SACAS Training Courses are SAATCA Approved for both in-house as well as online training.

See below for our selection of courses:

ISO 13485:2016

INTRODUCTION COURSE

COURSE DURATION: 1 DAY

Course Summary:

The introduction course provides the participant with an oversight on the requirements of ISO 13485:2016 standard. Our course is designed for personnel who are responsible for the understanding of quality management systems for medical devices. A practical application of the standard requirements provides the participant with the knowledge regarding quality management systems for medical devices requirements. The course prepares the participant to understand the requirements for preparation to implement quality management systems for medical devices as well as importance of Quality Management as a tool to ensure compliance with customer as well as statutory and regulatory requirements and continual improvement. It demonstrates how quality management contributes to the day-to-day business operations through the effective application and management of resources.

WHO SHOULD ATTEND:

- Those with the responsibility for quality management systems based on ISO 13485:2016 requirements.
- Those with an interest in quality management systems for medical devices especially ISO 13485:2016; and
- Those who manage sections or departments quality management systems for medical devices based on ISO 13485:2016 requirements.
- Those who have an interest in Quality Management Systems for Medical Devices.

PRE-REQUISITE:

No pre-requisite is required for this training course.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Understand the ISO 13485:2016 as a management tool.
- Understand the seven quality principles and the application of such.
- Identify the requirements as set by the standard.
- Understand and apply the process approach.
- Understand an apply risk-based thinking,
- Develop certain documented information required by the standard.

HOW WILL I BENEFIT?

- Guarantee understanding of the requirements of ISO 13485:2016 ensuring compliance with ISO 13485:2016 requirements.
- Ensure employees have quality management responsibilities and awareness.
- Understand how to manage all risks and maintain and improve a global benchmark in quality standards.
- Realise the key importance of Quality Management in a business operation; and
- Be able to participate in the development of the required documentation for the business based on ISO 13485:2016 processes.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

For any training requirements please feel free to do bookings at our training department at training@sacasireland.com or contact Jayne at (+353) 89 214 3630.

QUALITY CONTROL

SACAS

ISO 13485:2016

IMPLEMENTATION COURSE (MODULE 1)

COURSE DURATION: 3 DAYS

Course Summary:

The implementation course provides the participant with an in-depth level of knowledge on the requirements of ISO 13485:2016 standard. Our course is designed for personnel who are responsible for the development and implementation of the quality management systems for medical devices. A practical application of the standard requirements provides the participant with in-depth knowledge regarding the development, implementation, and maintenance of the quality management systems requirements. The implementation course prepares the participant to understand the requirements for auditing preparation as well as importance of Quality Management as a tool to ensure compliance with customer requirements and continual improvement. It demonstrates how quality management contributes to the day-to-day business operations through the effective application and management of resources as well as the understanding of the four risk classifications of medical devices as well as statutory and regulatory requirements.

WHO SHOULD ATTEND:

- Those with the responsibility for implementation of quality management systems based on ISO 13485:2016 requirements.
- Those with an interest in quality management systems especially ISO 13485:2016; and
- Those developing quality management systems based on ISO 13485:2016 requirements.

PRE-REQUISITE:

It is recommended that a minimum educational level of Matric or equivalent NQF level 4 qualification be attained to cope with the content.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Apply the ISO 13485:2016 as a management tool.
- Understand the seven quality principles and the application of such.
- Identify the requirements as set by the standard.
- Understand and apply the process approach.
- Understand an apply risk-based thinking,
- Develop certain documents required by the standard.
- Develop a thorough understanding of the interaction of the various processes as determined by the ISO 13485:2016 standard.
- Key features of risk assessment as defined in ISO 13485.
- The importance and relevance of legislation.
- The design requirements in ISO 13485.

- The significance of process and environmental controls (e.g., clean rooms, sterilisation, personnel controls).
- How to eliminate the causes of problems through effective corrective action.
- Evaluate certain management systems requirements through the application of the ISO 13485:2016 standard clauses; and
- Work with the processes for implementing documented information and processes.

HOW WILL I BENEFIT?

- Guarantee continuing compliance with ISO 13485:2016 requirements.
- Ensure employees have quality management responsibilities and awareness.
- Manage all risks and maintain and improve a global benchmark in quality standards.
- Realise the key importance of Quality Management in a business operation; and
- Be able to participate in the development of the required documentation for the business based on ISO 13485:2016 processes.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

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SACAS

ISO 13485:2016

INTERNAL AND SUPPLIER AUDITOR COURSE (MODULE 2)

COURSE DURATION: 3 DAYS

Course Summary:

Auditing of quality management systems forms an important part of the process to demonstrate continual improvement, thus the ISO 13485:2016 standard requires that the quality management system must be audited on a periodic basis. The Internal Auditor Course is designed for persons to conduct internal audits. The course material is based on sampling methods, interviewing techniques, effective listening skills, compiling non-conformities and value-added report writing. Special emphasis is devoted to clausing of non-conformances and effective development of corrective action requests. The internal auditor course is designed specifically those individuals responsible for carrying-out internal audits in accordance with ISO 13485:2016 standard requirements. This training course is presented at an advanced level and adds value as well as prepares a business for certification by an accredited certification body like SACAS. The course provides participants with opportunity to audit against procedures written for real world applications. Participants are exposed to real life scenarios and are equipped to conduct internal as well as supplier audits in a professional manner. Auditor roles and responsibilities including personal behaviour is also covered as well as the documentation forming part of the internal audit as well as supplier audit process and audit objectives, audit scope and audit criteria.

WHO SHOULD ATTEND:

- Those with the responsibility for internal auditing of quality management systems for medical devices based on ISO 13485:2016 requirements.
- Those with an interest in auditing quality management systems for medical devices based on ISO 13485:2016 requirements.
- Those developing a quality management system for medical devices based on ISO 13485:2016 requirements.

PRE-REQUISITE:

The level of focus and presentation is high, and it is therefore requested that participants demonstrate the following:

Successful completion of ISO 13485:2016 Implementation course or ISO 13485:2003 with the ISO 13485:2016 bridging course.

Practical experience in the management of a Quality Management Systems for Medical Devices based on ISO 13485:2016 requirements.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Relate to and apply the ISO 19011:2018 requirements for auditing management systems.
- Develop certain documents required by the standard.
- Develop auditing material required to conduct an internal audit.
- Plan and prepare the auditing process.
- Apply the principles of planning, executing, recording and close out of an audited scenario; and
- Develop and implement key documentation to ensure the auditing process is concluded in a professional manner.

HOW WILL I BENEFIT?

- Guarantee continuing compliance with ISO 13485:2016 requirements.
- Ensure employees have quality management responsibilities and awareness.
- Manage all risks and maintain and improve a global benchmark in quality standards; and
- Be confident that your organisation can rely on ISO 13485:2016 competent internal auditors.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

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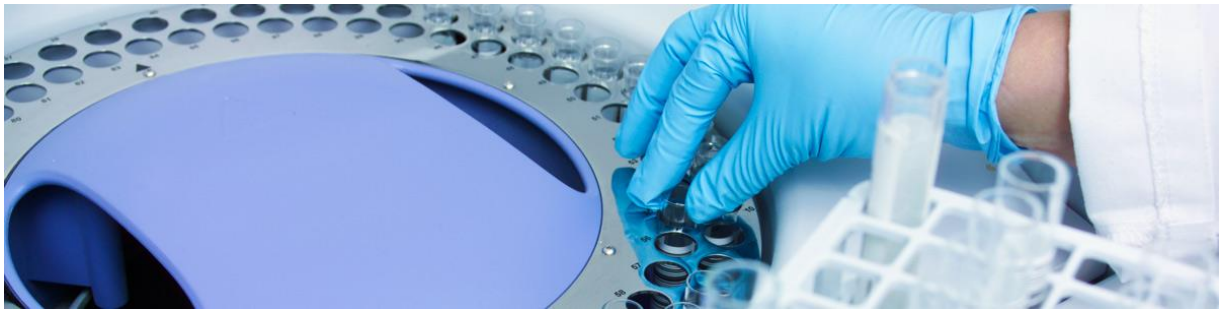

ISO 13485:2016
LEAD AUDITOR COURSE (MODULE 3)

COURSE DURATION: 5 DAYS

Course Summary:
(This course is in process of obtaining SAATCA registration and meets the training requirements of those seeking registration as an auditor/lead auditor under the quality scheme for medical devices at SAATCA)

This comprehensive five-day course provides hands-on training to ensure lead auditors thoroughly understand the role of the auditor and lead auditor and to ensure they acquire the expertise to perform audits effectively. This course addresses the principles and practices for effective internal and external audits in accordance with ISO 13485:2016, ISO/IEC 17021-1:2015, ISO/IEC 17023:2013, ISO/IEC TS 17021-3:2017, ISO 19011:2018 as well as IAF MD 8 and MD 9 requirements.

Auditing of quality management systems as a third-party auditor forms an important part of the process to demonstrate conformity to the ISO 13485:2016 standard, although the ISO 13485:2016 standard only requires internal audits, companies cannot be claimed to be compliant with ISO 13485:2016 unless certified by a legitimate accredited certification body who is a multilateral member of the IAF. The Lead Auditor Course is designed for persons to conduct audits internally or externally or who wants to become a SAATCA registered auditor/lead auditor. The course material is based on sampling methods, interviewing techniques, effective listening skills, compiling non-conformities and value-added report writing. Special emphasis is devoted to clausing of non-conformances and effective development of corrective action requests. The lead auditor course is designed specifically for those individuals responsible for carrying-out audits in accordance with ISO 13485:2016 standard requirements. This training course is presented at an advanced level and adds value as well as prepares auditors for registration as a SAATCA registered auditor or lead auditor. The course provides participants with the opportunity to audit against procedures written for real world applications.

WHO SHOULD ATTEND:

- Anyone involved with the auditing of ISO 13485:2016 Quality Management Systems for Medical Devices such as Quality Management Representatives, ISO 13485:2016 coordinators and Quality Control Managers.
- Those with an interest in auditing quality management systems for medical devices based on ISO 13485:2016 requirements especially as a third-party auditor/lead auditor; and
- Those developing a quality management system for medical devices based on ISO 13485:2016 requirements.

PRE-REQUISITE:

The level of focus and presentation is high, and it is therefore requested that participants demonstrate the following:

Successful completion of an ISO 13485:2016 Implementation course or ISO 13485:2003 module 1 plus ISO 13485:2016 bridging course)

Practical experience in the management of a Quality Management Systems for Medical Devices based on ISO 13485:2003 or ISO 13485:2016 requirements.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Relate to and apply the ISO 19011:2018, requirements for auditing management systems and ISO/IEC 17021-1:2015 conformity assessments - requirements for bodies providing audit and certification of management systems.
- Develop certain documents required by the standard.
- Develop auditing material required to conduct an audit.
- Plan and prepare the auditing process.
- Develop auditing material to conduct audits based on the understanding of the interaction of the various processes as determined by the ISO 13485:2016 standard.
- Audit the key features of risk assessment as defined in ISO 13485:2016.
- Audit relevant legislation requirements.
- To audit significant processes as well as environmental controls (e.g., clean rooms, sterilisation, personnel controls).
- To analyse ISO 13485:2016 clauses and suggest examples of evidence that would show conformance with these requirements.
- Apply the principles of planning, executing, recording and close out of an audited scenario; and
- Develop and implement key documentation to ensure the auditing process is concluded in a professional manner.

HOW WILL I BENEFIT?

- Guarantee continuing compliance with ISO 13485:2016 requirements.
- Ensure employees have quality management responsibilities and awareness.
- To audit
- Manage all risks and maintain and improve a global benchmark in quality standards; and
- Be confident that you are competent as an auditor/lead auditor.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

For any training requirements please feel free to do bookings at our training department at training@sacasireland.com or contact Jayne at (+353) 89 214 3630.

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BRIDGING COURSE FROM AN AUDIT PERSPECTIVE (MODULE 4)

COURSE DURATION: 2 DAYS

Course Summary:

(This course complies with requirements of those seeking registration as an internal auditor/auditor/lead auditor under the quality scheme ISO 13485:2016 whom has passed the ISO 13485:2003 Lead Auditors Course at a Registered approved Training Course Provider).

This comprehensive two-day course provides hands-on training to ensure lead auditors thoroughly understand the role of the auditor and lead auditor and to ensure they acquire the expertise to perform audits effectively. This course addresses the principles and practices for effective internal and external audits in accordance with ISO 13485:2016, ISO/IEC 17021-1:2015, ISO/IEC 17023:2013, ISO/IEC TS 17021-3:2017 as well as ISO 19011:2018.

Auditing of quality management systems as a third-party auditor forms an important part of the process to demonstrate conformity to the ISO 13485:2016 standard, although the ISO 13485:2016 standard only requires internal audits, companies cannot be claimed to be compliant with ISO 13485:2016 unless certified by a legitimate accredited certification body who is a multilateral member of the IAF. The bridging course is designed for persons to conduct audits internally or externally or who wants to become a registered auditor/lead auditor. The course material is based on sampling methods, interviewing techniques, effective listening skills, compiling non-conformities and value-added report writing. Special emphasis is devoted to clausing of non-conformances and effective development of corrective action requests. The lead auditor course is designed specifically for those individuals responsible for carrying-out audits in accordance with ISO 13485:2016 standard requirements. This training course is presented at an advanced level and adds value as well as prepares auditors for registration as a registered internal auditor, auditor or lead auditor based on ISO 13485:2016. The course provides participants with the opportunity to audit against procedures written for real world applications.

WHO SHOULD ATTEND:

- Anyone involved with the auditing of ISO 13485:2003 Quality Management Systems for Medical Devices who wish to change systems into ISO 13485:2016 and conduct audits based on ISO 13485:2016 such as Quality Internal Auditors, Auditors, ISO 13485:2016 coordinators and Quality Control Managers.
- Those with an interest in auditing quality management systems for medical devices based on ISO 13485:2016 requirements especially as a third-party auditor/lead auditor.
- Those developing a quality management system for medical devices based on ISO 13485:2003 or ISO 13485:2016 requirements.

PRE-REQUISITE:

The level of focus and presentation is high, and it is therefore requested that participants demonstrate the following:

Successful completion of an ISO 13485:2003 Implementation course.

Successful completion of an ISO 13485:2003 Internal Auditors or Lead Auditors course.

Practical experience in the management of a Quality Management Systems for Medical Devices based on ISO 13485:2003 requirements.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Relate to and apply the ISO 19011:2018, requirements for auditing management systems and ISO/IEC 17021-1:2015 conformity assessments - requirements for bodies providing audit and certification of management systems.
- Develop certain documents required by the standard.
- Develop auditing material required to conduct an internal audit.
- Plan and prepare the auditing process.
- Apply the principles of planning, executing, recording and close out of an audited scenario; and
- Develop and implement key documentation to ensure the auditing process is concluded in a professional manner.

HOW WILL I BENEFIT?

- Guarantee continuing compliance with ISO 13485:2016 requirements.
- Ensure employees have quality management responsibilities and awareness.
- Manage all risks and maintain and improve a global benchmark in quality standards; and
- Be confident that you are competent as an auditor/lead auditor.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

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ISO 13485:2016

BRIDGING COURSE (MODULE 5)

COURSE DURATION: 2 DAYS

Course Summary:

The implementation course provides the participant with an in-depth level of knowledge on the requirements of ISO 13485:2016 standard. Our course is designed for personnel who are responsible for the development and implementation of the quality management systems. A practical application of the standard requirements provides the participant with in-depth knowledge regarding the development, implementation, and maintenance of the new ISO 13485:2016 quality management systems for medical devices requirements. The implementation course prepares the participant to understand the requirements for auditing preparation as well as importance of Quality Management as a tool to ensure compliance with customer requirements and continual improvement. It demonstrates how quality management contributes to the day-to-day business operations through the effective application and management of resources.

WHO SHOULD ATTEND:

- Those with the responsibility for implementation of quality management systems based on ISO 13485:2016 requirements.
- Those with an interest in quality management systems especially ISO 13485:2016; and
- Those developing quality management systems based on ISO 13485:2016 requirements.

PRE-REQUISITE:

It is recommended that a minimum educational level of Matric or equivalent NQF level 4 qualification be attained to cope with the content.

Module 1 based on ISO 13485:2003.

OUTCOME:

With the successful completion of this course the participant will be able to:

- Apply the ISO 13485:2016 as a management tool.
- Identify the different requirements as set by the new standard.
- Develop certain documents required by the standard.
- Develop a thorough understanding of the interaction of the various processes as determined by the ISO 13485:2016 standard.
- Evaluate certain management systems requirements through the application of the ISO 13485:2016 standard clauses; and
- Work with the processes for implementing the Quality Documented Information and processes.

HOW WILL I BENEFIT?

- Relate to the background and process flow of a company and its quality management system.
- Describe what it is meant by Quality Management.
- Realise the key importance of Quality Management in a business operation; and
- Be able to participate in the development of the required documentation for the businesses' based on ISO 13485:2016 processes.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

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QUALITY MANAGEMENT SYSTEM

ISO 13485 CERTIFIED

ISO 14971:2019 PRINCIPLES

APPLICATION OF RISK MANAGEMENT TO MEDICAL DEVICES COURSE

COURSE DURATION: 3 DAYS

Course Summary:

Because ISO 14971:2019 was developed according to the ISO High Level Structure, this training course focuses on processes for managing risks associated with medical devices based on established principles of risk management conformance & performance of the organisation's arrangements & controls. In addition to introducing the principles & elements of Risk Management and Risk Assessment Manage. The course also includes the process & systems management principles & advocates a risk-based approach, allowing for easy integration with existing arrangements & complimenting existing initiatives, as well as all phases of the life cycle of a medical device. It also includes risks associated with a medical device, such as risks related to biocompatibility, data and systems security, electricity, moving parts, radiation, and usability.

WHO SHOULD ATTEND:

- Those with the responsibility for implementation of business management systems based on ISO 13485:2016 requirements.
- Those with an interest in safety, health, environmental and quality management systems especially ISO 13485:2016; and
- Those developing management systems based on ISO 13485:2016 requirements.

PRE-REQUISITE:

It is recommended that a minimum educational level of Matric or equivalent NQF level 4 qualification be attained to cope with the content.

OUTCOME:

- Delegates understand the benefits & requirements of a Risk Management and Risk Assessment.
- Better equips the organisation to manage its risk, arising from a business perspective.
- By developing, implementing & auditing a formal Risk Management structure, an organisation can self-regulate, provide stakeholder assurance & ensure the responsibility of its supply chain.
- Apply the ISO 14971:2019 as a management tool.
- Identify the different requirements as set by the standard.
- Develop certain documents (risk assessment and methodology) required by the standard.
- Develop a thorough understanding of the interaction of the various processes as determined by the ISO 14971:2019 standard.

- Evaluate certain management systems requirements through the application of the ISO 14971:2019 standard clauses.
- Mitigation of risks/threats and utilising opportunities.
- Work with the processes for implementing the processes.
- Four phases of the risk management process.
- Continual improvement.

COURSE VENUE:

Courses are presented at the SACAS Office in Roscommon, sites in Dublin, Cork, Galway, Athlone, Belfast, and Sligo on request as well as at customer sites throughout Ireland as public courses with a minimum of four attendees.

ADDITIONAL INFORMATION:

The maximum number of participants for this course is 15 with a minimum of 4.

- Participants are assessed to both individual and group performance competence levels.
- Attendance for the full duration of the course is required; and
- An attendance certificate is provided.

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