

4 Quality Management System

4.1 General Requirements

[See Process Flow Chart FC 4.1-1](#)

Alabama Specialty Products, Inc. has established, documented and implemented a Quality Management System (QMS) in accordance with the requirements of the ISO 9001:2008 Standard, it is not a stand-alone system, but is integrated within ASPI's operating discipline which encompasses the policies, requirements, and work processes of Environment, Health, Safety, Manufacturing, Human Resources and Quality.

Developed and endorsed by company management the QMS ensures that customers' receive quality, reliability and integrity in the products and services ASPI provides them and that customers' needs and requirements are met. The QMS calls for precise adherence to specifications, as well as legal and quality requirements.

Product quality is maintained through systems of standardization and process control. Service quality covers all aspects of customer transactions and is ensured by the function that is providing the service.

4.2 Documentation Requirements

4.2.1 General

The QMS documentation includes:

- A documented Quality Policy and objectives
- A Quality Manual, (requirements for the quality manual are contained in section 4.2.2)
- Documented procedures required by ISO 9001:2008 (i.e., sections 4.2.3, 4.2.4, 8.2.2, 8.3, 8.5.2 and 8.5.3)
- Documents (information and its supporting medium) needed by the organization to ensure the effective planning, operation and control of its processes
- Records required by ISO 9001:2008, (stating results achieved or providing evidence of activities performed)

4.2.2 Quality Manual

This Quality Manual has been prepared to describe Alabama Specialty Products, Inc. QMS. The scope and permissible exclusions of the QMS are described in section one of this manual. Each section of the manual references documented QMS procedures relating to the requirements outlined in that section. The [Process Flow Chart, FC 4.1-1](#), provides a description of the interaction between the processes of the QMS system.

4.2.3 Control of Documents

All the QMS documents are controlled according to the [Document Control Procedure, QP 4.2-1](#).

4.2.4 Control of Quality Records

Quality Records are maintained to provide evidence of conformity to requirements and the effective operation of the QMS. The records are maintained according to the [Control of Documents and Quality Records, QP 4.2-1](#).

Quality Manual Example

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Implementing ISO 9000:2000 Matt Seaver, 2001 This text is aimed at the busy manager or proprietor who needs to implement ISO 9001 It consists of a commentary against each clause of ISO 9004 guidelines for performance improvements explaining the practical benefits of implementing the guidance that is given in the standard *ISO 9001:2000 Quality Management System Design* Jay J. Schlickman, 2003 Provides a set of design rules for creating a quality management system that will naturally translate into successful ISO 9001 2000 certification The book identifies the key documentation components and supplies guidelines for outlining and writing the quality manual standard operating procedures work instructions forms and records Two case studies illustrate the upgrade and recertification of a corporation from ISO 9001 1994 to ISO 9001 2000 and the creation of a company's first quality management system The author is an auditor certified by the ASQ ANSI registrar accreditation board Annotation copyrighted by Book News Inc Portland OR [Developing an ISO 13485-Certified Quality Management System](#) Ilkka Juuso, 2022-03-20 Developing an ISO 13485 Certified Quality Management System An Implementation Guide for the Medical Device Industry details the lessons learned from a real world project focusing on building an ISO 13485 2016 Quality Management System QMS from scratch and then having it officially certified It is a practical guide to building or improving your existing QMS with tried and tested solutions The book takes a hands on approach first teaching the top 25 lessons to know before starting to develop a QMS and then walking you through the process of writing the quality manual and the standard operating procedures training the staff on the QMS organizing an internal audit executing a management review and finally passing the necessary external audits and obtaining certification It helps you to progress from one task to the next and provides all the essential information to accomplish each task as quickly and efficiently as possible It does not attempt to replicate the standard but instead drills into the standard to expose the core of each section of the standard and reorganize its contents into a practical workflow for developing maintaining and improving a Lean QMS The book includes a wealth of real world experience both from the author's personal dive into quality management and from the experiences of other companies in the field and provides handy checklists for ensuring key documents and processes are fit for use the emphasis here is to help ensure you have considered all relevant aspects In addition the book is not intended as a cheat sheet for the standard or as a review of the standard that only adds lengthy commentary on each of the clauses Instead the book fixes easy misunderstandings regarding QMS provides insight into why the various clauses are written the way they are and provides a great base to both understanding ISO 13485 QMS and developing your own QMS The book is intended to serve both experts and novices audiences it provides special insight on the most crucial and effective aspects of QMS [Manual of Food Quality Control](#) Food and Agriculture Organization of the United Nations, 1993-01-01 **Quality Engineering Handbook** Thomas Pyzdek, Paul A. Keller, 2003-04-09 Written by one of the foremost authorities on the subject the Second Edition is completely revised to reflect the latest changes to the ASQ

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