SACAS

South African Certification and Auditing Services

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 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 especially ISO 13485:2016; and
- Those whom manage sections or departments quality management systems for medical devices based on ISO 13485:2016 requirements;
- Those whom 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;
- 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 Head Office in Vanderbijlpark, sites in Johannesburg, Durban and Bloemfontein on request as well as at customer sites throughout South Africa 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@sacas.co.za or contact Jayne at (+2716) 931 2001.

QUALITY CONTROL

SACAS

South African Certification and Auditing Services

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 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 for medical devices based on ISO 13485:2016 requirements;
- Those with an interest in quality management systems for medical devices especially ISO 13485:2016; and
- Those developing quality management systems for medical devices 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;
- 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;
- 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.

SACAS

South African Certification and Auditing Services

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 Head Office in Vanderbijlpark, sites in Johannesburg, Durban and Bloemfontein on request as well as at customer sites throughout South Africa 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
- A prescribed pass rate of 60% for the written test is required to obtain a certificate on completion of this course.

For any training requirements please feel free to do bookings at our training department at training@sacas.co.za or contact Jayne at (+2716) 931 2001.

SACAS

South African Certification and Auditing Services

ISO 13485:2016

INTERNAL AND SUPPLIER AUDITOR COURSE (MODULE 2)

COURSE DURATION: 3 DAYS

Course Summary:

Auditing of quality management systems for medical devices 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 to 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 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.

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

SACAS

South African Certification and Auditing Services

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 Head Office in Vanderbijlpark, venues in Johannesburg, Durban, and Bloemfontein as well as at customer sites throughout South Africa 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;
- A prescribed pass rate of 70% for the written test as well as a practical assignment to be done afterwards at the work place, is required to obtain a certificate on completion of this course.

For any training requirements please feel free to do bookings at our training department at training@sacas.co.za or contact Jayne at (+2716) 931 2001.

SACAS

South African Certification and Auditing Services

ISO 13485:2016
LEAD AUDITOR COURSE (MODULE 3)

COURSE DURATION: 5 DAYS

Course Summary:

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 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 9001:2008 or 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 whom 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-conformance's 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 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.

SACAS

South African Certification and Auditing Services

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.

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 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 Head Office in Vanderbijlpark, sites in Johannesburg, Durban and Bloemfontein on request as well as at customer sites throughout South Africa 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;
- A prescribed pass rate of 70% for the written test as well as a practical assignment to be done afterwards at the work place, is required to obtain a certificate on completion of this course.

SACAS

South African Certification and Auditing Services

For any training requirements please feel free to do bookings at our training department at training@sacas.co.za or contact Jayne at (+2716) 931 2001.

SACAS

South African Certification and Auditing Services

ISO 31000:2018

PRINCIPLES OF RISK MANAGEMENT AND RISK ASSESSMENT COURSE

COURSE DURATION: 3 DAYS

Course Summary:

Because ISO 31000:2018 was developed according to the ISO High Level Structure, this training course focuses on the conformance & performance of the organisations 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.

WHO SHOULD ATTEND:

- Those with the responsibility for implementation of business management systems based on ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, ISO 13485:2016 or ISO 22000:2018 etc. requirements;
- Those with an interest in safety, health, environmental and quality management systems especially ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, ISO 13485:2016 or ISO 22000:2018 etc.; and
- Those developing management systems based on ISO 9001:2015, ISO 14001:2015, ISO 45001:2018, ISO 13485:2016 or ISO 22000:2018 etc. 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;
- Will directly reduce economic, business, social, occupational health and safety, environmental and quality use related costs & damage.
- Apply the ISO 31000:2018 as a management tool;
- Identify the different requirements as set by the standard;
- Develop certain documents (risk assessment and methodology) required by the standard;

SACAS

South African Certification and Auditing Services

- Develop a thorough understanding of the interaction of the various processes as determined by the ISO 31000:2018 standard;
- Evaluate certain management systems requirements through the application of the ISO 31000:2018 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 Head Office in Vanderbijlpark, sites in Johannesburg, Durban and Bloemfontein on request as well as at customer sites throughout South Africa 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
- A prescribed pass rate of 60% for the written test is required to obtain a certificate on completion of this course.

For any training requirements please feel free to do bookings at our training department at training@sacas.co.za or contact Jayne at (+2716) 931 2001.