



Training

# Quality Manager (Management Representative) Medical Devices

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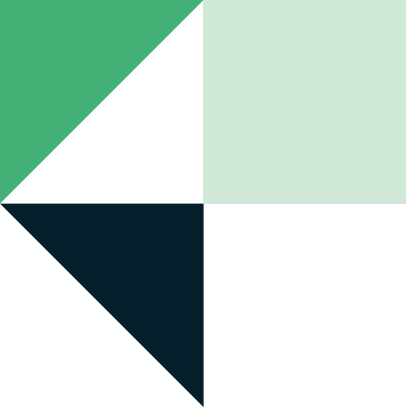
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# Introduction

Thank you for your interest in Kader Group's Quality Manager (Management Representative) training. Kader Group is dedicated to providing a solid foundation and in-depth expertise, enabling participants to strategically contribute to the continuous improvement and success of their organization.

In this brochure, we address all your questions about our Quality Manager (Management Representative) program.



## In this brochure you will find:

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### Contact

The training advisors are eager to assist you with answering your questions and providing additional information.

Phone number: 088 - 995 12 80  
kader-academy.nl | academy@kader.nl

**We are here to help!**

# Quality Manager (Management Representative)

Are you looking for an exciting and promising career in quality management? Then consider our comprehensive quality management course! Whether you are a seasoned professional looking to sharpen your skills or someone just starting their journey in the world of quality assurance, our course provides everything you need to be successful.

**Quality Management:** A quality manager is responsible for ensuring the quality of products, processes and services within an organisation. By implementing strict controls and procedures, a quality manager minimises the risk of defects, errors and complaints, resulting in higher customer satisfaction and loyalty.

Are you a seasoned professional looking to sharpen your skills, or are you starting your journey in quality management? Or, as an organization, are you seeking to enhance your QA-RA capabilities? In a landscape where patient safety and regulatory compliance are critical, the role as a Quality Management Representative, specifically defined in ISO 13485, is essential.

As a Quality Manager, you are responsible for ensuring the quality of products, processes, regulatory affairs and services within your organization.

Our specialized Quality Management Training, based on the ISO 13485 and Medical Device Regulation (MDR) requirements, is designed to equip both experienced professionals and those new to the field with the tools and knowledge needed to excel. You will gain practical insights to effectively implement, maintain, and continually improve your quality systems, ensuring compliance with international regulations while optimizing operational performance.

For your organization, this training ensures that you have a trained Quality Manager who plays a crucial role in maintaining quality, minimizing risks, and enhancing operational efficiency. This ultimately leads to increased customer satisfaction, higher profitability, and a stronger competitive position in the market.

For you, as a Quality Manager, it provides the expertise and leadership skills necessary to thrive in the role outlined in ISO 13485, positioning you to confidently lead through regulatory audits and achieve long-term quality success.



# What does the Quality Manager training entail?

## The result of the training

Our program provides a thorough and up-to-date knowledge base in the field of quality management and regulatory affairs. From the fundamentals of quality management to advanced techniques and methodologies, you will gain a deep understanding of all aspects of the field.

After this training, you will have a good overview of what a quality system entails, how it relates to laws and regulations, and the best ways to implement and integrate it into your company. Having gained a better understanding of the dynamics between business processes, you will be a better interlocutor for management and will be able to advance more easily in the role of quality manager.

By choosing Kader Academy, you are investing in a quality education that prepares you for a successful career, with a focus on personal growth. Take the next step towards becoming a professional Quality Manager with us!

## Lesson from specialists

Compliance is the daily work of Kader Group. In addition to their work as instructors, our instructors are active as consultants on a daily basis. Each instructor specialises in his or her own field. With this hands-on approach, we have developed training programs that meets your expectations.

Our instructors are experienced professionals in the field of quality management. They not only convey their in-depth knowledge and expertise, but also offer valuable insights and advice from their own practical experience.

## Certificate

When you successfully completed the program, you will receive an official Kader Academy certificate for Quality Management representative, including covered topics.

# Is the training suitable for me?

## For whom?

Professionals looking to advance their career in quality management and regulatory affairs.

Executives and managers responsible for ensuring quality within their organisations.

Anyone interested in acquiring valuable quality assurance and regulatory skills

## Admission requirements

- Analytical skills
- Knowledge of ISO 13485 (Quality Management System for medical devices)
- Understanding of (EU) MDR 2017/45 (Medical Device Regulations)
- Proficiency in English, both spoken and written

## How does training add value to my career?

A Quality Management certificate can enhance your career by validating your skills and meeting industry standards, leading to career advancement and higher-level positions. It provides a competitive edge and expands your professional network. Certifications also ensure you stay updated with industry trends and boost your confidence through a sense of accomplishment.

Whether you're aiming to work in manufacturing, healthcare, or any other sector within the medical device industry, quality management is an indispensable discipline. It is crucial for organizations of all sizes and types to ensure compliance, safety, and effectiveness in their products and processes.

Seize this opportunity to develop your skills, enhance your expertise and take your career to new heights. Enrol in our Quality Manager Training today and prepare yourself for a successful and rewarding future!

## What is the added value of training for my organisation?

A trained quality manager is invaluable to an employer for several reasons:

**Risk management:** A quality manager identifies potential risks and vulnerabilities in an organisation's operational processes and takes proactive measures to manage and minimise them. This helps prevent operational failures, production interruptions and legal problems, protecting the company's reputation and financial stability.

**Improving efficiency:** By continuously seeking process improvements and optimisation of workflows, a quality manager contributes to increasing operational efficiency and reducing waste. This results in lower operational costs and increased competitiveness for the company.

**Complying with regulations:** In many sectors, there are strict rules and regulations on quality and safety that companies must comply with. A quality manager ensures that the organisation complies with all relevant regulations and helps prepare for audits and inspections.

**Promoting quality culture:** A trained quality manager can promote a culture of quality awareness and continuous improvement within the organisation. By emphasising the importance of quality and involving employees.

**Summary:** A trained quality manager plays a crucial role in ensuring quality, minimising risks and improving an organisation's operational efficiency, ultimately resulting in greater customer satisfaction, higher profitability and a strong competitive position in the market.



# Planning and topics

## Study duration

10 working days

### Topics

- ◆ ISO 13485:2016 and ISO 14971:2021 Quality Management System and Risk management requirements medical devices as well as the (EU)MDR 2017/745
- ◆ Auditing according ISO 19011:2018 vs ISO 13485:2016 and MDR
- ◆ Electronic records and electronic signatures
- ◆ CE marking of medical device
- ◆ CAPAs
- ◆ PRRC
- ◆ Technical documentation

## Start dates

For actual information about the start dates we would like to refer you to our website.

# Investment and registration

## Financial investment

For current prices, please visit our website.

## This investment includes:

- Course materials
- Healthy lunch
- Coffee and tea

## And exclusive:

- Possible travel and accommodation costs

## This training at your location?

We also provide in-company training. We tailor the training to the needs of your organisation. For more information or a quotation, please contact us.

## Subscribe

You can register online on our website.





# About Kader Group

Kader Group improves the quality, safety, and sustainability of organizations, enabling everyone to care for people, the environment, and society. We achieve this through our consultancy & interim services, digital solutions, and training in the areas of quality, safety & health, cybersecurity, and environmental sustainability. Our mission: to create a safe and sustainable living environment to pass on to future generations. We are pragmatic, innovative, personal, and professional in this endeavor.

Kader Group was founded in 1994 and now consists of over 350 dedicated employees.

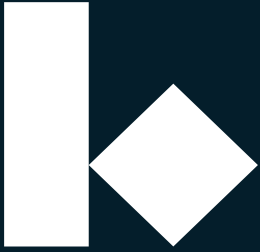
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