

# CERTIFICATION REQUIREMENTS

Medical Device Quality Management  
System Auditor (ISO 13485:2016)



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# Medical Device Quality Management System Auditor

## Introduction

This guide has been developed to help you achieve Certus personnel certification.

**Please read this entire guide before applying for certification.**

The Certus Medical Device Management System (ISO 13485) auditor certification program has been developed to provide international recognition for auditors who conduct medical device quality management system audits based on the ISO 13485:2016 medical device quality management system standard.

## Terms and Definitions

- **Certification of persons:** A process to ensure that a certified person fulfills the certification scheme requirements.
- **Certus personnel certification program:** A set of activities that lead to the certification of persons. Certus offers certification programs for management system auditors, such as quality management system auditors, environmental management system auditors, and occupational health and safety auditors.
- **Certification scheme:** The set of competency requirements within a determined field. For example, competency requirements related to quality management system audits or environmental management system audits, among others.
- **Competence:** The ability to apply knowledge and skills to achieve intended results.
- **Certification Grade:** A certification grade is defined by the level of competence. A grade is obtained after fulfilling the respective certification process. Certus offers four certification grades: Provisional Auditor, Auditor, Lead Auditor, and Master Auditor. A higher grade can be achieved as more competencies are attained.
- **Certificate:** A document issued by Certus to persons who have fulfilled our certification requirements.
- **Digital Badge:** An electronic mark issued by Certus to persons who have fulfilled the certification requirements. Digital badges may be shared on social media, websites, and email signatures. They are a great way to promote your Certus certification.
- **Assessment:** A process conducted by Certus to determine if a person fulfills the requirements of a particular certification scheme.
- **Applicant:** A person who has submitted an application to Certus for certification under one or more certification schemes.

## Certification Requirements

### HOW TO GET STARTED

To begin, visit our website at [www.certuspro.com](http://www.certuspro.com). Once there, you will need to create an account by clicking on the Login button in the upper right-hand corner of the screen. Once your account is set up, click on the Available Certifications button to begin the process. Select the scheme and grade desired. You will then be directed to pay your application fee and first year's certification fee. Once your fees are paid, you will then need to upload any required documents and to take and pass the relevant Certus examination for your scheme and grade. We will review your application once we have received all your documents and you have passed the exam. A certification decision is usually made within 24-48 hours of the receipt of your completed application.

All application information must be provided in English unless otherwise agreed with Certus. Where translations of documents are provided, these must be independently verified for accuracy and a fee may apply. Should you have any questions, contact Certus at [info@certuspro.com](mailto:info@certuspro.com).

### GRADES OF CERTIFICATION

A grade is a specific level within a personnel certification program that best describes the job role for that certification program. Available grades for the Certus Medical Device Quality Management System Auditor certification are shown below:

- **Provisional Auditor:** For those who have completed an auditor training course, but who do not yet meet the audit requirements of their desired grade. You may maintain provisional auditor certification for up to two years. After which, you must transition to a higher grade to maintain your certification. This is a good way to begin your auditing career as it gives you formal recognition of your training and abilities.
- **Auditor:** For those who audit solo or as a member of an audit team.
- **Lead Auditor:** For those who lead audits and audit teams.
- **Master Auditor:** For experienced auditors with at least ten years of lead auditor experience. This grade is for senior audit professionals with an extensive history of conducting audits, but who may no longer lead teams or audit regularly. Master auditors may move into training, consulting, or management roles.

### REQUIREMENTS BY GRADE

	Training	Exam	Professional Experience	Audit Experience
Provisional Auditor	✓	✓		
Auditor	✓	✓	✓	✓
Lead Auditor	✓	✓	✓	✓
Master Auditor	✓	✓	✓	✓

## EXPLANATION OF REQUIREMENTS

- **Training:** All applicants for all grades are required to submit evidence of the successful completion of a management system-based auditor or lead auditor training course (e.g., ISO 13485 lead auditor course). The course must be a minimum of four days (32 hours). Certus does not provide training. Applicants may choose the training provider of their choice. Training must have been completed within five years of the application date.
- **Exam:** All applicants for all grades are required to successfully pass the Certus Medical Device Quality Management System Auditor/Lead Auditor exam prior to certification. This will be administered online as part of your certification process.
- **Professional Experience:** The following professional experience is required:
  - *Provisional Auditor:* None
  - *Auditor:* At least two years' work experience, with at least one year of work experience in medical device quality management.
  - *Lead Auditor:* At least five years' work experience, with at least two years of work experience in medical device quality management.
  - *Master Auditor:* At least ten years' work experience, with at least ten years' audit experience at a lead auditor grade.
- **Audit Experience:** All applicants for all grades except provisional auditor are required to demonstrate the following audit experience:
  - *Provisional Auditor:* None
  - *Auditor:* You must have successfully completed a minimum of four medical device quality management system audits that cover all elements of the audit cycle, amount to a minimum of 20 days, and include a minimum of 15 days on site.
  - *Lead Auditor:* You must have successfully completed a minimum of three full medical device quality management audits as leader of an audit team, that are a minimum of 15 days in total, with a minimum of 10 days on site.
  - *Master Auditor:* No specific audit experience requirement beyond the 10 years of lead auditor experience.

*Audits must have been completed after completing a medical device quality management auditor/lead auditor training course and within five years of the date of application.*

The validity of the evidence provided by the applicant will be verified during the certification process

## CODE OF CONDUCT

All applicants for certification and recertification must agree to and adhere to the Certus Code of Conduct. Failure to adhere to the code of conduct may result in the revocation of your certification.

## LENGTH OF CERTIFICATION

Certus certification is valid for one year from the date your certification is approved. You will be notified 90 days in advance of your certification expiration date.

## CERTIFICATES AND DIGITAL BADGES

Once your certification is approved you will be issued an electronic certificate and a digital badge that you may share in your email signature, social media platforms, and other areas. These credentials are issued by our partner Accredible. You will receive an email from Accredible containing a link to access your certificate and digital badge.

## UPGRADING/DOWNGRADING YOUR CERTIFICATION

You may upgrade your personnel certification to a higher grade at any time during your certification through our online portal. To upgrade, you must provide evidence that is consistent with the desired grade. There is no upgrade fee; however, you will be required to pay the difference in certification fees, which will be pro-rated for the remainder of the year. You will pay the full, current rate of your new certification upon recertification.

You may also downgrade your certification to a lower grade at any time through our online portal. There is no fee to downgrade your certification. No fees are refunded when downgrading your certification. You will pay the rate for your lower grade upon recertification.

## Recertification Requirements

All Certus auditors are required to recertify every 12 months from the date of their initial certification. Recertification requires the certified professional to be in good standing with Certus by adherence to the Certus code of conduct, to pay the annual certification fee, to complete required continuing professional development, and to have completed any transition assessments required when a standard is updated. There are no fees for transition assessments.

## CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

All Certus medical device quality management auditors are required to engage in 20 hours of annual continuing professional development that is relevant to their profession as a medical device quality management auditor.

Valid CPD activities include:

- Attendance at conferences, webinars, or online events
- Attending in-person or online training sessions
- Teaching courses (in-person or online)
- Presenting sessions at conferences or webinars
- Writing books or articles
- Participating in scheme committees, ISO technical advisory groups, or other professional organizations relevant to your scheme.

See the Certus CPD log for allowances for the activities listed above. Work experience does not count toward your CPD hours.



## Certification Fees

Certification and recertification fees are due and payable in advance of the issuance of certification. Certification can and will be suspended or withdrawn if you fail to make payments, do not maintain required continuous professional development, do not meet assessment requirements, or violate our code of conduct.

Certification fees consist of a one-time application fee of \$49 and the annual certification fee. Application fees cover the cost of your initial assessment and are non-refundable.

Customers can pay up to one year in advance. Payments are to be made in U.S. dollars and do not include taxes. Payment may be made by credit card through our online portal only.

### INITIAL CERTIFICATION FEES

Fees due for your first year of certification per grade:

Grade	Application Fee	Certification Fee	Total
Provisional Auditor	\$49	\$99	\$148
Auditor	\$49	\$199	\$248
Lead Auditor	\$49	\$249	\$298
Master Auditor	\$49	\$249	\$298

### ANNUAL CERTIFICATION FEES

Fees for your second and subsequent years of certification per grade:

Grade	Certification Fee
Provisional Auditor	\$99
Auditor	\$199
Lead Auditor	\$249
Master Auditor	\$249

### MULTIPLE CERTIFICATION DISCOUNT

Customers who hold more than one certification are eligible for a multiple certification discount on each additional certification. Discounts do not apply to application fees and may not be combined with any other discount except the senior discount up to a maximum of 30%.

No. of Schemes	Discount
1	N/A
2	10%
3	20%
4	30%—maximum allowed

## SENIOR DISCOUNT

Customers age 65 or older are eligible for a 20% discount on certification fees. The senior discount does not apply toward application fees. Proof of age is required. The senior discount may be combined with the multiple certification discount up to a maximum of 30%.

## LAPSES IN CERTIFICATION

If you do not recertify within 90 days from the expiration date of your certification, your certification will be suspended. You have an additional 90 days to recertify before your certification is withdrawn. If your certification is withdrawn, you must re-apply as a new customer in order to reinstate your certification.

## Transitioning from Another Certification Body

You may transition your medical device quality management auditor certification to Certus if your certification was issued by one of the bodies listed below:

- Chinese Certification & Accreditation Association (CCAA)
- Exemplar Global\*
- International Register of Certified Auditors (CQI-IRCA)
- Korean Auditor Registration (KAR)
- Professional Evaluation and Certification Board (PECB)

There is no transition fee; however, an application fee and certification fee will be payable.

### What is required?

You must provide evidence of current certification in the form of a current certificate or official letter from the authorizing body. Invoices and receipts will not be accepted as proof of certification. The certification granted will reflect the scheme and grade shown on your certificate.

Additional requirements and fees may be applicable if you apply for a higher grade of certification.

\*Exemplar Global certified auditors whose initial certification was granted on or after January 1, 2018, must also pass the Certus auditor examination relevant to their scheme and provide evidence of audit experience per the Certus certification requirements.

### How to Transition?

Call or email us. We are happy to help you transition!

## DISCLAIMER

While every effort is made to ensure that the process for evaluating applications for certification is effective, Certus Professional Certification Inc. does not accept liability for the performance, conduct, or services provided by the certified person or organization.

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