ISO 13485 Certification Process

BJ Johnson, 26 May 2022

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Agenda

- What is a Certificate
- Application for Certification
- Audit Process
- Audit Reports
- Certification Process

What is a Certificate

A certificate is a document that is produced by a certification body to show that an organization has a compliant quality management system.

- Certificates are issued to a specific standard or regulation (i.e., ISO 13485)
- Certificates are valid for the certification cycle, in the case of ISO 13485 that cycle is 3 years
- Certificates can be issued in digital or paper format
- Certificates can cover multiple locations that have the same quality management system

What is a Certificate

The Certification document will contain:

- The name and location of the manufacturer
- The effective date of the granting of the certificate
- The expiration date of the certificate
- A unique identification code
- The management standard certified to

What is a Certificate - Continued

The Certification document will contain:

- The scope of the certification with respect to:
  - Types of activities
  - Product or service provided
- The name, address, and certification mark of the Notified Body
- Any other information required by the standard
- If the certificate is revised, a means of showing the revision

Certification Application

- An organization applies for certification with a Notified Body. The application will note:
  - The desired certification required
  - The desired scope
  - Relevant details of the organization
  - The aspects that may be outsourced
  - If past certification was received, by whom

Certification Application – Continued

- Notified body to review application to:
  - Determine if information provided is sufficient to develop an audit program
  - Resolve any difference in understanding from the application
  - Assure competence and ability of the Notified Body to complete the activity
  - Assure that the client knows the time required to complete the certification activities
  - Set up the initial audit

Audits and Audit Cycle

Audit Cycle

- There is a three (3) year cycle
- Audits are conducted once per calendar year
- The Initial Audit
- Surveillance Audits
- Re-Certification Audit

Audits within the cycle will cover each section of the ISO 13485 standard.

Audits and Audit Cycle

Initial Certification Audit

- To be conducted to ISO/IEC 17021 and ISO 13485
- Stage 1 – Documentation Review, Evaluation of Preparedness for Stage 2 Audit that is usually conducted off site
- Stage 2 - On site review of quality management system.

Audits and Audit Cycle

Surveillance Audits

- To be conducted to ISO/IEC 17021 and ISO 13485
- There are two (2) surveillance audits in the first and second years following the certification decision.
- Audits are not necessarily full system audits but can cover only partial QMS activities.

Audits and Audit Cycle

Recertification Audit

- To be conducted to ISO/IEC 17021 and ISO 13485
- The purposes of a recertification audit are to
  - evaluate the continued effectiveness and suitability of the organization's QMS (as a whole) to satisfy all applicable QMS requirements of ISO 13485; and,
  - confirm the continued relevance and applicability of the organization's QMS with respect to the scope of certification.
- Recertification audits can be shorter than initial audits through more selective and focused sampling.

Audit Reports

- Audit Reports are prepared using the template created by the Notified Body.
- Each Notified Body will have their own template.
- Reports are prepared in the language of the Notified Body.

Audit Reports

Report Contents:

- Cover Page, that identifies the organization and Notified Body
- Type of audit, audit criteria, objectives, and scope
- Identification of auditors and audit dates
- Notation of any nonconformances
- Recommendation of the audit team
- Disclaimer that the audit is based on a sampling of process/records
- Conclusion and confirmation that objectives have been fulfilled

Handling Nonconformities

What is a nonconformity

- ISO 17021-1:2015 defines as:
  - non-fulfilment of a requirement
- Major Nonconformity
  - Nonconformity that affects the capability of the management system to achieve the intended results
  - Nonconformities could be classified as major in the following circumstances:

    — if there is a significant doubt that effective process control is in place, or that products or services will meet specified requirements;

    — a number of minor nonconformities associated with the same requirement or issue could demonstrate a systemic failure and thus constitute a major nonconformity.
- Minor Nonconformity
  - Nonconformity that does not affect the capability of the management system to achieve the intended results

Handling Nonconformities

What actions are required

- The Notified Body will define time limits for correction and corrective actions to be implemented prior to the expiration of certification
  - Standard time is 30 days for the client to submit a corrective action plan
  - The plan will include the root cause, correction completed, and any planned corrective actions
- The Notified Body will review the plan and determine acceptability
- Closure of the corrective actions will be completed within the stated timeframe set by the Notified Body
  - Standard time is 90 days

Granting of Certificate

Certificates will be granted once Major Nonconformances are closed and Minor Nonconformances have an accepted plan.

- After the audit the auditor will propose a scope for the certificate
- Audit report along with proposed scope is reviewed
- Upon approval decision Certificates are created and sent

Removal of Certification

Certificates can be suspended, withdrawn, or have a scope reduction for the following reasons:

- Auditors are not allowed to conduct audits
- Nonconformances are not closed in agreed timelines
- Persistent or serious failure to meet certification requirements including effective implementation of the Quality Management System
- Client requesting transfer of process to another Notified Body

Removal of Certification

Actions that can be taken when removal is required:

- Letter warning of possible withdrawal of Certificate is sent
- Suspension of Certificate
- Withdrawal of Certificate

Thank **you!**