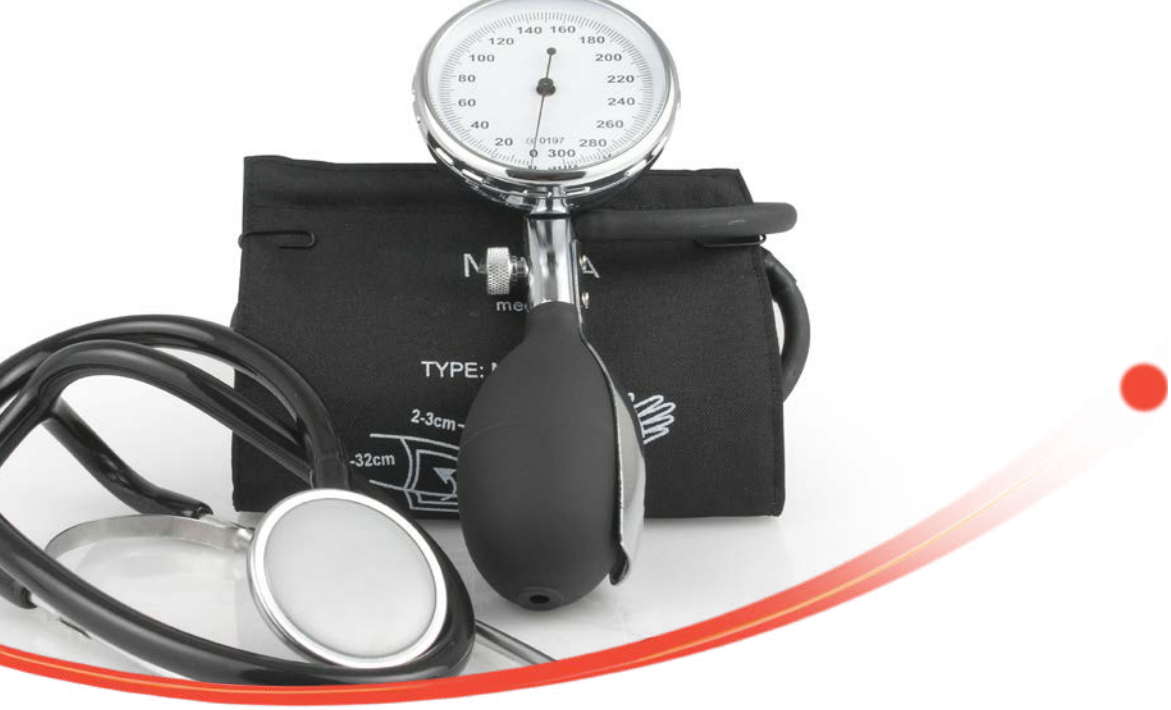

ISO Revisions

ISO 13485:2016 Readiness Review

Company name: .....

Address: .....

.....

Certification No.: .....

Date:: .....

Contact Name: .....

Job Title: .....

Telephone: .....

Email: .....

How ready are you for ISO 13485:2016?

BSI is committed to ensuring a smooth assessment for all clients wishing to certify to ISO 13485:2016, whether you are new to the standard or transitioning from ISO 13485:2003 / EN ISO 13485:2012.

This document allows you to detail how you intend to meet the additional requirements of the new standard, so should be used in conjunction with ISO 13485:2016. It is not an exhaustive checklist, but contains summary statements of most of the significant changes.

Completion of this form is not mandatory and does not need to form part of the transition process. However, you may find it a useful tool for analysing your progress prior to booking a transition assessment. Use the boxes below to list procedures, records and examples that address the additional requirements. This could be used as a gap analysis tool or as an aide memoire during your transition assessments.

If you have any questions during your journey please talk with you Client Manager or Assessor about your plans.

Clause 4 – Quality Management System

Clause 4.1 – General requirements

You will need to provide information on:

- Documenting the role of the organization;
- Awareness of the increased regulatory and risk based approach;
- Control of outsourced processes;
- Change management;
- Validation of software associated with the quality management system.

Click here for your response

Clause 4.2 – Documentation requirements

You will need to provide information on:

- Non-application relating to clauses 6, 7 and 8;
- The medical device file;
- Additional controls related to document and record amendment, security and integrity, confidential health information.

Click here for your response

Clause 5 – Management Responsibility

There are limited changes to this section, including:

- Increased focus on regulatory requirements;
- Documented procedures for management review; documented planned intervals; expanded inputs and outputs.

Click here for your response

Continued >>

Clause 6 – Resource Management

Clause 6.2 – Human resources

You will need to provide information on:

- Documented processes for competence, awareness and training;
- Risk based training effectiveness monitoring.

Click here for your response

Clause 6.3 – Infrastructure

You will need to provide information on:

- Processes for preventing product mix-up;
- Information systems infrastructure;
- Maintenance intervals for production or monitoring equipment.

Click here for your response

Clause 6.4 – Work environment

You will need to provide information on:

- Documentation requirements for work environment;
- Contamination controls for sterile medical devices.

Click here for your response

Clause 7 – Product Realization

Clause 7.1 – Planning of product realization

You will need to provide information on:

- Processes for risk management;
- Requirements for storage, handling, distribution and traceability.

Click here for your response

Continued >>

Clause 7.2 – Customer related processes

You will need to provide information on:

- Requirement and availability for any user training;
- Documented processes for communicating with stakeholders, including regulatory authorities.

Click here for your response

Clause 7.3 – Design and development

You will need to provide information on:

- Traceability of design inputs to outputs;
- Required resources, including competence of personnel involved in design projects;
- Additional details and documentation for verification and validation plans, including statistical techniques, sampling rationale and representative product and records;
- Documented procedures for design transfer and design change;
- Design and development files.

Click here for your response

Clause 7.4 – Purchasing

You will need to provide information on:

- Evidence of increased focus on supplier monitoring and risk;
- Documented agreements for prior notification of changes to supplied product;
- Linkage between verification of purchased product and change control.

Click here for your response

Continued >>

Clause 7.5 – Production and service provision

You will need to provide information on:

- Qualification of infrastructure;
- Analysis of service records;
- Documented procedures for validation including statistical techniques, sampling rationale, revalidation;
- Validation requirements for processes that cannot or are not subsequently monitored;
- Procedures for risk based software validation;
- Documented procedure for product identification/status during production; this may be Unique Device Identification (UDI), if required;
- Validation of sterile barrier systems;
- Suitability of packaging systems;
- Recording of measuring equipment adjustments.

Click here for your response

Clause 8 – Measurement, analysis and improvement

Clause 8.2 – Monitoring and measuring

You will need to provide information on:

- Linkages from customer feedback into risk management;
- Documented processes for ascertaining whether customer requirements have been met;
- Documented procedures for complaint handling;
- Communication processes for informing third parties of complaints;
- Documented plans for internal audits at defined intervals;
- Processes for the identification of test equipment.

Click here for your response

Clause 8.3 – Control of non-conforming product

You will need to provide information on:

- Processes for communication with external parties regarding non-conforming product;
- Additional controls for managing concessions;
- Linkages between rework and regulatory requirements.

Click here for your response

Continued >>

Clause 8.4 – Analysis of data

You will need to provide information on:

- Additional sources of data for analysis, such as service records and audits;
- Procedures that cover the application of statistical techniques;
- Linkages between the analysis and improvement processes.

Click here for your response

Clause 8.5 – Improvement

You will need to provide information on:

- How actions are taken without undue delay;
- The evaluation of actions for adverse effects on regulatory requirements and product safety and performance.

Click here for your response

Save

Find out more about how BSI can support your transition by visiting our website **bsigroup.com/iso13485revision**

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