

From a Series of e-Books published by deGRANDSON Global

THE FAQs ABOUT ISO 13485

The ISO Standard for Medical Device Manufacture



From deGRANDSON Global – the e-Learning Company



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Updated: September 2023

The ISO 13485 Standard

What is ISO?

The International Organization for Standardization (ISO for short) is the world's largest developer of voluntary International Standards. Their 21,000+ standards offer solutions and best practice guidance for all types of technology and businesses, helping companies and organizations increase performance while protecting consumers and the planet.

While most are product and technical standards, the ISO has developed 40+ management system standards.

The best known of these include [ISO 9001 \(quality\)](#), [ISO 14001 \(environment\)](#), [ISO 45001 \(health & safety\)](#) and ISO 27001 (information security management). The feature they all have in common is that they are auditable. They are written to facilitate auditing by an independent third party (e.g., CAB) to confirm compliance with the standards' requirements.

ISO 13485 is a quality management system standard based on ISO 9001, considered the parent of all the other standards.

For more, visit [ISO 13485 on the ISO website](#).

What is ISO 13485?

ISO 13485 (or, to give it its full title, ISO 13495:2016, Medical devices, Quality management systems - requirements for regulatory purposes) is an internationally recognized standard that sets out the requirements for a Medical Device Management System (MDMS).

It was initially published in 1996 as ISO 13485:1996 and revised in 2003. Associated standards since replaced by ISO 13485 include ISO 13488, EN 46001, and EN 46002. The EU has adopted the current Standard as a harmonized standard with the title EN ISO 13485:2016.

It is identical to ISO 13485, sometimes referred to as the international version, except for adding 3 Annexes related to EU Directives. These Annexes are now out-of-date as they do not correspond with the current [EU Medical Device Regulations](#) (EU Regulation 2017/725 for medical devices and EU Regulation 2017/726 for in-vitro medical devices).

A revision of ISO 13485 to take account of EU Directives, MDSAP adoption, FDA application of ISO 13485, the adoption of the HLS - high-level structure mandated for ISO management system standards, etc., has been mooted. Still, to date, ISO reports no progress and no due date for publication can even be guessed at other than that it is unlikely to be published before 2026.

Note that because of its now-antiquated structure and the regulatory focus of its requirements, it is not easy to integrate an ISO 13485 management system and an [ISO 9001 management system](#) into a single QMS. Most organizations working to both standards maintain two Quality manuals.

For more information, visit [13485 Medical Devices](#) on the ISO website.



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What is the purpose of ISO 13485?

The purpose of the Standard is to specify requirements for a quality management system that can be used by an organization involved in one or more stages of the life cycle of a medical device, including design and development, production, storage and distribution, installation, servicing and final decommissioning and disposal of medical devices, and design and development, or provision of associated activities (e.g., technical support).

The requirements in this International Standard can also be used by [suppliers or other external parties providing products](#) (e.g., raw materials, components, subassemblies, medical devices, sterilization services, calibration services, distribution services, maintenance services) to such organizations.

For more, visit [ISO 13485 and Supplying to the Medical Device Sector: FAQs](#).



What is a Medical Device Management System?

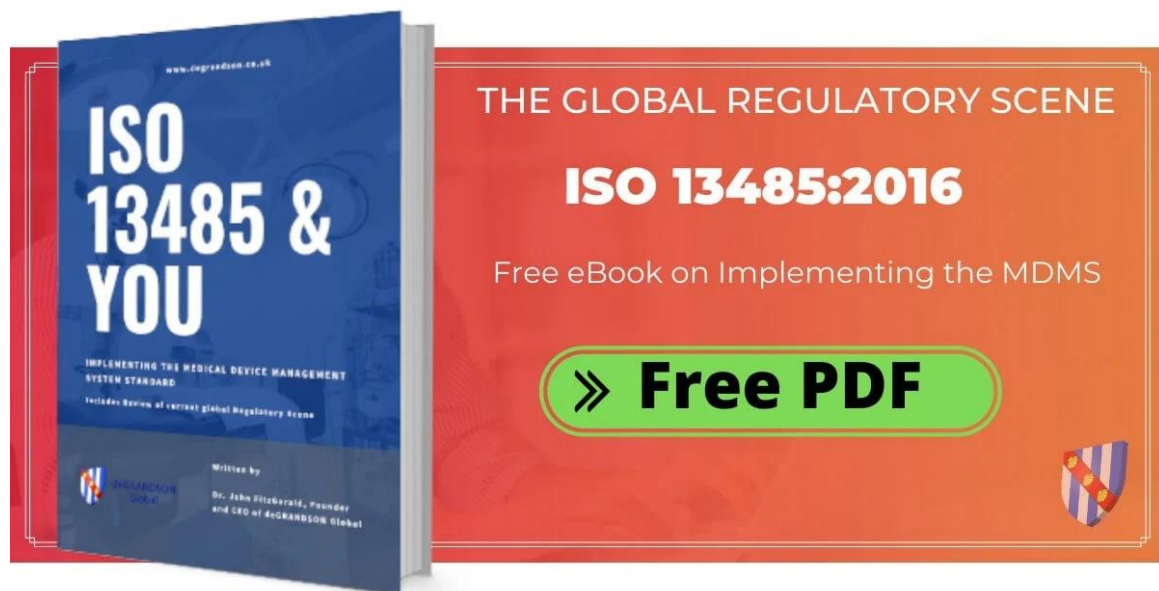
An ISO medical device management system is a formalized system that [documents](#) processes, procedures, and responsibilities covering all aspects of design, manufacturing, supplier management, risk management, complaint handling, clinical data, storage, distribution, product labeling, etc.

It is expressed as the organizational goals and aspirations, compliance with applicable regulations and standards, and the resources needed to implement and maintain them. Most medical devices will require some form of a QMS; the complexity of the MDMS will vary based on the classification of the device and the technical and manufacturing difficulties.



What is the Purpose of a Medical Device Management System?

A medical device management system helps coordinate and direct an organization's activities to meet Customer and regulatory requirements and improve its effectiveness and efficiency on a continuous basis. And to provide documentary and other evidence to facilitate third-party, independent auditing of the system to demonstrate compliance with the standard requirements.



Who needs a Medical Device Management System?

All organizations involved in one or more stages of the life cycle of a medical device, whether they realize it or not, already have an informal MDMS. You look after your customers, don't you? You strive to consistently provide customers with good medical device products, components, or services. You are always trying to improve to stay ahead of competitors?

So, you have an MDMS, and the fundamental question is, do we need to formalize the system? Invariably, the answer is yes.

As ISO 13485 becomes the recognized Standard throughout the medical device lifecycle, a formal medical device management system becomes a prerequisite. If you are a component manufacturer or logistics company wishing to break into the medical device sector, having an ISO 13485 Certificate to present will open doors.

And strangely, an organization does not need to be involved in medical device production or support in any way to qualify for an ISO 13485 Certificate. Intent to get involved is enough!



What are the benefits of a formal Medical Device Management System?

There are at least fourteen benefits that organizations with a medical device quality management system in place can enjoy, such as:

1. Immediate benefit #1: A body of evidence demonstrating compliance with applicable legal and regulatory requirements. Under EU MDR and IVDR, a formidable mass of documentation can be required.
2. Immediate benefit #2: Management systems are designed to a) Get it right the first time, b) Be consistent and reliable, c) Seek out the root causes of problems, and d) Not to repeat mistakes.
3. Immediate benefit #3: All aspects of supply, installation, and maintenance throughout the product lifecycle are done in compliance with applicable regulations.
4. Organized management: An organization certified to the Standard is managed in a standard and structured way
5. Clarity of Purpose: Staff know their responsibilities, authorities, and accountabilities.
6. Processes and procedures suited to the Mission and strategic objectives that you have set for the organization.
7. [Internal audits](#) to monitor compliance with requirements and highlight deficiencies.
8. [Corrective actions](#) to prevent the recurrence of errors - try to make mistakes only once, if at all.
9. Informed Board of Directors, knowing that the organization is focused on strategic objectives while satisfying compliance requirements and [planning and acting to address future challenges](#).
10. Management satisfaction knowing that the organization is functioning in line with strategic objectives.
11. Reduce errors: Fewer costly errors, less rework, replacement of goods and/or services, and increased productivity.
12. Fewer customer complaints as fewer errors occur.
13. Better retention of customers: again, a consequence of reduced errors.
14. Management performance improved as less time is spent apologizing to customers and managing the unnecessary repetition of work.

Certification to ISO 13485:2016

What is ISO 13485 Certification?

An ISO 13485 Certificate is recognition from a Certification Body – CAB (usually an accredited Certification Body), or in relation to EU regulations, a Notified Body, that an organization has implemented and is maintaining a quality management system that meets the [requirements of ISO 13485:2016](#).

Have you trained
your ISO 13485
Internal Auditors
yet?

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Do You Need ISO 13485 Certification?

Yes and No.

In many cases, such as that of component manufacturers, ISO 13485 Certification is not mandatory but can be a valuable tool to add credibility. You will be demonstrating that your product or service meets the expectations of your medical device manufacturing customers. For some industries, Certification is a legal or contractual requirement.



Who needs ISO 13485 Certification?

Organizations globally, both in the public and private spheres and from every economic sector involved in providing medical device products and associated services, need to demonstrate compliance with ISO 13485. Relevant organizations would include distributors and those trading in medical devices, and this can apply to any stage of the lifecycle.

For more, see [ISO 13485 Certification for the Medical Device Supply Chain](#).



Does ISO 13485 Certification require the services of a Notified Body?

We need to consider three different types of organizations here:

1. **Notified Bodies are only required for compliance with EU Regulations.** For all medical device classifications other than Class 1 and all IVDs other than Class A, a [Notified Body](#) is needed. In addition to certification audit services, the Notified Body will issue a Certificate of Conformity necessary for using CE Marking (and providing or arranging necessary laboratory, clinical, and other support).
2. **MDSAP Certification Body:** A limited number of Certification Bodies, most bodies operating globally and referred to as AOs, have been appointed to undertake certification audits under this scheme for medical device manufacturers.
3. **Accredited Certification Bodies:** For Class 1 medical devices and Class A IVDs in the EU, for the rest of the world where MDSAP does not apply, and for **all organizations in the supply chain** who are not manufacturers, these are the auditors to be used.

And what about the UK? At the time of writing, the UK's MHRA is following the EU Regulations pending a decision on the long-term requirements, which are expected later in 2023/4.

What are the Benefits of Having ISO 13485 Certification?

The effective implementation and maintenance of ISO 13485 certification come with at least six benefits, like those that come with having a formal Medical Device Management System. These include:

1. **Feedback:** First and foremost, ISO 13485 Certification is about confirming compliance with regulation and then through Feedback (including PMS - Post Market Surveillance) that the device remains fit-for-purpose in fulfilling its specification and purpose and identifying opportunities for improvement.
2. **Reputation:** be taken seriously as a prospective supplier, other than a manufacturer, as the holder of ISO 13485 Certification, based on the independent assessment of an accredited certification body.
3. **Qualify** for pre-tender and tender opportunities, especially for distributors to the public sector.
4. **Status:** On equal terms with the 'big' boys' – the size of your organization won't hold you back. And for newcomers, you demonstrate commitment to the medical device sector.
5. **Risk management** is implemented by manufacturers and others to ensure the safe and miss-use use of the device. Invariably, ISO 14971 is used here. Apart from this, a risk-based approach is applied to all processes.
6. **Objectives and improvement** obligations focus you on setting targets for improvement and then planning and implementing them in a timely manner.

Is ISO 13485 Feedback the same as ISO 9001 Customer Satisfaction?

They are **not** the same, and this is a very common mistake. The difference is easily determined if we compare the definitions for the two standards.

For ISO 9001, Customer satisfaction is defined as the Customer's perception of the degree to which the Customer's requirements have been fulfilled.

- Customer complaints are a common indicator of low customer satisfaction, but their absence does not necessarily imply high customer satisfaction.
- Even when customer requirements have been agreed with the Customer and fulfilled, this does not necessarily ensure high customer satisfaction.

For ISO 13485, Feedback is defined as opinions, comments, and expressions of interest in a product, a service, or a complaints-handling process.

- Product-focused feedback is the requirement here and not customer-focused satisfaction.
- Feedback is vital for gathering production and post-production information, the latter being the foundation of Post-Market Surveillance (PMS) and the revision and updating of product safety risk assessments.

Why does ISO 13485 call for documentation many times while ISO 9001 does not?

The title of this Standard focuses on Regulations, which then focuses on assembling documentary evidence to demonstrate compliance with applicable Regulations (ISO 9001 avoids any mandatory documentation to be as flexible and wide-ranging as possible in its application).



Is ISO 13485 intended for Medical Device Manufacturers only?

The 2016 version of the Standard makes clear that ISO 13485 is **not intended for manufacturers alone**. It states in Section 1, Scope:

This International Standard specifies requirements for a quality management system where an organization needs to demonstrate its ability to provide medical devices and related services that consistently meet Customer and applicable regulatory requirements. Such organizations can be involved in one or more life cycle stages, **including design and development, production, storage and distribution, installation or servicing of a medical device, and design and development or provision of associated activities (e.g., technical support)**. This International Standard can also be used by suppliers or external parties that provide products, including quality management system-related services to such organizations.

Yet many organizations are scared off by talk of CE Marking, Notified Bodies, regulatory inspections, unannounced/surprise audits, and the like. It's all nonsense (well, almost all). There could be a lot of high-margin business that you're missing out on.

For more, see [ISO 13485 and Supplying to the Medical Device Sector: FAQs](#).



Do applicable regulatory requirements mentioned in ISO 13485 include ISO 14971 and other ISO Standards?

All harmonized ISO Standards (i.e., the ones beginning EN ISO) are officially optional in the EU. If these Standards are not applied where they could be applied, Auditors will ask for evidence of alternative methods used to achieve the same result. Both ISO 14971 and ISO 15223-1:2016 (the medical device labeling Standard) need special mention.

[ISO 14971](#) is a standard for the application of risk management methods for the safe use of medical devices throughout their life cycle. ISO 13485 Clause 7.1, planning for product realization, states, 'Further information can be found in ISO 14971'. This means that the use of ISO 14971 is not mandatory. However, almost without exception, every medical device manufacturer uses ISO 14971 to address product safety.

The use of ISO 15223-1 for labeling, etc., while not mentioned in ISO 13485, is a requirement in MDR, so this Standard must be used.

The number and status of [EN ISO Standards for medical devices](#) is under constant review. Visit [Commission Implementing Decision \(EU\) 2021/610 of 14 April 2021 for harmonized standards](#).

In the UK at the time of writing, the EU MDD and IVDD continue to apply, and the commentary above for the EU continues to apply. Change to a new UK regulatory regime is expected soon with the transition of the EU to MDR and IVDR regulations.

In the USA, the FDA continues to tease out its formal adoption of ISO 13485 in US regulation. Clarification is expected by year-end.

How much does ISO 13485 Certification Cost?

The cost of [ISO 13485 certification](#) varies hugely based on the organization's size, geographical location, and economic prosperity.

Let's take the example of an SME with ten employees. Here are some typical prices from the UK for 2021 for a Class 1 Device (1) or for a distributor, component manufacturer, or logistics company, where we consider three scenarios ...

Scenario (2)	Do-it-yourself (3)	Minimum Consultancy Support (4)	Maximum Consultancy Support (5)
Develop MDMS (8 days)	1000£	2000£	5000£
Implement MDMS (8 days)	1000£	2000£	5000£
Maintain MDMS (2 x 3 years)	600£	600£	3000£
Certification Year 1	2500£	2500£	2500£
Year 2	1000£	1000£	1000£
Year 3	1000£	1000£	1000£
Total 3-year cost	£7100	£9100	£17500
Typical duration to Certification	11 months	5 months	4 months

Notes:

1.

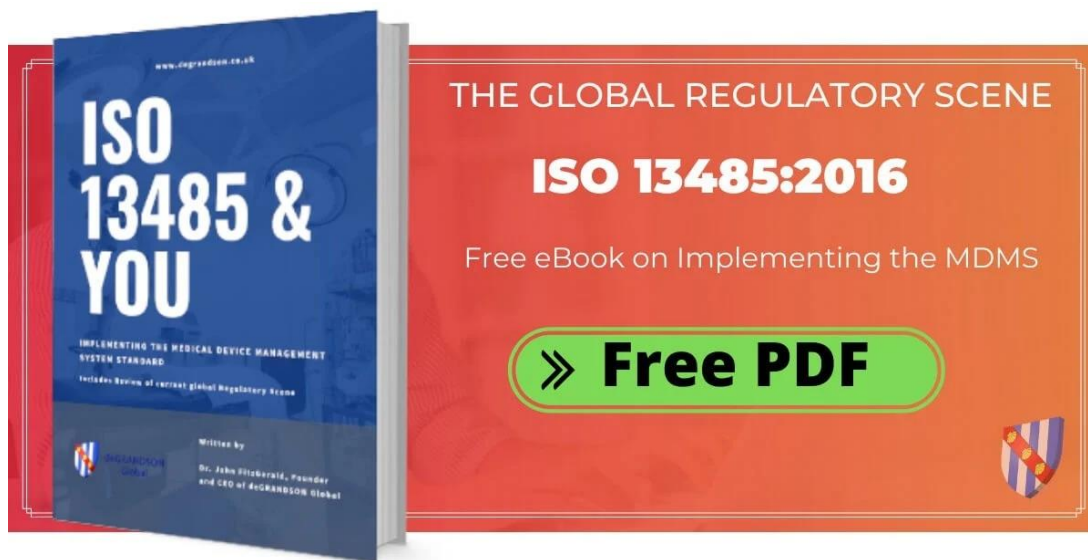
1. Other than for Class 1 medical devices and Class A IVD, the services of a Notified Body are required. The costs here will pale into insignificance when compared to

the six-figure sums that will be involved in using a Notified Body.

2. It is necessary to examine a 3-year horizon as CABs play games with their quotations, which can be confusing. What is a given, however, is that CAB Audits and the associated contract must, [under IAF rules](#), be based on a 3-year cycle.
3. No outside help. The project leader would need [ISO 13485 Lead Implementer Training](#).
4. Four days of [consultancy support](#) are included here. Priced at £ 500 p.d., consultancy costs range from £300 to £700 per day. Satisfactory references must be obtained for previous ISO 9001 projects.
5. Maintenance here includes two days annually for [internal auditing](#) and Management Review support.

The best advice for controlling costs is to shop around and recheck the competitiveness of your chosen CAB regularly.

For more, visit the [ISO 13485 Lead Implementer Certification Course](#). Also, see [Path to ISO 13485 Certification](#).



Who Issues ISO 13485 Certification?

The ISO develops International Standards, such as ISO 9001 and ISO 14001, but is not involved in their Certification.

ISO does not issue certificates. ISO 13485 certification is performed by external [certification bodies](#). So, a company or organization cannot be certified by the ISO organization itself.



How to Get an ISO 13485 Certificate?

Certificates are issued by CABs to organizations after they have undergone an [ISO Certification process](#). And is based on a comprehensive 2-stage audit (itself based on the [auditing standard, ISO 19011](#)) that involves a documentation review and an independent on-site audit.

The CAB gathers and documents objective evidence of compliance with the requirements of ISO 13485. After the CAB has confirmed that all the requirements of the ISO 13485 Standard have been implemented and are being maintained, a Certificate is issued as is permission to use logos to publicize the fact.

How to Choose a Certification Body?

The choice of CAB is important. An accredited CAB (e.g., BSI) should be used wherever possible, and with ISO 13485, one won't be difficult to find.

Accreditation, issued by a nationally recognized Accreditation Board (e.g., [UKAS](#)), is an essential confirmation of the legitimacy of the CAB. To help ensure an international 'level playing field' for CAB auditing standards, National Accreditation Boards have their own international organization, the [International Accreditation Forum \(IAF\)](#), which oversees an ongoing program of witnessed self-assessment of IAF Members of each others' activities.

A Certificate from an accredited CAB will carry three logos: #1 the CAB's logo, #2 the Accreditation Boards logo, and #3 the IAF logo. If you present an ISO 13485 Certificate to a customer or potential Customer that does not carry all three logos, expect to be challenged. Without a plausible explanation, you can expect your approach to be rejected.

Are online ISO 13485 Certificates that you can get within 30 days Legitimate?

Legally speaking? Yes. But the certificate is **worthless**. There are 'cowboy' CABs (whom you should ask to explain how an organization can create three months of records, the minimum needed to prove maintenance of a medical device management system, in 7 days) and even 'cowboy' Accreditation Bodies.

With ISO 13485 Certificates, making sure you have the real thing fundamentally means choosing a CAB that will get you an IAF logo for your certificate. Ask about it by name and accept nothing else.

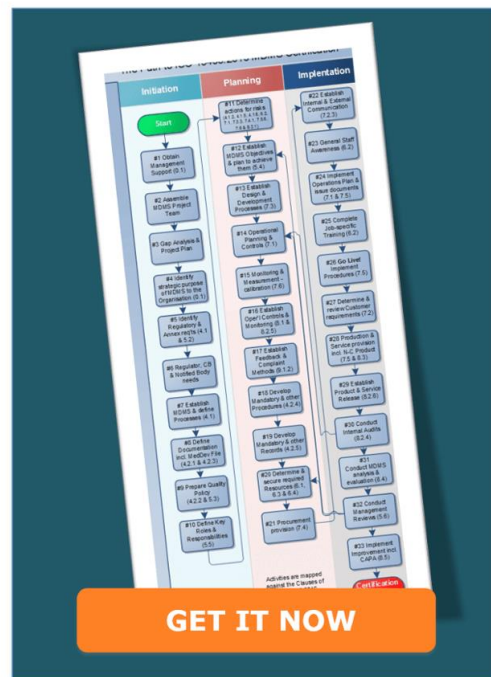


Why is it Important to Get Certified by the Proper Certification Body?

Remember that those reviewing tender and quotation documents are unlikely to be inexperienced. They will recognize a phony Certification instantly. And your offering will go directly into the rubbish bin with the hard work you've expended to develop products and services you are proud of totally wasted.

Most importantly, you wouldn't want an ISO Auditor to find such bogus Certificates when checking your evaluation of external providers (suppliers).

For more, visit [Is IAF Accreditation possible for all ISO Standards?](#) and [Your Accreditation Body must follow IAF Guidance.](#)



How does the ISO 13485 Certification Process Go?

As you will have seen in the cost data above, there are two stages in securing ISO 13485 Certification:

Stage 1. Develop, implement, and maintain a suitable MDMS for your organization and

Stage 2. Engage the services of a CAB to undertake the necessary evaluations and ISO Certification Audits.

Stage 1. Develop, implement, and maintain a suitable QMS for your organization:

Our Infographic shown here nicely illustrates the [multi-step process](#) of [preparing for Certification](#) (click on the infographic image to get a copy for yourself). Whichever of the three approaches you choose (or variants thereof), you will benefit from our ISO 13485 Lead Implementer Course in managing and directing your ISO 13485 Project.

Stage 2. Engage the services of a CAB to undertake the necessary evaluations and audits:

When choosing a certification body, you should:

- Evaluate several certification bodies.
- Check if the certification body auditing activities include ISO 13485:2016.
- Check if it is accredited. Accreditation is not compulsory, and non-accreditation does not necessarily mean it is not reputable, but it does provide independent confirmation of competence. To find an accredited certification body, contact the national accreditation body in your country or visit the [International Accreditation Forum](#).

Note: The terms '[certification](#)' and '[accreditation](#)' [cannot be used interchangeably](#), though it is not uncommon. The differences between Certification and accreditation are as follows:

Certification – the provision by an independent body of written assurance (a certificate) that the product, service, or system in question meets specific requirements.

Accreditation – the formal recognition by an independent body, generally known as an accreditation body, that a certification body operates according to international standards.

For more, visit the [International Accreditation Forum/about us/](#) and [10 Reasons to change your ISO Certification Body](#).

How to check the ISO 13485 Certification of an organization?

The IAF, after struggling with the issue for many years, launched IAF CertSearch. This service is an exclusive global database for accredited management system certifications. Other databases, irrespective of the organization publishing them, should be treated with skepticism or, better still, ignored.

Currently, CertSearch has over 400,000 valid certifications across more than 150 economies covering a range of sectors, 4,000 certification bodies, and 68 IAF MLA signatory accreditation bodies. While highly dependable, this database is a long way from being complete when one considers that there are one million-plus organizations certified to ISO 9001:2015 alone.

Businesses and governments can digitally validate an organization's Certification (s) to determine if a certificate is valid and if the Certification Body issuing the certificate is accredited to issue certifications to that Standard.

The direct route is, of course, always open to you – ask the organization for a copy of their current certificate. Many will have their certificate on display on their website.

For more, visit [IAF CertSearch](#).

Do Management Representatives or others responsible for a Medical Device Management System need training?

The training of a Management Representative or others with day-to-day responsibility to maintain an MDMS is NOT mandatory.

Training is implied as part of developing competence but not a specific stand-alone requirement. So, unless you are determined to outsource this support indefinitely (technically, that's not permitted), you need to train your Management Representative. And you're in luck. We've got precisely the Course you need.

For more, visit our [ISO 13485 Lead Implementer Course page](#).



The Knowledge
and Skills for
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Do Internal Auditors need training?

Again, training here is not mandatory. However, [effective internal audits](#) are [essential to doing a professional job in maintaining your Medical Device Management System](#) and avoiding nasty surprises at your next Certification Body audit.

Also, if you don't train them, your auditors won't have any of the [skills necessary](#) to 'harvest' those improvement suggestions from the people in your organization who actually do the work.

For more, visit our [ISO 13485 Internal Auditor Course](#) page.



Got a Question we haven't answered?

We'd love to hear it and, if possible, answer it for you. Just use our Support Ticket System. You'll find a Knowledge Base there that might have an immediate answer for you. Otherwise, fill in a Ticket.

For more, visit [deGRANDSON Support Ticket](#).