

> AUDITING

Global life sciences organizations face a unique set of challenges. They must be able to assess the compliance and effectiveness of their quality systems at multiple sites and in varying cultures. Often these sites are tasked with following not only FDA requirements, but also corporate requirements and the requirements of other governments. Maetrics understands the challenges that these organizations are up against, and has developed an audit approach that is tailored to the global life sciences industry. As we begin the process, we spend time carefully identifying the primary site where audits should begin. The entire core audit team then participates in the audit of the identified site. For the remaining sites to be audited, the team can either split up individually to expedite completion of the audits, or audit in pairs. Members of our client's staff can participate on the audit team to provide a specific corporate perspective, and to gain valuable experience. Regardless of which option is taken, at least one member of the core audit team participates in each subsequent audit. All core audit team members are involved in discussions throughout the course of the audits, and participate in a comprehensive debriefing at the conclusion of each audit before a report is issued. Draft audit reports for all sites are shared with the core audit team so that observations are developed and presented in a consistent, harmonized manner. Recommendations are included in every audit report if desired by the client. At the end of each day, for all audits, a summary meeting is held by the audit team, site management and the client's lead contact. There are no surprises at the end of the audit, and no awkward situations that arise due to misunderstandings.

Our Team

Our auditors have diverse and extensive experiences in the life sciences industry, and range from former FDA investigators to individuals with over 30 years of industry experience. All of our auditors have been formally trained, and have verified expertise as auditors. Additionally, our auditors are experienced in developing and implementing remediation plans. They not only identify problems and opportunities for improvement, but also provide ideas for practical solutions. Our audit experiences include:

- Domestic and international firms
- Start-ups to multi-national corporations
- Individual processes at a single site to full system audits of multiple sites
- Solo audits to leading large audit teams

> EXAMPLE CASE STUDY #1

Initial State

A global life sciences organization has found itself out of compliance with its own requirements. The company decided its requirements were valid and needed outside assistance to complete the required supplier audits.

Objective

The first objective was to perform supplier audits for the client by order of highest risk potentials and identify key areas requiring attention. Secondly, Maetrics was to address the critical findings of these audits and provide remediation guidance. Finally, Maetrics was tasked with developing a manageable schedule for the client to maintain in performing future supplier audits.

Maetrics Engagement

Our experts have years of industry experience, and proven track records of success. The following items and tasks led to successful audits, and manageable scheduling with suppliers:

- Maetrics has now conducted over 15 audits of the key suppliers in the past year. Another 15 audits are scheduled for the next year.
- Maetrics is providing a detailed report to the supplier as well as the client.
- Maetrics provides improvement plans to some of the suppliers upon their request. These plans discuss the specific audit findings from a global perspective to demonstrate how compliance can be achieved in a lean business environment.
- Maetrics was able to leverage web 2.0 technologies to facilitate a major project to remove a “Ship Hold” for one key supplier.

Results

Supplier audits are now entirely outsourced to Maetrics. It is our responsibility to schedule and audit a specified list of suppliers, and provide status reports and schedules to the client on a monthly basis. By utilizing the Maetrics team to efficiently manage supplier audits on an ongoing basis, this organization was able to reduce the number of full-time employees dedicated to supplier audits while still successfully managing the schedule and success of supplier audits in a cost-effective manner.

> Example Case Study #2

Initial State

An industry leader spent many months in remediation after a warning letter was issued. They expected a return visit from the FDA within two months.

Objective

The client requested an outside opinion with regard to their new compliance level.

Maetrics Engagement

Maetrics has several ex-FDA inspectors on staff to assist with the concerns the customer was faced with.

- A “mock-FDA” audit was performed based on the QSIT approach.
- When needed, training was provided on the subject of how to answer probable questions from the FDA.
- A detailed list of current gaps was created, prioritized by risk.
- Maetrics helped close current gaps uncovered during the “mock-FDA” audit.

Results

The customer’s next inspection was successful and several new products were approved once the warning letter status was removed. The actual inspection followed the same path as the “mock-audit”; however, there were no longer gaps in the system.