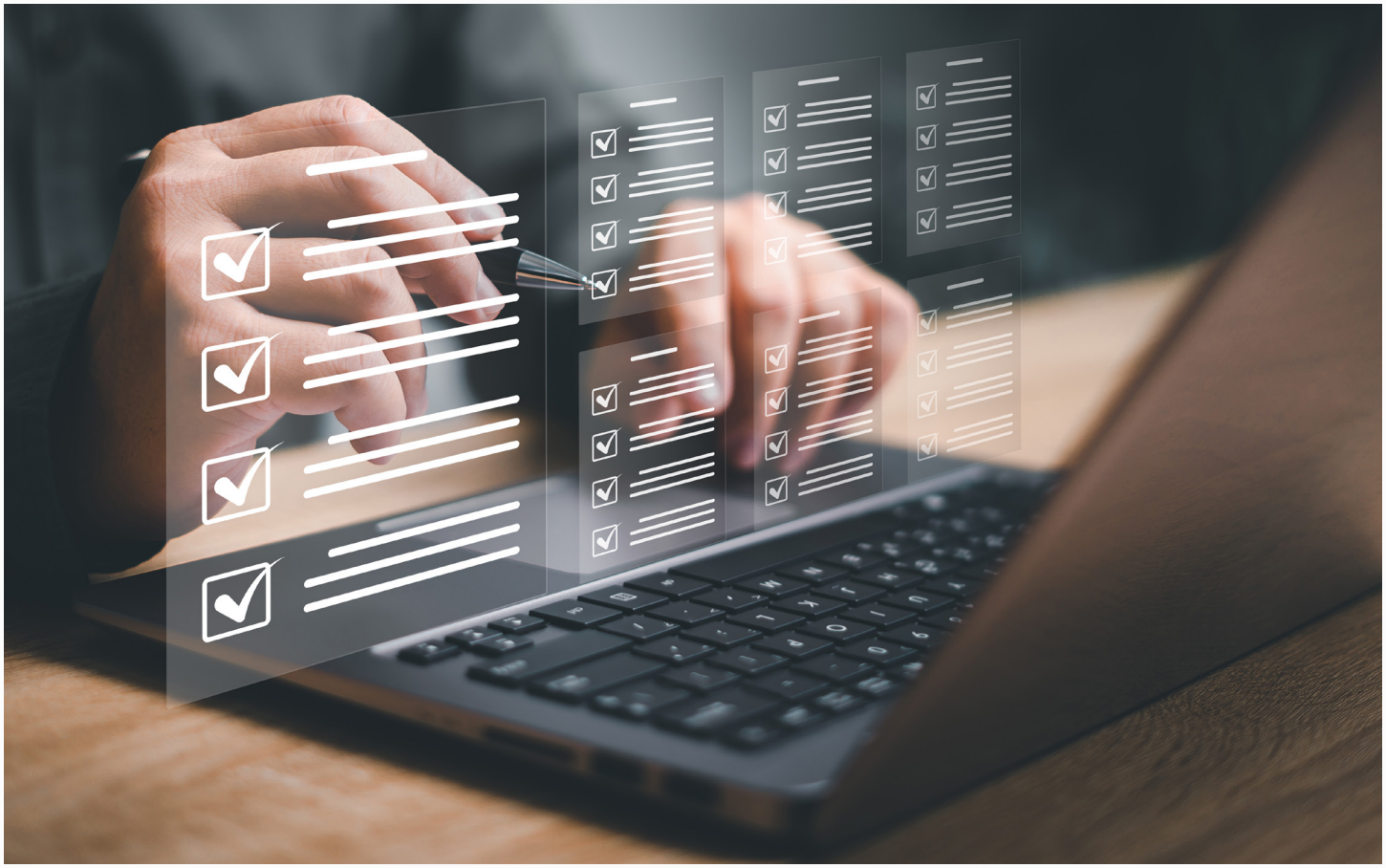
Introduction

In the life science industry, regulatory inspections can carry substantial weight and result in complications. It is important to be appropriately prepared for regulatory inspections, especially when it comes to your audit backroom, which operates behind the scenes. Having a well-established backroom can lead to a successful inspection and decrease the stress on audit participants. It is essential that audit backroom preparation is complete before a regulatory inspection and on a continuous improvement basis. This whitepaper will discuss the importance of an audit backroom, including the crucial role of subject matter experts (SMEs), management of audit requests, and the review of objective evidence before it enters the hands of an inspector (e.g., data, Investigations, SOP's, etc.).



Understanding Regulatory Inspections

Regulatory bodies, such as the Federal Drug Administration (FDA), European Medicines Agency (EMA), and others, ensure that companies in the life science industry are compliant with regulations set to ensure patient safety. To evaluate a company's adherence to the regulations and standards set, inspections are performed. Notification of a regulatory inspection can often raise concerns with the stakeholders and participants of the inspection. Prior to undergoing inspection, organizations should know what their most vulnerable areas are and have an established strategy of how to navigate and respond to questions and requests. During a regulatory inspection, a company should be proactive and not reactive. One way to be proactive is to ensure that your audit backroom is "ready" prior to an inspection.

Role of the Audit Backroom

During regulatory inspections, organizations usually utilize a “front room” and “backroom” to manage the inspection process. The front room is where direct interaction with the inspector(s) occurs, and it consists of the lead organization contact, the SMEs, a scribe (or note taker), and a regulatory specialist. The audit backroom is the operational center of a successful regulatory inspection. It operates behind the scenes and facilitates the inspection process. The audit backroom consists of quality assurance personnel, document control specialists, additional SMEs, management representatives, and compliance advisors. Responsibilities in the audit backroom should be clear, and no employee should question their role. The roles used in an audit backroom include SME preparedness, organization of audit requests, and objective evidence review.

SME Preparedness

SMEs possess a deep knowledge in a specific area relevant to the audit, usually driven by an inspection request. SME preparedness should not start with the inspection but should be part of an organization’s audit preparedness training. SMEs should receive training on the inspection process, including how auditors conduct interviews, the types of questions that may be asked, and how to respond to the inspectors. SMEs possess technical knowledge that often requires complex or technical terms. As a result, they should be prepared to explain technical aspects in layman’s terms for effective communication with the inspector(s). SMEs should also be informed and review previous audit findings related to their area of expertise.

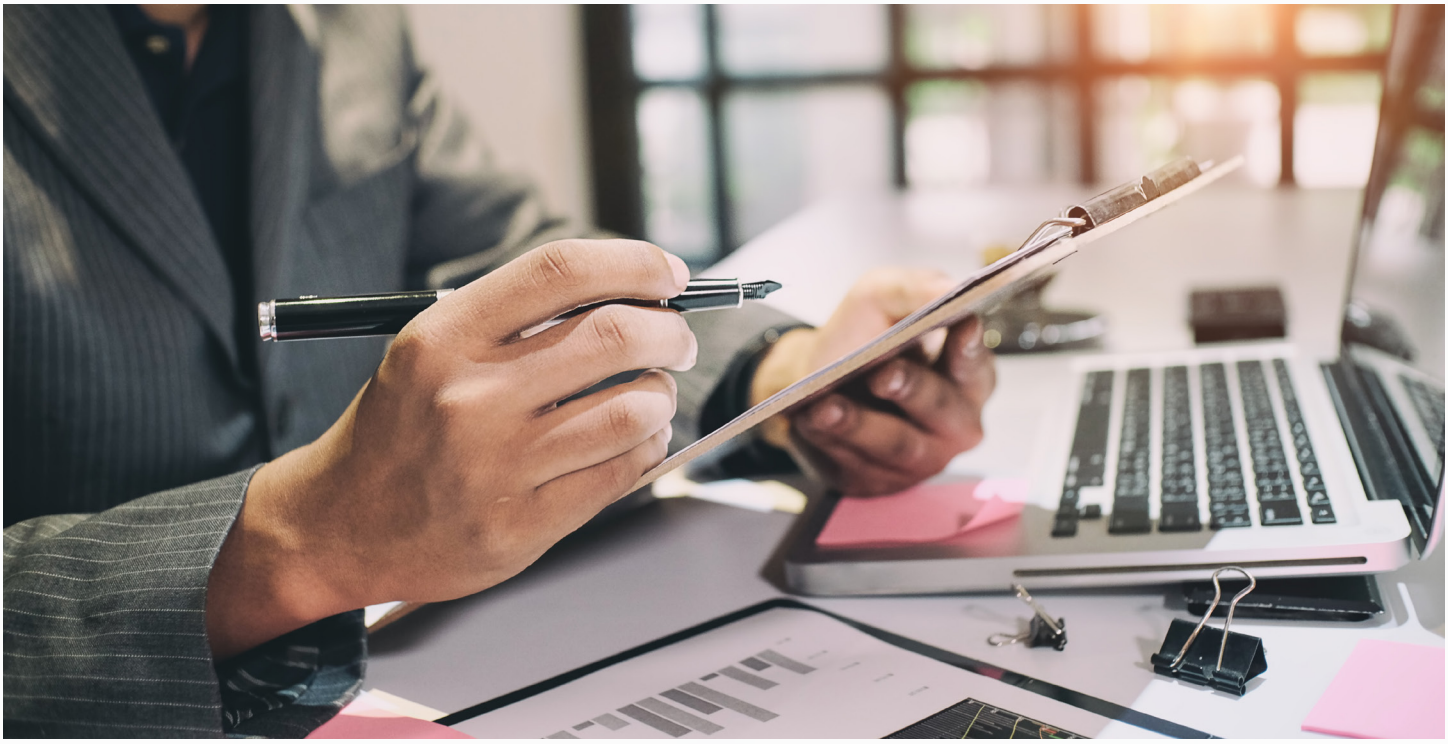
A key to a successful inspection is a trained audit team. To prepare, organizations should practice simulated interviews to mimic an inspector’s questioning. They should understand the dos and don’ts in an inspection. Conducting mock audit or interview exercises can be beneficial for SMEs who will be supporting inspection requests.

The backroom will ensure the SME understands the audit scope, objectives of the inspection, and request(s). This is to ensure the SME is aware of what the inspector is looking for so that the team can tailor their response appropriately and not offer additional or out-of-scope information to the inspector. The backroom should work with the SME to identify the key points that need to be communicated. Additionally, it’s their responsibility to make sure SMEs are prepared to handle inquiries for which they do not have immediate answers. And, of course, the backroom should state the importance of honesty with the SME and provide support and reassurance.

Organization of Audit Requests

Accuracy, efficiency, and timeliness in providing audit requests are central to backroom effectiveness. The audit backroom should be the primary contact for receiving and managing requests. A process for receiving, reviewing, and distributing these requests should be established and communicated with the audit team. Some organizations have audit management systems that allow for the tracking of audit requests (i.e., Audit Utopia, Audit360). If no audit management system is in place, a project management tool (i.e., Smartsheet) can be used to track audit requests. The audit request tracker should detail the request description, time request was received, the department or SME the request is assigned to, the due date or time, and the progress or status. Requests should be fulfilled in a timely manner. While the FDA does not necessarily set timelines, all requests should be fulfilled within a few hours. Once requests are fulfilled and ready to be presented to the inspector, there should be a process in place to ensure the information provided is accurate, complete, and meets the auditor's request.

Following submission, a process should also be in place to ensure that documents that are presented for audit requests are returned to the original location once the request is fulfilled. Often, the requests are successfully completed, but there is no system in place for the proper return of documentation. That can lead to a risk of loss or misplaced evidence.



Reviewing Objective Evidence

Objective evidence is the backbone of a regulatory inspection. All objective evidence should be meticulously organized to allow for easy access and review. A reviewer should perform an initial assessment to ensure documentation adheres to GOOD DOCUMENTATION PRACTICES (GDocP). The reviewer should check for ALCOA (attributable, legible, contemporaneous, original, and accurate). Evidence should also be reviewed to check that they are complete with no missing data or other supportive documentation. The backroom should engage an SME for evidence pertaining to their area of expertise. If issues are identified during review of the objective evidence, determine the necessary corrective action, and ensure that the correction is reviewed.

Once the review of objective evidence is completed, the audit backroom should release the evidence to be presented to the auditor. Objective evidence should be organized and labeled. Organizations should implement a labeling system that works for them, but labeling objective evidence with the audit request number and document control identifiers is a good place to start. Objective evidence should be presented to the auditor in a coherent and logical manner.

After the Audit Closeout

Once the inspection is complete, the audit team should review their processes for lessons learned and opportunities for improvement. This review can provide insights that can be used to improve future inspections. Involving SMEs and other audit participants in the review process allows for diverse perspectives, ensuring that the organization learns from the audit and takes steps toward improvement.

Conclusion

A prepared and proficient backroom yields several advantages in the life science industry. It minimizes compliance violations, alleviates inspection-related stress on the audit team and SMEs, and showcases professionalism and a commitment to compliance.

About Azzur Group

From Discovery to Delivery™, Azzur Group provides the life science community full life-cycle solutions for all of their GxP needs.

From Azzur Cleanrooms on Demand™ facilities, to our labs, training centers, and consulting offices across the nation, Azzur Group helps organizations start, scale, and sustain their growing enterprises. With nearly four decades of service to the life science community, we have become a trusted partner to the world's leading pharmaceutical, biotechnology, medical device, and healthcare companies, as well as their supply chain.

For more resources on this topic, or to learn about solutions Azzur Group provides to organizations in the life science community, visit our website.

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Eliza Deriso is a seasoned professional with a strong background in quality management and auditing. With a career spanning over a decade in both the automotive and life science industries, Eliza has amassed extensive experience in driving quality initiatives. Following a transition from the automotive sector to the life science industry, Eliza joined Azzur Group in 2021 and now leads an audit program that encompasses GMP, GLP, GCP, medical device, and mock FDA audits, among others.