

ISO 13485 LEAD IMPLEMENTER Medical Devices Quality Management PECB CANADA

Who can do?

- Managers or consultants involved in Medical Devices Quality Management
- Expert advisors seeking to master the implementation of a Medical Devices Quality Management System
- Individuals responsible for maintaining conformance with MDQMS requirements
- MDQMS team members

**100,000+ Students
have been Trained**

**since
1997**

**Program is
offered by**

**3D EDUCATORS
INT**
22 Years of
Excellence in
Training &
Development

**Invest in
People the
only Asset
that Appreciates**



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Why should you attend?

ISO 13485 Lead Implementer training enables you to develop the necessary expertise to support an organization in establishing, implementing, managing and maintaining a Medical Devices Quality Management System (MDQMS) based on ISO 13485. During this training course, you will also gain a thorough understanding of the best practices of Medical Devices Quality Management Systems and be able to improve an organization`s overall performance by consistently providing safe and qualitative medical devices.

After mastering all the necessary concepts of Medical Devices Quality Management Systems, you can sit for the exam and apply for a “PECB Certified ISO 13485 Lead Implementer” credential. By holding a PECB Lead Implementer Certificate, you will be able to demonstrate that you have the practical knowledge and professional capabilities to implement ISO 13485 in an organization.



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Program Details

Inauguration

The Training Program will be inaugurated by a senior member of 3D EDUCATORS

Program Structure

No of classes **5 Full Days**

Duration of each class **3-Hour**

Other Learning Activities

Develop the implementation techniques of ISO guidelines In your organization **01**

Presentations by Trainees **01**

ABOUT THE PROGRAM INSTRUCTOR

ISO 13485 Lead Implementer and Auditor, PECB EnMS Registered Lead Implementer, BRC Approved Lead Implementer, The Trainers who are conducting this program have the following positions in the different organization are also accredited trainer of PECB Canada:

- ✓ Lead Auditors & Implementer
- ✓ ISO Consultants
- ✓ Master Accredited Trainers

Highly qualified and experienced trainers with huge hands-on and un-match-able experience in implementation of ISO 13485 Standards

They trainers are foreign qualified and having the degrees of PhD, MBA, M.Sc., and MS. More they are also the member of ISO.





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PREREQUISITES

A fundamental understanding of ISO 13485 and comprehensive knowledge of implementation principles.

COURSE AGENDA

Day 1: Introduction to ISO 13485 and initiation of a MDQMS

Day 2: Plan the implementation of a MDQMS

Day 3: Implementation of a MDQMS

Day 4: MDQMS monitoring, measurement, continuous improvement and preparation for a certification audit

Day 5: Certification Ex



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LEARNING OBJECTIVES

- Acknowledge the correlation between ISO 13485 and other standards and regulatory frameworks
- Master the concepts, approaches, methods and techniques used for the implementation and effective management of a MDQMS
- Learn how to interpret the ISO 13485 requirements in the specific context of an organization
- Learn how to support an organization to effectively plan, implement, manage, monitor and maintain a MDQMS
- Acquire the expertise to advise an organization in implementing Medical Devices Quality Management System best practices



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EXAMINATION

The “PECB Certified ISO 13485 Lead Implementer” exam fully meets the requirements of the PECB Examination and Certification Program (ECP). The exam covers the following competency domains:

Domain 1: Fundamental principles and concepts of a Medical Devices Quality Management System (MDQMS)

Domain 2: Medical Devices Quality Management System (MDQMS)

Domain 3: Planning a MDQMS implementation 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: Preparing for a MDQMS certification audit

For specific information about exam type, languages available, and other details, please visit the [List of PECB Exams](#) and the [Examination Rules and Policies](#).



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EDUCATIONAL APPROACH

- This training is based on both theory and best practices used in the implementation of a MDQMS
- Lecture sessions are illustrated with examples based on case studies
- Practical exercises are based on a case study which includes role playing and discussions
- Practice tests are similar to the Certification Exam

CERTIFICATION

After successfully completing the exam, you can apply for the credentials shown on the table below. You will receive a certificate once you comply with all the requirements related to the selected credential. For more information about ISO 50001 certifications and the PECB certification process, please refer to the [Certification Rules and Policies](#).



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Credentials	Exam	Professional Experience	MDQMMSP Project Experience	Other Requirements
PECB Certified ISO 13485 Provisional Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	None	None	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	Two years: Two years of work experience in Medical Devices Quality Management	Project activities: a total of 200 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Lead Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	Five years: Two years of work experience in Energy Management	Project activities: a total of 300 hours	Signing the PECB Code of Ethics
PECB Certified ISO 13485 Senior Lead Implementer	PECB Certified ISO 13485 Lead Implementer Exam or equivalent	Ten Years: Seven years of work experience in Medical Devices Quality Management	Project activities: a total of 1,000 hours	Signing the PECB Code of Ethics



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General information

- Certification and examination fees are included in the price of the training course
- Training material containing over 450 pages of information and practical examples will be distributed
- An attestation of course completion worth 31 CPD (Continuing Professional Development) credits will be issued to the participants who have attended the training course.
- In case of exam failure, you can retake the exam within 12 months for free



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Terms & Conditions

WITHDRAWAL FROM THE DIPLOMA/CERTIFICATION

Students are not allowed to withdraw from the Diploma. If a student cannot continue the Diploma his/her fee will be forfeited.

CONDUCT AND DISCIPLINE

A disciplinary action, leading to rustication, will be taken against students whose conduct is found objectionable at any time during the course of study. Reference will be made to 3D Educators code of conduct.

EVALUATION AND GRADING

The performance of students is evaluated through continuous observation of a student's performance in the Diploma – class participation, submission of assignments, quizzes and exercises.



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The student will be examined through three hourly exams conducted at the midterm and a final exam at the end of the program. Total marks for passing the Diploma will be 60 out of a total of 100.

Students who do not meet the attendance or any other eligibility criteria will not be allowed to appear in the final examination.

The following grading plan will be applicable for the Diploma:

A	87 - 100
B+	81 -86
B	72 - 80
C+	66 - 71
C	60 - 65
F	below 60



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*Note: PECB Certified Individuals who do possess the Lead Implementer and Lead Auditor Credentials are qualified for the respective **PECB Master Credential**, given they have taken 4 additional Foundation Exams which are related to this scheme. For more detailed information about the Foundation Exams and the overall Master Requirements, please go to the following link: <https://pecb.com/en/master-credentials>.*

To be considered valid, these implementation activities should follow best implementation practices and include the following activities:

1. Drafting a MDQMS plan
2. Initiating a MDQMS implementation
3. Implementing a MDQMS
4. Monitoring and managing a MDQMS implementation
5. Performing continual improvement measures



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Students who are unable to appear for the final exam are required to submit a written application stating the reason for not appearing for the exam. 3D Educators reserves the right to approve or deny such applications. If approved, the student will be allowed to sit for the exam within one month. Failure to do so, the student will be resubmit the examination fee and sit the future schedule exam. Without passing of the exams no certification will be awarded.



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ONLINE LIVE CLASSES FACILITY AVAILABLE

- Instructor Led Training
- Real Time Presentations
- Interactive Classes
- Complete Notes and Other Stuff shall be provided through our Secure Student Login Member's Area
- For Online Live Classes, you may please download the Admission Form through our website <http://www.3deducators.com>. Fill it properly and attached the required document along with Picture and send back to info@3deducators.com with scanned fee submitted voucher in the bank.
- For Pakistan you may submit the fee at any MCB Branch with the title of "3D EDUCATORS-TRAINERS & CONSULTANTS".
- If you are outside Pakistan then you may transfer via Bank to Bank or any western union, Fast Track, Money Gram or else International Transfer Body.
- After Admission, if you don't have GMAIL Account then you are requested to kindly make one GMAIL Account and shared it info@3deducators.com. Then further correspondence shall be made by our institute official.
- Extra Bandwidth Charges shall be incurred.

DISTANCE NOT MATTER

You can join in the live classes Sessions of 3D EDUCATORS – TRAINERS & CONSULTANTS from anywhere of the world.

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PRECAUTIONARY MEASURES

- During Classes, you are requested to make sure that you are in isolated room, where no noise should be there except your voice.
- Kindly Switch Off your Cell Phone during the class, because it will disturb the quorum of class.
- If you have taken the admission in the course online lonely, then ethically it is recommended and suggested that you alone in the class.
- Recording of Lectures are not allowed at your end.

This world is emerging and growing in the 21st Century very rapidly because of latest and remarkable technologies and its advancement. Due to advancement of technology, we 3D EDUCATORS offer Live Interactive class sessions

3D EDUCATORS believe on Information Technology and its systems. Now you can also avail this facility at your home.

CONTACT US

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info@3deducators.com
<http://www.3deducators.com>

Get the Admission Form

Download Form | 

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Global Recognized Certification from PECB CANADA



Professional Evaluation and Certification Board

hereby attests that

is awarded the title

PECB Certified ISO 31000 Risk Manager

having met all the certification requirements, including all examination requirements, professional experience and adoption of the PECB Code of Ethics

Certificate Number: RMRM1013367-2016-07

Issue Date: July 7, 2016

This certificate is valid for three years for the purpose of PECB certification

Issued by: Fatou Akia, President

SAMPLE CERTIFICATE