INTERNATIONAL CERTIFICATION BODY
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ISO 13485:2016

Medical Devices - Quality Management Systems

www.mqa.international

What is ISO 13485:2016?

ISO 13485 is defined as the internationally recognized standard which specifies requirements for a Quality Management System where an organization needs to prove its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

The current version of ISO 13485:2016 was released in March 2016.

The requirements specified in this standard are generic and intended to be applicable to all organizations, or parts thereof, regardless of type and size, except where explicitly stated. ISO 13485 can also be used by suppliers that provide medical product to such organizations.

Benefits of ISO 13485:2016 Certification

ISO 13485 helps organizations to ensure their customers receive a high-quality product, which in turn brings many benefits where some benefits are mentioned below:

Improved Process Performance

Increased Customer Satisfaction

Reduced Operating Costs

Efficient Management Approach

Increased Focus on Risks

Greater Compliance

Gain Competitive Advantage

Improved stakeholder relationship

International Recognition

Journey to Certification

ISO 13485 Certification is a 3rd party audit performed by MQA, during the audit we will verify that your organization is following the requirements of ISO 13485, if received positive results then we will issue an ISO 13485 certificate. This certification is then maintained through annual surveillance audits by MQA, with re-certification of the ISO 13485 Certification after three years. See below cycle to know how you can get started on the road to certification:

MQA Certification Cycle

Year 1

Step 1.1 (Initial Application)

- Client request a quotation.
- MQA will assess Client's requirements.
- MQA will share proposal with client.
- Client signed the 3-year Certification Contract with MQA.

Step 1.2 (Certification Audit)

- MQA will conduct:
  - Gap Assessment (Readiness Review)
  - Stage-1 Audit (Documentation Review)
  - Stage-2 Audit (Implementation Review)
- MQA Auditor will share the audit reports to MQA's Certification Decision Committee.

Step 1.3 (Certificate Management)

- If certification decision is positive, then certificate is issued by MQA.
- If certification decision is negative, then verification audit is planned by MQA.
- Client will receive the MQA Portal access to:
  - View the Audit Reports.
  - Download the ISO Certificate.
  - Review & Respond to Audit Findings, etc.

Year 2 & 3

Step 2.1 (Renewal Request)

- MQA request for renewal.
- Client agreed for Surveillance Audit.

Step 2.2 (Surveillance Audit)

- MQA will conduct a Surveillance Audit
- MQA Auditor will share the audit reports to MQA's Certificate Decision Committee.

Step 2.3 (Certificate Management)

- If no critical non-conformity is found, then the certificate is renewed by MQA.
- If any critical nonconformity is found, MQA will plan a verification audit.
- Client have the MQA Portal access to:
  - View the Audit Reports.
  - Download the ISO Certificate.
  - Review & Respond to Audit Findings, etc.

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Stay Updated!