SAMPLE PACKAGE

ISO 9001 QMS

Policies, Procedures & Forms

ABR211

This Sample Package contains:

Part A: Overview of the Sample Package (1 page)
Part B: Abridged Table of Contents (5 pages)
Part C: Policy, procedures and form set (6 pages)

A: Overview of the Sample Package

Thank you for viewing this sample content from the **ISO 9001 QMS Policies, Procedures & Forms.**

The following 5 pages contain an abridged version of the Table of Contents, with key sections shown in full detail and supporting sections listed as Tab Headings only.

Following the Table of Contents is a complete policy, procedures and form(s) set from this manual. This policy for ***Pre-production Quality Planning*** exemplifies the content, writing style and format of the full manual. The ***Pre-production Quality Planning Policy*** is located in the manual under Tab 4: QMS Quality Procedures.

TERMS AND DEFINITIONS

Manual: A system of approved policy statements and corresponding procedural guidelines and supporting forms that direct an organization toward its operational goals.

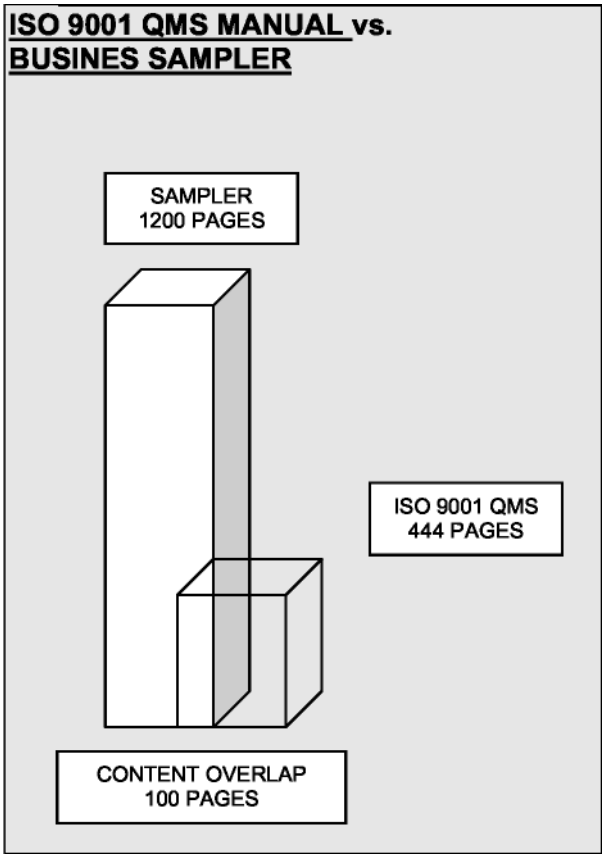
Policy: A stated course of action with a defined purpose and scope to guide decision making under a given set of circumstances within the framework of corporate objectives, goals and management philosophies.

Procedure: A series of prescribed steps followed in a definite regular order which ensure adherence to the guidelines set forth in the Policy to which the Procedure applies

Activity: An action, element or decision representing a prescribed step in the Procedure process.

Task: A detailed component of an Activity specifying required behavior to complete the activity.

Form: A pre-formatted document containing instructions and place-holders for data entry to monitor progress through a particular Procedure and to ensure proper recordkeeping.



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Sample prewritten policy and procedure statements are provided as examples of the minimum set of ISO 9001:2000 based policies and procedures used by other companies. These samples can be used to generate ideas or to model policy and procedures for your own ISO 9000 program.

Modifications are needed, as appropriate and as necessary, to ensure they accurately reflect your company's quality assurance system.

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QP1240 - INTERNAL QUALITY AUDITS

Continue to next page to view sample Policy, Procedure and Form Set Ä

SOP # _____ Revision: _____ Prepared by:

Effective Date: _____ Approved by:

TITLE: QP1120 - Pre-Production Quality and Planning

Purpose: It is the policy of the company that programs and procedures will be developed and continually maintained and redefined for assuring that appropriate pre-production activities are correctly performed that will result in the orderly development and transfer into production of a new or modified product.
This procedure outlines the steps, planning and reviews for implementing the orderly transfer of a new or modified product upon completion of its design phase into full-scale production.

Scope: This procedure applies to all departments and individuals involved with the development and release of a new or modified product prior to full-scale production.

Definitions: Intrinsic quality is the inherent quality designed into a product and the associated manufacturing processes.
Achieved quality is assured through procedures for orderly transfer of the design information into the production department followed by controlled manufacturing of the product.

Responsibilities:
Design and development is responsible for overseeing the release of the product design including completing all forms and documentation as identified in this procedure.
Quality Assurance ensures that all product specifications have been met as required.
Manufacturing is responsible for producing the product to specifications in a timely and cost efficient manner by providing input and feedback as requested in this procedure before the product is released.

Procedure:

1.0 Design Completion

1.1 Upon completion of the Design and Development Validation phase, the product is ready to transition to manufacturing.

1.2 Upon completion of the design phase, any changes, modifications or corrections made to the product or existing documentation must adhere to proper document change and design change procedures. See Quality Procedures: QP1110 - DESIGN CHANGE and QP1000 - DOCUMENT CONTROL.

2.0 Design Transfer and Documentation

2.1 During design reviews and the verification and validation phases of design and development, Quality Assurance and Manufacturing give consideration to the orderly transfer of the product into production.

2.2 Pre-production quality planning by this team must include consideration of all significant aspects of the product, the manufacture of it, and its ultimate use. Reviews should be performed to make certain that the following two goals are fully met:

- The quality objectives and requirements for the product are clearly defined in product and/or processes specifications.
- The processes are capable of achieving the quality objectives.

If a product design is not adequately translated into correct specifications as needed to procure components and manufacture finished devices, the resulting product may be unsafe, ineffective and/or unreliable. Therefore, a complete and adequate product and process documentation, including all labeling and data forms, must be drafted and approved before full-scale production and before commercial distribution of the product.

3.0 Production Plan

3.1 Production processes should be planned, developed, validated and documented to assure they will routinely achieve the intrinsic level of quality designed into the new or modified product.

3.2 Process validation where the resulting output cannot be verified by subsequent inspection is particularly important, especially in processes where deficiencies become apparent only after the product is in use. Process validation demonstrates the ability of the process to achieve the planned results. Validation includes defined criteria for review and approval of the process:

- Approval of equipment
- Qualification of personnel
- Use of specific methods and procedures
- Specific records to be maintained
- Revalidation requirements

3.3 The adequacy of present facilities and equipment or requirements for additional space and/or equipment for manufacturing the product should be determined in conjunction with the anticipated production rate or volume. Included in this determination should be the facilities used in, and equipment used for:

- Environmental Control
- Assembly or Manufacturing
- Inspection
- Testing
- Labeling Control
- Component or Product Handling
- Packaging and Shipping

3.4 Manufacturing, customer, or vendor problems associated with previous product designs should be analyzed to eliminate or reduce similar problems in new or modified products.

3.5 As discussed above, the product, and as appropriate, the packaging must be defined in terms of desired attributes, such as physical and performance characteristics. These attributes must then be translated into written product specifications, as discussed, and manufacturing specifications to assure that the finished product conforms to the approved design.

3.6 Acceptable ranges or limits must be established for each attribute. The validity of the acceptance specifications should be verified through testing and challenge of the product, packaging and manufacturing processes during their development and later during pilot-production.

3.7 The manufacturing processes and equipment and inspection and testing processes and equipment should be designed and/or selected so that in-process and finished product specifications are consistently achieved. This selection should be done with the participation of all appropriate groups that are concerned with assuring a quality device (e.g., Engineering, Production and Quality Assurance). The next step is to arrange, obtain and install and qualify equipment and tooling for the processes.

3.8 Process Failure Mode and Effects Analysis (FMEA) (see procedure QP1100DESIGN AND DEVELOPMENT for the definition of FMEA) should be used to identify potential process problems that could result in product nonconformities (see procedure QP1290 - PREVENTIVE ACTION).

3.9 After process equipment is designed or selected, it should be reviewed, calibrated, evaluated and tested to verify that it is capable of operating satisfactorily within the operating limits required by process specifications.

3.10 Information obtained from qualification studies of process equipment and ancillary systems should be documented and used to:

- Establish written equipment calibration and maintenance procedures
- Establish manufacturing procedures for the monitoring, operation and control of the equipment including the minimum number of operators
- Establish any needed environmental controls and procedures
- Ensure that the work area has sufficient space to perform the processing and associated activities.

3.11 The production planning process should also include development of programs to train personnel as required to produce the new or modified product. One very valuable training technique is to require manufacturing personnel assist engineering in assembling and evaluating prototypes. This technique:

- Achieves advance training for manufacturing personnel
- Reduces production problems by improving the producibility of the product based on the expertise and input of the manufacturing personnel
- Improves communications and technology transfer between the various departments

3.12 The evaluation of a new product and its associated manufacturing processes should usually include pilot production of a few units. Pilot production is recommended as it helps debug the product design and overall production

program. Thus, pilot production should be planned so that manufacturing activities are monitored, problems are discovered and resolved and documentation is updated.

3.13 As part of the quality assurance program for new or modified products, final prototypes or pilot-production models must be evaluated by the product development group to determine that the product conforms to specifications. A QP1120-1 Product Design Release form should be completed and all evaluation data and associated records should be submitted to the design review group for review.

3.14 Any discrepancies in the finished products versus the specification and other elements of the design and development, or quality objectives must be resolved before the product is released for full-scale production. If pilot models are to be commercially distributed, the pilot units must meet master record requirements and be approved for release. Pilot models may be used internally for technical writers or in training programs for production and service personnel or as marketing displays as an alternate.

Effectiveness Criteria:

Smoothness of transition
Overall process yield
Conformance to Project Schedule

References:

Quality Procedures:

- QP1000 - DOCLTMENT CONTROL
- QP1100 - DESIGN AND DEVELOPMENT
- QP1110 - DESIGN CHANGE
- QP1290 - PREVENTIVE ACTION

Records:

Process Validation records
QP1120-1 Product Design Release Form
Process FMEAs

Revision History:

Revision	Date	Description of changes	Requested By
0	06/29/O1	Initial Release	

QP1120-1 PRODUCT DESIGN RELEASE FORM

Product Name: Model:

DOCUMENTATION	COMMENTS*
1) Master Record Index -	
2) Device Master Record - (Overall Review)	
3) Verified Device Specifications -	
4) Verified Test and Inspection Procedures -	
5) Production Validation Documentation -	
6) Labels, Artwork -	
7) Packaging -	
8) Purchase Specifications -	
9) Vendor Evaluations -	
10) SOP & QA Manual References -	
MANUFACTURING	**COMMENTS**
11) Equipment -	
12) Personnel -	
13) Process -	
14) Pilot Production -	
15) Pilot Release -	
REGULATORY	**COMMENTS**
1) FDA Pre-market Approval -	
SERVICE	**COMMENTS**
1) Servicing Plan -	
2) Personnel -	

* The following comment abbreviations may be used to save time, attach additional sheets if necessary.

U= Unsatisfactory NA = Not Applicable NI = Needs Improvement S= Satisfactory

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PRODUCT	Item #	Title	Price

California residents add 7.75% sales tax $

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~ FedEx Standard $39.99-by 3:OOp

INVOICE TOTAL $

~ FedEx priority $49.99 by 10:30a

PAYMENT INFORMATION

Visa ~ MasterCard ~ American Express ~ Discovery

Expiration (M/Y) _____

Card Number

Name on Card

CWM Security* #

Last 3 digits located on back of Visa/MC/Disc

Four small digits on front of Amex

COMMENTS:_____

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