

## Introduction

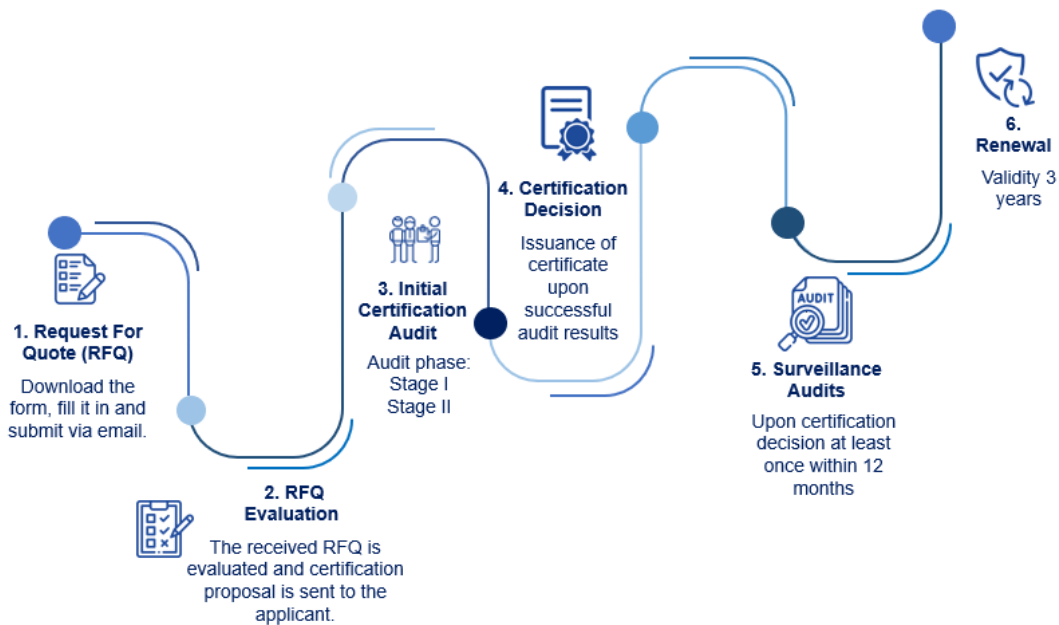
Medical device manufacturing is one of the most regulated sectors, requiring stringent quality system and product requirements to ensure safety and performance.

A robust Quality Management System (QMS) is crucial for maintaining high standards in manufacturing and operations while complying with regulatory requirements. A well-implemented QMS fosters improvement, effectiveness, and trust in both the manufacturer and the medical devices produced.

EN ISO 13485: Medical devices - Quality management systems - Requirements for regulatory purposes is the globally recognized standard for QMS specific to the medical device industry. It helps manufacturers establish and maintain processes that ensure the safety and quality of medical devices, covering aspects from design and development to production, installation, and disposal.

NOTICE is an accredited certification body that provides EN ISO 13485 QMS certification, ensuring compliance with regulatory requirements.

## EN ISO 13485 QMS CERTIFICATION ROADMAP



\*NOTICE accepts QMS documents and correspondence in English only.

## 1. Request for quote (RFQ)

Information on the requested scope, processes, and organization details is provided by the applicant organization through the Request for Quote (RFQ) form.

## 2. RFQ Evaluation and Planning Audits

RFQ is evaluated based on internal criteria. If the RFQ is accepted, a certification proposal is issued to the applicant. Once proposal signed by the client, the audit program is prepared. Stage 1 and Stage 2 audits are carried out as follows based on the audit program.

## 3. Stage 1 Audit

The Stage 1 is an on-site audit which checks the readiness of client's QMS for the Stage 2 audit. During Stage 1 audits, the following key elements are assessed:

- **Determination of Certification Scope:** The scope of certification and identification of any non-applicable clauses are confirmed.
- **Site Condition Assessment:** The adequacy of site conditions for manufacturing products or providing services within the certification scope is ensured.
- **Compliance Evaluation:** The client's procedures and operational documents are assessed against the EN ISO 13485 standard and related requirements.
- **Site and Personnel Readiness:** The specific conditions of the client's location and the preparedness of personnel for the Stage 2 audit are reviewed.
- **Understanding of Standard Requirements:** The client's awareness and understanding of standard requirements, management system objectives, processes, key performance indicators, and identification of critical parties are evaluated.
- **Internal Audits and Management Reviews:** The planning of internal audits and management reviews, as well as the readiness of the management system for the Stage 2 audit, are verified.
- **Site Visit Planning:** The sites to be visited during the Stage 2 audit and the respective timeframes are determined.
- **Additional Supplier/Subcontractor Audits:** The necessity for additional audits of suppliers or subcontractors is assessed.
- **Assessment Personnel:** The need for additional assessment personnel during the Stage 2 audit is determined.
- **Translation Needs:** The requirement for a translator during the Stage 2 audit is identified.

The readiness audit will confirm the planned duration for the Stage 2 certification audit and may lead to a revision of the quotation if necessary.

## 4. Stage 2 Audit

After successful completion of Stage 1 audit, an in-depth review of client's QMS against the applicable regulations and standards is conducted. After that, an initial report at the closing meeting will be handed to the client. Based on the audit outcomes, the rectification of non-conformities, if any, expected from client within proper timeframe. Upon successful rectification of non-conformities, decision making process is initiated.

## 5. Follow-Up Audits

Follow-up audits are conducted in case the audit team decides the necessity of verification of closure of the detected nonconformities on site.

## 6. Auditing Outsourced Processes and Critical Suppliers

Suppliers whose auditing has been deemed necessary by NOTICE, will be audited as a part of the certification process.

## 7. Certification Decision

Upon closure all the detected nonconformities, decision on granting or rejecting the certification is taken and communicated to the client.

## 8. Certificate Issue

The Client's certificate will be issued in 1 English copy. The issued certificates can be tracked on our website.

## 9. Maintaining Your ISO QMS Certificate

Once issued, your EN ISO 13485 certificate is typically valid for 3 years, during which the QMS must be maintained.

### a. Surveillance Audits

Surveillance audits are carried out to control the client's conformity continuity to EN ISO 13485 requirements. Surveillance audits shall be conducted every 12 months from the certificate date.

### b. Short Notice Audits

In case of complaints with objective evidence, NOTICE will perform extraordinary short-notice audits.

### c. Change Audits

After signing the agreement, all the planned changes in the client's quality management system or the products shall be communicated to NOTICE via SI.FR.08.11 Planned Change Notification Form. After the evaluation in case site audit is deemed necessary, the change audit will be performed.

## 10. Re-Certification Audits

Certificate renewal audits are conducted prior to the expiration of their validity period (3 years).

## 11. Suspension or Withdrawal of Certificate

Non-compliance with certification agreement may result in suspension or withdrawal of the certificate. Suspensions are not exceeding 6 months. Certification will be restored upon resolution of the issues. Withdrawal is irreversible, requiring a new certification process.

## 12. Extension or Reduction of Certificate Scope

The scope of the certificate may be extended on approved request or reduced based on compliance as outlined in SI.IL.0003 - Certificates Scope Reduction, Suspension & Withdrawal. Scope extensions for additional activities or sites can be scheduled with surveillance or renewal audits.

## 13. Use of NOTICE Logos

Once certification is granted, the manufacturer is all to use the NOTICE logo on promotional materials, correspondence and advertisements as outlined in SI.IL.0005 - Use of Certification Marks.

### **Contact Information**

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