PECB

When Recognition Matters

EXAM PREPARATION GUIDE

PECB Certified ISO 13485 Lead Implementer

The objective of the "PECB Certified ISO 13485 Lead Implementer" examination is to ensure that the candidate has the knowledge and skills to support an organization in implementing and managing Medical devices--Quality Management System based on ISO 13485:2016.

The target population for this examination is:

- Project managers or consultants wanting to prepare and to support an organization in the implementation of a Medical devices--Quality Management System
- Medical devices--Quality Management System auditors who wish to fully understand the Medical devices--Quality Management System implementation process
- Managers responsible for Medical devices--Quality Management System or conformity
- Members of a Medical devices--Quality Management System team
- Expert advisors in Medical devices--Quality Management System
- Technical experts wanting to prepare for a Medical devices--Quality Management System function or for a MD-QMS project management function

The exam content covers the following domains:

- Domain 1: Fundamental principles and concepts in Medical Devices Quality Management
- Domain 2: Medical Devices Quality Management Best Practices based on ISO 13485
- Domain 3: Planning a MDQMS based on ISO 13485
- Domain 4: Implementing a MDQMS based on ISO 13485
- Domain 5: Performance evaluation, monitoring and measurement of a MDQMS based on ISO 13485
- Domain 6: Continual improvement of a MDQMS based on ISO 13485
- Domain 7: Preparation for a MDQMS certification audit

The content of the exam is divided as follows:

Domain 1: Fundamental principles and concepts in Medical Devices Quality Management

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can understand, interpret and illustrate the main Medical Devices Quality Management concepts related to a Medical Devices Quality Management System (MDQMS)

Competencies	Knowledge statements
1. Understand and explain the operations of the ISO organization and the development of Medical Devices Quality Management standards 2. Ability to identify, analyze and evaluate the Medical Devices Quality Management compliance requirements for an organization 3. Ability to explain and illustrate the main concepts in Medical Devices Quality Management	1. Knowledge of the application of the management principles to Medical Devices Quality Management 2. Knowledge of the main standards in Medical Devices Quality Management 3. Knowledge of the different sources of Medical Devices Quality Management requirement for an organization: laws, regulations, international and industry standards, contracts, market practices, internal policies 4. Knowledge of the main Medical Devices Quality Management concepts and terminology as described in ISO 13485 5. Knowledge of the difference between preventive, detective and corrective controls and their characteristics

Domain2: Medical Devices Quality Management Best Practice based on ISO 13485

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can understand, interpret and provide guidance on how to implement and manage Medical Devices Quality Management requirements based on best practices of ISO 13485

Competencies	Knowledge statements
1. Ability to identify, understand, classify and explain the clauses with requirements from ISO 13485 2. Ability to detail and illustrate the requirements and best practices by concrete examples 3. Ability to compare possible solutions to a Medical Devices Quality Management issue of an organization and identify/analyze the strength and weakness of each solution 4. Ability to select and demonstrate the best Medical Devices Quality Management solution in order to address Medical Devices Quality Management objectives stated by the organization 5. Ability to create and justify an action plan to implement a Medical Devices Quality Management by listing the activities related 6. Ability to analyze, evaluate and validate action plans to implement a specific requirement	1. Knowledge of operational planning and control 2. Knowledge of various Medical Devices Quality management methodologies and their incorporation in organizational Medical Devices Quality management system based on ISO 13485 3. Knowledge of Medical Devices Quality Management strategy 4. Knowledge of establishing and implementing Medical Devices Quality Management procedures 5. Knowledge of Medical Devices Quality Management Best Practices 6. Knowledge on requirements that come from clauses 4 to 8 of the ISO 13485 7. Knowledge on continual improvement philosophy and practical implementation based on ISO 13485

Domain 3: Planning a MDQMS based on ISO 13485

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can plan the implementation of a MDQMS in preparation for an ISO 13485 certification

Competencies	Knowledge statements
1. Ability to manage a MDQMS implementation project following project management best practices 2. Ability to gather, analyze and interpret the necessary information to plan the MDQMS implementation 3. Ability to observe, analyze and interpret the external and internal environment of an organization 4. Ability to perform a gap analysis and clarify the Medical Devices Quality Management objectives of an organization 5. Ability to state and justify a MDQMS scope adapted to the Medical Devices Quality objectives of a specific organization 6. Ability to select and justify the selected approach and methodology adapted to the needs of the organization	1. Knowledge of the main project management concepts, terminology, process and best practice 2. Knowledge of the principal approaches and methodology frameworks to implement a MDQMS 3. Knowledge of the main concepts and terminology related to organizations 4. Knowledge of an organization's external and internal environment 5. Knowledge of the main interested parties related to an organization and their characteristics 6. Knowledge of techniques to gather information on an organization and to perform a gap analysis of a management system 7. Knowledge of the characteristics of a MDQMS scope in terms of organizational, technological and physical boundaries

Domain 4: Implementing a MDQMS based on ISO 13485

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can implement the processes of a MDQMS required for an ISO 13485 certification

Competencies

1. Ability to understand, analyze needs and provide guidance on the attribution of roles and responsibilities in the context of the implementation and management of a MDQMS
2. Ability to define the document and record management processes needed to support the implementation and the operations of a MDQMS
3. Ability to define and design processes and document them
4. Ability the define and writing a MDQMS policy and Medical Devices Quality Management policies & procedures
5. Ability to implement the required processes of a MDQMS
6. Ability to define and implement appropriate Medical Devices Quality Management training, awareness and communication plans
7. Ability to define and implement an customer support process based on Medical Devices Quality Management best practices
8. Ability to transfer a MDQMS project to operations and manage the change management process

Knowledge statements

1. Knowledge of the roles and responsibilities of the key actors during the implementation of a MDQMS and in its operation after the end of the implementation project
2. Knowledge of the main organizational structures applicable for an organization to manage Medical Devices Quality Management
3. Knowledge of the best practices on document and record management processes and the document management life cycle
4. Knowledge of the characteristics and the differences between the different documents related to MDQMS: policy, procedure, guideline, standard, baseline, worksheet, etc.
5. Knowledge of model-building controls and processes techniques and best practices
6. Knowledge of controls and processes deployment techniques and best practices
7. Knowledge of techniques and best practices to write Medical Devices Quality Management policies, procedures and others types of documents include in a MDQMS
8. Knowledge of the characteristics and the best practices to implement Medical Devices Quality Management training, awareness and communication plans
9. Knowledge of the characteristics and main processes of a Medical Devices Quality management customer support process based on best practices
10. Knowledge of change management techniques best practices

Domain 5: Performance evaluation, monitoring and measurement of a MDQMS based on ISO 13485

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can evaluate, monitor and measure the performance of a MDQMS in the context of an ISO 13485 certification

Competencies	Knowledge statements
1. Ability to monitor and evaluate the effectiveness of a MDQMS in operation 2. Ability to verify the extent to which identified Medical Devices Quality management requirements have been met 3. Ability to define and implemented an internal audit program for ISO 13485 4. Ability to perform regular and methodical reviews regarding the suitability, adequacy, effectiveness and efficiency of a MDQMS with policies and objectives of an organization 5. Ability to define and implement a management review process and counsel management on it	1. Knowledge of the techniques and best practices to monitor the effectiveness of a MDQMS 2. Knowledge of the main concepts and components related to a Medical Devices Quality Management Measurement Programme: measures, attributes, indicators, dashboard, etc. 3. Knowledge of the characteristics and the differences between an operational, tactical and strategic Medical Devices Quality Management indicators and dashboard 4. Knowledge of the techniques and methods to define and document an adequate and reliable indicators 5. Knowledge of the main concepts and components related to the implementation and operation of a MDQMS internal audit program 6. Knowledge of the differences between the concepts of major nonconformity, minor nonconformity, anomaly and observation 7. Knowledge of the guidelines and best practices to write nonconformity report 8. Knowledge of the best practices on how to perform management reviews

Domain 6: Continual Improvement of a MDQMS based on ISO 13485

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can provide guidance on the Continual improvement of a MDQMS in the context of ISO 13485

Competencies

1. Ability to understand the principle and concepts related to continual improvement
2. Ability to counsel an organization on how to continually improve the effectiveness and the efficiency of a MDQMS
3. Ability to implement MDQMS continual improvement processes in an organization
4. Ability to determine the appropriate business improvement tools to support continual improvement processes of a specific organization
5. Ability to identify, analyze the root-causes of nonconformities and proposed action plans to treat them
6. Ability to identify, analyze the root-cause of potential nonconformities and proposed action plans to treat them

Knowledge statements

1. Knowledge of the main concepts related to continual improvement
2. Knowledge of the characteristics and the difference between the concept of effectiveness and the efficiency
3. Knowledge of the concept and techniques to perform a benchmarking
4. Knowledge of the main processes, tools and techniques used by professionals to identify the root-causes of nonconformities
5. Knowledge of the characteristics and the difference between corrective actions and preventive actions
6. Knowledge of the main processes, tools and techniques used by professionals to develop and proposed the best corrective and preventive action plans

Domain 7: Preparation for a MDQMS certification audit

Main objective: To ensure that the ISO 13485 Lead Implementer candidate can prepare and assist an organization for the certification of a MDQMS against the ISO 13485 standard

Competencies	Knowledge statements
1. Ability to understand the main steps, processes and activities related to a ISO 13485 certification audit 2. Ability to understand, explain and illustrate the audit evidence approach in the context of an ISO 13485 audit 3. Ability to counsel an organization to identify and select a certification body that meets their needs 4. Ability to review the readiness of an organization for a ISO 13485 certification audit 5. Ability to coach and prepare the personnel of an organization for an ISO 13485 certification audit 6. Ability to argue and challenge the audit findings and conclusions with external auditors	1. Knowledge of the Knowledge of evidence based approach in an audit 2. Knowledge of the different types of evidences: physical, mathematical, confirmative, technical, analytical, documentary and verbal 3. Knowledge of the difference of the stage 1 audit and the stage 2 audit 4. Knowledge of stage 1 audit requirements, steps and activities 5. Knowledge of the documentation review criteria 6. Knowledge of stage 2 audit requirements, steps and activities 7. Knowledge of follow-up audit requirements, steps and activities 8. Knowledge of surveillance audits and recertification audit requirements, steps and activities 9. Knowledge of the requirements, guidelines and best practices to develop action plans following a ISO 13485 certification audit

Based on these 7 domains and their relevance, 12 questions are included in the exam, as summarized in the following table:

				Level of Understanding (Cognitive/Taxonomy) Required					
		Question Number	Points per Question	Questions that measure Comprehension, Application and Analysis	Questions that measure Synthesis and Evaluation	Number of Questions per competency domain	% of test devoted to each competency domain	Number of Points per competency domain	% of Points per competency domain
Competency/Domains	Fundamental principles and concepts in Medical Devices Quality Management	1	5	X		3	25.00	15.00	20.00
		2	5	x					
		3	5	x					
	Medical Devices Quality Management best practices based on ISO 13486	4	10	X		1	8.33	10	13.33
	Planning a MDQMS based on ISO 13485	9	5		x	1	8.33	5	6.67
	Implementing a MDQMS based on ISO 13485	7	5		x	3	25.00	20	26.67
		8	5		x				
		10	10	x					
	Performance evaluation, monitoring and measurement of a MDQMS based on ISO 13485	6	10		X	2	16.67	15	20.00
		11	5		x				
	Continual Improvement of a MDQMS based on ISO 13485	12	5		X	1	8.33	5	6.67
	Preparation for a MDQMS certification audit	5	5		X	1	8.33	5	6.67
		Total points	75						
		Number of Questions per level of understanding		5	7				
		% of Test Devoted to each level of understanding (cognitive/taxonomy)		41.67	58.33				

The passing score is established at **70%.**

After successfully passing the exam, candidates will be able to apply for the credentials of PECB Certified ISO 13485 Lead Implementer, depending on their level of experience.

TAKE A CERTIFICATION EXAM

Candidates will be required to arrive at least thirty (30) minutes before the beginning of the certification exam. Candidates arriving late will not be given additional time to compensate for the late arrival and may be denied entry to the exam room (if they arrive more than 5 minutes after the beginning of the exam scheduled time).

All candidates will need to present a valid identity card with a picture such as a driver's license or a government ID to the invigilator.

The exam duration is three (3) hours.

The questions are essay type questions. This type of format was chosen because the intent is to determine whether an examinee can write a clear coherent answer/argument and to assess problem solving techniques. Because of this particularity, the exam is set to be "open book" and does not measure the recall of data or information. The examination evaluates, instead, comprehension, application, analysis, synthesis and evaluation, which mean that even if the answer is in the course material, candidates will have to justify and give explanations, to show they really understood the concepts. At the end of this document, you will find sample exam questions and their possible answers.

As the exams are "open book"; the candidates are authorized to use the following reference materials:

- A copy of the ISO 13485:2016 standard,
- Course notes from the Participant Handout,
- Any personal notes made by the student during the course and
- A hard copy dictionary.

The use of electronic devices, such as laptops, cell phones, etc., is not allowed.

All attempt to copy, collude or otherwise cheat during the exam will automatically lead to the exam's failure.

PECB exams are available in English. For availability of the exam in a language other than English, please contact examination@pecb.com

RECEIVE YOUR EXAM RESULTS

Results will be communicated by email in a period of 6 to 8 weeks, after taking the exam. The results will not include the exact grade of the candidate, only a mention of pass or fail.

Candidates who successfully complete the examination will be able to apply for a certified scheme.

In the case of a failure, the results will be accompanied with the list of domains in which the candidate had a low grade, to provide guidance for exams' retake preparation.

Candidates who disagree with the exam results may file a complaint. For more information, please refer to www.pecb.com

EXAM RETAKE POLICY

There is no limitation on how many times a candidate can retake the same exam. However, there are some limitations in terms of allowed time-frame in between exams.

When candidates fail the examination, they are only allowed to retake the examination once within 12 months after the first attempt. If second examination is unsuccessful, candidates will be allowed to retake the exam only after 1 year (12 months). Retake fee applies.

Only candidates, who have completed a full PECB training but fail the written exam, are eligible to retake the exam for free, under one condition:

"A candidate can only retake the exam once and this retake must occur within 12 months from the initial exam's date."

When candidates fail the same examination for the second time, their file is automatically closed for 1 year.

CLOSING FILES

Closing a file is equivalent to rejecting a candidate's application. As a result, when candidates request that their file be reopened, PECB will no longer be bound by the conditions, standards, policies, candidate handbook or exam preparation guide that were in effect before their file was closed.

Candidates who want to request that their file be reopened must do so in writing, and pay the required fees.

EXAMINATION SECURITY

A significant component of a successful and respected professional certification credential is maintaining the security and confidentiality of the examination. PECB relies upon the ethical behaviour of certificate holders and applicants to maintain the security and confidentiality of

PECB examinations. When someone who holds PECB credentials reveals information about PECB examination content, they violate the PECB Code of Ethics. PECB will take action against individuals who violate PECB Policies and the Code of Ethics. Actions taken may include permanently barring individuals from pursuing PECB credentials and revoking certifications from those who have been awarded the credential. PECB will also pursue legal action against individuals or organizations who infringe upon its copyrights, proprietary rights, and intellectual property.

SAMPLE EXAM QUESTIONS AND POSSIBLE ANSWERS

1. Interpretation of ISO clauses

For each of the following clauses of the ISO 13485 standard, please provide an action plan with at least two concrete actions that would be acceptable to ensure conformity to the clause and fulfill control objectives.

Clause 6.1 Provision of resources

Possible answers:

- *Resources policy detailed*
- *Provision of resources inquiry (feedback notes)*

2. Development of metrics

For each of the following clauses of the ISO 13485 standard, please provide two examples of metrics that would be acceptable to measure the conformity to the clause.

- **5.6 Management Review**

Possible answers:

- *Meeting(s) minutes from management reviews*
- *Any decisions and actions generated as the output from the management review and follow-up to those decisions.*

3. Recommendations

The management of the organization would like to receive recommendations from you to improve the processes in place to comply with the requirements of ISO 13485 on control of documents

Possible answers:

1. Document and implement a procedure for control of documents
2. Maintain a log for documents changes with records of the approvals.
3. Communicating the new process and organize training session.