INSERT COMPANY NAME/LOGO HERE

ISO 9001:2015 - with - ISO 13485:2016 Quality Management Systems - The Gap Analysis Checklist

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This gap analysis checklist is prepared for use in evaluating your Quality Management System (QMS) against the requirements of ISO 9001:2015 and ISO 13485:2016. Each requirement of ISO 9001:2015 is expressed as a question that the user (auditor / assessor) can ask to evaluate your QMS capabilities. You will need to have copies of the ISO 9001:2015 and ISO 13485:2016 standards to use along with this checklist so that you can refer to the requirements if necessary.

While the two versions of the standard do not line up when comparing the requirements:

- The left-hand column follows the format of ISO 9001:2015 (10-Section Annex SL Format)
- The right-hand column in green shade follows the format of ISO 13485:2016 (8-section format, based upon ISO 9001:2008) to help identify and locate where in the requirements are relevant.
- In the green shaded right-hand column, the ISO 13485:2016 requirements IN ADDITION TO ISO 9001:2015 are highlighted in yellow.
- The intent of the main clauses of the ISO 9001:2015 standard is shown in **bold blue font.**

After you have prepared an audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist for the auditors working with that section. As you work through the checklist take notes on what is in place, and what needs to be developed. In the space for 'currently in place', list or reference the procedures or other documents, or evidence that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, that is, will they need to be revised for the new system, or can they be used as is? Also note where processes are in place, but documentation is needed. Focus on what is in place, and what needs to be developed.

While you do want to know if documented information is in place and if procedures and processes are being complied with, compliance is not your main focus for this audit. Remember that the final outcome of this audit should be a list of things that your company needs to do to comply with both ISO 13485:2016 and ISO 9001:2015.

ISO 13485:2016 (8 section format) with ISO 9001:2015 (10-Section Annex SL Format)

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ISO 9001:2015 - with - ISO 13485:2016 Quality Management Systems - The Gap Analysis Checklist

ISO 9001:2015 QUALITY MANAGEMENT SYSTEMS REQUIREMENTS	Currently in Place	Compliant YES / NO?	If NO - % Complete	Items Needed	ISO 13485:2016 Medical devices- QMS Requirements
4 CONTEXT OF THE ORGANIZATION					**4.0 Quality management system**
This clause introduces two sub-clauses relating to the context of the organization, (1) understanding the organization and its context and (2) understanding the needs and expectations of interested parties. Together they require that you determine the issues and requirements that can impact on the planning of the Quality Management System (QMS). In addition, the scope of the QMS and the QMS processes along with their applicability and interactions need to be determined.					The intent of the main clauses of the ISO 9001:2015 standard is shown in bold blue font.
4.1 Understanding the organization and its context					----
Does your company determine the external and internal issues that are relevant to your purpose and strategic direction?					
Do you consider the relevant issues that affect your ability to achieve the intended results of the Quality Management System (QMS)?					
Does your company monitor and review the information related to the external and internal issues?					
4.2 Understanding the needs and expectations of interested parties					----
With consideration given to their impact or potential impact on your company's ability to consistently provide products and services that meet customer and applicable					

statutory and regulatory requirements, do you determine:					
• The interested parties that are relevant to the QMS?					
• The requirements of these interested parties that are relevant to the QMS?					
Does your company monitor and review the information about these interested parties and their relevant requirements?					
4.3 Determining the scope of the quality management system					**4.1 General requirements**
To establish the scope of the QMS, does your company determine the boundaries and applicability of the QMS?					4.2.2 a) The scope of the QMS is required in a quality manual
When determining the scope of the QMS, do you consider the:					
• External and internal issues (per 4.1)?					
• Requirements of relevant interested parties (per 4.2)?					
• The products and services of your company?					
When a requirement of ISO 9001:2015 can be applied, is the requirement applied by your company?					

The right-hand column in green shade follows the format of ISO 13485:2016 (8-section format, based upon ISO 9001:2008)

When requirements cannot be applied, and to claim conformity to ISO 9001:2015, how do you determine if your ability or responsibility to ensure conformity of products and services are not affected?	the ISO 13485:2016 requirements IN ADDITION TO ISO 9001:2015 are highlighted in yellow				4.2.2 a) Justifications for exclusions are required to be included in the quality manual
Is the scope of the QMS available and maintained as documented information?					4.2.2 a) The scope of the QMS is required in a quality manual
Does the scope state the products and services covered by the QMS?					
Does your company provide justification for any instance where a requirement of the standard cannot be applied?					1 Scope - Exclusions permitted with justifications for clauses 6, 7, or 8 in ISO 13485:2016
4.4 Quality management system and its processes			----		
4.4.1 As required by ISO 9001:2015, do you establish, document, implement, maintain, and continually improve the QMS?					4.1.1 Establish, implement, document a QMS and maintain its effectiveness per ISO 13485:2016 standard and regulatory requirements.
					4.1.1 Document the roles undertaken by the organization under the regulatory requirements.
Does your company determine the processes needed for the QMS, their interactions and applications throughout your company?					4.1.2 a) Determine the processes needed for the QMS and their application throughout the organization