

Procedure Text/ISO Reference	Discussion	Objective Evidence
	<p>Introduction and General Commentary - This Quality Procedure covers the requirement to prepare and maintain a description of the regulatory requirements a manufacturer has considered in the design and development of a product. Manufacturers are required to summarize this information in a Device Master Record, sometimes called a STED or Technical File, for each device or group of related devices a manufacturer offers for sale. This file contains objective evidence of compliance to the regulatory requirements of the jurisdictions where you offer the product for sale and it describes the approved device design. Therefore the Technical File can never be the device history record, which pertains to a single production run such a batch or lot. When developing your Technical File it is recommended that all information be collated into a single file, not one file for each jurisdiction. Regulatory authorities appreciate products which are circulated throughout the world and value market approvals from other jurisdictions, however they will simply ignore the parts of the file which do not pertain to their requirements. From the manufacturer's perspective developing and maintaining a single file for this purpose makes the process simpler to manage.</p> <p>The actual contents of your file are based on the jurisdictions where the product is to be offered for sale and the nature of the product itself. This template outlines the typical requirements for <i>in vitro</i> diagnostic devices offered for sale in the United States (USFDA), European Union (CE Marking) and Canada (Canadian Medical Device Regulations) which is a typical configuration. If a requirement does not pertain to your device then simply indicate such with a rationale on that decision; do not simply delete something. Also, the skills and experience of the person making these decisions should be sufficient to justify why they are relied upon to make such decisions. Which person makes each decision should be recorded. Lastly, please remember that ISO 13485:2003 is not a good source for the contents of your technical file, you must consider the regulations and laws where you intend to sell your product.</p> <p>The first column provides the typical text found in a Regulatory Requirements Procedure. This text has been assessed by auditors/inspectors on numerous occasions and found to be adequate. The discussion column expands on the procedure's text using examples to illustrate what is commonly required. The objective evidence column describes the documentation that an auditor/inspector would anticipate finding in order to establish compliance. Some insight is provided into what would satisfy an auditor/inspector. All of this information adds value to a company's operation and therefore is much more than a simple exercise in passing an audit.</p>	

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<p>1. Purpose</p> <p>The purpose of this procedure is to ensure ABC Medical Systems is in full compliance with the requirements of:</p> <ul style="list-style-type: none"> • US FDA Quality System Requirement (QSR), cGMPs and cGLPs, • European <i>In Vitro</i> Diagnostic Directive, and the • Canadian Medical Device Regulations (CMDR) <p>including holding the appropriate approvals or licenses, technical files, CE Marking, labelling and mandatory incident reporting.</p>	<p>You will very often find an inspector/auditor will know a great deal more about your company and product line than you think they do. This information will be gleaned from your regulatory submissions, website, advertising literature and similar public information.</p> <p>An inspector/auditor will be able to readily identify which regulatory approvals you will require and one of the primary goals of their review will be to clearly establish all required licenses or approvals are in place.</p> <p>When establishing this procedure, clearly identify where you intend to offer your product for sale and then obtain all required regulatory approvals. Keep in mind that this is a very fluid requirement as your company will enter and leave markets quite readily.</p>	<p>At least twice a year, as part of management review, we recommend that the entire product line be evaluated. This review should include validating the risk classification, intended use, reviewing unintended or off-label use, field corrections or other adverse information and lastly any changes implemented during the year. Is it not unusual for marketing to move ahead of regulatory and begin selling your product in a new jurisdiction or for a new indication. Therefore establish some discipline around reviewing and updating regulatory approvals; including holding people accountable for obtaining new approvals when required. Address any issues brought about by “product creep” which is where an established product undergoes changes that may require a new regulatory approval.</p> <p>Provide clear objective evidence that the review took place, what products were considered, notifications made, new regulatory approvals obtained, changes to the technical file, risk assessment or regulatory approvals, etc., and enter them into the CAPA process. Include a rationale for when no changes or notifications are made.</p> <p>Safeguard all approvals like treasured family heirlooms, that is - in pristine condition, and be readily able to produce them when requested.</p>