IRISH QUALITY CENTRE

Training Manual

ISO 13485:2016

QMS LEAD AUDITOR TRAINING

CERTIFIED COURSE

CQI and IRCA Certified Training

Welcome to your CQI and IRCA Certified ISO 13485 Lead Auditor course

Irish Quality Centre (IQC) has been independently assessed and approved by the CQI and IRCA. This means they have the processes and systems in place to deliver certified courses to the highest standard.

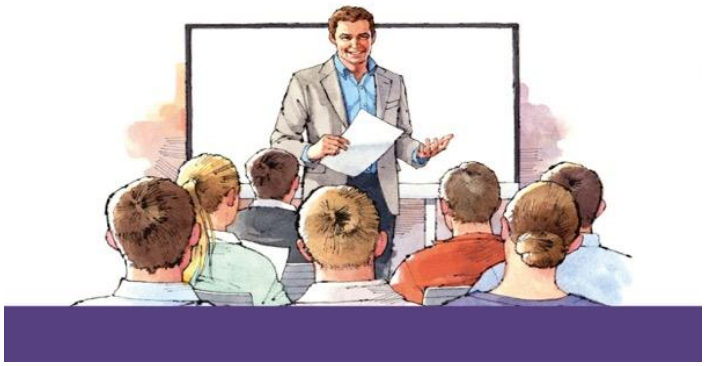
About the CQI and IRCA

The CQI is the only chartered professional body dedicated entirely to quality. IRCA is its specialist division dedicated to management system auditors.

Take the next step in your career and become a member. Join a unique global network of nearly 20,000 quality professionals and gain unrivalled professional recognition as an individual and in your career.

Find out more about the CQI and IRCA at **www.quality.org**

We hope you enjoy your course.



1. COURSE OBJECTIVES

By the end of the course participants will be able to:

- **Describe** the purpose of a quality management system (QMS), and the benefits it brings to the business.
- **Understand** the fundamental concepts of quality management and auditing and explain the 7 principles of quality management.
- **Explain** the relationship between quality management and customer satisfaction.
- **Explain** the purpose, content and interrelationship of ISO 9000, ISO 13485, other relevant QMS standards, ISO 9004 and ISO 19011.
- **Understand** the structure and key requirements of ISO 13485, and the process approach.
- **Interpret** the requirements of ISO 13485 in the context of an audit.
- **Demonstrate** the use of the Plan-Do-Check-Act cycle in management and auditing.
- **Describe** the role of internal audit in the maintenance and improvement of management systems.
- **Understand** the different types of audits.
- **Explain** the 7 Principals of Auditing.
- **Describe** managing an audit programme
- **Discuss** the establishing and implementing of audit programmes and associated objectives
- **Describe** the competence, assessment of and roles and responsibilities of auditors and lead auditors.
- **Plan** and **conduct** an audit in accordance with ISO 19011, demonstrating ability to:
    a) plan and prepare effectively.
    b) gather objective evidence, through effective interviewing, observation, sampling and note taking.
    c) analyse and interpret information in order to determine conformance with requirements, effectiveness, and areas for improvement.
- **Prepare** and distribute and audit report (including writing valid, factual and value-adding audit reports).
- **Undertake** audit follow-up activities, including evaluating the effectiveness of corrective action.
- **Explain** how to Monitor, Review and Improve the Audit Programme.

During the five days participants will acquire knowledge and skills in auditing. However, auditing like any other acquired skill requires practice. The best place to practice and extend your experience is during actual audits.

2. FUNDAMENTALS OF QUALITY

Fundamental Concepts
How is quality achieved?
Relationship between ISO 13485 and Product/Service Quality
Benefits of QMS

Fundamental Concepts

Quality management concepts give the organisation the capacity to meet challenges presented by an environment that is profoundly different from recent decades. By providing fundamental concepts to be used in the development of a Quality Management System (QMS), ISO 13485:2016 provides a way of thinking about the organisation more broadly.

The fundamental concepts outlined in ISO 9000 are:

- Quality
- QMS
- Context of an organisation
- Interested parties, and
- Support.

1. Quality

Quality is defined in ISO 9000 as the *"degree to which a set of inherent characteristics of an object fulfils requirements"*.

- A characteristic, for example can be,

  "physical, (e.g. mechanical, electrical, chemical or biological characteristics);
  sensory, (e.g. related to smell, touch, taste, sight, hearing);
  behavioural, (e.g. courtesy, honesty, veracity);
  temporal, (e.g. punctuality, reliability, availability);
  ergonomic, (e.g. physiological characteristic, or related to human safety);
  functional, (e.g. maximum speed of an aircraft)."

Requirements can be, for example, "product requirement, quality management requirement, customer requirement, quality requirement".

2. Quality Management System

ISO 9000 defines a QMS as *"part of a management system with regard to quality"*.
A management system is a "set of interrelated or interacting elements of an organisation to establish policies and objectives, and processes to achieve those objectives".

Note 1: Quality Management includes establishing the Quality Policy, Quality Objectives, and Processes to achieve these quality objectives through Quality Planning, Quality Assurance, Quality Control, and Quality Improvement.

Note 2: Generally, the Quality Policy is consistent with the overall policy of the organisation and provides a framework for setting quality objectives. The seven quality management principles can form a basis for establishing the Quality Policy.
Note 3: Quality Objectives should be based on the Quality Policy.
Note 4: "Part of Quality Management focused on setting Quality Objectives and specifying necessary operational processes and related resources to fulfil the Quality Objectives". (ISO 9000)
Note 5: "Part of Quality Management focused on providing confidence that quality requirements will be fulfilled". (ISO 9000)
Note 6: "Part of Quality Management focused on fulfilling quality requirements". (ISO 9000)
Note 7: "Part of Quality Management focused on increasing the ability to fulfil quality requirements". (ISO 9000)

How Is Quality Achieved?

Quality is achieved by the application of the closed loop Plan-Do-Check-Act cycle at all levels in all business processes and ensuring that these processes function as a coherent system

Key Points:

- Achievement of quality involves all stages of the Business Cycle.
- These are some examples of some key business processes.

Relationship Between ISO 13485 And Product/Service Quality

Having ISO 13485 means you can demonstrate capabilities of consistently meeting customers' and applicable regulatory requirements.

Key Points:

- ISO 13485 specifies requirements for a quality management system where an organisation needs to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.
- It is important to differentiate between the requirements for a Quality Management Systems (QMS) and the requirements for Products. Requirements for QMS are specified in ISO 13485. Requirements for a QMS are generic and applicable to all organisations.

- Requirements for products can either be specified by customers or by the organisation in anticipation of customer requirements, or by regulation.

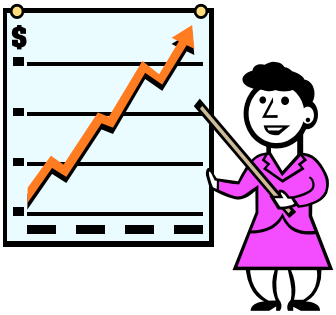
The requirements for products and, in some cases, associated processes, can be contained in, for example, technical specifications, product standards, process standards, contractual agreements and regulatory requirements.

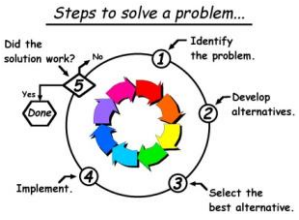
In all Quality Management Systems, the priority is the PRODUCT/SERVICE.

NEVER LOSE SIGHT OF THE PRODUCT/SERVICE WHEN DEVELOPING, IMPLEMENTING, IMPROVING AND AUDITING A QMS.

Benefits of a QMS

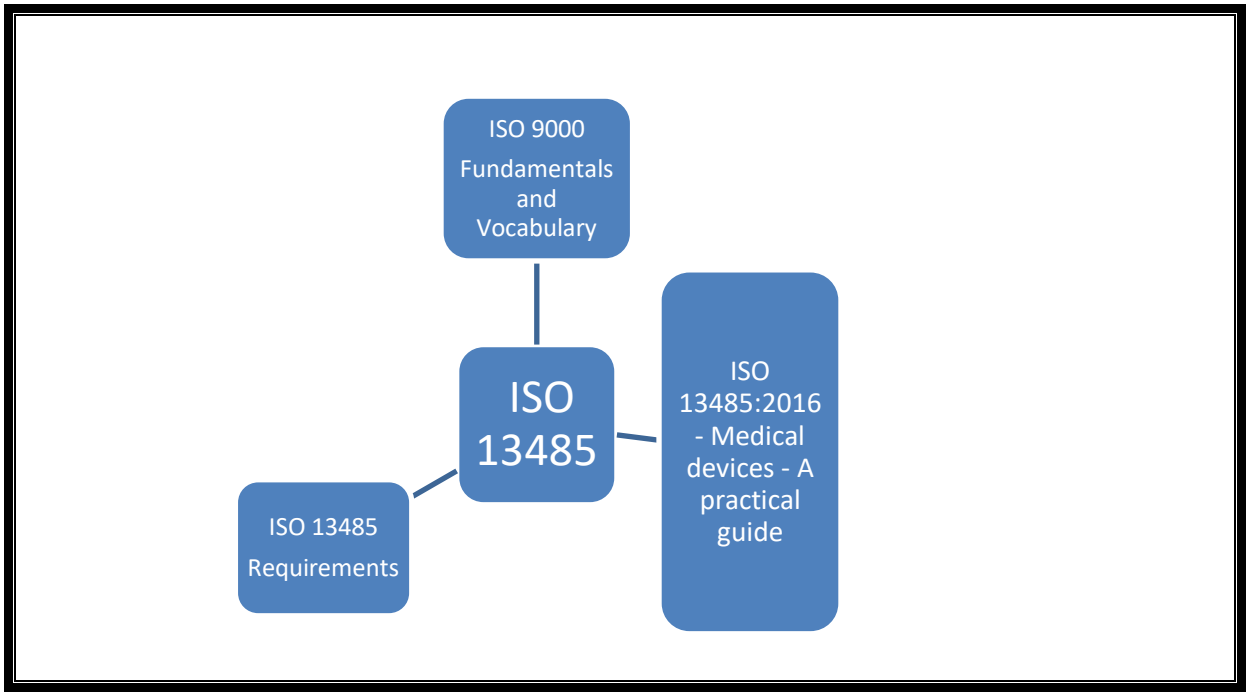
- **Improved finances**
  - lost opportunities in the marketplace if ISO 9001 is a requirement and you are not certified
  - less waste through more effective and efficient processes
- **Enhanced** reputation through improved ability to satisfy customers
- **Greater** internal clarity and confidence through the
  - setting of objectives
  - measurement of performance, and
  - feedback to employees on the effectiveness of processes
- **Better** trained employees
- **Encourages** an open approach to problem solving through the corrective action process and hence less likelihood of their repetition





3. INTRODUCTION TO QMS STANDARDS

- **ISO 19011: Auditing**
- **Sector-specific standards**
- **Integrated Management Systems**
- **Registration System**
- **7 Quality Management Principles**
- **Developing a QMS**
- **Process Management**



Key Points:

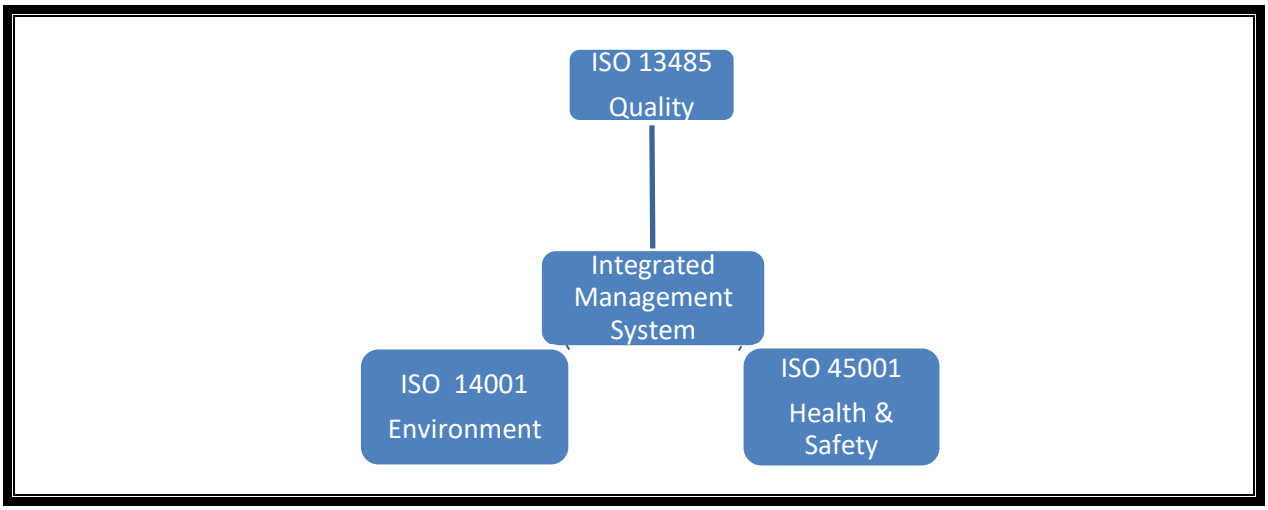
- ISO 13485 are the requirements; ISO/TR 14969 is intended to give guidance
- ISO 9000 provides the fundamental concepts, principles and vocabulary for quality management systems (QMS) and provides the foundation for other QMS standards.

Sector-Specific Standards

ISO 13485 (Medical Devices)	ISO/TS 16949 (Automotive)
ISO 22000 (Food)	TL 9000 (Telecommunications)
AS 9100 (Aerospace)	cGMP's (Pharma and Medical Devices)

Key Points:

- Some of these sector-specific standards use the requirements within ISO 9001 as the basic requirements…

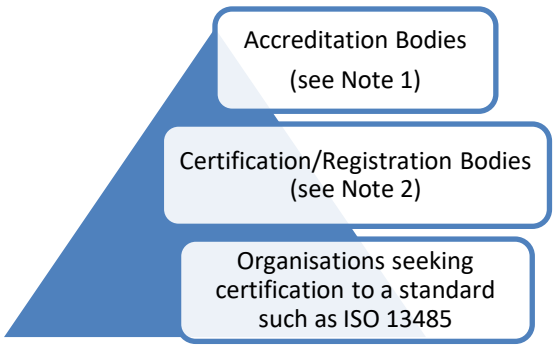


Integrated Management Systems

Different management systems can be integrated into a single management system using common elements, such as the use of Annex SL, which specifies the framework for a generic management system.

- *However, at this stage ISO 13485 does not use this framework.*
- None the less, Integration can facilitate planning, allocation of resources, defining complementary objectives and evaluation of the overall effectiveness of the organisation.
- Integrated audits can save time and money.

Registration System



Note 1: Examples are

- INAB (Irish National Accreditation Board)
- UKAS (United Kingdom Accreditation Service)
- ANAB (ANSI – ASQ National Accreditation Board)

Accreditation bodies are established in many countries with the primary purpose of ensuring that conformity assessment bodies are subject to oversight by an authoritative body.

Note 2: NSAI and BSI are examples of Certification Body (s)

ISO/IEC 17021-1:2015 contains principles and requirements for the competence, consistency and impartiality of bodies providing audit and certification of all types of management systems.

7 Quality Management Principals

Key Points:

The requirements in ISO 13485 are based on the seven quality management principles.

- *Customer Focus:* Organisations depend on their customers, and therefore, should understand current and future customer needs, meet customer requirements and strive to exceed customers' expectations.
- *Leadership:* Leaders establish unity of purpose and direction of the organisation. They should create and maintain the internal environment in which people can become fully involved in achieving the organisation's objectives

- *Engagement of People:* Competent, empowered and engaged people at all levels throughout the organisation are essential to enhance the organisation's capability to create and deliver value.

- *Process Approach:* Consistent and predictable results are achieved more effectively and efficiently when activities are understood and managed as interrelated processes that function as a coherent system.

- *Improvement:* Successful organisations have an on-going focus on improvement.

- *Evidence-based decision making:* Decisions based on the analysis and evaluation of data and information are more likely to produce desired results.
- *Relationship management:* For sustained success, organisations manage their relationships with interested parties, such as providers.

Fundamental Concepts (ISO 9000) + Principals = Quality Management System (QMS)

Developing a QMS **using the fundamental concepts and principles**
Organisations share many characteristics with humans as a living and learning social organism. Each is adaptive and comprises interacting systems, processes, and activities. In order to adapt to their varying context, each needs the ability to change. Organisations often innovate to achieve breakthrough improvements. An organisation's QMS model recognises that not all systems, processes and activities can be predetermined; therefore, it needs to be flexible and adaptable within the complexities of the organisational environment (see the Introduction Section in ISO 13485 in relation to the design and implementation of an organisation's quality management system).

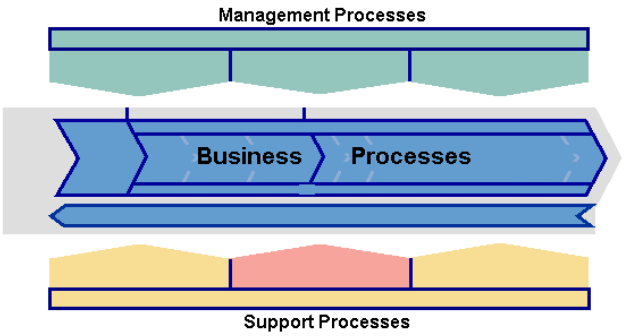
All organisations consist of a system, processes, and activities.

- **System**

Organisations seek to understand the internal and external context to identify the needs and expectations of relevant interested parties. This information is used in the development of the QMS to achieve organisational sustainability. The outputs from one process can be the inputs into other processes and are interlinked into the overall system. Many organisations have similar processes, such as Sales and Purchasing, but each organisation and its QMS is unique.

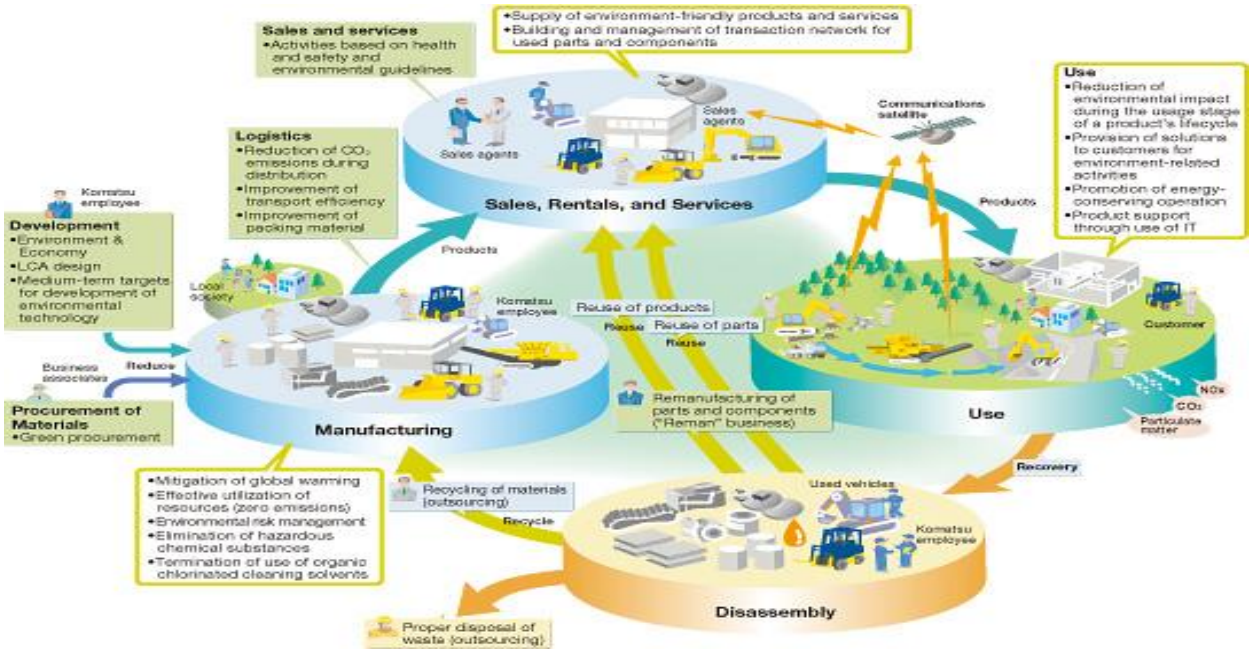
- **Processes**

The organisation has processes that can be defined, measured, and improved. These processes interact with each other, and cross functional boundaries to deliver results consistent with the organisation's objectives. Processes have inter-related activities, which take inputs (such as manpower, material, method, and machinery) and transforms them into outputs.



- **Activities**

People collaborate within a process to carry out their daily activities. Some activities are prescribed in documented information, while others may not and react to external stimuli to determine their nature and execution.



Development of a QMS

A QMS is a dynamic system that evolves over time through periods of improvement. A formal QMS provides a framework for planning, executing, monitoring and improving the performance of activities. ISO 13485 can be used to develop a QMS which is flexible, based on the needs of the organisation and interested parties, and the environment/context in which it operates. The QMS does not need to be complicated, the simpler it is, the better it will be understood.

A core part of any QMS will be the adoption of the process-based approach. (refer to your Student Workbook)

A process is defined in ISO 9000 as a *"set of interrelated or interacting activities that use inputs to deliver an intended result".*

- Examples in business include:

Purchasing	Production
Design	Sales

- The process approach is one of the seven Quality Management Principles.
- The adoption of the process approach is a key requirement in ISO 13485

Process Approach and Organisational Structure

Key Points:

- Identification of Processes
  - Identify product and service offerings to the customer(s)
  - Key business processes are the different stages (e.g. Design, Production, Service Delivery) involved in realising the product/service offerings.
- Different levels
  - System (inter-related key business processes)
  - Key Business Processes
  - Sub Processes
  - Activities

- Also, have support processes, such as HR, Equipment Maintenance, IT Support, etc.
- Processes operate cross-functionally (approx. 80% of problems happen at the interface between functions).
- All processes have some common characteristics:

<table>
<tr><td colspan="2">They have someone who is held accountable for how well the process performs (the process owner)</td><td>They have well-defined boundaries</td></tr>
<tr><td colspan="2">They have well-defined internal interfaces and responsibilities</td><td>They have documented information</td></tr>
<tr><td>They have training & development requirements</td><td colspan="2">They have measurement and feedback controls close to the point at which the activity is being performed</td></tr>
<tr><td rowspan="2">They have customer-related measurements and targets, such as service, quality and cost</td><td colspan="2">They have known cycle times</td></tr>
<tr><td colspan="2">They have formalised change procedures</td></tr>
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- Reference material on process management is available from your tutor

"Guidance on the concept of and use of the Process Approach for Management Systems"
"Identification of Processes"
"Understanding the Process Approach"

www.iso.org/tc176/sc2 and *www.iso.org/tc176/ISO9001AuditingPracticesGroup*

4. SUMMARY ISO 13485: 2016 REQUIREMENTS

Introduction to the 2016 Standard and Key Changes

The new ISO 13485:2016 (published on February 25, 2016) specifies an effective framework to implement requirements specific for medical technology organisations and related service providers. In summary, there are basically five sections in the standard of the ISO 13485 where major changes have been made:

Regulatory requirements

The first section establishes an emphasis on regulatory requirements that we see across the standard. This includes not only the local requirements that apply to your facility, but if you are an organisation that commercialises its products globally, you also need to take into consideration all relevant international requirements. There are many references to this throughout the ISO 13485:2016 standard.

Risk management

Another theme that permeates the standard is the need to incorporate risk management into all the main processes within your organisation.

Validation, verification, and design transfer

The ISO 13485:2016 standard puts a lot more structure into place surrounding these activities. You must have plans in place and documented evidence to show what you have been doing for validation, verification, and design transfer activities.

Outsourced processes and supplier control

The ISO 13485:2016 standard asks organisations to do a lot more when it comes to outsourcing processes and putting into place controls for assessing your suppliers, again based on risk.

Feedback

Finally, the ISO 13485:2016 requires you to monitor and measure the performance of your quality management system not only during production, but also post-market. You also must incorporate those activities as part of your risk management process.

In addition, the new ISO 13485 standard is more flexible than the old. In the past, organisations could **only exclude section 7 requirements** (on product realisation) and then only if they could justify their decision. Now, they can exclude any requirement in sections 6, 7, or 8 if they can justify doing so because of the nature of their activities or products.

Summary of Requirements

- Quality Management System
- Management Responsibility
- Resource Management
- Product Realisation
- Measurement, Analysis and Improvement

QMS

The **general requirements** are that an organisation shall document a QMS and maintain its effectiveness in accordance with ISO 13485 and regulatory requirements. A risk-based approach is required. The focus is on identifying and managing processes necessary to achieve customer satisfaction, regulatory requirements, and product safety.
Computer software used for the QMS must be validated prior to initial use and after any change is made.
The **documentation requirements** include:

- documentation required by the organisation and
- documentation required by ISO 13485.

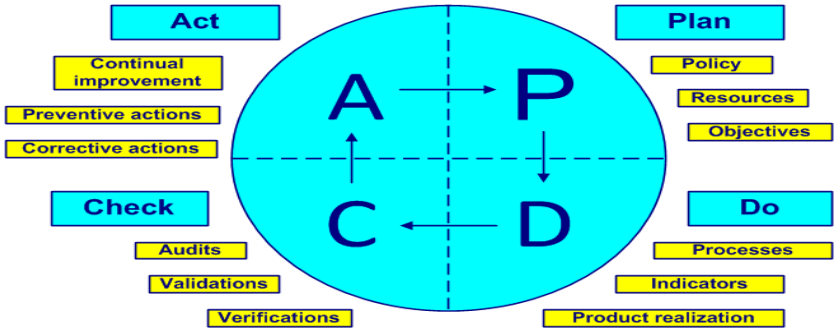
There are many examples throughout the standard where documented procedures are required, including the control of nonconformity, corrective action, preventive action, internal audit, control of documents and control of records.

A **Quality Manual** is necessary which describes the QMS in use within the organisation.

A **Medical device file** is required for regulatory purposes.

Documents and records need to be controlled. Documents must be approved, current, available where required and adequately controlled. Control of records, required by the QMS, include identification, storage, retrieval, protection, retention time and disposition.
In addition, the establishment of methods to protect confidential health information is also required.

Management Responsibility



Quality objectives shall be established and measurable and consistent with the Quality Policy Objectives should be:

S: Specific
M: Measurable
A: Achievable
R: Results-orientated or Relevant
T: Timeframe

and include those needed to meet product and regulatory requirements.
Quality Policy (i.e. overall intentions) needs to be documented, communicated and understood.
Quality Planning includes the planning involved in identifying the processes of the QMS, the resources needed to achieve the desired results (such as customer and regulatory requirements), verification and validation activities, criteria for acceptability and, records required.
Planning must also ensure that change is carried out in a controlled manner.

Responsibilities and authorities shall be defined, documented and communicated.
A management representative must be appointed to:

- ensure that processes are established and maintained
- report on the performance of the QMS, and
- promote awareness of the QMS and regulatory requirements.

Communications relating to the QMS and its effectiveness are necessary.

A **Management Review** shall be carried out to ensure the continuing suitability, adequacy and effectiveness of the QMS.

Resource Management
The organisation shall determine and provide the **resources** needed to establish, maintain and improve the QMS processes, and to meet regulatory and customer requirements.

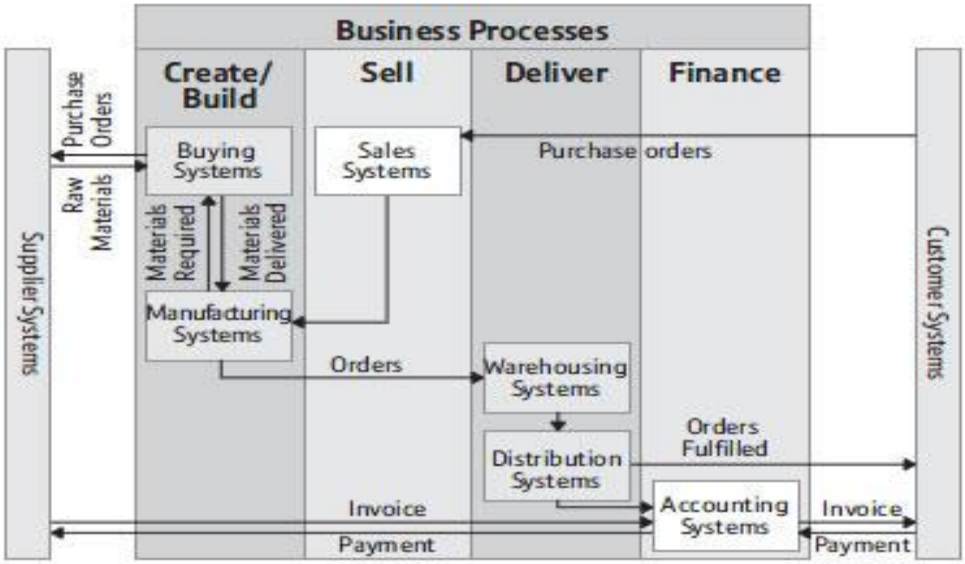
Personnel shall be **competent**.

The necessary **training and development** must be provided, and its effectiveness evaluated.

Infrastructure, such as buildings, workspace, equipment (hardware and software) and supporting services shall be defined, provided and maintained.

The human and physical factors of the **work environment** needed to achieve product and service conformity shall be defined and managed. This includes the controls relating to microorganisms and particulate matter, as appropriate.

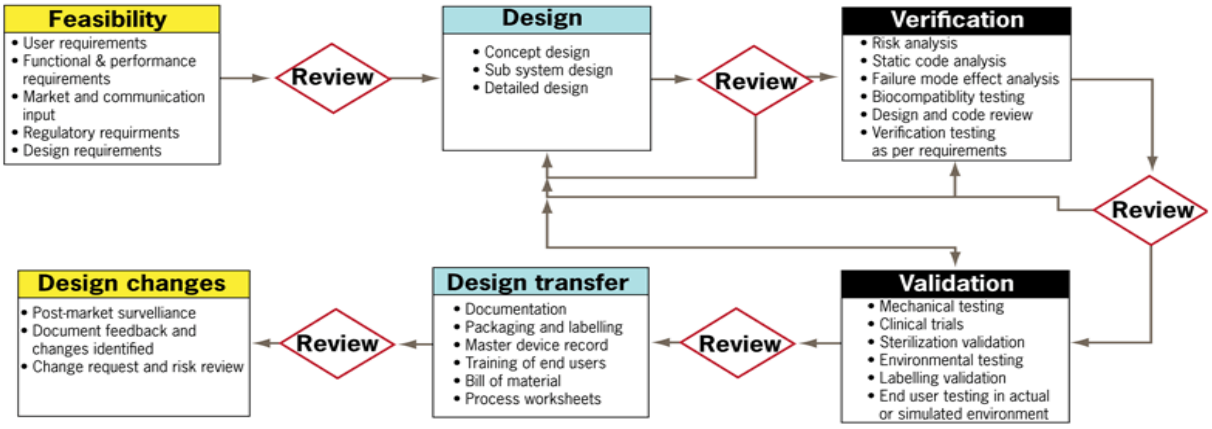
Product Realisation (Supply Chain Management)



In **planning** the processes such as design and production, the organisation needs to determine controls such as risk management, objectives, product requirements, product acceptance criteria, documents, verification, validation, inspection and test handling, storage, distribution, traceability, and records.

Customer-related processes include identification and agreement of customer and regulatory requirements, user training, and a review of such requirements to ensure that the organisation can meet them. Customer-related processes also include customer and regulatory communications, enquiry handling and customer complaints.

Design and development require documented procedures for planning, controlling and verifying product design and development. There are requirements for design and development planning, inputs, outputs, review, verification, validation, transfer, change control, and design and development files.



Purchasing requires that purchased product conforms to specified requirements; this is ensured through supplier evaluation and selection, risk management, clear and accurate purchasing information and verification of purchased product.

Production and Service operations include controls relating to:

availability of documented procedures,	qualification of infrastructure,
the availability and use of suitable measuring and	monitoring equipment,
the implementation of suitable monitoring and measurement activities,	suitable methods for the release,
Delivery,	applicable post-delivery activities,
cleanliness of product,	installation activities,
servicing activities,	identification and traceability,
control of sterile devices,	care of customer property,
handling, storage and packaging where applicable	process validation.

Measuring and monitoring equipment used to assure conformance of product shall be calibrated. Software used for measuring and monitoring of specified requirements shall be validated.

Measurement, Analysis and Improvement

Monitoring and measurement include:

- feedback on customer satisfaction and quality performance,
- complaint handling (not just customer complaints; a definition of complaint is given in "Terms and definitions" at the beginning of the standard),
- reporting to regulatory authorities,
- carrying out internal audit and
- process and product monitoring and measurement.
- Product and service which does **not conform** to requirements shall be identified and controlled to prevent unintended use or delivery.

The organisation shall collect and **analyse data** to determine the suitability, adequacy and effectiveness of the QMS.

The QMS shall be **improved**. A procedure for **corrective action** is required to eliminate the causes of nonconformity A procedure is required for **preventive action** to eliminate or minimise the causes of **potential problems.**	**Several clauses in ISO 13485 are closely associated with improvement:** • **Process improvement (8.5)** • **Leadership and commitment (5.1)** • **Internal Audits (8.2.4)** • **Management Review (5.6), and** • **Improvement (8.5, 8.4, 5.6, 8.2.1)**

5. INTRODUCTION TO QUALITY AUDITING

- **ISO 19011**
- **What is Auditing?**
- **Principles of Auditing**
- **Purpose of Auditing**
- **Types of Audits**
- **Human Elements**
- **Managing an Audit Program**

ISO 19011

ISO 19011 is an international standard which provides guidelines for auditing management systems.

Key Points:

- ISO 19011:2018 provides guidance on the fundamentals of auditing, the management of audit programmes, the conducting of management system audits and the qualifications for management system auditors.
- It is applicable to all organisations and the carrying out of both internal and external audits.
- The sections in this course manual on auditing uses ISO 19011 as the basis for both their structure and content.

Key Points:

Four main clauses:

- Principles of auditing
- Managing an audit programme
- Performing / Carrying out an audit, (refer to chapter 8)
- Competence and evaluation of auditors (refer to chapter 6)

- Guidance for all users; for 3rd party auditing (e.g. certification), requirements are specified in ISO/IEC 17021:2011

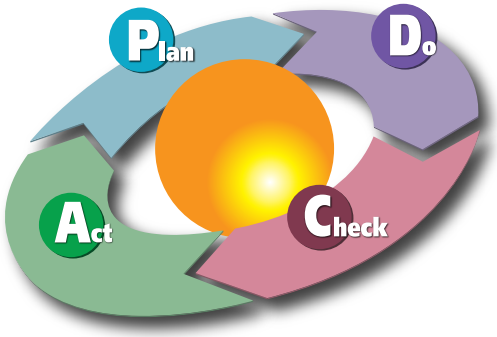
What is Auditing?

ISO 9000 defines an Audit as a "systematic, independent and documented process for obtaining objective evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled".

Key Points:

- Auditing is a bit like going to your doctor for a health check. You have a medical check and compare results to the standard. Here are some examples:

Metric	Standard	Actual	Comments
Temperature	37°C	37°C	Conforms
Average adult pulse rate at rest	70 beats per minute	70	Conforms
Total Cholesterol	No greater than 5 millimoles per litre of blood	5.8	Needs Improvement

The focus for improvement is cholesterol. Your doctor should be able to advise you on this. You then put a plan in place and after a period of time get another health check done.	**This sequence follows the cycle of** 

- **Audit Evidence** in ISO 9000 is defined as *"records, statements of fact or other information which are relevant to the audit criteria and verifiable".*
- **Audit Criteria** in the same standard ISO 9000 is defined as *"set of policies, procedures or requirements used as a reference against which objective evidence is compared".*
  Notes:
  - Procedures can be documented or not
  - Audit criteria are used as a reference against which audit evidence is compared
- Is the Quality System effective (not just compliant)?
- Is the Quality System suitable to achieve objectives set (indeed are measurable objectives set)?
- How am I going to divide my time during the audit? What proportion of time should be spent on;
  - Conformance (34%)?
  - Effectiveness, and (33%)?
  - Improvement (33%)?

  May decide to do a higher proportion of conformance-based auditing of the QMS in its early days or when there have been major changes made.

Principles of Auditing

- **Independence:** the basis for the impartiality of the audit and maintain objectivity
- **Fair presentation:** the obligation to report truthfully and accurately system inadequacies and non-conformities
- Due **professional** care be diligent and have the ability to make reasoned judgements
- **Confidentiality:** security of information
- **Evidence-based** approach: audit evidence should be verifiable
- **Integrity:** carry out audits with honesty, be sensitive to influences that may be exerted on your judgement, impartial.
- **Risk Based Approach.**

NOTE: Refer to your Student Workbook for more on "Principals of Auditing"

The Internal Audit Requirements of ISO 13485

8.2.4 Internal audit

The organisation shall conduct internal audits at planned intervals to determine whether the quality management system:

a) conforms to planned and documented arrangements, requirements of this International Standard, quality management system requirements established by the organisation, and applicable regulatory requirements;

b) is effectively implemented and maintained.

The organisation shall document a procedure to describe the responsibilities and requirements for planning and conducting audits and recording and reporting audit results.

An audit program shall be planned, taking into consideration the status and importance of the processes and area to be audited, as well as the results of previous audits. The audit criteria, scope, interval and methods shall be defined and recorded (see 4.2.5). The selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.

Records of the audits and their results, including identification of the processes and areas audited and the conclusions, shall be maintained (see 4.2.5).

NOTE See ISO 19011 for guidance.

Purpose of Auditing

- To determine the **effectiveness** of the implemented quality system in meeting specified quality objectives.
- **Conformance** to Quality system standards, such as ISO 13485 (standard also requires that an internal audit be performed)
- To provide the Auditor with an opportunity to highlight areas for **Improvement.**
- To permit the listing of the audited organisation's quality system in a register.
- To meet regulatory requirements such as the Food and Drug Administration's (FDA) Good Manufacturing Practices in the USA.
- Management requires assurance that the quality system can deliver quality products and services that meet agreed customer requirements and customer expectations.

Key Points:

Auditing should be looked on as a means of helping the organisation identify and **improve** the **effectiveness** and efficiency of its practices in pursuit of the organisation's objectives. This is different from simply identifying compliance to those practices. Adding value during the audit process ensures not only the business is doing things right but also that the right things are being done.

The last reason given above is becoming increasingly important for organisation's whose quality systems are maturing. At this stage, the major issue may not be compliance, but continuous improvement. The audit in essence, is used as a proactive tool to identify opportunities for improvement throughout the system.

Types of Audits

(Based on Who is Auditing)	
1st Party -	evaluate an organisation's own quality system against a quality system standard.
2nd Party -	evaluate a supplier. Purpose is usually to award a contract to supply or for the rating of an existing supplier.
3rd Party -	to achieve 3rd Party Registration / Certification or meet regulatory requirements.

Key Points:
The benefit of 3rd party certification is that International Standards are strategic tools and guidelines to help companies tackle some of the most demanding challenges of modern business. They ensure that business operations are as efficient as possible, increase productivity and help companies access new markets.

The benefits include:

- **Cost savings** - International Standards help optimise operations and therefore improve the bottom line
- **Enhanced customer satisfaction** - International Standards help improve quality, enhance customer satisfaction and increase sales
- **Access to new markets** - International Standards help prevent trade barriers and open up global markets
- **Increased market share** - International Standards help increase productivity and competitive advantage
- **Environmental benefits** - International Standards help reduce negative impacts on the environment.

Certification Audits (Based on What is being Audited)

Relevant Standard e.g. ISO 13485		Stage 1 Audit
↓	↖	
An Organisations QMS	↗	
↓	↖	Stage 2 Audit
Effective Implementation	↗	Conformance/ Compliance, Effectiveness & Improvement

Key Points:

- The initial certification audit of a management system is conducted in two stages: ***stage 1 and stage 2***.
- A ***Stage 1*** audit is used as a basis for planning the detailed Stage 2 audit – to ensure that the relevant quality system requirements have been taken account of and included in their operations.
- A ***Stage 1*** audit includes;

An evaluation of the location and site-specific conditions.
Determining preparedness for the Stage 2 audit.
A review of the clients' understanding regarding requirements of the standard.
Collecting information regarding scope and related statutory and regulatory requirements.
A review of the resources required for Stage 2.

An evaluation of internal audits and management review; that they are being planned and performed.
In preparation for a 3rd party audit, a preliminary site visit may be necessary to obtain the above information.

The purpose of this visit is to:

- ✓ clarify with the management of the organisation to be audited the scope of the audit and areas to be audited
- ✓ agree the procedures to be adopted during the Audit
- ✓ confirm the documentation being used with the organisation being audited
- ✓ discuss any points which need clarification

The benefits of such a visit is that:

- ➢ it imparts a sense of co-operation
- ➢ it identifies any special needs for the audit team such as skills, knowledge, facilities, protective clothing, etc.
- ➢ it identifies the layout of the facility so that a more accurate estimate of the number of auditors and time required can be made.

A Stage 1 audit provides a focus for planning Stage 2.

ISO / IEC 17021 states the following in relation to the ***Stage 2*** audit:

The purpose of the Stage 2 audit is to evaluate the implementation, including effectiveness, of the client's management system. The Stage 2 audit shall take place at the site(s) of the client. It shall include a review of all clauses.	

Human Elements of Auditing

- If being introduced for the first time, auditing can be a cultural issue (even after years).
- Will operate smoothly only if it is accepted as a valuable improvement tool – must educate management and all employees of the benefits.
- Must carefully select and instruct your auditors; auditors should be good at putting people at ease and not nit-pick.

Managing an Audit Program

General Requirements		
Programme Objectives - Establishing audit programme objectives* (what, where, when, why, who, how…) - Determining and evaluating audit programme risks and opportunities - Establish the Audit Program) Scope, schedule, type, criteria ….		**P**
Preparation for Audit – Consider…….		**L**
(a) Understanding auditee's organisation (c) Critical Success Factors (e) Initial auditee contact (g) Surveillance audit (i) Study documentation and information (k) Work documents (m) Team assignments (o) Productive meetings	(b) Process approach (d)Audit Plan (f) Type of audit (h) Preliminary visit (j) No Formal QMS (l) Audit Checklists (n) Classifying nonconformities	**A** **N**
Implementing audit programme … Consider ….		
(a) Objectives/scope/criteria (c) Audit team (e) Managing records (g) Audit scope	(b) Audit methods (d) Managing outcome (f) Auditor Selection (h) Schedule and frequency	
Carrying out / conducting the Audit – Consider …….		**D**
(a) Opening meeting (c) Audit Methods (e) Audit of Effectiveness & Improvement (f) Key tasks (h) Collecting information (j) Audit sampling (l) Prep for closing meeting	(b) Auditing a Process (d) Sequence (g) During the Audit (i) Communications (k) Audit findings (m) Closing meeting Audit Report Preparation and Distribution (ch 9 & 10)	**O**
Completing the Audit		**C**
Audit Report (ch 9 & 10)	Confirmation of CA's	**H**
Classification of CA's	Effectiveness of CA's	**E**
Audit Closure		**C**
Monitoring the Auditing Program ….		**K**
Review the Auditing Process	Is it effective?	
Conducting Audit Follow Up / Improve the Audit Program		**A**
Management Review	Continuous Improvement	**C**
		T

* When establishing Audit program objectives, the following should all be considered stakeholder needs and expectations

• characteristics of and requirements for processes, products, services and projects (and any changes to them)	
• the need to evaluate external providers	• management system requirements
• the auditee's levels of risk and opportunity	• the auditee's level of performance
• the results of their previous audits.	• the maturity of their management system(s)

Examples of audit programme objectives can include the following:

- identify opportunities to improve management system and its performance;
- evaluate the capability of the auditee to determine its context;
- evaluate the capability of the auditee to determine risks and opportunities and to identify and implement effective actions to address them;
- conform to all relevant requirements, e.g. statutory, regulatory requirements, commitments, requirements for certification to a management system standard;
- obtain and maintain confidence in the capability of an external provider;
- determine the continuing suitability, adequacy and effectiveness of the auditee's management system;
- evaluate the compatibility and alignment of the management system objectives with the strategic direction of the organisation.

The individual(s) managing the programme should now present to the audit client the risks and opportunities they have determined during the development of the audit programme along with the programme's associated resource requirements, presumably to ensure accuracy.

Determining and evaluating audit programme risks and opportunities

There are risks and opportunities related to the context of the auditee that can be associated with an audit programme and can affect the achievement of its objectives. The individual(s) managing the audit programme should identify and present to the audit client (auditee) the risks and opportunities considered when developing the audit programme and resource requirements, so that they can be addressed appropriately.
There can be risks associated with the following:
planning, e.g. failure to set relevant audit objectives and determine the extent, number, duration, locations and schedule of the audits;
resources, e.g. allowing insufficient time, equipment and/or training for developing the audit programme or conducting an audit;
selection of the audit team, e.g. insufficient overall competence to conduct audits effectively;
communication, e.g. ineffective external/internal communication processes/channels;
implementation, e.g. ineffective coordination of the audits within the audit programme, or not considering information security and confidentiality;
control of documented information, e.g. ineffective determination of the necessary documented information required by auditors and relevant interested parties, failure to adequately protect audit records to demonstrate audit programme effectiveness;
monitoring, reviewing and improving the audit programme, e.g. ineffective monitoring of audit programme outcomes; availability and cooperation of auditee and availability of evidence to be sampled.

Managing audit programme results

The individual(s) managing the audit programme should ensure:
a) evaluation of the achievement of the objectives for each audit within the audit programme;
b) review and approve audit reports regarding the fulfilment of the audit scope and objectives;
c) review of the effectiveness of actions taken to address audit findings;
d) distribution of audit reports to relevant interested parties;
e) determination of the necessity for any follow-up audit.

Managing and maintaining audit programme records

Audit records should be generated, managed and maintained to demonstrate the implementation of the audit programme. Processes should be established to ensure that any information security and confidentiality needs associated with the audit records are addressed including:

Records related to the audit programme, such as:

- schedule of audits;
- audit programme objectives and extent;
- those addressing audit programme risks and opportunities, and relevant external and internal issues;
- reviews of the audit programme effectiveness.

Records related to each audit, such as:

- audit plans and audit reports;
- objective audit evidence and findings;
- nonconformity reports;
- corrections and corrective action reports;
- audit follow-up reports.

Records related to the audit team covering topics such as:

- competence and performance evaluation of the audit team members;
- criteria for the selection of audit teams and team members and formation of audit teams;
- maintenance and improvement of competence.

The form and level of detail of the records should demonstrate that the objectives of the audit programme have been achieved.

Monitoring audit programme

The individual(s) managing the audit programme should ensure the evaluation of:

a) whether schedules are being met and audit programme objectives are being achieved;
b) the performance of the audit team members including the audit team leader and the technical experts;
c) the ability of the audit teams to implement the audit plan;
d) feedback from audit clients, auditees, auditors, technical experts and other relevant parties;
e) sufficiency and adequacy of documented information in the whole audit process.

Some factors can indicate the need to modify the audit programme. These can include changes to:

audit findings;	external providers;
effectiveness of the audit programme;	audit scope or audit programme scope;
the auditee's management system;	identified conflicts of interest;
standards, and other requirements to which the organisation is committed;	demonstrated level of auditee's management system effectiveness and maturity;
the audit client's requirements.	

Reviewing and improving the audit programme

The individual(s) managing the audit programme and the audit client should review the audit programme to assess whether its objectives have been achieved. Lessons learned from the audit programme review should be used as inputs for the improvement of the programme.

The individual(s) managing the audit programme should ensure the following:

- review of the overall implementation of the audit programme;
- identification of areas and opportunities for improvement;
- application of changes to the audit programme if necessary;
- review of the continual professional development of auditors, in accordance with 7.6;
- reporting of the results of the audit programme and review with the audit client and relevant interested parties, as appropriate.

The audit programme review should consider the following:
a) results and trends from audit programme monitoring;
b) conformity with audit programme processes and relevant documented information;
c) evolving needs and expectations of relevant interested parties;
d) audit programme records;
e) alternative or new auditing methods;
f) alternative or new methods to evaluate auditors;
g) effectiveness of the actions to address the risks and opportunities, and internal and external issues associated with the audit programme;
h) confidentiality and information security issues relating to the audit programme.
And possibly matching the level of **competence of the audit** team to the level of competence needed to achieve the audit objectives and finally aligning **audit dates** with the availability of auditee's key staff.

ISO 19011:2018 Process Flowchart for Auditing

	Plan	Do	Check	Act
P	5.2 Establish Audit Programme Objectives			
H	5.3 Determining and evaluating audit programme risks and opportunities			5.7 Reviewing and improving audit programme
A	5.4 Establishing audit programme	5.5 Implementing audit Programme	5.6 Monitoring audit Programme	
S				
E	6.2 Initiating The Audit			
	6.3 Preparing Audit Activities	6.4 Conducting Audit Activities		6.7 Conducting Audit Follow Up.
		6.5 Prepare and Distribute Audit Report	6.6 Completing the Audit	

6. PLANNING THE AUDIT PROGRAMME

- **Initial stages**
- **How much auditing?**
- **Auditors' Responsibilities**
- **Auditor Selection**
- **Audit Scope, Schedule, Frequency**

Initial Stages of the Life Cycle

No audit can be adequately carried out unless the programme is *authorised by top anagement* – must be seen as a valuable tool.
Prior to any detailed preparation need to determine *feasibility* e.g. if there is inadequate co-operation from auditee, inadequate time, or insufficient information about the scope, there is little point in proceeding.
What are the ***audit objectives*****?**
An example might be
"To determine the **effectiveness,** level of **conformance** and opportunities for **improvement** in the Sales Order process".

How much Auditing?

The extent of the Audit Programme depends upon factors such as,
- the audit *scope*
- the *frequency*; some critical activities may be audited more frequently
- the *duration*; may depend on the budgeted hours made available
- the *size of the organisation*; the bigger organisations normally require more auditing time
- the *complexity of the processes*
- the *audit criteria* such as standards, regulations & legislation
- more auditing generally required in *regulatory* environment
- results of *previous audits*
- *concerns* expressed by management, and
- significant changes.

Auditor's responsibilities

Auditors are responsible for:
- complying with the applicable audit requirements.
- communicating and clarifying audit requirements.
- planning and carrying out assigned responsibilities effectively and efficiently.
- documenting the observations.
- reporting the audit results.
- verifying the effectiveness of corrective actions taken as a result of the audit.
- retaining and safeguarding documents pertaining to the audit, and submitting such documents as required.
- ensuring such documents remain confidential.
- treating privileged information with discretion.
- co-operating with and supporting the Lead Auditor.

Lead Auditor's Responsibilities

- Ultimately responsible for all phases of the audit.
- Should have management capabilities and experience.
- Should be given authority to make final decisions regarding the conduct of the audit and any audit observations.

The Lead Auditor's responsibilities also cover:

- assisting with the selection of other audit team members.
- preparation of audit plan.
- representing the audit team with the auditee's management.
- submitting the audit report.

Auditor Selection

Auditor selection is crucial when carrying out audits against ISO 13485

Key Points:

Select Auditors at *different management levels* within the organisation. Initially:

- Effectiveness & Improvement – Auditors from a more senior level in the organisation.
- Conformance & Compliance – Auditors from front line.

Audit in pairs:

- Combine Auditors from more senior level with front line.
- Gives individual Auditors more confidence.

The person managing the audit programme should appoint the **members of the audit team, including the team leader if relevant and any technical experts needed.**

Audit competence and evaluation of auditors

Confidence in the audit process and the ability to achieve its objectives depends on the competence of those individuals who are involved in performing audits, including auditors and lead auditors.

Competence should be evaluated regularly through a process that considers personal behaviour and the ability to apply the knowledge and skills gained through education, work experience, auditor training and audit experience.

This process should take into consideration the needs of the audit programme and its objectives. The evaluation of auditor competence should be planned, implemented and documented to provide an outcome that is objective, consistent, fair and reliable. The evaluation process should include four main steps, as follows:

a) determine the required competence to fulfil the needs of the audit programme;
b) establish the evaluation criteria;
c) select the appropriate evaluation method;
d) conduct the evaluation.

The outcome of the evaluation process should provide a basis for the following:

— selection of audit team members
— determining the need for improved competence (e.g. additional training)
— ongoing performance evaluation of auditors.

Auditors should develop, maintain and improve their competence through Continual Professional Development and regular participation in audits

Determining auditor competence
When determining the necessary competence for an audit, an auditor's knowledge and skills related to the following should be considered:
a) the size, nature, complexity, products, services and processes of auditees;
b) the methods for auditing;
c) the management system disciplines to be audited;
d) the complexity and processes of the management system to be audited;
e) the types and levels of risks and opportunities addressed by the management system;
f) the objectives and extent of the audit programme;
g) the uncertainty in achieving audit objectives;
h) other requirements, e.g. those imposed by the auditee or other relevant interested parties.

Personal Behaviour
Auditors should possess the necessary attributes to enable them to act in accordance with the principles of auditing. Auditors should exhibit professional behaviour during the performance of audit activities. Desired professional behaviours include being:
a) ethical, i.e. fair, truthful, sincere, honest and discreet;
b) open-minded, i.e. willing to consider alternative ideas or points of view;
c) diplomatic, i.e. tactful in dealing with individuals;
d) observant, i.e. actively observing physical surroundings and activities;
e) perceptive, i.e. aware of and able to understand situations;
f) versatile, i.e. able to readily adapt to different situations;
g) tenacious, i.e. persistent and focused on achieving objectives;
h) decisive, i.e. able to reach timely conclusions based on logical reasoning and analysis;
i) self-reliant, i.e. able to act and function independently while interacting effectively with others;
j) able to act with fortitude, i.e. able to act responsibly and ethically, even though these actions may not always be popular and may sometimes result in disagreement or confrontation;
k) open to improvement, i.e. willing to learn from situations;
l) culturally sensitive, i.e. observant and respectful to the culture of the auditee;
m) collaborative, i.e. effectively interacting with others, including audit team members and the auditee's personnel.

Auditor Knowledge and skills
Should include knowledge and skills necessary to achieve the intended results of the audits And generic competence and a level of discipline and sector-specific knowledge and skills. For example:
a) Audit principles, processes and methods: knowledge and skills in this area enable the auditor to ensure audits are performed in a consistent and systematic manner.
An auditor should be able to:

- understand the types of risks and opportunities associated with auditing and the principles of the risk-based approach to auditing;
- plan and organise the work effectively;
- perform the audit within the agreed time schedule;
- prioritise and focus on matters of significance;

- communicate effectively, orally and in writing (either personally, or through the use of interpreters);
- collect information through effective interviewing, listening, observing and reviewing documented information, including records and data;
- understand the appropriateness and consequences of using sampling techniques for auditing;
- understand and consider technical experts' opinions;
- audit a process from start to finish, including the interrelations with other processes and different functions, where appropriate;
- verify the relevance and accuracy of collected information;
- confirm the sufficiency and appropriateness of audit evidence to support audit findings and conclusions;
- assess those factors that may affect the reliability of the audit findings and conclusions;
- document audit activities and audit findings, and prepare reports;
- maintain the confidentiality and security of information.

b) Management system standards and other references: knowledge and skills in this area enable the auditor to understand the audit scope and apply audit criteria, and should cover the following:

- management system standards or other normative or guidance/supporting documents used to establish audit criteria or methods;
- the application of management system standards by the auditee and other organisation's;
- relationships and interactions between the management system(s) processes;
- understanding the importance and priority of multiple standards or references;
- application of standards or references to different audit situations.

c) The organisation and its context: knowledge and skills in this area enable the auditor to understand the auditee's structure, purpose and management practices and should cover the following:

- needs and expectations of relevant interested parties that impact the management system;
- type of organisation, governance, size, structure, functions and relationships;
- general business and management concepts, processes and related terminology, including planning, budgeting and management of individuals;
- cultural and social aspects of the auditee.

d) Applicable statutory and regulatory requirements and other requirements: knowledge and skills in this area enable the auditor to be aware of, and work within, the organisation's requirements. Knowledge and skills specific to the jurisdiction or to the auditee's activities, processes, products and services should cover the following:

- statutory and regulatory requirements and their governing agencies;
- basic legal terminology;
- contracting and liability.

NOTE Awareness of statutory and regulatory requirements does not imply legal expertise

Discipline and sector-specific competence of auditors

Audit teams should have the collective discipline and sector-specific competence appropriate for auditing the types of management systems and sectors.

Generic competence of leader auditors

In order to facilitate the efficient and effective conduct of the audit an audit team leader should have the competence to:
a) plan the audit and assign audit tasks according to the specific competence of individual audit team members;
b) discuss strategic issues with top management of the auditee to determine whether they have considered these issues when evaluating their risks and opportunities;
c) develop and maintain a collaborative working relationship among the audit team members;
d) manage the audit process, including:

- making effective use of resources during the audit;
- managing the uncertainty of achieving audit objectives;
- protecting the health and safety of the audit team members during the audit, including ensuring compliance of the auditors with the relevant health and safety, and security arrangements;
- directing the audit team members;
- providing direction and guidance to auditors-in-training;
- preventing and resolving conflicts and problems that can occur during the audit, including those within the audit team, as necessary.

e) represent the audit team in communications with the individual(s) managing the audit programme, the audit client and the auditee;
f) lead the audit team to reach the audit conclusions;
g) prepare and complete the audit report.

Knowledge and skills for auditing multiple disciplines

When auditing multiple discipline management systems e.g. Integrated Management Systems) the audit team member should understand the interactions and synergy between the different management systems.

Achieving auditor competence

Auditor competence can be acquired using a combination of the following:
a) successfully complete training programmes that cover generic auditor knowledge and skills;
b) experience in a relevant technical, managerial or professional position involving the exercise of judgement, decision making, problem solving and communication with managers, professionals, peers, customers and other relevant interested parties;
c) education/training and experience in a specific management system discipline and sector that contribute to the development of overall competence;
d) audit experience acquired under the supervision of an auditor competent in the same discipline.

Establishing auditor evaluation criteria

The criteria should be qualitative (such as having demonstrated desired behaviour, knowledge or the performance of the skills, in training or in the workplace) and quantitative (such as the years of work experience and education, number of audits conducted, hours of audit training).

Selecting appropriate auditor evaluation method

The evaluation should be conducted using two or more of the methods given in Table 2. In using Table 2, the following should be noted:

a) the methods outlined represent a range of options and may not apply in all situations;

b) the various methods outlined may differ in their reliability;

c) a combination of methods should be used to ensure an outcome that is objective, consistent, fair and reliable.

Table 2 — Auditor evaluation methods

Review of records	To verify the background of the auditor	Analysis of records of education, training, employment, professional credentials and auditing experience
Feedback	To provide information about how the performance of the auditor is perceived	Surveys, questionnaires, personal references, testimonials, complaints, performance evaluation, peer review
Interview	To evaluate desired professional behaviour and communication skills, to verify information and test knowledge and to acquire additional information	Personal interviews
Observation	To evaluate desired professional behaviour and the ability to apply knowledge and skills	Role playing, witnessed audits, on-the-job performance
Testing	To evaluate desired behaviour and knowledge and skills and their application	Oral and written exams, psychometric testing
Post-audit review	To provide information on the auditor performance during the audit activities, identify strengths and opportunities for improvement	Review of the audit report, interviews with the audit team leader, the audit team and, if appropriate, feedback from the auditee

Conducting auditor evaluation

The information collected about the auditor under evaluation should be compared against the set criteria. An auditor who does not fulfil the criteria should be given additional training, work or audit experience should be undertaken and a subsequent re-evaluation should be performed.

Maintaining and improving auditor competence

Auditors and audit team leaders should continually improve their competence. Auditors should maintain their auditing competence through regular participation in management system audits and continual professional development. This may be achieved through means such as additional work experience, training, private study, coaching, attendance at meetings, seminars and conferences or other relevant activities.

The individual(s) managing the audit programme should establish suitable mechanisms for the continual evaluation of the performance of the auditors and audit team leaders.

The continual professional development activities should take into account the following:

a) changes in the needs of the individual and the organisation responsible for the conduct of the audit;

b) developments in the practice of auditing including the use of technology;

c) relevant standards including guidance/supporting documents and other requirements;

d) changes in sector or disciplines.

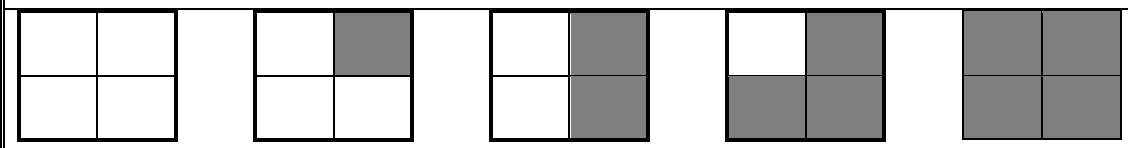
Audit Scope and Schedule/frequency

Scheduling audits of single quality system elements (e.g. documentation, calibration) may not be the best way – may result in missing important functional interfaces.

Should schedule based on *key processes*.

Audit Schedule

Audit Schedule for year:			**Revision: .....**				
Schedule Approved by:			**Date: .....**				
Area / Activity	**ISO 13485 Elements**	**Procedure Number**	**Audit Number**	**Month**			
				Jan	**Feb**	**Mar**	**etc.**
Production/ Delivery of Service	**Relevant parts of Sections 4, 5, 6, 8, & 9. Sections 7.1, 7.5, 7.6.**	**Select relevant procedures & keep record of those audited**	**15-001**				
Design Control	**Relevant parts of Sections 4, 5, 6, 8, & 9. Sections 7.1, 7.3.**		**15-002**				
Purchasing	**Relevant parts of Sections 4, 5, 6, 8, & 9. Sections 7.1, 7.4.**		**15-003**				
etc.							
One can incorporate an audit tracking mechanism into the above figure. This could be done as follows:							



Indicates an audit is scheduled for this month	**Indicates the audit has been conducted**	**Indicates that corrective actions have been agreed**	**Indicates that corrective actions are reported complete**	**Indicates that corrective actions have been verified**

Frequency of Audits

9.0 *The organisation shall refer to ISO 13485 clause 8.2.4*

The following should be considered:

- The *importance of the operation* in relation to quality output.
- *Significant changes* in management organisation, policy, technologies or techniques that could affect the quality system.
- *Changes to the system* itself.
- *Results of previous audits*.

7. AUDIT PREPARATION (Planning)

- Risk Based Approach to Planning
- Understanding the Organisation
- Critical Success Factors
- Auditee contact
- No formal QMS
- Audit checklists
- Classification of non-conformity
- ISO 9001 Auditing Practices Group
- Process Approach
- Audit Plan
- Studying Data and Documentation
- Work documents
- Team assignments
- Guidelines for Productive Meetings
- The Role and Value of the Audit Checklist

Risk Based Approach to Planning

The **Lead Auditor** should adopt a risk-based approach to planning the audit based on the information in the audit programme and the documented information provided by the auditee. Audit planning should consider the risks of the audit activities on the auditee's processes and provide the basis for the agreement among the audit client, audit team and the auditee regarding the conduct of the audit. Planning should facilitate the efficient scheduling and coordination of the audit activities in order to achieve the objectives effectively.
When planning the audit consider the following:
a) the composition of the audit team and its overall competence;
b) the appropriate sampling techniques (see A.6);
c) opportunities to improve the effectiveness and efficiency of the audit activities;
d) the risks to achieving the audit objectives created by ineffective audit planning;
e) the risks to the auditee created by performing the audit.
Risks to the auditee can result from the presence of the audit team members adversely influencing the auditee's arrangements for health and safety, environment and quality, and its products, services, personnel or infrastructure (e.g. contamination in clean room facilities).

Understanding the Organisation

Information and data input	DETERMINE	Planned for by defining	What Auditor looks for
(1) Agreed customers' requirements and expectations (7.2)	(2) Product and services to be sold.	(3) Product and service design features.	(4) Product descriptions; Design specifications (7.3.4)
(5) Product descriptions and design specifications (7.3.4)	(6) Processes to be performed (4.1)	(7) Sequence and interaction of the processes (4.1); Process requirements (7.1)	(8) Process map or plan; Quality plan; Process specifications (7.1)
(9) Process map or plan; Quality Plan (7.1)	(10) How processes are grouped together (4.1)	(11) Organisational hierarchy; reporting levels and responsibilities for each process and group of processes (5.5.1)	(12) Organisation chart; Job descriptions (5.5.1)
(13) Process specifications (1.1); Job descriptions (5.5.1)	(14) Competencies required for the process (6.2)	(15) Job specifications (5.5.1)	(16) Job specifications (5.5.1)
Note: Numbers in brackets relate to the sections of the ISO 13485 standard.			

Key Points:

- The above is an example of an Audit Trail which extends from basic data and information about the marketplace to defining how the organisation is structured and is an essential part of audit preparation.

Process Approach

Key Points: Refer to your Student Workbook for more on "Process}

- An understanding of the process approach will help to maintain the "helicopter" view and prevent getting involved in unnecessary detail.
- Organisations work through processes. Process improvement is key to continual improvement – better quality, higher productivity and reduced costs.
- Be familiar with the process being audited.

Critical Success Factors

A critical success factor (CSF) can be described as a factor that to a large extent impacts the organisation's competitiveness and its performance in the marketplace.

Key Points:

- Examples are price, quality, knowledge and so on depending on the type of business. In other words, what is it that our customers truly value about our organisation? The answer is usually the critical success factors.
- It is important to know as much as possible about these prior to auditing so that the audit can focus on what's really important to the customer. For example, if competitive advantage relates to the service elements within the organisation such as cycle time or responsiveness, this is where a significant portion of audit time should be devoted.
- Critical success factors should ideally be related to the key processes, which have most impact on such factors.

Audit Plan

The audit plan (defined in ISO 9001 as *"description of the activities and arrangements for an audit"*) should include the following, as appropriate, depending on the size and complexity of the audit:

An audit plan should include

- Purpose;
- The audit objectives;
- Audit scope;
- Audit type;
- The audit criteria;
- Reference documents;
- The dates and place where the audit activities are to be conducted;
- The identification of the processes, organisational and functional units to be audited;
- The identification of the sites, activities and management system processes that are essential to meeting audit objectives in order to allocate appropriate resources to critical areas of the audit;
- The expected time and duration for audit activities, including meetings with the auditee's management and audit team meetings;
- The working and reporting language(s) of the audit;
- The identification of roles and responsibilities of the audit team members and any accompanying persons;
- The audit report topics (including any methods of non-conformance gradings), format and structure, expected date of issue and distribution;
- Logistical arrangements (travel, on-site facilities, etc.);
- Matters related to confidentiality;
- Any arrangements for audit follow-up actions.

Initial Auditee Contact

The contents of the Audit Plan should be communicated to the Auditee prior to the audit.
Ensure communication with people in *all relevant functions* as process audits typically move across functions.
Request relevant documentation, data analysis, and, records approximately 1 – 2 weeks beforehand to allow *enough time to prepare.*

Studying Data and Documentation

Know the relevant sections of the *QMS standard.*

Know what the *Key Performance Indicators* or objectives are for the process or area.
Study performance measures (e.g. yields, defects, customer complaints) against these objectives to determine *effectiveness*; use the results to help you focus during the audit.
Have *all relevant documentation* such as manuals, procedures, standards, contracts, etc. study these. They will form part of the audit checklist.
Results from previous audits

No Formal System

What if there is no formal, documented system in place?

In a situation where there is no formal documented system in place, the following steps should be taken:

1. Purpose, Objective, Scope:
   Establish or agree on purpose, objective and scope of the Audit?
2. Criteria: Identify criteria against which the audit is to be performed,
   including any quality standard or contract requirements?
   Determine whether requirements of a standard or contract apply and which?
3. Documentation: Ask for any documented policy statement and quality objectives?
   Ask for any instructions, procedures, forms, records, brochures or any other documents that relate to the activities to be audited?
4. Checklist: Prepare checklist of people, activities, documents and records to be reviewed.

Plan Audit as normal

Work Documents

There are several work documents used by the audit team for the purpose of reference and recording the proceedings of the audit. These include the following:

- audit procedure
- audit checklists
- sampling plans (maybe informal such as 10%), and
- forms for recording information, records of meetings and audit findings.

Key Point:

It is necessary for Auditors to ensure that they are adhering to the audit procedure.

Audit Checklists

Audit checklists are a set of prompts or reminders of important topics to inquire about, and things to look for, based on the descriptions of the operations being examined.
There can be two types of checklists, like the two types of audits

- Systems
- Conformance, Performance and Improvement.

Advantages:	Disadvantages:
• The checklist gives the auditor confidence. • It ensures that the really important questions are not overlooked. • Aids concentration keeps Auditor on track. • Enables the Auditor to remain focused after a delay or diversion. • It facilitates notetaking. • Auditee knows what to expect during audit. • Helps with time management.	• Auditors can become too reliant on the checklist and fail to adequately understand the process being audited. • It can interfere with the Auditor's conversational style if treated as a script. • It can be followed too rigidly and inhibit following new leads. • The routine can become familiar to the auditee if the same checklist is kept and re-used.

Finally, checklists can be in a number of different formats. Some checklists are in the form of questions. An Auditor with more experience and a good knowledge of the activity being audited might simply record the key words.

- Guidance from ISO 9001 Auditing Practices Group available form your tutor or (check www.iso.org/tc176/ISO9001AuditingPracticesGroup for latest version)

Teamwork

Audit Team Work Assignments

Need to assign to each team member responsibility for auditing specific management system processes, functions, sites, areas or activities.

Key Points:

- Responsibilities assigned by Audit Team Leader in consultation with the audit team.
- Such assignments should consider the need for auditor independence, competence and efficient use of resources.
- The audit team members should review all relevant information related to their audit assignments and prepare any work documents necessary for those assignments.
- More information on audit team members and their responsibilities are given in Section 10 of this Course Manual.

Classification of a non-conformity

- Prior to the commencement of an audit a decision needs to be made if a classification system is going to be used for non-conformities that may arise during an audit.
- ISO 9000 defines a non-conformity as *'nonfulfillment of a requirement'*. The definition covers the departure or absence of one or more quality characteristics or quality system elements from specified requirements.
- There is no universal grading system for non-conformities. Some organisations do not use any grading system.
- The purpose of a grading system is to prioritise tasks for those who need to take corrective action and to help management to prioritise findings. Any grading system is somewhat arbitrary.

Key Points: One examples of a Classification System is as follows:

Major

Major quality system deficiency / Lack of a system

- *Product or service deficiency***.**

For example, in the case of a system deficiency, ISO 13485 states that "the organisation shall determine and apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements". If a company has no established practices for doing this, then they do not fulfil the requirements.

Minor

- *Isolated non-conformity*

The non-conformity genuinely appears to be isolated without any clear underlying cause and perhaps where no corrective action can be formulated. There is a defined system, documented procedures and arrangements are in place which generally satisfy agreed requirements. The activity being audited is able to demonstrate an acceptable level of implementation overall, but there are minor discrepancies.
An example of a minor discrepancy is where training records are available, but not sufficiently detailed.

Observation

This is an observation and relates to a situation which does not represent an outright non-conformity. In the auditor's judgment it warrants clarification or investigation, to improve the overall status and effectiveness of the quality system.

Another example of a classification system, in this case in the pharmaceutical industry is as follows:
A **critical** non-conformity is one that can affect the quality and safety of the product and may cause harm to the patients if administered.
A **major** non-conformity is one that may affect the quality and safety of the product, and includes unauthorised process changes, unvalidated manufacturing processes that have a major impact on quality.

A **minor** non-conformity is not likely to affect the quality and safety of the product. These include deficiencies arising out of lapses in discipline e.g. failure to review an SOP at the due date, using correction fluids to amend records, etc.

Guidelines for Productive Meetings

There are many stages during an audit where meetings are held. These could include:

- A preparatory meeting among the auditors
- Opening Meeting with the Auditee
- Auditor team meeting prior to the closing meeting, and
- Closing meeting with the Auditee.

Some general guidelines for conducting meetings are useful to ensure that meetings are as productive as possible. Refer to your STUDENT WORKBOOK

8. CARRYING OUT THE AUDIT

- **Opening Meeting**
- **Auditing a process**
- **Audit methods**
- **Sequence for audit**
- **Auditing Effectiveness and Improvement**
- **Key tasks to look at**
- **During the audit**
- **Collecting information**
- **Communications**
- **Audit Sampling**
- **Preparing for Closing Meeting**
- **Closing Meeting**
- ***ISO 9001 Auditing Practices Group***

Guidance available from your Tutor on:

***Top management**	***Audit Trail**
***Processes**	***Demonstrating conformity to the standard**
***Context**	***Documenting a Nonconformity**
***Risk-based thinking**	***Evidence collection**
***Organisational knowledge**	***Service organisations**

Opening Meeting

- A 2nd and 3rd party audit will commence with a *formal* opening meeting where the audit team will meet representatives of the audited company's management team.
- During a 1st party audit you may judge that the same degree of formality is not necessary. Nevertheless, a more formal opening meeting will impress the importance of internal audits when this discipline is first introduced.

- The way this meeting is conducted will have a critical influence on the success of the audit. This meeting sets the *tone* for the overall audit and you never get a second chance to make a first impression.

Key Points:

- **Introduce** the members of the audit team.
- Re-emphasise the **purpose and scope** of the audit and ensure it is understood.
- Confirm the **standard and audit criteria** to be used as the basis for the audit.
- Explain what **each auditor** will be looking at with approximate Timetable.
- Give a short **summary of the methods and procedures** to be used.
- Method of **reporting and classification** of non-conformities.
- Clarify any **interim meetings** which may be necessary.
- Give details of the purpose of the **closing meeting** and who should attend.
- Ensure that **audit guides** are available and that they have been briefed.
- Confirm that the **domestic arrangements** for office accommodation, meals, etc.
- Verify the organisation's **staff have been informed** that the audit is taking place.
- Confirm relevant work **safety, emergency and security** procedures for the audit team.
- Arrange a **tour** of the premises or map it out for the audit team.
- Mention the **confidentiality** aspect of the audit.

Auditing a Process

Key Points:

Refer to your STUDENT WORKBOOK

To **adequately audit a process,** auditors need to gather information on or determine the following about the process, whether the process is documented or not (numbers in brackets indicate clauses of ISO 13485):

- Process being evaluated **(4.1)**
- Boundaries of Process to be audited? **(4.1)**
  - Beginning boundary step(s)
  - Ending boundary step(s)
  - Interlinked processes feeding into and out of process
  - Activities/sub-processes that make up process
- Process **objectives and related targets, measures, actions and current results**? **(7.1)**
- **Inputs/resources** and related suppliers' requirements, measures and results? **(7.1)**
- Outputs/outcomes and related customers, **requirements (targets), measures and results? (7.1)**
- Recent **changes** to process and evidence of control? **(4.1.4)**
- **Trend analysis of data** on process/product including quality of output, non-conformances, scrap, on-time deliveries, customer feedback (internal & external), etc. that indicate performance of process? **(8.4)**

Inputs to the Process

- Relevant process components such as
  - Manpower (or personnel) (**6.1, 6.2, 5.5)**
  - Machinery (or equipment) (**6.1, 6.3, 7.6)**
  - Material (including incoming, work in progress and final product), (7.4, 7.5)
  - Methods (**4.2)**
  - Measurement **(8.2)**
- Environment for the operation of the processes is important **(6.4)**
- Improvement programme in place. **(8.5)**

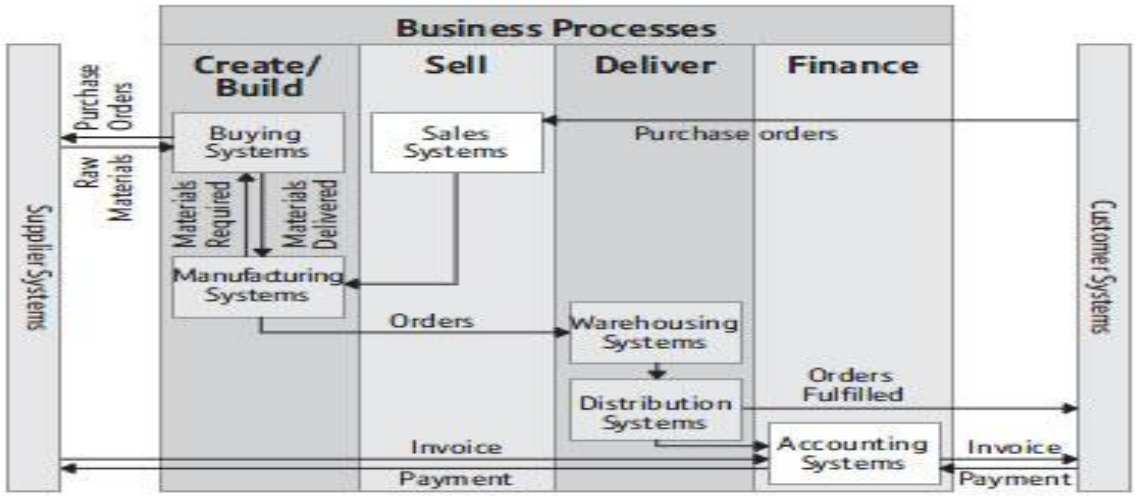
Once understood, the auditor might draw a flowchart or process map as guide.

Once understood, the auditor might draw a flowchart or process map as guide.

To simplify the above, you could use the following formula for auditing:

(E + I) + 4M's + Work Env,
Where E = Effectiveness
I = Improvement
4M's = Manpower, Machinery, Material, Methods.
Env = Whole work environment, buildings, utilities, facilities, etc

Brackets indicate you may need to take time out to assess the E and I before deciding specifics to look at in the 4M's / Work Env.



Audit Methods

- **Trace Forward**
- **Trace Back**
- **Random Department**

Key Points:

Trace forward:

This involves starting at the sales or customer contract stage and following the product or contract through the various work areas and departments associated with the process stages.

The end point is where the product is handed over to the customer and any subsequent customer support. This method can also apply to a sub-process.

Trace Back:
This method works in the opposite direction and can involve the selection of a particular product or contract and "challenging" the various process steps it has gone through.

Random Department:
Auditor visits the departments or work areas that are of interest in whatever order the auditor chooses.
Major disadvantage of this method is that organisational problems such as interdepartmental interfacing difficulties are not readily apparent.

Sequence for Audit

A useful sequence for the audit is:
1. **Effectiveness:** Compare results obtained against the objectives or targets set. Study trends for approx. past 6 months.
2. **Improvement:** Discuss improvement plans based on how effective the process is and what the plans are to close the "gaps".
3. **Conformance:** Based on the above findings, check relevant conformance issues. Eg if a reason for not achieving the objectives or targets is likely to be related to the Process Inputs.

Key Points:
The above approach uses Risk-Based Auditing, i.e. the audit focuses on where the risks are to the business. Guidance from ISO 9001 Auditing Practices Group available from your tutor (check www.iso.org/tc176/ISO9001AuditingPracticesGroup for latest version).

Auditing Effectiveness and Improvement

Conformance type auditing is relatively easy and straight forward. What is more difficult is auditing Effectiveness and Improvement.
Effectiveness looks at performance measures against the objectives set and the extent to which planned activities are realised.
Key questions to ask during a *Performance and Improvement* Audit are:
(numbers in brackets indicate clauses of ISO 9001)

- What are the objectives? (Section 6.2 /8.1)
- Is the data analysed? And how often (Section 9.1.3)
- What sort of trends appear?
- What methods of analysis are used to improve the process and to improve product?
- Do the methods get to the root cause(s) of the problem?
- What levels of improvement in product / process is the auditee achieving? (10)
- Over what period of time have these improvements been obtained?

The sum of those questions enables the auditor to conclude the existence or otherwise of an improvement programme and its efficiency. In addition to looking at the auditee's improvement programme, the auditor may also make their own suggestions for improvement. This may result from their own experience or during discussions with auditees throughout the areas being audited. Most personnel are quite happy to get the opportunity to suggest improvements.

If continual improvement is a requirement (as in the case of ISO 9001), a Corrective Action Request (CAR) is justified in the following circumstances:

- The auditee has no programme or policy for pursuing continuous improvement
- The auditee has such a policy or programme but it is not being implemented
- The auditee is implementing such a policy or programme but has realised no or very little improvement over a reasonable period.

Most of the above questions will be directed at senior and middle management. A more detailed set of questions can be developed by examining the "Context of the organisation", and "Leadership" requirements specified in ISO 9001, and turning these requirements into a set of questions.

Next Level of Auditing

Based on the outcome of the audit on Effectiveness and Improvement, the auditor will then need to examine in greater detail those tasks posing greatest risks. Refer to your STUDENT WORKBOOK "Key activities To Look at During An Audit"

During the Audit

The **Auditor** needs to control:
- the time - the interview, and - the sample

The **Auditor** selects:
- the people with whom to speak - the records to look at

Auditing is done to find facts, through objective evidence, not to find fault
The purpose is not to apportion blame or impose a specific corrective action.

Collecting Information

- **Sources of information**
- **Collect information by proper sampling**
- **Audit evidence**
- **Audit Findings (obtained by comparing the evidence against the audit criteria)**
- **Audit Conclusions**

Key Points:

Get the broad picture before focusing on the detail.
Information may be obtained from several sources such as:

- *interviews*;
- *observations* of activities and the surrounding work environment and conditions;
- *documents*, for example, policy, objectives, plans, procedures, instructions, licenses and permits, specifications, drawings, contracts, orders

When conducting a document review the auditor should consider if the information in the documents provided is:
- complete (all expected content is contained in the document)
- correct (the content conforms to other reliable sources such as standards and regulations
- consistent (the document is consistent in itself and with related documents)
- current (the content is up to date).

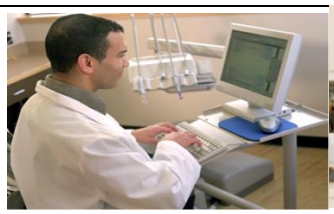
- *Records*, such as inspection records, minutes of meetings, reports or logbooks on customer complaints and other relevant communication from external interested parties, audit reports, monitoring programmes and results of measurements;
- *Reports* from other sources, for example, customer feedback, external reports and vendor supplier ratings; data summaries, analyses, metrics and performance indicators.
- Information should also be collected relating to interfaces between functions, activities and processes.

Interviews are an important means of collecting information and should be carried out taking the following into account:

- interviews with persons from different levels and function, and especially with persons performing activities or tasks under consideration.
- whenever possible, the interview should be conducted during normal working hours and at the normal workplace of the interviewed person;
- initially introduce yourself;
- every attempt should be made to put the interviewed person at ease;
- the reason for the interview and any note taking should be explained;
- interviews may be initiated by asking the persons to describe their work;
- be systematic and don't "jump around" too much;
- speak the person's language; there are a lot of buzz words in ISO 13485. Rephrase the question if necessary;
- speak clearly and carefully;
- if the information is unavailable, agree a time that it will be given to you; the onus is on the auditee;
- if the auditee feels threatened or anxious, back off, rephrase the question or ask a different question;
- **the results from the interview should be summarised and any finding should be verified with the interviewed person where possible;**
- the interviewed persons should be thanked for their participation and co-operation.

Applicable Audit Methods

Extent of involvement between the auditor and the auditee	**Location of the auditor (On-site)**	**Location of the auditor (Remote)**
Human interaction	- Conducting interviews. - Completing checklists and questionnaires with auditee participation. - Conducting document review with auditee participation - Sampling	Via interactive communication means: — conducting interviews; — completing checklists and questionnaires; — conducting document review with auditee participation
No human interaction	- Conducting document review (e.g. records, data analysis). - Observation of work performed. - Conducting on-site visit. - Completing checklists. - Sampling (e.g. products)	- Conducting document review (e.g. records, data analysis). - Observing work performed via surveillance means, considering social and legal requirements. - Analysing data.
On-site audit activities are performed at the location of the auditee. Remote audit activities are performed at any place other than the location of the auditee, regardless of the distance. Interactive audit activities involve interaction between the auditee's personnel and the audit team. Non-interactive audit activities involve no human interaction with persons representing the auditee but do involve interaction with equipment		




Key Points:

An Auditor should not ask too many follow-up questions pertaining to the one item. There is a danger here that the Auditor goes off on a tangent, gets involved in too much 'nitty-gritty' and as a result may lose focus. This could cause frustration for both the Auditor and Auditee.

Communication

Asking Questions - Listening - Notetaking - Behaviour - Conflict Management

❖ **Questions** Who, What, Why, Where, When and How (most Questions to open with one of these six)	
- Combination of Open and Closed Questions; The six are open-ended questions and do not get a "yes" or "no" reply	
- When discussing about documents and records, objective evidence can be requested by "Please show me"	
- Hypothetical question; "What procedure would you use if there was a non-conforming product or service?"	
- Silent questions; information volunteered due to silence (use sparingly)	
Listening	
There has been a lot of research into the different ways in which people communicate with each other. **The consensus seems to be that on average words account for only 7% of the message.** **Tone of voice accounts for about 13% and a mighty 80% of the message is conveyed through body language.** Clearly there is a whole lot more to listening than just straight-forward word recognition. Words are important, but they are only at the surface of what the listener needs to know.	L = Look interested – get involved I = Involve yoursef by responding S = Stay on target T = Test your understanding E = Evaluate the message N = Neutralise your feelings

Hearing and listening

Hearing and listening are not the same thing at all. The key difference is that hearing is done with the ears, and listening is done with the mind. Ability to hear therefore is a physical attribute whilst ability to listen is a mental one, and it is important to understand this from the start.

Note-taking

Taking notes is one obvious method listeners can use to bolster their memory of what is being said. Excessive notetaking, however, is distracting and off-putting to the speakers. And it is not especially useful to the listener either.

Much research has been done into the value of notetaking as a memory jogging technique. The results seem to indicate that, whilst notes are important, the fewer you make the better. There are two reasons why:

a) compulsive note-takers do not have time to make the signals or gestures which tell the speaker how their message is being received - so the speaker gets little or no feedback.

b) nobody can write as fast as people speak. So, in trying to make detailed notes the listener gets left behind and will probably miss whole chunks of the speaker's message because of it.

The first and most important rule about notetaking therefore is that notes should be brief and to the point: *KEEP IT SHORT AND SIMPLE.*

The second rule is to be *DISCRIMINATING***,** and to use notes only for the important things, so as an aid to memory.

Some examples of what to record during the audit are outlined next and should be read in conjunction with the ISO 9001 Auditing Practices Group guidance document on Audit Trail at the back of this section of the Course Manual. These examples relate back to some of the key task elements described earlier.

Example of what to record during an AUDIT TRAIL	
Activities / Task / element	**Examples of records to keep during the Audit process**
Personnel	• Persons name or employee number • Notes relating to evidence found during the audit of activities
Equipment	• Serial number • Asset number • Notes relating to evidence found during the audit of activities
Product	• Part number • Batch number • Quantities • Supplier • Notes relating to evidence found during the audit of activities
Methodology	• Document number • Revision number • Approvals • Notes relating to evidence found during the audit of activities
Measurement	• Method reference • Name of Inspector • Sampling Plan • Acceptance criteria • Notes relating to evidence found during the audit of activities
Work environment	• Area visited • Notes relating to evidence found during the audit of activities

Behaviour

In most cases the area being audited is a customer of the Auditor. The Auditor is providing a service. Therefore, AUDITOR behaviour should relate to a supplier-customer relationship.
It is also useful to keep in mind that most of the time during an audit, the Auditee should be in the talkative mode. Therefore, anything the auditor can do to facilitate this will tend to make an audit more successful.
The following are some guidelines which could be used:

be courteous	be composed
be punctual	have a good sense of humor
be resilient	one-upmanship is not recommended
be professional – deal with issues and not personalities	discuss problems as they arise; this saves time and avoids seeking clarification later
when necessary, be assertive	agree to disagree – don't argue
be aware of time wasting by the Auditee.	

Conflict Management

1. Calm the situation
2. Empathise
3. Listen (Do not interrupt)

Audit Sampling

As previously stated, an audit will only consist of a sample.
It has been shown from experience, that a relatively small number of samples is enough to reveal a major problem.
Depending on the audit objectives, it may be reasonable to select 3 – 5 samples, provided no non-conformities are found. If, however, the sample shows up one or more non-conformities, then the auditor must take further samples or request the auditee to purge the area further to discover the true extent of the problem.

What is adequate sampling?

There is no statistical or mathematical formula to establish the right number of samples to be taken during an audit. Defining the number of samples (e.g. one, five, or even more sample of records for a requirement) to be taken to confirm compliance to the requirements is not efficient and does not ensure compliance. It is of course a fact that by increasing the number of samples taken, the auditor has a greater confidence regarding the actual status of the implementation of the QMS. Adequate sampling is the sample taken during interviews and record reviews for confidence building that the auditee QMS is implemented as described and is effective.

Audit Evidence

- Audit evidence (that is, records, verified statements of fact or other information relevant to the audit) should be identified and recorded.

- *If in doubt, give the benefit to the Auditee*

- Audit evidence collected during an audit will inevitably be only a sample of the information available, since an audit is conducted during a finite period of time and with limited resources. There is thus an *element of uncertainty* inherent in all audits, and attention of users of the audit conclusions should be drawn to this uncertainty.

Key Points:

*Collected audit **evidence** needs to be evaluated against the audit **criteria** (i.e. set of policies procedures or requirements against which collected audit evidence is compared) to generate the audit findings (defined in ISO 9000 as "results of the evaluation of the collected audit evidence against audit criteria").*

*An **audit finding** can indicate either **conformity** or **non-conformity** with requirements. Audit findings may be graded in accordance with the audit plan.*

***Conformities** should be summarised to at least indicate locations, functions or requirements audited. Individual audit findings of conformity should also be documented if within the agreed scope.*

***Non-conformities** should be recorded and supported by audit evidence.*

***Non-conformities** should be reviewed with an appropriate auditee representative to obtain acknowledgement of the audit evidence. The auditee representative's acknowledgement indicates that the audit evidence is accurate, and that the nonconformity is understood.*

Every attempt should be made to resolve any divergence of opinion concerning the audit evidence, and unresolved points should be recorded.

Regular meetings may be scheduled with the auditee and/or client to report progress and findings. For example, meetings may be held for audits that last longer than a day.	
The Auditor should explain it may not be possible to write and grade observations and non-conformities until the end of the audit, when the whole of the management system has been audited and the significance and impact of the problem understood.	

Preparing for the Closing Meeting

After all activities have been audited, the audit team should review all of their findings to determine which are to be reported as conforming **(strengths)** and **non-conformances** areas for **improvement.**

Key Points:
Ensure findings are documented in a clear, concise manner and are supported by objective evidence.

Non-conformities should be identified in terms of the specific requirements of the standard or other related documents against which the audit has been conducted.

Documenting findings

- There are three key elements to documenting findings:
  - **State the requirement and where it came from**
    - Example: "Procedure XYZ states …."
    - Example: "ISO 9001 Clause 7.1 states …"
    - Example: "Management intent is for …"

State what you observed

Example: "Two of five employees interviewed did not have Job Required Descriptions"

State whether it is a non-compliance, observation or conformance and with what requirement

- Example: "Non-conformance for failure to follow the requirements of Procedure XYZ Section 3.1"
- Example: "Non-conformance for failure to follow the requirements of ISO 9001 7.1"

If a classification system for non-conformities is being used, non-conformities should be classified at this stage.

> *Guidance from ISO 9001 Auditing Practices Group available from your tutor (check www.iso.org/tc176/ISO9001AuditingPracticesGroup for latest version)*

Closing Meeting
For 2nd and 3rd party audits, a formal meeting is essential. In a 1st party audit the meeting can be shorter, less formal and even somewhat fragmented, but the principle still holds.
Key Points:

- **Thank** the organisation or area for their help and co-operation.
- **Introduce** the team and clarify the **objective** of the audit and the **method** used
- Report the **audit findings**, strengths non-conformities and observations (OIs)
- Discuss the audit **conclusions**
- Discuss **corrective actions** (caution required, process owner should do this)
- Agree corrective action **timescales**. Based on risk.
- Indicate when the **written report** will be available.
- In the case of 2nd and 3rd party audits, the Lead Auditor would normally indicate whether they are **going to recommend** that the company be added to the Approved Vendor Listing (2nd party) or recommended for certification/registration (3rd party).
- Indicate the approximate date for the **next audit**.
- A **hand-written copy** of non-conformities is given to management at this stage but would be followed up by a typed version later.

Remember that the audit team will normally have been feeding back information to the Auditee during the audit, so there should be **no** reason for any **surprises** at the closing meeting.

The **Audit Team Leader should chair** the meeting and summarise. However, each team member could introduce the strengths and areas for improvement that they themselves have identified.

- During a 1st party audit it is normal for the management and supervision of the area being audited to be present at this meeting. In the case of a 2nd and 3rd party audit more senior management would be present.
- In relation to giving advice, the Auditor may also make **recommendations** to the Auditee for improvements to the quality system. Recommendations are not binding on the Auditee. It is up to the Auditee to determine the extent and means of actions to improve the quality system.
- If you have kept people informed on the progress of your findings during the audit, and the information you present at the closing meeting is detailed and based on objective evidence, there is little scope for disagreement. However, in the case of a **disagreement**, rather than leaving an area for improvement without any Auditee management commitment, it may be necessary to obtain a signature on the audit report on the understanding that it signifies only that the finding claimed is understood, not necessarily accepted. In this case the date to be filled in is the date by which the manager, having investigated the claim, will come back with a response.

In the case of a complete impasse it may be necessary to hand the problem over to a higher level. Indeed, some organisations internal audit procedures specify the steps to be taken in this situation. In the case of a 3rd party audit, the company has a right to appeal to the management of the certification / registration body. It is a requirement of accreditation of the certification / registration body that such an appeals procedure is defined.

9. AUDIT REPORT

- **Audit Report**
- **Report Templates**
- **Audit Report Status Log**

Guidance from ISO 9001 Auditing Practices Group;

An Audit Report is an important part of Auditing

Key Points:

- Include in the Audit Report
  - *Introduction* (purpose, audit objectives, scope, type, criteria, date(s), duration, auditors, auditees, confidentiality).
  - *Executive Summary*
  - *Strengths* (start with these and in order of priority)
  - *Areas for Improvement* (list in order of priority)
  - Timescales for Improvements
- Keep the report simple.

REFER to YOUR STUDENT WORKBOOK

The Report is completed in the following manner:

- Auditor completes Report up to and including 'Non- Conformity'.
- Both company representative and Auditor signs the form.
- The Company representative completes the 'Corrective Action' and 'Action Taken to Prevent Recurrence' sections.

A similar type Report can be prepared where there is no non-conformance, but for example, an observation made by the Auditor which could lead to improvement.

Distributing the audit report

The audit report should be issued within an agreed period of time. If delayed, the reasons should be communicated to the auditee and the individual(s) managing the audit programme. The audit report should be dated, reviewed and accepted, as appropriate, in accordance with the audit programme.

The audit report should then be distributed to the relevant interested parties defined in the audit programme or audit plan.
When distributing the audit report, appropriate measures to ensure confidentiality should be considered.

10.CORRECTIVE ACTION

- **Corrective Action**
- **Verifying Corrective Action**

Guidance from ISO 9001 Auditing Practices Group; Guidance for Reviewing and closing nonconformities

Corrective Action

Less auditing and more action (improvements) should be the motto. Continual improvement should be the ultimate aim for the internal audit programme

Key Points:

- Where action has not been taken by the agreed timeframe, highlight this to management. Have this as part of the audit procedure so nobody is surprised. Don't annoy the auditee by continuously following up on outstanding issues.
- Follow up on the **major issues**; minor ones generally take care of themselves.

Verifying Corrective Action

- Make a special return visit (e.g. major problem).
- Have amended documentation sent to you (e.g. minor problem).
- Wait until the next scheduled visit (e.g. Minor problem).

Key Points:

Whatever the method for following up on corrective actions, it is advisable to enter all non-conformances on a company database and to prioritise corrective actions frequently, such as monthly.

It may not always be easy to verify the effectiveness of action. Short-term actions might involve re-training.

Whereas short-term actions are usually easy to define, the long-term actions may be more difficult to formulate. When the auditor revisits, it is necessary to seek evidence that the action was successful. It may be some time before enough data is available on which to base a judgement. If there is any evidence that a corrective action was not successful, then a new CAR should be raised and cross-referenced with the previous one.

Guidance from ISO 9001 Auditing Practices Group from your tutor (check www.iso.org/tc176/ISO9001AuditingPracticesGroupfor latest version).

11.AUDIT PROGRAM REVIEW & GOLDEN RULES

Audit Programme Review and Improvement

The operation of the audit programme needs to be monitored and periodically reviewed to assess whether objectives have been met.
This can be done as part of management review. **(Section 5.6 – ISO 13485) [P D C A]**

Key Points:

Monitoring should be carried out on-going; examples include:

- the ability of the audit team to meet audit objectives
- conformity with audit programme and schedules
- feedback from audit client, auditee and auditors
- observing an auditor
- interviewing auditors to identify gaps in knowledge

The audit programme review should be carried out to assess its effectiveness and identify opportunities for its improvement by considering, for example:

- Results and trends from monitoring;
- conformity with procedures;
- evolving needs and expectations of interested parties;
- audit records;
- alternative or new practices.

Golden Rules for Auditing

Preparation

- Understand how all processes knit together.
- Understand the process to be audited.
- Know what the key Risks to the process are.
- Know the requirements of the relevant standard.
- Determine up front what emphasis will be on during the audit.
    - Effectiveness
    - Improvement
    - Conformance / Compliance
- Have an audit plan.
- Have a checklist
- If on a team, know what your role is.

Audit

- Think “big picture”, don’t get lost in detail.
- Check that the PDCA methodology is being applied to all key business processes.
- Establish customer (external / internal) satisfaction with the process.
- Check that process improvements are where processes are not achieving their KPI’s.
- Don’t allow the checklist to take over.
- Randomly select (cross section of people, equipment, etc.).
- Don’t just audit documents and records, look at other sources of information.

- Take time to examine and study evidence presented to you.
- Don’t go looking for fault.
- Keep a check on your personal attributes.
- Set the right tone.
- Keep an open mind.
- Listen
- Neutralise your feelings.
- Keep notes short and simple
- Use your judgement for interpretation of requirements of standards.

Report

Keep Reports factual, short / simple; should reflect what was agreed at the Close Meeting.

Corrective Action

- Prioritise for follow-up on corrective actions.

12. AUDIT GUIDES AND CERTIFICATION SCHEME FOR QMS AUDITOR

Audit Guides

Audit Guides are important to ensure the smooth running of an audit. They are particularly relevant during a 2nd and 3rd party audit. Guides are generally selected from senior or middle management depending on the size of the organisation. Once audits have become routine, some organisations allocate this role to less senior management.

Like Auditors, guides should be open-minded, mature and possess sound judgement; can perceive situations in a realistic way to understand complex operations from a broad perspective and to understand the role of individual units within the overall organisation.

National Auditor Certification

This Registration process is similar for the different National Auditor Certification bodies. The one described here is for IRCA.

In order to be eligible for registration, successful participants should make application to IRCA within a three-year period from the date of the course (Lead Auditor Only).

IRCA registration is an important qualification which proves that a management system auditor is highly competent. IRCA registration gives employers confidence that an auditor has the necessary skills and experience to audit their management systems effectively. Equally, auditors gain professional recognition and improve their job prospects.

For more details about the benefits of becoming IRCA registered, see www.irca.org.

Notes

CQI and IRCA Certified Training

Help us to improve your experience

We hope you enjoyed your course. As part of our internal assurance process, you will shortly be contacted by the CQI and IRCA for feedback on the course and your Approved Training Partner (ATP). If you do not receive the survey within two weeks of finishing your course, please contact your ATP to ensure they have your correct details on record.

Completing this short survey will help to ensure the continuing high standards of these courses.

The CQI and IRCA offer a range of services to support you throughout your career. For more information, please visit **www.quality.org**

AUDITING / CONSULTANCY / TRAINING

Irish Quality Centre (IQC) is one of Ireland's leading providers of training, consultancy and auditing in **Quality Management Systems**, Environment, Health and Safety and Continuous Improvement.

Our internationally IRCA-approved Lead Auditor Training courses are delivered across Ireland and Europe.

We have recently expanded and now have a specialist Quality Expert team supporting the Pharma, Biopharma and Medical Device industries.

We offer specific Pharmaceutical QMS auditor training programs (Internal Auditor, Lead Auditor, Supplier Auditing).

Auditing

Having difficulties with your internal or supplier audit programmes? We will carry out both internal and supplier audits for you focusing on effectiveness of the systems, compliance, and continuous improvement.

Training

The real value-added obtained from training is having your own quality training courses customised to suit your specific needs. This is where the IQC tailored training courses can help organisations who require more than generic off the shelf training solutions.

Consultancy

Confidence in the advice you receive is of paramount importance to your business. IQC is respected for its level of expertise and down to earth approach on standards such as **quality management systems**, safety management systems and environmental management systems.

Internationally approved by IRCA

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