# 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, OP 4.2-1.

# **Sample Quality Manual Template**

Jay J. Schlickman

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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 **Sample Quality manual for** AAC blocks manufacturing, 2020-03-20 This book Sample Quality manual for AAC blocks manufacturing useful for all AAC Block manufacturing companies It has contents such as Raw material selection and testing for AAC blocks manufacturing Process description and troubleshooting over AAC blocks manufacturing problems All testings of AAC blocks Marketing user Modern Aspects of Pharmaceutical Quality Assurance Minal Ghante, Manohar Potdar, Vidhya guide with best policies Bhusari, 2024-03-11 The pharmaceutical quality system ensures that the process performance is suitably achieved the product quality is regularly met improved opportunities are identified and evaluated and the knowledge is constantly expanded Auditing also plays a crucial role within the pharmaceutical industry It helps to assess and review quality to improve and build a better system for the benefit of companies This book aims to develop a tool that will substantially decrease the number of Inspectional Observations and Warning letters thus eliminating Import Alerts and Consent Decree This book targets the Pharmaceutical Industry and students of Pharmaceutical Quality Assurance so they can get in hand ready consolidated information on Pharmaceutical Quality guidelines Quality metrics and implementation of simplified SOP guidelines plant layouts to implement Quality metrics for Pharmaceutical Manufacturing systems in tablets capsules liquid orals and semi solid dosage forms The chapters cover the various aspects of Pharmaceutical Quality Assurance The selection of topics is mainly based on the requirements of Pharmaceutical regulatory guidelines of India the UK the USA Australia and South Africa Each chapter includes the abstract detailed explanation implementation guidelines flowcharts layouts and Standard Operating Procedure of quality metrics for the Pharmaceutical Manufacturing System 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 **Ouality Assurance** and Quality Improvement Handbook for Human Research Leslie M. Howes, Sarah A. White, Barbara E. Bierer, 2019-11-05 Helping human research protection program professionals create implement and evaluate quality assurance quality improvement programs Quality Assurance and Quality Improvement Handbook for Human Research is the first comprehensively designed instructional manual aimed at teaching human research protection program HRPP professionals

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