Insert Your Company Name/Logo Here

ISO 13485:2016

and

FDA.QSR (21 CFR 820)

Quality Systems Manual

Document No. QMD-002

Street Address

City,

State / Province

Zip / Postal code

QSR requirements are highlighted in yellow

INSERT YOUR COMPANY LOGO HERE

Instructions:

This manual is used as a template in developing your ISO 13485:2016 Quality Management System. This Quality Manual is designed for ISO 13485 and can accommodate the FDA Quality System Regulation (21 CFR 820).

The basic additions for the Quality System Regulation are highlighted in yellow and the applicable part of the regulation is indicated.

For example, in section 3.0 of the manual, the QSR 820.3 bb notation refers to part 820.3 Definitions; and in section 4.2 of the manual, the reference to QSR 820.30.j indicates a requirement in part 820.30 Design controls.

- Methods and systems used in the development and operation of the QMS vary widely from company to company.
- The blue text and suggestions displayed in the manual are intended to offer some options and to highlight the areas that need attention / update / replacement.
- Review the text and suggestions and at a minimum replace or update them to reflect the unique / customized information of your quality system requirements.
- Delete the blue text after each task is completed.
- Use replace function – enter “Your Company” in find space, enter your company name in replace space – system should make changes throughout the entire document.
- Additional details and instructions in the use of the QMD-002 manual template are included in a separate file “QMS-Template-Instructions”.

Additional documentation review.

- Similarly, the blue text and suggestions displayed in the QMS documentation (that will follow) for the procedures, instructions, attachments, forms, and flow diagrams are intended to offer some options and to highlight the areas that require update or replacement.

unscheduled maintenance is collected by the maintenance manager, and summarized for management review.

5.3.1 Employees are encouraged to report any real or perceived problems with the equipment that they use. The Equipment Problem Report, F-630-001 is provided for that purpose.

5.3.2 Preventive maintenance schedules may be changed based on the analysis of data at management review.

5.4 For QSR 820.70.d, controlled conditions for requirements for the health, cleanliness, personal practices, and clothing of personnel are outlined in the procedure P-751 for production and process controls.

5.5 For QSR 820.70.g/h, specific infrastructure requirements for buildings and equipment related to the creation of maintenance schedules, inspections and adjustment of equipment, and manufacturing materials are implemented.

5.5.1 Maintenance Schedule

Schedules for the adjustment, cleaning, and other maintenance of equipment to ensure that manufacturing specifications are met are established and maintained. Maintenance activities are documented and include the date and individual(s) performing the maintenance activities.

5.5.2 Inspection

Periodic inspections are conducted to ensure adherence to applicable equipment maintenance schedules. The inspections are documented and include the date and individual(s) conducting the inspections

5.5.3 Adjustment

Inherent limitations or allowable tolerances are visibly posted on or near equipment requiring periodic adjustments or are readily available to personnel performing these adjustments.

5.5.4 Manufacturing Material

Where a manufacturing material could reasonably be expected to have an adverse effect on product quality, such material is removed or its use limited to an amount that does not adversely affect the quality of the medical device. The removal or reduction of such manufacturing material is documented.

You may need to detail some work instructions to cover the activities specific to your requirements.