

WHAT ARE THE OUTCOMES THAT YOU WANT FOR YOUR AUDIT PROGRAMME?

A set of questions to ask in order to fully develop a concept of what your internal audit programme will deliver. Using these questions will result in a set of outcomes that will give assurance that all aspects have been systematically covered. A well-formed outcome is also an essential step toward achieving improved results.

Modify these questions to suit your own situation and ask them each year, as you begin to plan your audit programme. Some answers will be the same as last year. Some will be different as circumstances change. Others may be different as your expertise and expectations build.

These questions do not cover the content of the standards and regulations that drive your systems, nor do they include results of trends from your NC and CAPA systems and elsewhere. I have assumed that these are already covered in your QMS. If not, add them to your own set of questions.

These questions also do not specifically include the supplier audit programme, though they will provide some inputs to that.

1. BIG PICTURE

1. What do your **quality policy** and **quality objectives** say that should be included in the audit programme?

Compliance will be there, maybe improvement. Plans to meet annual quality objectives can be monitored within process audits.

2. What are the **key processes** to build an audit schedule around?

It is not necessary to have separate audits for support processes such as record control and training; cover these within audits of your key processes. Maybe you could combine linked processes, e.g. production planning, purchasing, receipting goods, inwards inspection, warehousing, delivery to production, accounts payable. Note outsourced processes to include in the supplier audit programme.

3. What changes is the **business plan** flagging for this year?

Examples of changes that might prompt audit focus include a shifted production line; new production process; new regulatory market; a lot of new people coming into an area diluting the expertise. Maybe down-sizing in an area, affecting resource and morale, and therefore potentially affecting quality.

4. What would **top management** like you to audit?

Management review minutes and CAPAs are sources of information about management attention. Talk with the CEO and senior managers and ask them. Is auditing for improvement important, or minimisation of waste?

5. What should be the **range and scope** of your audit programme?

Would it be beneficial to include other departments or other sites, e.g. the Accounts department, or a remote sales office, or a distributor?

2. CRITERIA

If you are organising your audits around your processes, then you need to consider the different criteria against which a process needs to be audited.

1. What **regulations and standards** need to be considered as criteria for the audit?

Beyond the basics of Part 820 and ISO13485, what else should be covered? Maybe the company is going into Japan and there are particular factory requirements which need to be considered? Should local regulations about hazardous materials or trade waste be included?

2. What regulations or standards have **changed or are changing**?

For example, if you have an EU certificate, the relevant annex of the European harmonised version of ISO14971 should be considered ([more here](#)), and auditing should check that a gap analysis and action plan has been appropriately completed.

3. Do you have **other management systems** that could be audited together with your QMS in integrated audits?

If you have an environmental or an occupational health and safety management system, maybe aspects of these have been integrated with your QMS. Even if not integrated, it could be useful to integrate their requirements into your process audits. On a production line, have the hazards to staff been identified and controls applied? Has the disposal of a device been included in design requirements for the product currently under development?

4. What **customer requirements** should be included in the internal audit programme?

Do you have customer quality agreements with particular requirements? Are there quality requirements buried in contracts that quality might not have seen? Have customer audits or other interactions indicated expectations that might not have been explicit in the quality agreement but nevertheless should be met? While you are surveying customer requirements, look out for points that need to be included in the supplier audit programme.

3. SOFT FACTORS

In our analytical, technical world of medical devices, soft factors can be missed from audit programme planning, but they can make the difference between continuing success and just adequate.

1. What have you observed **working really well** in the audit programme?

Could you incorporate more of that? Maybe one auditor is getting really good results – how is she doing that? Maybe a particular type of audit trail worked well for a process audit and could be used in others. What did the audit team notice that worked well?

2. What **learning outcomes** could you achieve from audits for **auditees**?

How do you need auditees to feel during the audit to put them in the best state for learning? Deming's 12th principle: drive out fear. How do auditors need to be to achieve a learning state in auditees? How do you, as audit programme manager, need to be to achieve that state in auditors?

3. How do you want **auditors** to feel about doing an audit?

Frustrated because they need to take time out from their already busy schedules or looking forward to an interesting task and the opportunities it will provide? How does your programme need to be to achieve that? How do the auditors want their managers to be thinking about the audit programme, so they don't have a conflict to deal with?

4. What **learning outcomes** could we achieve for **auditors**?

Robert Packard's [adjacent link auditing](#) practice of getting auditors to audit upstream and downstream from their normal roles will give an auditor an internal customer's perspective. What other areas are individual auditors interested in exploring and learning about? What other areas of the business should an auditor know more about for the benefit of the business or their career?

5. How do you want your organisation to **perceive the audit team and the audit programme**?

What do you want to hear people saying about the audit programme over the water cooler? What do you want to hear management saying? What conversation do you want to be having with your boss about the programme? How do you want to feel about the audit programme when you hear people talking about it? How will these conversations impact on the resources available to you for the audit programme?