The Gap Analysis Checklist

This list has been prepared for you by The 13485 Store. You will need to have a copy of the ISO 13485:2003 Standard to use along with this checklist. There are some spaces on the checklist that you will need to fill in from the Standard. You will see these as you review the checklist.

After you have prepared your audit schedule, and assigned responsibility to your auditors for different areas or processes to audit, copy each section of the checklist (and the standard??) 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. Reference procedures or other documents that you have reviewed and that will provide information for the new QMS. Take notes on the status of the documents, 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 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 organization needs to do to comply with ISO 13485:2003.

Quality Manual, Procedures and Forms

For a complete set of ISO 13485:2003 documentation, visit www.13485store.com, We have designed and documented a Quality Management System for you to use as the foundation of your documentation system. This system addresses all of the requirements of the standard, from setting quality objectives and measurement criteria for your processes to internal audits and continual improvement. All the procedures interrelate to provide you with an efficient, effective quality management system.

Customize these documents instead of starting from scratch and benefit from the expertise of our ISO 13485 professionals. We guarantee our products and are confident that using our documentation will save you time and effort and result in a superior Quality Management System.

Our ISO 13485 professionals support our products and are available to answer your questions as you proceed with your project. Add our expertise to your implementation team and let us help you succeed.

4 QUALITY MANAGEMENT SYSTEM

	REQUIREMENTS	CURRENTLY IN PLACE (List documents or evidence)	COMPLIANT Y/N? Estimated % Complete	ITEMS NEEDED
	General Requirements			
This clause asks you to identify how management applies the process approach to achieve the effective and efficient control of processes, resulting in maintaining the effectiveness of the quality processes. . Specifically this section is looking for an overall process evaluation of all quality related processes and their interrelationships. Look to see that your organizational processes are defined and documented, and that consideration is given to those items described in a) through f).				
	a) Look for documentation of the processes included in the QMS.	Note- pictorial based is recommended, but not required.		
	b) Look for documented procedures on the relationship and sequence of the QMS processes.			
	c) Ask Management if operation and control of processes is effective. How do they know if it is effective			
	d) Ask how they are able to know if resources and information needed to support processes have been provided			

	e) Is there any information on the effectiveness of processes? Are Internal Audits conducted? Do you have a system for Corrective and Preventive Action			
	f) How is effectiveness of the process maintained?			
	§ What processes does your organization outsource? How is the process controlled?			
	Documentation Requirements			
This section addresses how you use documents and records to support effective and efficient operation of your organization. A review of your procedures, work instructions, and records will determine if the standard requirements and regulatory requirements are met.				
	General			
	Does your quality system documentation include the documentation required by ISO 13485? Such as:			
	Documented statements of the Quality Policy or Quality Objectives?			
	A Quality Manual?			

	a) Is there a list or other means of identifying other documentation required by your QMS? Are the required documents available?			
	b) Does the QMS documentation include Quality Records?			
	Quality Manual			
	Review the Quality Manual if available.			
	a) What is the scope of your QMS?			
	b) What processes have been excluded? Is this appropriate?			
	c) Is a description or illustration of the interrelation of the processes included?			
	d) Does the Quality Manual describe the procedures that are used in the QMS?			
	Control of Documents			
A documented procedure is required for the control of documents. Documents such as, work instructions, procedures, specifications, forms and records, must be controlled.				
	Do you have a formal procedure regarding the control of documents for your organization?			
	a) Are documents approved?			

	b) Are documents updated and re-approved?			
	c) How are changes identified?			
	d) Are documents available to those that need to use them? How is the most current version kept in the correct locations?			
	e) Can users easily identify documents? Can users easily read the documents?			
	f) If documents such as reference books, user's manuals and other outside documents are used, how are they controlled?			
	g) How are old documents handled? Are they removed from use? Are they labeled? Is a copy maintained for reference? Is there any chance that an old document could be used by accident?			
	h)			
	Control of Quality Records			
A documented procedure is required by this clause of the standard.				