

Section 4: Quality Management Systems

4.1 General Requirements.

Suburban Manufacturing, Inc. has established, documented and implemented a Quality Management system in accordance with the requirements of ISO 9001:2008. The system is maintained and continually improved through the use of quality objectives, internal and external audit results, analysis of data, corrective and preventative action, and management review. To design and implement the quality system, Suburban Manufacturing, Inc. has:

- 4.1.1 Identified the processes needed for the QMS and their applications throughout the organization. These are documented on the Process Interaction diagram at the end of this section.
- 4.1.2 Identified the sequence and interaction of these processes, and illustrated them on the Process Interaction diagram.
- 4.1.3 Determined criteria and methods needed to ensure the operation and control of the processes are effective. These are documented through the manufacturing software structure and data analysis.
- 4.1.4 Secured the continuing availability of resources and information necessary to achieve planned results and for the continual improvement of these processes.
- 4.1.5 Established systems to monitor measure and analyze the processes.
- 4.1.6 Established processes to identify and implement actions necessary to achieve planned results and continual improvement of these processes.

4.2 Documentation Requirements.

- 4.2.1 Suburban Manufacturing, Inc.'s documentation includes:
 - 4.2.1.1 Suburban's Quality policy and quality objectives.
 - 4.2.1.2 The Quality manual, providing a general overview of the QMS, is in place at Suburban. Policies and procedures are referenced in this manual. There is no paper copy showing all documents and their revision status. All critical documentation is kept on the computer server network.
 - 4.2.1.3 Operational, Departmental Procedures and records. Departmental activities and records that affect other departments or procedures common to the organization.

Pharmaceutical Quality Manual Template

Judd E. Hollander



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