

How to prepare for an audit

Audits can be very stressful, but the key to decreasing the stress and increasing the benefits is preparation, preparation and more preparation...

In an ideal world, all complaints will be written up at the time the complaint was received and then closed out straight away. Maintenance would complete all the maintenance requests from the last GMP assessment undertaken. Suppliers would provide you with all copies of their certificates without you having to chase them. Internal audits wouldn't be pushed into next month because marketing decided that they needed to change the artwork or research and development decided that product launch couldn't wait.

Time has this nasty habit of creeping up on us and before you know it your next external audit is due. The more organized you are during the audit, the more organized you and the company will appear to the auditor. The old saying "don't judge a book by its cover" is hard to apply in the auditing world where initial impressions of the premises, the Quality Manager's preparation and the documentation are often difficult to overlook.

Try these useful tips to take the stress out of your next audit.

2-3 months before the due date

Book the audit!

1. If you know that your audit is approaching and you haven't heard from us, contact us to arrange an audit date. The further in advance you book the date, the more likely you'll get a date that you want
2. Ensure the date(s) you book doesn't coincide with key team members leave or company events
3. Be realistic about the duration of the audit. If your last auditor was on site for 10 hours, request that two days are allocated. Spending eight hours being audited in a day is difficult – it does not get any easier after 10 hours
4. Make sure that you'll be manufacturing the product(s) covered under the scope of the audit on the day(s) of the audit. This is particularly important for product specific certification. This can be hard to predict as production relies on orders. However, you can't be audited if you aren't making the product
5. If your processes start and finish early, request that the audit starts earlier. The auditor must see your processes in operation

When the audit has been booked

1. Advise key staff members of the confirmed audit date
2. Assign tasks to key staff members to ensure that they have reviewed their documentation and records and are prepared for the audit

1-2 months before the audit

1. Ensure you have access to current copies of the standards that are the subject of your audit. A number of standards have guidance documents that are also auditable – ensure you're aware of and have access to these
2. If the standards have changed, check that your Management System has been reviewed and updated to reflect these changes
3. Make sure the system has been reviewed and verification activities have been carried out as per your verification schedule. If you have allowed enough preparation time prior to the audit you should have time to address any activities that may be running late. An auditor will look more favorably on the company if these errors have been identified, addressed and action has been taken to ensure that they don't get missed again
4. Review corrective actions, customer complaints, GMP inspections and internal audits. Are these all up to date with appropriate close-out actions?
5. Make sure you can locate everything you will require during the audit. It is extremely inefficient for the audit process when a company cannot find information within its own system. Remember the auditor is trying to ensure that there is an effective system in place. If the person responsible for the system doesn't know where everything is, how can the auditor have confidence in your system? You don't have to know where every little detail is, but make sure there is a good directory or table of contents in place. Alternatively have a cheat sheet with some of the little details that get added to the manual
6. If a consultant has been reviewing or writing your manual make sure that they give you back the manual with enough time for you to read and understand it prior to the audit
7. Ensure you know who is responsible for different aspects of the system – i.e. training is often managed by HR
8. If you are from a large organization with a head office located elsewhere and rely heavily on an Intranet for information, ensure that you have access and know your way around the system. Ensure that you know who to contact if there is something that you can't find during the audit

1 week before the audit

1. Ensure that you have cleared your commitments on the day of the audit. An audit may go past your normal "home" time and being stressed out that no-one can pick up the children from school makes the audit process even more daunting
2. Ensure that there is adequate space for the auditor to use. Most auditors now work electronically and therefore require a desk and a power source (extension cords are also useful)
3. Ensure that senior management is available to attend the entry and exit meeting. Absence of these people is an automatic non-conformance for some standards. Auditors are looking for evidence that management support the Food Safety and/or Quality Management System and attendance at these meetings demonstrates some evidence towards this
4. Ensure that the processing staff have been briefed about the audit. Some staff members can become very stressed during an audit – especially if it's their first time. Let them know what to expect and what they may need to do if an auditor asks them a question
5. Ensure that you have access to keys for locked areas within the processing area – auditors are required to enter all areas on site
6. Tidy your office and desk. This creates a sense that the Quality Department is under control

The day before the audit

1. Gather all the documentation that the auditor will need. This includes access to records as far back as the last audit
2. Walk the premises and review what the staff are doing in terms of CCP and QCP monitoring as well as basic hygiene practices
3. Check that all maintenance work being carried out has been cleaned up
4. Talk to the staff and reassure them about the audit and what the auditor may ask