



BUL 1045

# Preparing for a Third-Party Audit in Food Manufacturing

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## Introduction

THERE ARE MANY DIFFERENT TYPES of third-party audits in the food industry (Verburg-Hamlett 2021). Regulatory audits (carried out by the FDA [United States Food and Drug Administration], USDA [United States Department of Agriculture], the State Department of Agriculture, or state health districts) are some examples. Producers of organic, halal (food that is manufactured using machinery, equipment, and/or other tools that have been cleaned according to Islamic law), non-GMO (genetically modified organism), or other specialized food might need a different type. Or a client might require an audit of your food-safety and food-quality systems before you qualify as an approved supplier for their vendor approval program. By outlining the crucial issues your business needs to work through prior to undergoing a third-party audit (Figure 1), this bulletin better prepares your business to successfully go through it, no matter its type or purpose.

## What Kind of Audit Do You Need?

Ensure you understand the requirements and purposes of the third-party audit. Do you need a GFSI (Global Food Safety Initiative) benchmarked audit or a generic cGMP/HACCP (Current Good Manufacturing Practices/Hazard Analysis and Critical Control Points) audit? If conducting an audit to meet a customer requirement or to improve your own programs, make sure you understand which type of audit is the most appropriate. If you are undergoing a third-party audit because of a customer requirement and it is not a GFSI audit, ask if the customer has a preferred list of audit companies. You do not want to complete the audit and then find out that the audit company you used is not approved by the customer.

If you decide to undergo a GFSI audit, there are currently twelve certification programme owners (CPOs) recognized by GFSI (<https://mygfsi.com/how-to-implement/recognition/>). These include SQFI (Safe Quality Foods Institute, <https://www.sqfi.com/>), BRCGS (<https://www.brcgs.com/>), FSSC 22000

(<https://www.fssc22000.com/>), and Primus GFS (<http://primusgfs.com/>). To determine which CPO is the most appropriate for you, read the code requirements and find out what is common in your industry. For example, SQFI and BRCGS are appropriate for all food sector categories; FSSC 22000 is frequently used by processors that are familiar with ISO (International Standards Organization) requirements; and Primus GFS is common for producers that focus on Good Agricultural Practices (GAPs), including produce packhouses. Each CPO has licensed CBs (certification bodies) that conduct the audit.

## Prior to Audit Decision

- Determine what audit is needed for your business and customers.
- Research the audit companies that provide the audit. Investigate costs and fees, potential time frames, number of auditors available, and other services they offer. Establish a good business relationship with the audit company.

## Before the Audit

- Obtain the audit checklist/requirements.
- Perform a gap assessment of your policies, procedures, and programs compared to audit requirements.
- Correct any deficiencies from the internal gap assessment and determine the appropriate audit time frame; then schedule the audit.

## During the Audit

- Auditor arrives on-site, so conduct an opening meeting. The auditor reviews your programs for compliance to the audit requirements (documentation review, facility/process observation, interviewing).
- The Closing Meeting occurs, where you review the noncompliances the auditor has found (both those to be written in the final report and any other potential comments of improvement).

## After the Audit

- Correct any noncompliances and as required communicate with the audit company.
- Reflect on the audit. Determine the continuous improvement strategies that you can maintain.

## Audit Company

Once you have determined the type of audit, research the audit companies that provide that audit and service. Discuss the following issues with several of them, because although the audit requirements are similar, the costs and services that each audit company provides can vastly differ.

- **Cost structure.** How much does the audit company charge for the audit, including other ancillary costs? Other costs could include auditor travel, charges for questions, charges for report writing, charges for possible disputes regarding the results, etc. So, get quotes from at least a couple of companies to make the most fiscally prudent decision.
- **Time frame of the audit.** Most audit companies use an equation to determine the audit duration. The equation typically involves the number of food-safety plans, square footage of the facility, number of employees, whether a translator is needed, and whether there are any unique processes. Some types of audits have required minimums. A small facility with only a few products would likely be a one-day audit; however, GFSI audits require at least two days. Discuss your facility and business with the audit company to determine the length of the audit.
- **Do the auditors have experience in your food sector category?** If an audit company only has a couple of auditors that have experience with your food product, there may be additional complexities. Typically, if an auditor consults for your company, they cannot be your auditor for several years after the engagement because

Figure 1. The third-party-audit process.

of conflict-of-interest issues. Also, if an audit company only has a couple of auditors with knowledge in your products and processes, scheduling the audit may be a challenge, because you will need to work around their schedule.

- **Location of auditors.** Ask the audit company if they have any auditors that are local to your area—at least within a few surrounding states. An auditor who is geographically close to your facility usually incurs reduced travel charges.
- **Does the audit company have any other audits scheduled in your area?** If the company has multiple audits in the area, find out if you can split the travel costs with the other facilities.
- **Any other services they offer.** If you are going to need some help from a consultant, does the audit company offer that service and at what cost? If you need some additional training or certifications to meet the audit requirements, does the audit company offer those services and, again, at what cost? If you utilize their auditing service, do you get a discount on their other services, like consulting or training?

It is important that you have a *good working relationship* with your audit company. The audit company determines if you pass or get an audit certificate. If the company isn't responsive or does not return your messages, that company may not be the best fit for you and your business.

## Gap Assessment

Once you have determined the audit and the audit company, review the audit requirements. Every audit has a code or document that outlines the requirements with which you need to comply to obtain the certificate. To get a copy of the document, check the auditor's website or directly request a current copy from the audit company. Carefully review each item/requirement and compare your programs, systems, and facility. Look over each item of the code and critically examine your programs and systems. What do you have in place, what needs improvement, what do you not have at all? Although you may be audited by a regulatory body, the third-party audit may have some additional requirements. **Even if you pass or receive satisfactory results from regulatory audits, that does not mean you automatically pass**

**(or can sidestep or opt out of) any other audit, including one conducted by the GFSI or cGMP.**

More questions to ask yourself prior to the audit: Do you have the knowledge to conduct the gap assessment and Do you have the time and ability to conduct the audit or to correct any gaps? Many resources are available to help you conduct and correct a gap assessment. Some examples include your local food Extension professional, your Manufacturing Extension Partnership center, local consultants, consultants that work with the audit company, trade associations, and professionals from other food companies, etc. Evaluate your budget, knowledge, and time constraints to understand what you can do in-house and what you are going to need some help with. Completing all the steps yourself is cheaper but it requires the most knowledge and has the highest time commitment. Having a consultant create all of your programs and conduct the gap assessment requires the least knowledge and time but then of course costs the most. Caution: the programs and systems that are put in place must become part of your culture and be embraced by all personnel. Hence if you decide to use a consultant, do your due diligence—write your programs and make sure you understand what the consultant creates and why so you can maintain the programs after the consultant's work is done.

Most audits expire annually, so you must repeat them every year. Once the programs and systems are in place, maintain them daily to pass the audit the next time. You may need to look at your current staffing situation and determine to verify that those programs and policies can be maintained. In addition, have backups for key personnel so that in the event of an absence or a person leaving your company the programs will still be maintained.

## Audit Date

Once you have conducted the gap assessment you will have a better understanding of what areas you need to improve. If modifying your facility is required, and will require capital expenditures and contractors, you will need to estimate the lead times. In addition, if creating and applying many new programs or documentation are called for, you will need time to train the staff and ensure the program

or system is functioning for your facility and staff. Understanding how long it will take to complete your corrective actions per your gap assessment is important to help you better schedule the audit. Many audit companies require that substantial programs like this be in place at least ninety days prior (including having all your documentation regarding it) so that they can review and assess the materials and your company's progress accurately during the audit.

Most audits work on a scoring system. Every noncompliance or unmet requirement costs you points. Whether you pass an audit or gain certification depends on the score. If you score too many noncompliances during the audit you will not pass the audit or gain the certificate. This can cost you a customer or orders. After you have conducted your gap assessment, determined the number of noncompliances, and how long it will take to correct them, you will have a better idea of when to schedule the audit. Some audit companies are very busy and thus may schedule audits several months in advance. Consequently, once you have determined the approximate time frame needed to make corrections, schedule your audit with the audit company. That also provides a date to work toward.

## Prepare for the Audit

After you have conducted your gap assessment and determined an audit date, continue following up on your corrective actions. Review your audit contract and know its terms if you need to reschedule the audit. Verify that any corrections you have made will be completed in time. If something comes up and they cannot be completed in a timely fashion, discuss that with your audit company and move the audit date to something more doable. Note that most audit companies appreciate lead time for these kinds of scheduling changes, otherwise it may incur a fee or charge.

During this time, discuss with your staff the audit, audit purpose, and what is going to happen.

Frequently, as part of the audit requirements, the auditor talks to and observes the actions of the staff. Ensure that everyone understands this kind of surveillance is not personal—it is part of the

process of gathering evidence to determine whether or not your systems meet code requirements. In anticipation of the audit, you likely will be creating or modifying some of your existing programs and procedures. Inform the staff about this so that they understand why the changes are occurring and the importance of complying.

The auditor uses the code or audit requirements to observe your system to ensure you are meeting the requirements, so make sure you have all the documentation and programs readily available to share with the auditor. The audit will progress smoother if you are prepared and have the necessary proof and documentation as the auditor asks, so spend some time organizing and preparing.

## Audit Date Nearing

As the audit date nears, review your audit documentation, know when the auditor will be arriving on-site, and familiarize yourself with the preliminary schedule. You must be in production during the audit. The auditor may want to see production activities, sanitation activities, and any critical food-safety or food-quality activities. Staff appropriately to accommodate processing/sanitation and audit activities. For more information on what happens during the audit see Verburg-Hamlett 2021.

## Summary

Third-party audits are important to a food-manufacturing business. As yours develops and grows, you will need to have at least one third-party audit. Ensuring that you have selected the correct audit and audit company is an important business decision. Preparing for an audit can be expensive and time consuming so it is important to ask the correct questions and to conduct a gap assessment. If you follow the recommendations herein, don't worry—you will pass!

## Further Reading

Verburg-Hamlett, J. 2021. *An Introduction to Third-Party Auditing in a Food-Manufacturing Facility*. University of Idaho Extension Bulletin 996. <https://www.uidaho.edu/extension/publications/bul/bul996>.

