1.1 QUALITY POLICY

QUALITY POLICY

<Company Name> is committed to meeting customer requirements and enhancing customer satisfaction through continual improvement of its products, services and the quality management system.

This policy is too general, and it should not be considered as an example of a proper policy. It is included here only to illustrate how the policy could be presented in the manual.

1.2 INTRODUCTION

This section includes an introduction, a definition of operations and products to which the quality system applies, and statement of any exclusions of ISO 13485 requirements (per ISO 13485 Clause 1 and Clause 4.2.2).

1.2.1 <Company Name> developed and implemented a quality management system to demonstrate its ability to provide medical devices and related services that consistently meet customer and applicable regulatory requirements.

The introductory paragraph is suitable for OEM companies (it is taken from 13485 Clause 1). If you are not OEM, rephrase this sentence to reflect your involvement in one or more stages of the life-cycle, including design and development, production, storage and distribution, installation, or servicing of a medical device; and design and development or provision of associated activities (e.g. technical support).

1.2.2 The quality system complies with the international standard ISO 13485:2016.

List any other standards with which your quality system complies, for example, ISO 9001, 21 CFR Part 820 (FDA's QSR), other national regulations, etc..

1.2.3 The manual is divided into eight sections modeled on the sectional organization of the ISO 13485:2016 standard. Sections are further divided into several subsections representing main quality system processes. Each subsection defines general policies and basic principles for the pertinent quality system process; summarizes responsibilities and methods; and references relevant operational procedures and other associated documents.

1.2.4 The purpose of this manual is to define and describe the quality management system, to define authorities and responsibilities of the management personnel involved in the operation of the system, and to provide a general description of all processes comprising the quality system.

1.2.5 Another purpose of this manual is to present the quality system to customers, suppliers, regulators and other external interested parties, and to inform them what specific controls are implemented at <Company Name> to assure quality.

1.3 APPLICATION AND ROLE

Define the products (medical devices) and services for which this quality system applies. Where applicable, in addition to manufacture and delivery you may add design, development, distribution, installation, servicing, etc., of the products. If you don't apply the system to all categories of products, name specifically these products to which the system applies. Here, you can also directly use the scope of your ISO 13485 certification.

1.3.1 The quality management system defined in this manual applies to the design, manufacture and distribution of medical devices offered by <Company Name>.

Instead of "medical devices" name the products specifically (or generally by categories or types of products).

1.3.2 <Company Name> has the role of a manufacturer under US FDA regulatory requirements.

This is a new requirement in ISO 13485:2016 Clause 4.1.1. The role can be: manufacturer, authorized representative, importer and distributor. If you are regulated by different regulatory jurisdictions, define you role for each.

1.4 SCOPE AND EXCLUSIONS

This section pertains to ISO 13485 Clause 1.2, Application, allowing for claiming exclusions from certain requirements of the standard. Under previous editions, organizations could choose between ISO 13485 and ISO 13488, depending on the nature of their operations and needs. Now there is only one specification of requirements, ISO 13485, but organizations may claim exclusions from various requirements that do not apply to their operations.

The intention is primarily to allow exclusions of design control requirements where there are no design activities (old ISO 13488). But you can also exclude other requirements that don't apply, for example, 7.5.4, Customer property.

Note that in some countries you may be able to exclude design control requirements even when you design products. Contact your registrar or regulatory agency to find out if this would apply in your situation.

This clause starts with a short procedure explaining briefly the rules for taking exclusions, who makes these determinations and who approves them, and how exclusions are documented. Although not explicitly required, the procedure helps to demonstrate that there is a deliberate process for identifying applicable exclusions, and thus adds credibility to the validity of the claimed exclusions.

1.4.1 The quality management system shall be relevant to the nature of our organization and products, and to customer and regulatory requirements. For this reason, those requirements of ISO 13485 that do not apply are excluded from the scope of our quality system.

1.4.2 An ISO 13485 requirement may be excluded only when the following three conditions are met:

The following two conditions are identical to those stated in ISO 13485 Clause 1.2.

- The requirement must be within ISO 13485 Clause 7, Product Realization;
- The exclusion may not affect our ability, nor absolve us from the responsibility, to provide product that meets specified requirements; and
- The exclusion may not affect our ability to carry out corrective action.

1.4.3 Processes which are applicable to the medical device(s), but which are performed by outside contractors, do not qualify for exclusion. They are accounted for in the quality system to ensure control over such outsourced processes.

1.4.4 The <QA Manager> is responsible for identifying those requirements of ISO 13485 that do not apply to our organization or products, and to propose to the top management that such requirements be excluded from the scope of the quality system.

1.4.5 Top management evaluates the proposed exclusions and determines whether they are appropriate. The evaluation and approval of exclusions are conducted within the framework of management reviews of the quality system (refer to Operational Procedure QOP-56-01, Management Review).

Formal approval of exclusions by the top management is not explicitly required in the standard. Thus, you may delete this paragraph if you feel that it is not appropriate, or does not apply in your company. I included it here because decisions regarding the scope of the quality system are often important enough to warrant direct involvement of the top management, and because these decisions may have direct bearing on the compliance status of the company.

1.4.6 Any exclusions taken are documented in this section of the quality manual. The excluded requirements are precisely identified with reference to specific clauses and/or statements in the standard. There is also a brief justification why the exclusion is taken and why it is appropriate.

CLAIMED EXCLUSIONS

If all requirements of ISO 13485 Section 7 apply, write here "No exclusions taken." You still need this section in the manual to define how exclusions will be identified, should this become relevant in the future.

If you identified any exclusions, document them as in the two examples below. The first example illustrates how a company may justify exclusion of design and development requirements. The second example may be relevant to a company that does not receive any products or documents from its customers.

I. **Exclusion:** ISO 13485 (2016) Section 7.3, Design and Development, including all subsections

Justification: <Company Name> does not design or develop products. All principal product characteristics are specified by the customers or their consultants. Our engineering activities are limited to developing methods and means of production, fabrication, or installation.

II. **Exclusion:** ISO 13485 (2016) Section 7.5.5, Particular requirements for sterile medical devices

Justification: Devices manufactured by <Company Name> are not sterilized .