YOU'RE CLOSER THAN YOU THINK
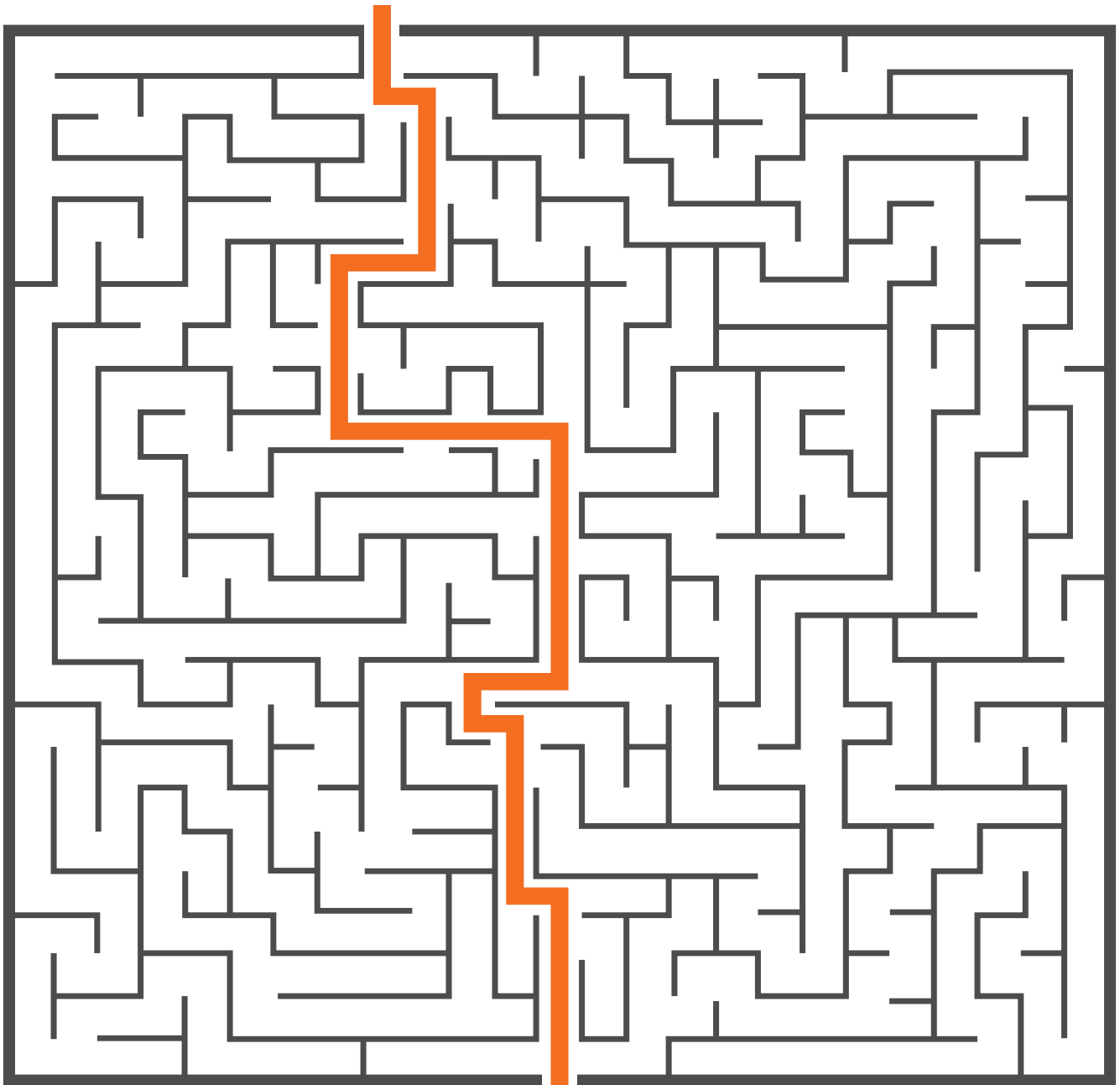
**ISO 13485:2016
READINESS CHECKLIST**

SGS

We understand that some of our customers would like to be able to check how close they are to meeting the requirements of ISO 13485:2016. To help, we have developed a Readiness Checklist to outline the new requirements contained in ISO 13485:2016.

The checklist has been designed to help you to understand the additional requirements over and above the existing requirements in ISO 13485:2003 and to highlight the areas where your business activities may already comply. Working through the Readiness Checklist will provide you with an overview of the additional work that you may need to carry out prior to your SGS Transition audit.

It is important to note, however, that the Readiness Checklist cannot count as evidence for your transition audit, as our auditors will have to confirm compliance with the standard during your transition audit visit.

HOW DOES THE CHECKLIST WORK?

This checklist breaks down the additional ISO 13485:2016 requirements (over and above the requirements currently defined in ISO 13485:2003) by clause. During each section you will be asked whether you feel you have fulfilled the new criteria. You have the choice to mark your response as:

Ready – this indicates that you feel you are ready to demonstrate this, and you should look to transition during your next visit from SGS.

Nearly Ready – this indicates that, with some more work on implementing the new requirements, you would be able to demonstrate this. We would recommend looking to transition during your next SGS visit.

Work To Do – this option means that there will need to be further preparation for your audit, or perhaps even training with the SGS Academy.

You can find the relevant next steps at the end of the checklist, where you should have a much better idea on how close you are to transitioning

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INTRODUCTION
CLAUSE 1 – SCOPE
CLAUSE 3 – TERMS & DEFINITIONS

Organisation must meet the requirements of its own QMS, standards and regulatory requirements. Requirement to document impacts of environment changes and regulatory requirements on design and implementation of QMS. Terms and definitions updated. Focus on risk, regulatory and product requirements.

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Ensured that your organisation meets the requirements of its own QMS? (0.1)			
Documented the impact of: i) Organisational Environment Changes ii) Regulatory requirements applicable to organisational activities on the design and implementation of your QMS? (0.1)			
Understood and applied the new/clarified concepts and terms and definitions? (0.2, 3 – 3.20)			
Applied the process approach including the 4 key elements? (0.3)			
Recorded justification for the exclusion of any requirement in Clauses 6, 7 or 8? (1.0)			

CLAUSE 4 – QUALITY MANAGEMENT SYSTEM

Emphasis on meeting regulatory requirements, risk management and risk based controls. Roles of the organisation must be defined and documented. Control of changes and responsibility for outsourced processes is specified. New requirements added for documented records and medical device file(s).

HAVE YOU CONSIDERED THE NEED TO:	READY	NEARLY READY	WORK TO DO
Document the role(s) undertaken by the organisation under the applicable regulatory requirements, and considered these role(s) when defining QMS processes? (4.1.1)			
Apply a risk based approach to the control of QMS processes? (4.1.2)			
Consider and comply with all applicable regulatory requirements, including maintaining records of compliance? (4.1.3)			
Evaluate changes to processes for their impact on the QMS and medical devices, and applied appropriate control of changes? (4.1.4)			
Control outsourced processes in accordance with regulatory requirements proportionate to risk? Written Quality Agreements? (4.1.5)			
Validate all software, prior to use and after changes, in accordance with documented procedures, based on risk and application of software, and maintain records? (4.1.6)			
Maintain a 'Medical Device File' (Technical File) containing or referencing documents demonstrating conformity to ISO 13485:2016 and regulatory requirements? (4.2.3)			
Prevent deterioration or loss of documents, maintain security and integrity of records incl. confidential health information? External documents identified and distribution control? Ensure changes to records remain identifiable? (4.2.4, 4.2.5)			

CLAUSE 5 – MANAGEMENT RESPONSIBILITY

Management maintains responsibility for meeting regulatory requirements and setting relevant objectives. QMS processes must be documented. A documented procedure for management review is now required, with additional requirements for inputs and outputs related to new elements of this standard.

HAVE MANAGEMENT ENSURED:	READY	NEARLY READY	WORK TO DO
Regulatory requirements are determined and met? (5.2)			
Objectives (related to regulatory, quality and product requirements) are set at relevant functions and levels? (5.4.1)			
Processes needed for the QMS are documented? (5.5.2)			
Management Review procedure is documented, including frequency and new input and output requirements, implemented and records maintained? (5.6)			

CLAUSE 6 – RESOURCE MANAGEMENT

Documented processes are now required for training, effectiveness checks proportional to risk. Infrastructure, work environment cleanliness and contamination control requirements must be documented.

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Documented process(es) for establishing competence, providing training, evaluating effectiveness in proportion to the risk? Ensured awareness of personnel? (6.2)			
Documented infrastructure requirements to prevent product mix-up and ensure orderly handling of product, including information systems? (6.3)			
Defined maintenance requirements for production equipment, control of work environment and monitoring and measurement? (6.3)			
Documenting requirements for work environment needed to achieve product conformity? Ensuring competence/competent supervision for any temporary work under special conditions? (6.4.1)			
Documented planned arrangements for control of contaminated or potentially contaminated product? Documented and maintained requirements for control of contamination with microorganisms or particulate matter (sterile devices)? (6.4.2)			

CLAUSE 7 – PRODUCT REALISATION

Usability and user training needs, resource and competence, and traceability of design outputs to design inputs must now be considered as part of the design process. Risk analysis is emphasised here again. New requirements for verification and validation plans (including methods, considering connected/interfaced devices, software validation, validation on representative product). New procedure/record requirements, including maintenance of a design history file for each device type or family. New clause for reporting to regulatory authorities. Purchasing identifies risk based control of suppliers and changes to purchased product.

7.1 PLANNING OF PRODUCT REALISATION

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Planned product realisation including infrastructure and work environment? (7.1.b)			
Documented requirements for handling, storage, distribution, traceability, measurement and criteria for product acceptance? (7.1.c)			

7.2 CUSTOMER-RELATED PROCESSES

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Determined user training required for safe use and effective performance of the device, and ensured this training is planned or available? (7.2.1.d / 7.2.2.d)			
Reviewed requirements related to product to ensure applicable regulatory requirements are met? (7.2.2.c)			
Documented arrangements for communicating with customers? Communicated with regulatory authorities in accordance with requirements? (7.2.3)			

7.3 DESIGN & DEVELOPMENT

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Documented, maintained and updated design and development planning documents throughout the process? Including stages, reviews, verification, validation and transfer activities, responsibilities and authorities, traceability of design outputs to design inputs, resources including competence? (7.3.2)			
Included design inputs for usability requirements (IEC 62366-1), applicable standards, regulatory requirements, product and process development? Ensured inputs can be verified or validated? (7.3.3)			
Design review records include identification of the design under review, participants and date of review? (7.3.5)			
Verification and validation plans include methods, acceptance criteria, statistical techniques with rationale for sample size, confirming design inputs are met when device is interfaced or connected? Records include conclusions and necessary actions? (7.3.6, 7.3.7)			
Validation completed on representative product (with rationale recorded) prior to release to the customer? (7.3.7)			
Documented procedures for the transfer of design and development outputs to manufacturing? Verified that outputs are suitable for manufacturing and that production capability can meet requirements prior to transfer? (7.3.8)			
Documented procedure for control of design and development changes, including evaluating significance to function, performance, usability, safety and applicable regulatory requirements; effect on product in process, inputs and outputs of Risk Management, product realisation processes? Maintain records of change review and necessary actions? (7.3.9)			
Maintained a Design & Development (Design History) file for each medical device type or medical device family (records demonstrating conformity, change records, link to manufacturing specifications)? (7.3.10)			

7.4 PURCHASING

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Established criteria for the evaluation and selection of suppliers in accordance with 7.4.1? Planned and implemented monitoring and re-evaluation of suppliers? Used monitoring data in supplier re-evaluation? Maintained records including actions arising? (7.4.1)			
Addressed non-fulfilment of purchasing requirements with suppliers, proportionate to the risk associated and regulatory compliance (7.4.1)			
Ensured that purchasing information includes product, specification, acceptance and supplier personnel qualification requirements? Written agreement that supplier will notify in advance of any changes? (7.4.2)			
Reviewed proposed changes for effect on product realisation, medical device and verification/validation requirements? (7.4.3)			
Verification activities for purchased product based on risk associated and supplier evaluation results? (7.4.3)			

7.5 PRODUCTION & SERVICE PROVISION

HAVE YOU CONSIDERED THE NEED TO:	READY	NEARLY READY	WORK TO DO
Documented procedures and methods for the control of production, qualification of infrastructure, monitoring of process and product? (7.5.1)			
Documenting requirements for cleanliness and/or contamination control of product (7.5.2)			
Servicing of medical devices: analyse records for complaints and inputs to the improvement process. (7.5.4)			
Documented process validation procedure (including for sterile barrier systems) and records including: acceptance criteria, criteria for re-validation, statistical techniques and rationale for sample sizes, recording and approving changes to validations, software validation, proportionate to risk? Records maintained of validation results, conclusions and actions? (7.5.6, 7.5.7)			
Identifying product status wrt monitoring and measurement throughout production, storage, installation and servicing) to ensure only conforming product (or product under an approved concession) is released? (7.5.8)			
Unique device identification applied to the medical device in accordance with a documented system? (if regulatory requirement) (7.5.8)			
Implants: traceability records maintained by distributors or suppliers of distribution services, and records available for inspection? (7.5.9.2)			
Protect product from alteration, contamination or damage under expected conditions and hazards during processing, storage, handling and distribution: • design and construct suitable packaging and shipping containers (shipping studies), • Document, control and record requirements for special conditions if packaging alone is not adequate to preserve product (7.5.11)			

7.6 CONTROL OF MONITORING AND MEASURING EQUIPMENT

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Recorded adjustments or re-adjustments to measuring equipment? (7.6.b)			
Performed calibration or verification in accordance with documented procedure(s)? (7.6)			
Documented procedures for the validation & revalidation of software used for monitoring and measurement of requirements, proportionate to risk associated? Maintained records of results, conclusions and actions? (7.6)			

CLAUSE 8 – MEASUREMENT, ANALYSIS AND IMPROVEMENT

New requirements specified for complaint handling and reporting to regulatory authorities. Feedback system must be linked to risk management and include gathering data from production and post-production activities. Non-conforming product requirements are now split based on when in the process the non-conformance is identified. Additional rework requirements are specified. Improvement is now linked to medical device performance rather than just improvement of the QMS. CAPA must be assessed for impact on regulatory, safety or performance requirements.

8.2 MONITORING AND MEASUREMENT

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Documented a feedback process including gathering data from production and post-production activities, and methods for obtaining and using this information, including input to risk management and product realisation/improvement? (8.2.1)			
Documented procedures for timely complaint handling in accordance with applicable regulatory requirements, covering the minimum requirements and responsibilities in 8.2.2? Documented corrections and corrective actions, or justification if complaint not investigated? (8.2.2)			
Maintaining records of reporting to regulatory authorities? (8.2.3)			
Documented internal audit procedure including responsibilities and requirements for planning, conducting, recording and reporting? Audits cover QMS compliance with documented arrangements and regulatory requirements? Records maintained including criteria, scope, intervals, method, processes and areas, results and conclusions? (8.2.4)			
Records identify test equipment used to perform measurement activities? (8.2.6)			

8.3 NONCONFORMING PRODUCT

HAVE YOU:	READY	NEARLY READY	WORK TO DO
Procedure includes controls and responsibilities for identification, documentation, segregation, evaluation and disposition of non-conforming product, requirement for records? Records include evaluation, investigation and rationale for decisions? (8.3.1)			
Document justification and approval for acceptance of product under concession? (8.3.2)			
Records of issue of advisory notices and actions maintained? (8.3.3)			
Documented rework procedures: take account of the potential adverse effect of rework on product? Verify that product meets acceptance criteria and regulatory requirements after rework? Maintain records of rework? (8.3.4)			

8.4 ANALYSIS OF DATA

HAVE YOU CONSIDERED THE NEED TO:	READY	NEARLY READY	WORK TO DO
Data analysis procedures include determination of appropriate methods, including statistical techniques and extent of their use; analysis includes input from sources in 8.4, evaluates suitability, adequacy effectiveness of the QMS; deficiencies input to improvement process? (8.4)			

8.5 IMPROVEMENT

HAVE YOU CONSIDERED THE NEED TO:	READY	NEARLY READY	WORK TO DO
Changes and improvements implemented to ensure and maintain QMS adequacy and medical device safety and performance? Post-market surveillance used as an input to the improvement process? (8.5.1)			
Corrective actions taken without any undue delay? Procedure defines requirements for planning, documenting and implementing actions and verifying that actions do not adversely affect regulatory, safety and performance? Records maintained of investigation, results and actions? (8.5.2)			

YOUR NEXT STEP

Hopefully this ISO 13485:2016 Readiness Checklist has helped you to understand more about the changes of the new standard, and what is required from you to achieve a successful transition. Below is an indication of what your answers indicate in terms of any additional work that you may need to carry out prior to your transition.

If the majority (or all) of your answers have covered Ready (with Nearly Ready making up the minority):	If the majority of your answers are Nearly Ready, with a mix of Ready and Work to Do making up the minority:	If the majority of your answers are returning Work to Do, with the minority showing either Ready or Nearly Ready:
Congratulations! You are ready to book your transition audit with SGS. This can be done by advising SGS directly via your usual contact.	Continue to progress implementation of the new requirements in preparation for your next SGS audit which would include ISO 13485:2016. A proposal will be sent to you prior to the audit being scheduled. To do this, please contact your SGS Auditor or regional office directly	It seems there is still some areas of the new standard that you are not quite up-to-date with yet, but this can be resolved in a variety of ways. • SGS Academy – The SGS Academy host a variety of transition training courses. Aimed at organisations already certified to the previous version of ISO 13485, the transition courses last for one day and offer a time-efficient way of understanding the recent changes.

RESOURCE MATERIAL TO HELP SUPPORT YOUR TRANSITION

The decision to book your transition audit should be a simple one; however aspects surrounding the publication of a new standard can seem daunting. SGS is committed to making the transition as easy as possible for our customers.

SGS has various resources available to assist you with the transition to ISO 13485:2016:

• Transition webinars

  www.sgs.co.uk/13485transitionwebinar

• Training

  The SGS Academy has a number of courses available to assist our clients with the changes to the standard. These sessions are available on an open basis in a number of locations, or can be delivered at your site, tailored to your specific requirements.

  ISO 13485:2016 Transition
  The objective of this course is to provide attendees with the knowledge of ISO 13485:2016, along with the interpretive skills necessary to understand the requirements of the Standard. More Info/Book Course ▶

  ISO 13485:2016 Internal Auditor
  This intensive course aims to provide delegates with the skills needed to conduct internal assessments of their quality management system to the requirements of ISO 13485:2016. More Info/Book Course ▶

For more information, contact the UK Medical Devices team via email to sgsmedicaluk@sgs.com or call +44(0) 1934 522917

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WHEN YOU NEED TO BE SURE

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