ISO 13485

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Introduction

A quality management system forms the backbone for the activities and tasks of a medical device manufacturer. It ensures that internal and external regulations to be complied with are reliably taken into account and adhered to.
Appropriate certification enables a manufacturer to build confidence in its processes and products and demonstrate its commitment to safety and quality.

ISO 13485 is a stand-alone quality management system scheme for medical device manufacturers. It is applicable to legal manufacturers and suppliers of parts or services into the medical device sector.

ISO 13485 supports medical device manufacturers in designing and implementing their management system using a process-oriented approach. In addition, it covers aspects related to medical device manufacturers including design, development, production, installation, servicing, delivery and disposal of medical devices.

Regulatory approval programs for medical devices or in vitro diagnostic medical devices are often based on requirements of ISO 13485.
Certification to ISO 13485 requires us to assess specific requirements related to the effectiveness of the management system through a series of audit activities.

This document provides information regarding the main stages for ISO 13485 audits.

Overview of the ISO 13485 assessment process

Medical device manufacturers can apply for ISO 13845 certification.

We will ask you to complete our Basic Data Form and submit it to us with additional supporting documentation we need to perform a pre-application review. Where the information you provide indicates that we can proceed we will request the completion of an Application Form. We will perform a remote application review of the documentation submitted..
Where the application has been accepted, we will provide a quotation for the certification with a plan of assessment activities required for ISO 13485 certification.

If you accept the quotation and our proposed timelines are suitable, we will implement the planned assessment activities.

Throughout the process, we will provide you with the information that you need to make the process run smoothly.

Pre-application

If you wish to apply for ISO 13485 certification with DQS, we will need you to complete our Basic Data Form. We may need other documentation based on your organisation and its structure. Our team will make sure you have the list of documentation required for the submission.

We will verify that your activities fall within our scope of accreditation, your certification is IAF accredited.

Application

You will be required to submit a formal application with any additional documentation we have identified. Our team will make sure you have the list of documentation required for the submission.

We will perform a review of the information provided, provide a quote and producing a plan for the assessment activities required up to and including your certification renewal. Once the quote has been accepted, we will enter into contract with you to allow us to proceed.

Initial audit

The initial audit is usually performed in two, separate stages:
Stage 1 – is a document review and planning visit.
Stage 2 – is a full assessment of the effectiveness of your management system and its implementation.

The stage 1 assessment:

- Determines whether your management system processes and other documentation required for ISO 13485 certification are in place and implemented so that a meaningful stage 2 audit can be implemented.
- Collects information about your organisation, processes and activities to make sure that you are ready for the stage 2 audit.
- Confirms that the scope of certification that you have requested is appropriate.
- Verifies that the assessment team requirements and timings for the stage 2 audit are consistent with the scheme requirements.
- Answers any questions you may have about the certification process.

During the Stage 1 audit, we will identify any weaknesses or omissions in your system that need to be addressed before the stage 2 audit.
The stage 1 audit allows the stage 2 audit to be planned.
We will provide a report on the stage 1 audit activities.

The stage 2 audit follows the plan from the stage 1 audit and verifies that:

- Your policies, objectives, processes and procedures are effectively implemented.
- Your management system is effective and meets the requirements of ISO 13485.
- You are managing your processes effectively.
- You have effectively addressed the weaknesses and omissions identified in the stage 1 audit.
- Document and record control is effective.
- Risk assessment and monitoring and measuring activities are proportionate and effective.
- Commitment of senior management.
- Your internal audit process, managing of findings, CAPA process and management review process are effective

The stage 2 audit will include a tour of your facilities and witnessing implementation of key processes.
During the Stage 2 audit, we will raise findings relating to nonconformities.

We will provide a report covering the stage 2 audit and the findings will be followed up according to our normal process.

Audit activities

We will work with you to establish dates and the documentation and/or access we need to ensure that audit activities are implemented smoothly.

All audits will follow our standard process:

- The visit starts with an opening meeting with senior management. Our assessor will explain how we perform our assessments, the purpose and scope of the current assessment activity and the plan for the assessment. You will be able to introduce your organisation and agree the plan.
  Our assessor will implement the plan assessing your company against the requirements. You should expect:
  - Review of your requested scope of approval.
  - Examination of your management system, processes, documentation and records against this scope and the requirements.
  - Visit of the production sites.
  - Review of changes and the effectiveness of their implementation.

Additional activities may be required.

During our assessments there are regular update meetings to recap on activities completed, discuss next activities and present any findings. You will be informed of these meetings and should make sure the appropriate staff are present to be informed and confirm you accept the findings.

At the end of the audit, we will grade the findings.

The visit ends with a closing meeting to present our report and agree the next stage of the assessment process.

Reporting

During the closing meeting of your audit, we will present our findings. Our report documents the audit. We aim to provide a final report within 7 days of the closing meeting. The timelines depend on the complexity of your certification. We will also provide a plan of the audit activities to maintain your certification.

Findings

Our report will document any findings based on the information we assessed. We will classify findings as minor and major.

Minor findings do not affect the capability of the management system to achieve the intended result, including product conformity, but need to be addressed to ensure the future capability of the system.

Where minor findings are raised in an assessment that leads to certification, our assessor will ask you to provide details of your proposed impact assessment, correction (where applicable), and root cause analysis and corrective action. This information will be part of our package that we send to independent review (see Certification). Where minor findings are raised at surveillance audits, we will usually review them at our next visit.

Major findings affect the capability of the management system to achieve the intended result. Examples could be the absence of, or failure to implement and

maintain, one or more management system elements. Major findings also include:

- situations that would raise significant doubt that there is effective process control in place.
- situations that would raise significant doubt that products or service will meet specified requirements.
- there are a number of minor findings relating to the same requirement.
- There is an issue that could demonstrate a systematic failure.
- A situation that requires immediate containment.

Major non-conformities will need to be closed before we can issue the certification

and we may need to perform additional on-site assessment to verify the effectiveness of the actions you have implemented.

Our assessor will present all findings in the closing meeting of your assessment and ensure that you understand the finding and the next steps.

Certification

Once we have a package of information that demonstrates the requirements for ISO 13845 certification have been met, we will advance it to our independent review and certification decision stage with a recommendation for certification.

Where we cannot demonstrate that requirements have been met, the Regulatory Affairs Manager may make a recommendation to refuse certification or limit the scope of certification.

You will be kept informed of the progress of your project and any recommendations.

The independent reviewer confirms that our processes have been followed and their agreement with the recommendation.

The package is then sent to our Certification Decision Maker, who will check the completeness of the package and confirm that a certification decision can be made. The Certification Decision Maker will decide whether or not certification can be issued. You will be informed of the outcome of this decision.

Before we issue your certificates, we will, where possible, send a draft version for your approval. You will then confirm that the address and other administrative details are correct.

We will then issue the certificate to you.

Maintaining certification

As ISO 13485 certificates are valid for 3 years, to maintain your certification, we will implement 2 annual surveillance audits and then a recertification audit.

You will need to inform us of significant changes to your organisation and we have prepared an information note to support you (CIN – Change Notification).

Surveillance audits

Once we have issued the certificate, we will need to perform surveillance activities. Our planned annual surveillance audits aim to confirm that the continued maintenance, implementation and effectiveness of your

management system. We also assess the implications of any changes to the system and your products and services. We will consider whether you continue to meet the requirements of ISO 13485.

Assessment activities are implemented as described above.
We will communicate the scope of the surveillance visit at the previous visit and we will confirm these details at the opening meeting to take into consideration new information. Such information includes:

- Changes to the organisation and management system.
  Outcomes of your internal audit and management review process.
- Progress you have made in reaching your objectives.
- Risk analysis and CAPA processes, including feedback and complaints.

We will also review findings from our previous audit and confirm the correct use of our marks and name. Findings are graded as described above.
Where we raise major findings at a surveillance audit, we will arrange a special audit to review the implementation of the corrective action plan. This is normally within 3 months of the surveillance audit. This is the first stage in the suspension and withdrawal process (see CIN – Certification).

At the closing meeting, we will present our report and each finding to ensure you ISO understand the next steps, including any addition activities due to major nonconformities. At the second surveillance audit, we will also discuss recertification.

Recertification

Before your certificate expiry, you will need to decide whether you wish to renew your certification with us. We will discuss recertification at your second surveillance audit and remind you well in advance of expiry. We recommend recertification audits take place at least 3 months before the certification expiry date to allow for major findings to be managed.

To apply for recertification, you will need to submit an application form. The application process is similar to that for initial certification and also includes:

- Trend information on complaints and performance indicators.
- Management system changes and improvements.
- Trends in our findings.
- Other performance indicators.

Based on this review, we will identify any risks related to the effectiveness of the current management system.

As with an initial assessment, the outcome of the application is a new quotation that, once accepted, will allow us to produce an audit plan for the next certification cycle.

The recertification audit follows a stage 2 audit, like the initial assessment, to ensure that your management system continues to meet your organisation's needs and comply with the requirements of ISO 13485.

Changes

Where your organisation requires changes to the certification, we ask you to submit a change notification (see CIN – Change Notification). Depending on the nature and impact of the change, we may need to perform additional assessment activities.

Closing remarks

Assessments are based on sampling. This means that your previous assessments may not have identified an issue that could be identified in the future. Even where you have a history of compliance, any audit can identify previously undetected and new issues.

Should you have any questions, please do not hesitate to ask us using our enquiries email box dqs-uk@dqs.de

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