Preparation for Hosting a Third Party Audit

Note: This White Paper focuses some of the successful strategies used to prepare for and host a Third Party Audit for manufacturing based organizations. For the context of this Paper, the term 'Third Party' refers to an independent entity, such as a Notified Body, typically under representation of a Registrar when seeking ISO 9001 or ISO 13485 certification.

Terms used in this document:

Auditor(s) – refers to the third-party audit team that will perform the audit on-site at a particular company.

Audit Team – refers to the team assembled internally that will host the audit; put together by the company receiving the audit.

GAP-MAP – refers to a mapping of a gap analysis, typically in spreadsheet format that provides a measure of general compliance to a standard or set of standards. Not to be confused with a formal audit, which is more in-depth and usually scripted via an audit checklist.

INTRODUCTION

Developing a strategy to prepare for and successfully host a third-party audit has become a critically important aspect of for manufacturing companies' commercial success. The implications of a negative audit outcome to a company's ability to market and sell product have become more acute in recent years. Efforts to measure adherence to compliance have been considerably increased by Notified Bodies and their corresponding Regulatory Agencies. This increased scrutiny calls for improved audit preparation and execution for host companies. The following is a non-exhaustive list of items that can be used to improve audit outcomes. This list is honed from years of experience hosting and performing audits, with keen observation as to what have become the best strategies to prepare for and host audits.

High priority items to consider:

1. Develop a GAP-MAP
2. Assess internal compliance against the GAP-MAP
3. Prioritize the GAPs (based on risk)
4. Execute on the GAP-MAP Plan

5. Prepare a Front Room / Back Room system
6. Select your Audit Team
7. Train the Team & Employees
8. Perform a Mock Inspection

Following these strategies provides a good foundation for a strong preparation effort prior to any audit. These steps can further be enhanced with specific auditor reconnaissance and preparations based on the individual nature of the audit and the auditors.

GAP-MAP (STEPS 1 THROUGH 4)

A GAP-MAP is a great way to get a general assessment of a company's internal compliance to specific standards. A typical GAP-MAP will have columns with sections for:

1) the Standard and its elements,
2) the document number by which compliance is verified against the standard,
3) the process owner
4) the state of approval for the referenced document
5) details on the contents of the referenced document
6) the relative risk of the referenced document that it IS NOT in compliance and
7) key element of the Standard by which the referenced document is not in compliance.

Note that it is critically important to known which standard (and which version) will be used during the audit. Ask the auditors well in advance of the audit. The standard, in this example is 21 CFR 211&211, for current good manufacturing processes for Pharmaceutical product, which is listed by Section and Subsection in the spreadsheet rows. Across the top are columns to enter relevant data, such as the referenced documents, what state that document is under (e.g. draft, approved, etc.), description of the evidence of compliance, risk assessment if there is a lack of compliance and any further references required.

21CFR210/211	Elements	Document No.	Process Owner	Doc. Status P=planned, D=Draft, A=Approved, I=Implemented				What/How Many/Detail Default Statement: MC_____, Client_____	Risks and Opportunities (Priority)	References/Regulatory Status (FDA, Data, EU?)
				P	D	A	I		Green=Low Risk; Yellow=Medium Risk; Red=High Risk	
210.1	Status of current good manufacturing practice regulations.									
c										
210										
1	Sec. 210.1 Status of current good manufacturing practice regulations.									
2	Sec. 210.2 Applicability of current good manufacturing practice regulations.									

Figure 1: GAP-MAP Headers

Multiple sheets of a GAP-MAP many be needed if the audit encompasses more than one standard. As an example, if a Medical Device company is audited by a Notified Body for ISO 13485:2012 compliance and is also being assessed against FDA's Quality System Regulation, then there would be two tabs on the spreadsheet (one for ISO 13485 and one for 21 CFR 820). Note that there is often overlap from multiple standards, which would be noted in the comments section and cross-referenced to avoid duplicate efforts.

The GAP-MAP process goes row by row down the list and assess the general level of compliance for each Section and Sub-Section, as evidences by policies and procedures documented in Quality Manuals, SOPs, Form, Work Instructions, etc. The GAP-MAP also serves as a great tool for inventorying the state of all Quality Management System (QMS) related SOPs and documents, and can help the Audit Team become more aware of these documents and their current state. Note that a GAP-MAP generally focuses its assessment around the QMS, and as such, does not thoroughly check Manufacturing and QC processes, facilities, equipment and utilities, all of which are common inspection subjects during a third-party audit. See the Section on Mock Inspections for this type of preparedness.

The key element to the GAP-MAP is the risk assessment component. This serves as a prioritization of the gaps (non-compliances) found during the exercise. High-risk gaps are clearly the most important to rectify before an audit. Given enough time, all risks should be addressed (or at least acknowledged and understood) prior to the audit. This part of the GAP-MAP then serves as the action plan for rectifying shortcomings.

AUDIT PREPARATION (STEPS 5 THROUGH 8)

After a GAP-MAP assessment and action plan have been executed, focus should shift to audit team preparation. A well-selected and focused team will contribute enormously to the success of the actual audit. The auditors will also appreciate these efforts, as it makes their jobs easier from an organization standpoint.

You should start with consideration of the logistics of how the audit will be performed. It is recommended to use a Front Room / Back Room approach, where a conference room is typically utilized for the Front Room (the location that will be used for the Opening Meeting, Document Review and Closing Meeting), and the Document Control Area/Room is typically used as the Back Room (the location that documents are prepared and sent to the Front Room).

The Back Room can also serve as the “War Room”, where the audit team and executives can get up-to-the-minute feedback and make strategic/tactical decisions on based on audit progress.

The Front Room is typically closed to all other employee entry, with the exception of the designated team members that are directly working with the auditors at that moment. Requested documents (and copies for the company) are generated, checked and presented to the auditors promptly and without issue via the Back Room. Note that producing documents during the audit should be practiced and tested prior to the audit, with consideration as to how the documents are to be presented (e.g. electronically, printed hard copy or originals).

The next consideration is the evaluation and selection of the audit team. Typical established roles for this team are; Audit Lead, Escort, Secretary, Back Room Manager & Subject Matter Experts. The overall preparation, coordination and logistics prior to and during the audit is the responsibility of the Audit Lead. The Escort (which can sometimes be the same person as the Audit Lead), stays with the auditors at all times of the audit and must be technically familiar with the areas being audited. Note that auditors with multiple team members may require several Escorts as they view different areas at the same time.

The Back Room Manager must be familiar with the documentation system and be able to rapidly produce documents when they are requested. Note that an inspection binder prepared prior to the audit with pre-printed documents addressing commonly inspected/viewed areas and pre-requested documents will save considerable time and stress. The Secretary acts as the scribe. This person must take notes in an unbiased, unvarnished manner. The Secretary must also have broad understanding of the overall business/process of the company to properly context the notes. Subject Matter Experts are chosen based on their overall and detailed knowledge of their Departments. For examples, The Head of QC, QA, Manufacturing/Operations, and Warehousing should all be prepared and knowledgeable prior to the inspection and be ready for walk- throughs of their respective areas.

Training and preparing of the entire audit team on proper behaviors and expectations is a critical component of audit success. This cannot be over-emphasized, since human behavior is one of the most uncontrollable aspects of an audit. This includes the auditors, with their own agendas, biases and hot-button topics. Reducing the variability of behaviors and responses within the audit team at least provides some measure of control to this process.

It is highly recommended to have the audit team participate in a course on inspection behavior prior to the audit. It is also imperative to train the entire company staff on

expectations, general audit processes, and following the instructions of the audit team when in front of the auditors. Again, a general course (abbreviated) for staff on audit behavior is highly recommended.

Finally, a Mock Audit is a great way to get company staff and the audit team ready and rehearsed for the actual audit. Consider this a dry run; there will be issues. Audit logistics will be problematic. Compliance concerns will be raised. Behavioral/response issues will be discovered, from both the audit team and the general staff. This is normal. It is also far better to discover these issues *prior* to the actual audit than *during* the audit. The Mock Audit also is an opportunity to check/assess compliance of the physicals areas that will be audits (e.g. processes, equipment, facilities, QC labs and warehouses).

SUMMARY

Focused preparation is the key to audit success. Understand and acknowledge your gaps (via a GAP-MAP). Address and rectify those gaps as much as can prior to the audit.

Carefully select and prepare the audit team. Practice the audit logistics and personnel behaviors with a mock audit.

These steps have been shown to dramatically improve the outcomes of any type of audit. There is no such thing as too much preparation.

About the Author: *Peter Knauer serves as a Senior Compliance Advisor to Biotechnology and Medical Device companies. Peter has twenty-five years of experience in Regulatory/Quality Compliance, Product Development and Operations. Peter has lead nine successful NDA/BLA approvals, and multiple 510(k) medical device clearances. Previously, Peter served as COO, Vice President and Head of QA/RA/CMC for companies such as Symic Biomedical, BioUtah and British Technology Group (BTG) in the United Kingdom. He has also held leadership positions for Protherics UK Limited and MacroMed in Salt Lake City, UT. Peter started his career at Genentech, Inc. where he held numerous positions in pharmaceutical engineering and drug delivery management. Peter holds a Master's Degree in Mechanical Engineering from San Francisco State University and a Bachelor's Degree in Materials Science Engineering from the University of Utah.*