Food safety audit results

Improving your performance

bsi.

Whether it's next month or next quarter, you've probably already started thinking about your next food safety audit and what you can do to meet the associated KPIs established by your organization.

This isn't easy as most Global Food Safety Initiative (GFSI) standards are evolving; moving the 'best practice' expectation to even higher levels of due diligence, organizational commitment and engagement.

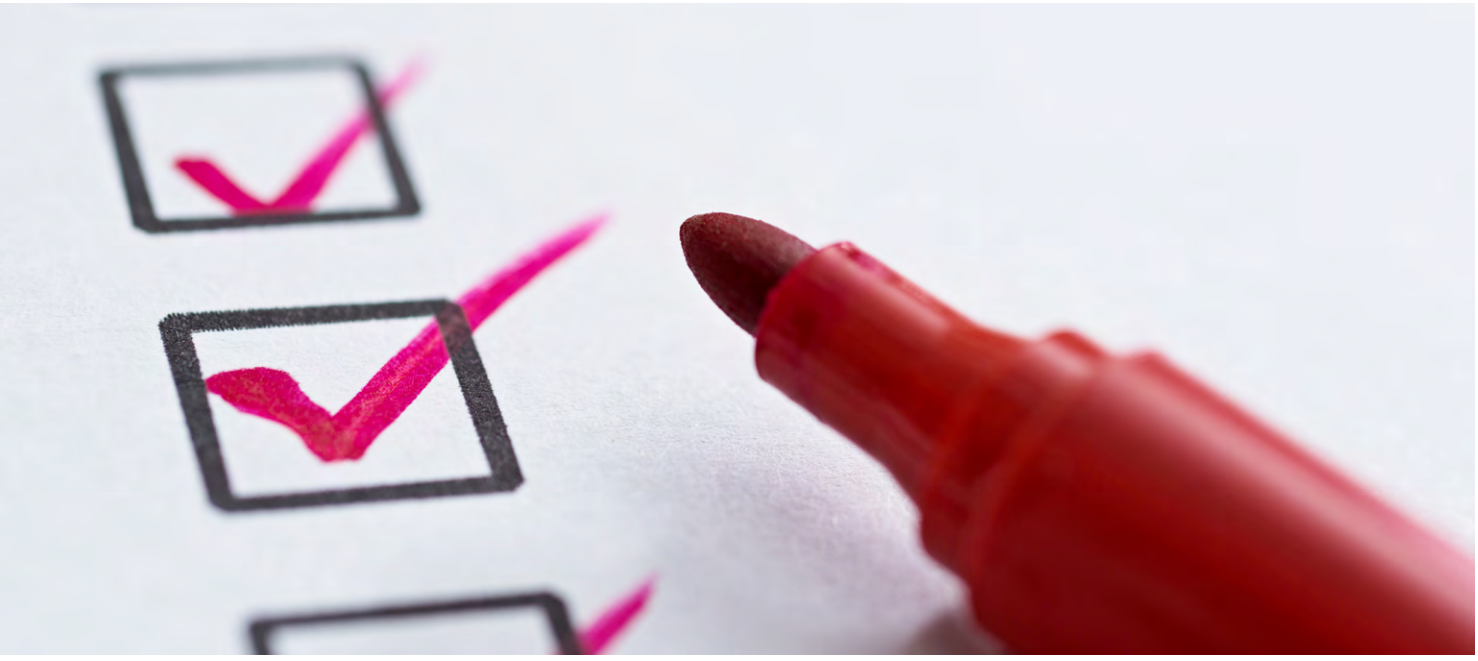
Each GFSI standard has a similar intent for senior management commitment, HACCP, site standards, personnel as well as product and process controls. Staff engagement, available resources and the underpinning food safety culture within your organization will have major influence on compliance and your capability to achieve best practice.

Where are organizations going wrong?

Changes to GFSI standards normally translate to a spike in audit non-conformances due to a new requirement that has not been actioned or implemented before an audit. But, surprisingly, the top five non-conformances identified by BSI auditors in 2017 related to:

1. **Building fabric**
2. **Housekeeping and hygiene**
3. **Contamination**
4. **HACCP systems**
5. **Maintenance / Pest Control**

These results aren't unique to BSI clients; our list matches the top violations identified by FDA inspections for 2017[1]. In addition to your internal and regular GMP audit programmes, our food safety team used audit data to develop this series of proactive tips to help you identify potential non-conformances.



References:

[1] https://foodsafetytech.com/news_article/fda-inspections-top-five-violations-fy2017/ (accessed 18 December 2018)

Building fabric issues topped the list which is not surprising as most of the GFSI standards have prescriptive requirements on walls, floors and ceilings that all add up as individual non-conformances. A strong focus on building fabric and construction issues will remain in all of the standards as the facility can present significant contamination risks. The upkeep and maintenance of building fabric requires ongoing resources that must be prioritized to minimize risks to processes and products. Surprisingly, many building fabric related non-conformances identified during audits are already known to the organization.

Auditor tips:

- ✓ Roughly three months before your audit (or, ideally, each quarter), walk around your facility specifically looking at walls, floors, ceiling, doors, drains, window opening etc. to identify issues. This 'inspection' should be completed as a separate activity to routine GMP audits, as the specific focus on building fabric can be lost when following a predetermined checklist.
- ✓ Stand at any open process areas and look up to check the condition of the ceiling; look down to check the condition of the floor and drains; look at the walls to identify any damage that may impact the effectiveness of cleaning and pest control programs.
- ✓ Assess the building fabric. Is it in good condition:
    - Is there sufficient lighting to allow for inspection?
    - Are there temporary walls and screening in place for onsite construction and equipment installation projects?
    - If so, are these maintained intact and clean?
- ✓ Is there evidence of wear and tear on surfaces that needs to be reported to maintenance? Many non-essential tasks will require sufficient lead time to be completed prior to an audit.
- ✓ Access all areas of your facility. There have been many audit experiences where the auditor accesses areas that are not frequently used, resulting in surprises for both the auditor and auditee.
- ✓ By doing this check on building fabric well in advance of your audit, there will be sufficient time to take action on any issues that you find and/or you will be able to show an auditor plans for rectifying building fabric defects are in place.

Robust Good Manufacturing Practices (GMP) are essential to demonstrate your due diligence. If issues with building fabric are not able to immediately rectified, you will need to demonstrate how any potential risks of contamination are monitored and managed until the issue is actioned. A risk assessment may be a useful interim measure to show as objective evidence during an audit.

Housekeeping and hygiene issues are also common findings in most audits. Many of these non-conformances are point-in-time and are not always indicative of a failure in the overall hygiene or sanitation programme. The most frequent non-conformances raised relate to the standard of cleanliness, suitability of cleaning equipment, verification of cleaning program effectiveness and validation of Cleaning in Place (CIP) systems.

Auditor tips:

- ✓ Housekeeping and hygiene are shared responsibilities, so creating a shared, pre-audit schedule for the technical/quality team and maintenance can prevent scrambling in the last few days before an audit.
- ✓ Review the results of your current and past GMP audits as these will help you identify 'problem' areas in your facility. And remember, auditors also look at your GMP audit results to get the same information.
- ✓ All facilities will have areas that are difficult to access for cleaning. Identify these areas and ensure that they are covered within routine cleaning activities.
- ✓ High risk/care areas need to be maintained to high standards of microbiological cleanliness. The validation and verification of these cleaning practices will need to be assessed during the audit. It's time efficient if this information, including rotational swabbing plans, results of tests and actions for out of specification results are collated ready for review during your audit.
- ✓ Assess the cleanliness and condition of cleaning tools and equipment. It sounds obvious however it is surprising how often cleaning equipment itself becomes the contaminant in the facility.

Product contamination risks, whether actual or potential, are always a focus of food safety audits. Auditors will actively look for these risks throughout your facility. Foreign matter (anything that is out of place) is the most common finding so it's important that everyone in your facility has a high level of awareness on foreign matter and that there is a consistent and sustained effort to reduce the number of foreign matter findings.

Auditor tips:

- ✓ Review the results of your previous foreign matter audits. Do they indicate that the same types of foreign matter are routinely found? If so, this will indicate to an auditor that the root cause analysis (RCA) has not been effectively applied. Review the RCA to determine additional corrective and preventative actions required for improvement.
- ✓ Some auditors will collect foreign matter found during the site inspection and cross reference these findings with your HACCP plan to confirm that the physical hazards and foreign matter identified as hazards in your HACCP plan match what is found in practice.
- ✓ Check that your glass and hard plastics register is up to date. It's common for auditors to look for damaged items during the site inspection to challenge the glass and brittle material register. Best practice is to have a photo inventory of all items as this allows for identification of the item and to do a check on damage or deterioration since the last recorded check.
- ✓ Auditors will often request the glass breakage record to see if there have been any damages since the last audit or if this record is ever used. No glass breakages recorded for a period of years is unlikely as overhead lights need to be replaced etc. Recording glass breakages demonstrates due diligence whereas an empty record can look suspicious.
- ✓ Review the labels on decanted chemicals and how secure the storage of all chemicals is as chemical identification, storage and handling is often identified as problematic.

HACCP plans are the road map to food safety in your organization so they need to be good. HACCP plans that have been in place for a number of years, with minimal verification, are at risk of becoming irrelevant.

Common audit issues:

- Product descriptions that are inaccurate or incomplete
- Flow diagrams that have process steps or inputs missing and annual verification not completed
- Hazard risk assessments that don't align with the flow diagram or aren't reviewed annually
- CCP and critical limit validation information that is incomplete for the theoretical and/or process capability data
- Monitoring activities that have insufficient detail and discrepancies in the frequency of monitoring activities
- Corrective actions that have not been taken when critical limits are breached
- Records that are incomplete, not signed by the person who recorded the monitoring result and incomplete verification
- HACCP verification activities that have not been completed as planned or ineffective verification that doesn't challenge the existing HACCP plan to identify new or emerging hazards and review the suitability of the CCPs, critical limits, monitoring activities or predetermined corrective actions

Auditor tips:

- ✓ Review any product descriptions for new products introduced since the last audit as it's likely that these will be sampled during an audit. The intended use is also required to be complete.
- ✓ Auditors will always request the flow diagram for the products in process during an audit so it's essential that all flow diagrams are verified annually and that they include all process steps. Process steps not included may not have been assessed for hazards. Common oversights include water addition points, direct steam injection into products, gas flushing processess for packaging and rework.
- ✓ Keep the original flow diagrams used in the physical walk-though of the process as amendments made on these documents demonstrate that the verification was completed and indicate any corrections made.
- ✓ Revise your hazard assessment to confirm that it's current. Have there been any recent food safety incidents or product recalls in your industry? If so, were these due to a hazard that has not been identified in your hazard assessment? Do the physical hazards indicated in your hazard assessment match what is found in foreign matter audits?
- ✓ Retain the CCP decision methodology as this may be reviewed by an auditor. Have validation data readily available during the audit as this may also need to be reviewed.
- ✓ Review a sample of CCP monitoring records to check for systematic errors. When auditors review monitoring records, they're looking for specific information such as the critical limit, the date, the signature of the monitoring operator or verification of the records. You can use the same technique to identify gaps or trends in records so that proactive action and/or retraining of staff can be completed to ensure the records demonstrate retrospective proof of compliance.
- ✓ Print a copy of your HACCP verification schedule and manually check off each activity to ensure all activities have been completed as planned. In the event that a verification activity that hasn't been completed as planned is identified, reschedule the activity to demonstrate that the activity hasn't been forgotten and that there's a plan to complete the activity as soon as possible.

Maintenance and pest control tied for fifth place as the most common non-conformance. Specific maintenance issues routinely identified include a lack of control for temporary repairs and incomplete records for hygiene clearance following maintenance works. These are all avoidable audit non-conformances.

The most frequent issue raised for pest control is evidence of pests or live pest sightings during an audit.

Auditor tips:

- ✓ Look for temporary repairs in your site inspection or GMP audits and confirm that these have been reported for a permanent repair. Good practice is to use a visual system that provides a prompt to highlight the use of a temporary repair, together with the date the repair was applied to confirm timeliness of action.
- ✓ Confirm hygiene clearance or handover protocols between maintenance and production and ensure records are completed for this activity. Priority may be given to intrusive maintenance activities as these are higher risk.
- ✓ Print a copy of your current bait station map and complete a cross reference inspection with external and internal bait stations and moth pots to ensure the plan is up to date. Many auditors do this during the walk around the external areas.
- ✓ Pest sightings need to be reported to the contractor for action so confirm pest sighting registers are utilized and reported to the pest control contractor.
- ✓ Ensure any evidence of pest activity observed is promptly actioned to prevent any contamination issues. Records of additional pest control treatments will need to be provided at your audit as evidence of action taken.

Failing to prepare is preparing to fail

Being well prepared for an audit will ease some of the stress and time pressure that both auditees and auditors feel. The key audit outcome is being able to effectively demonstrate that you have proactive systems and practices to identify, risk assess and manage food safety issues, supported with a history of records demonstrating your due diligence.

Auditor tips:

- Organize and collate the electronic and hardcopy information needed so that it's easily accessible during the audit.

  Typical documents to be reviewed include but are not limited to:
  - Organizational structure and selected position descriptions
  - HACCP plans including flow diagrams for product and processes at the time of audit
  - Food safety and quality management system overview
  - Supplier approval processes
  - Specifications for raw materials (ingredients and packaging), work in progress (WIP) and finished products
  - Product recall protocols
  - Product recall data
  - Food defense assessment (TACCP)
  - Metal detector valiation process (if metal detection is used)
  - Preventative maintenance schedule, records of preventative and breakdown maintenance activities and maintenance handover and hygiene clearance
  - Product labelling protocols
  - Allergen management protocols
  - Product authenticity (VACCP) risk assessment
  - Product release protocols
  - Calibration schedule
  - Training plan(s)

  Typical records to be reviewed include, but are not limited to:
  - Minutes of management review
  - Evidence of HACCP verification activities
  - Supplier approval (generally required for the product selected for a vertical audit)
  - Customer complaint data and investigations
  - Internal system audits and GMP/hygiene audits
  - Test results for utilities including water, ice, steam, compressed air and gases
  - Pest control treatments and/or visit records
  - Product results for microbiological, chemical and physical tests
  - Calibration records
  - Training records
  - Validation records
- Share the compliance responsibilities in your organization. Encourage supervisors and operators in each area to interact with the auditor to encourage ownership and to upskill the audit process.
- Mezzanine platforms are ideal to use as an observation point as the height will also allow you to observe the top of equipment and conveyor belts below.

Preparing for an audit presents challenges, but it also provides the opportunity for improvement. Through our training academy, we've seen our clients enjoy a reduction in non-conformances as their skillsets increase and evolve. Depending on your experience and the standards your organization is certified to, we recommend the following types of training:

- Internal auditor
- HACCP refresh
- Senior management briefings
- Allergen management
- Implementing VACCP and TACCP

If you have concerns about the level of your audit readiness but may not have time to attend training, BSI also offers a gap analysis service against many of our food safety standards. We can help you identify where your food safety management system needs to be improved before your audit to help reduce the likelihood of non-conformance issues.

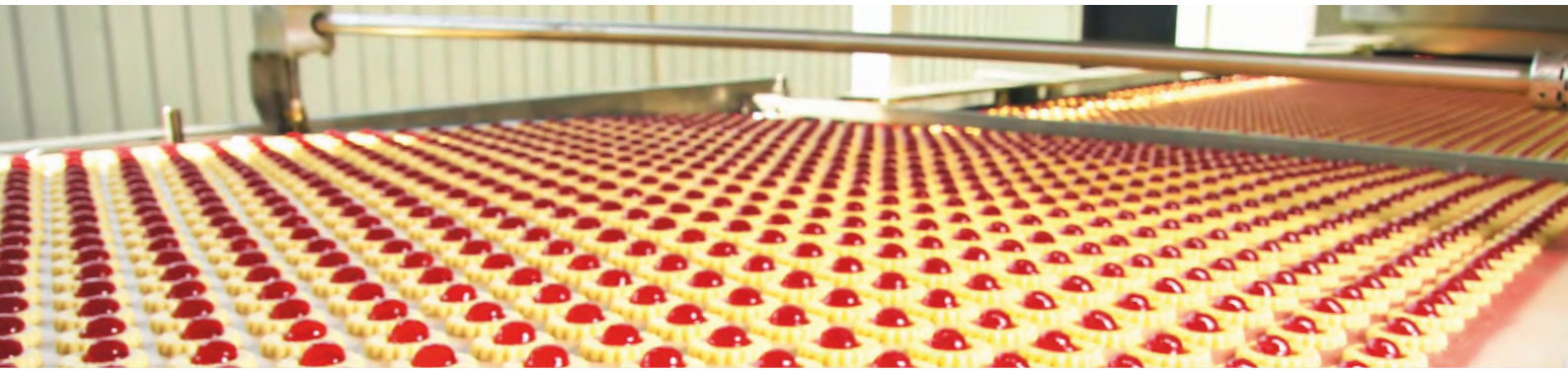
Why BSI?

The food industry impacts every person on the planet. Though what the world's population may eat may differ depending on the geography, wealth, age, gender and availability of goods, no other sector plays such a vital role in all of our day-to-day lives and culture. Economically, food represents 10% of Global GDP (valued at US$48 trillion by the World Bank).

But the food sector also faces significant challenges. Each year, food-borne illness makes one in ten people ill and is the cause of death for millions around the world. Population growth projections and an increasing middle class suggest that the demand for food will increase 70% by 2050. And, consumers are increasingly conscious about what goes into their food, how it's made, its impact on ecosystems and where it comes from.

BSI believes the world deserves food that is safe, sustainable and socially responsible. We support the food sector by developing and publishing standards of best practice, supply chain solutions as well as training and certification to not only the most popular food safety standards, but other business improvement standards that work together to make organizations more resilient.

Working in 172 countries, we pride ourselves on the expertise, integrity and professionalism of our people. Our mission is to help our 80,000 clients, ranging from high-profile global brands to small local companies, survive and prosper in today's world.



Our products and services

Knowledge

The core of our business centres on the knowledge that we create and impart to our clients.
In the standards arena we continue to build our reputation as an expert body, bringing together experts from industry to shape standards at local, regional and international levels.
In fact, BSI originally created eight of the world's top 10 management system standards.

Assurance

Independent assessment of the conformity of a process or product to a particular standard ensures that our clients perform to a high level of excellence. We train our clients in world-class implementation and auditing techniques to ensure they maximize the benefits of standards.

Compliance

To experience real, long-term benefits, our clients need to ensure ongoing compliance to a regulation, market need or standard so that it becomes an embedded habit. We provide a range of services and differentiated management tools which help facilitate this process.

For more information on improving your organization's business continuity practices, visit **bsigroup.com.my** or email **info.malaysia@bsigroup.com**

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