QUALITY MANUAL

JADE PRECISION MEDICAL COMPONENTS, LLC
105A James Way
Southampton, PA 18966

Table of Contents

1. Purpose & Scope

This manual describes the Quality Management System (QMS) established by and for

Jade Precision Medical Components LLC (JPMC).

The principles and policies on which this manual is based; along with operating procedures, work instructions, and other supporting documents; govern all processes that affect quality throughout the organization.

2. Applicable Standards

2.1 The QMS is structured and intended to be in compliance with the following standard.

- ISO 13485:2003
  Medical Devices · Quality Management Systems · Requirements for Regulatory Purposes
  (Exclusions and Exceptions noted below.)

2.2 Normative References

- ISO 9000:2000 · Quality Management Systems · Fundamentals and Vocabulary
- ISO/TR 14969
  Medical Devices · Quality Management Systems · Guidance on the Application of ISO 13485:2003

3. Business Profile

3.1 Description

JPMC, with one facility located at 105·A James Way, Southampton, Pennsylvania, 18966, USA, is a contract manufacturer of precision medical components typically used in the orthopedic, arthroplasty, and dental implant fields.

3.2 Organization Chart

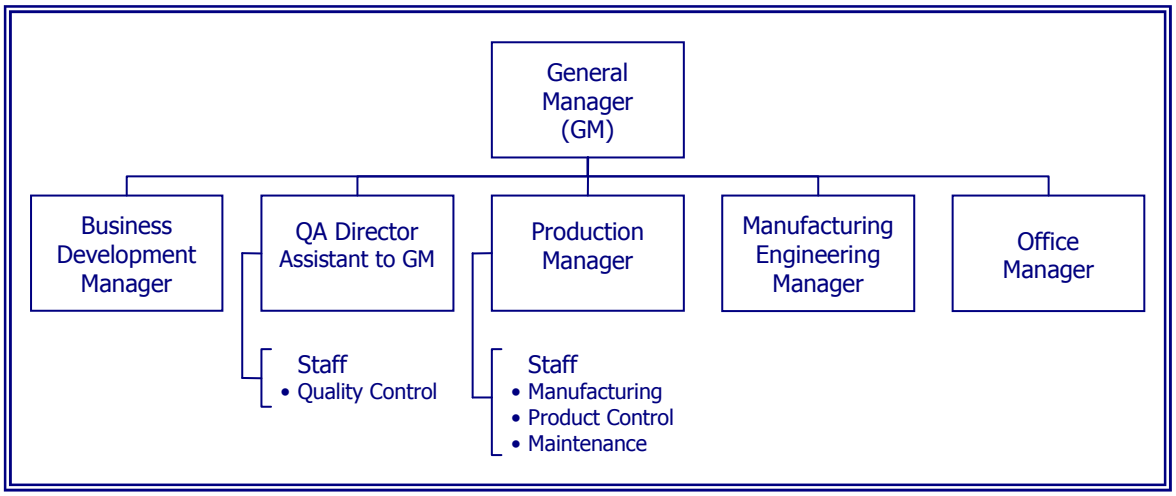


Figure 1

4. Authority & Responsibility

4.1 This manual is issued under the authority of the General Manager.

4.2 It is the responsibility of the QA Director (the designated Management Representative) to ensure that the principles of this manual, the quality policy, and quality objectives are communicated to and understood by all JPMC employees.

5. Terms & Definitions

5.1 **Customer**

1. A business entity and the individuals representing it that specify and purchase products produced by JPMC.
2. A business entity considering JPMC as a potential supplier.

5.2 **Customer Complaint**
Written, electronic, or oral communication that alleges deficiencies related to the identity or quality of a medical device received by a customer.

5.3 **Process**
A set of interrelated resources and activities; i.e. people, materials, equipment, environment, methods; used to transform specific inputs into specific outputs.

5.4 **Product**

1. The end result of activities performed and resources applied by JPMC; a process output.
2. Purchased goods, including outsourced services.

5.5 **Corrective Action**
A process improvement methodology aimed at identifying and eliminating the causes of known nonconformities to prevent their recurrence. A problem solving process.

5.6 **Preventive Action**
A process improvement methodology aimed at identifying and eliminating potential causes of nonconformities before they occur. A risk analysis process.

5.7 **Qualified**
Having attained the knowledge, skills, or other attributes necessary to perform a particular activity or task in accordance with specified requirements.

6. Policy & Objectives

6.1 **Quality Policy**

> Our goal, at JPMC, is to provide products and services that exceed our customers' expectations. This will be accomplished through employee involvement and ongoing education to ensure continuous improvement of our processes.

The quality policy is communicated to all employees as part of their training, with the intent of providing a clear, common understanding, directly applicable to their work. The quality policy is reviewed at least once per year for continuing suitability and adequacy.

6.2 **Quality Objectives**

- Only Defect-Free Product shipped to customers
- Continuous Improvement in Delivery Performance
- Maintenance/Continuation of ISO 13485:2003 Certification

7. Application

7.1 The QMS described in this manual is applicable in contractual situations entailing the manufacture of medical components/devices.

7.2 **Exclusions**

7.2.1 ISO 13485:2003 · Clause 7.3 · Design & Development · including all sub-clauses.

JPMC is a *contract manufacturer* and *does not design, develop, test, or market its own products/brand(s)*. All medical components/devices produced by JPMC are manufactured in accordance with specifications provided and authorized by our customers.

Planning, execution, and control of design and development activities are, therefore, not addressed in this manual and are excluded from the QMS.

7.3 **Exceptions** due to **Non-Applicability**

7.3.1 ISO 13485:2003 · Clause 7.5.1.2.1 · Cleanliness of Product and Contamination Control
At the manufacturing stage in which JPMC is involved, no special cleaning or decontamination processes are necessary. JPMC only performs the type of cleaning expected in a precision metalworking facility and makes no other special accommodations.
Control and verification of special cleaning or decontamination processes is, therefore, not applicable to JPMC.

7.3.2 ISO 13485:2003 · Clause 7.5.1.2.2 · Installation Activities
JPMC does not perform or support any installation activities.
Control and verification of installation activities is, therefore, not applicable to JPMC.

7.3.3 ISO 13485:2003 · Clause 7.5.1.2.3 · Servicing Activities
JPMC does not perform or support any servicing activities.
Control and verification of servicing activities is, therefore, not applicable to JPMC.

7.3.4 ISO 13485:2003 · Clause 7.5.1.3 and Clause 7.5.2.2
Particular Requirements for Sterile Medical Devices
At the stage in which JPMC is involved with manufacturing and handling of medical devices, no sterilization of any kind is applicable nor required. Accordingly, JPMC is not equipped to perform sterilization.
Control and record maintenance of sterilization processes are, therefore, not applicable to JPMC.

8. Quality Management System

8.1 **General**

8.1.1 JPMC has developed, documented, implemented, and maintains its QMS in accordance with ISO 13485:2003.

8.1.2 The QMS is based on a process approach to quality management and JPMC applies continuous process improvement methodology, i.e. the Plan-Do-Check-Act Cycle (Figure 2), to ensure its ongoing effectiveness.

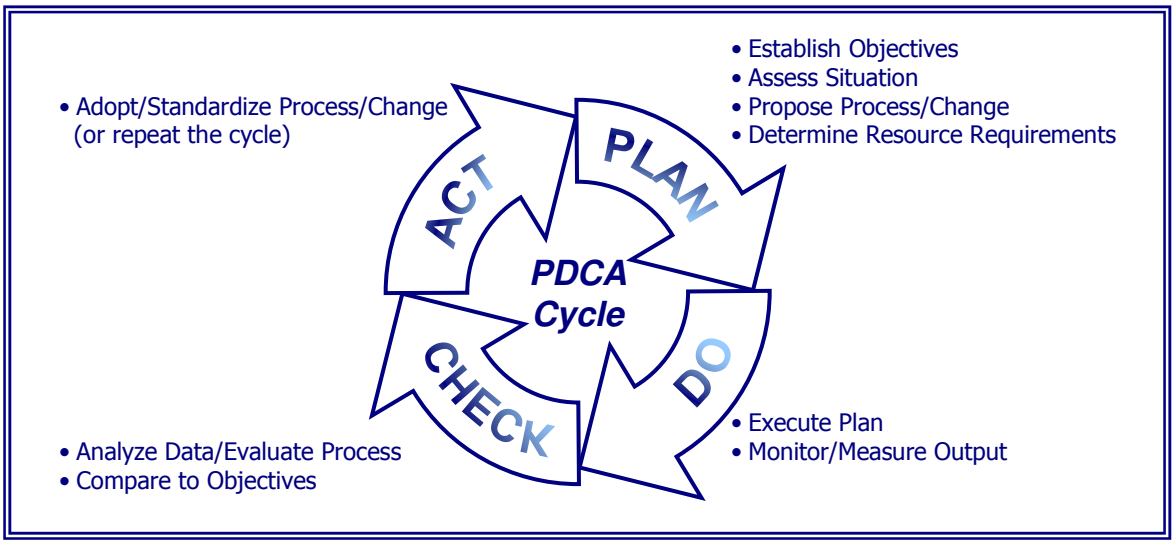


Figure 2

8.1.3 System processes, including their interrelationships and correlation to ISO 13485:2003 sub-clauses, are described in the appendices of this manual.

8.2 Document Control

8.2.1 The document system is tiered as shown in Figure 3.

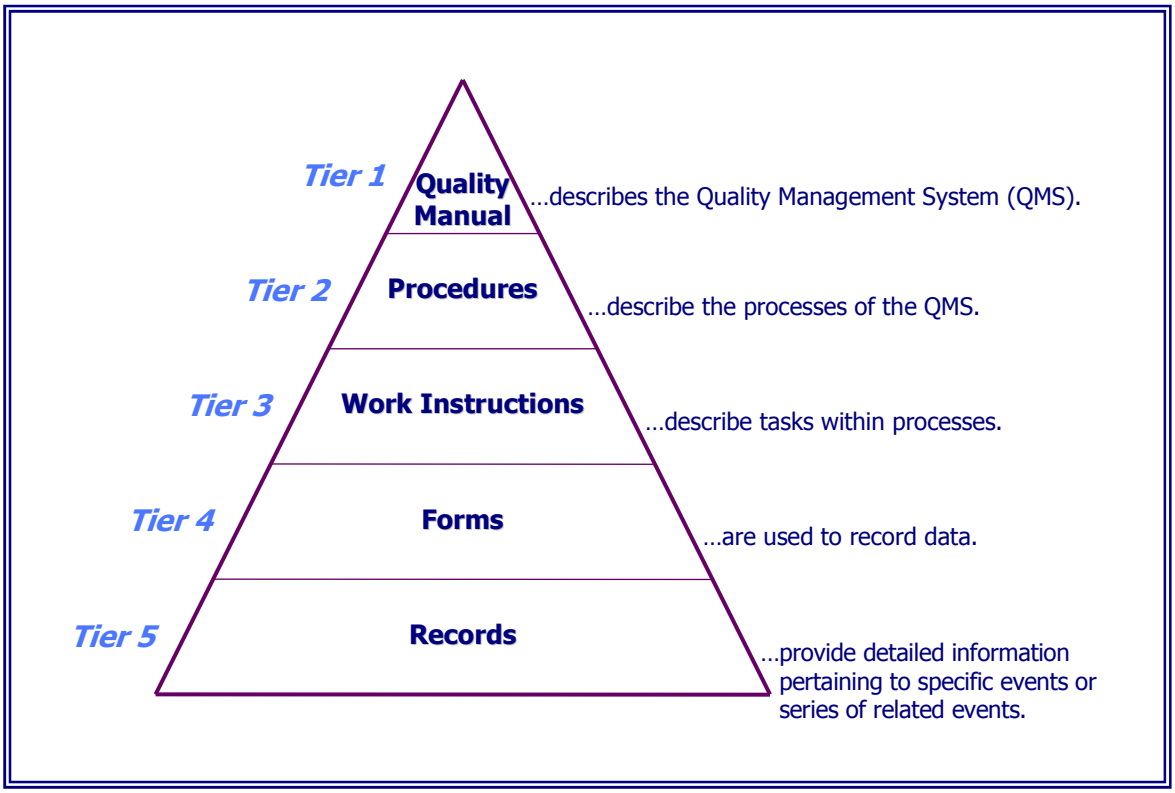


Figure 3

8.2.2 All documents comprising the QMS; i.e. this Quality Manual, Procedures, Work Instructions, Forms; their current revision level and file type are listed in record *RE-42-001 Document Register.*

8.2.3 QMS documents are controlled as prescribed by procedure *PR-42-001 Control of Documents.*

8.2.4 Records required by the QMS and ISO 13485:2003 are maintained in accordance with procedure *PR-42-002 Control of Records*.

8.3 **References**

RE-42-001 · Document Register
PR-42-001 · Control of Documents
PR-42-002 · Control of Records

9. Management Responsibility

9.1 **General**

9.1.1 JPMC management is committed to the development and implementation of the QMS, in accordance with ISO 13485:2003, and fully supports maintaining its effectiveness by

- communicating, to all functions and levels within JPMC, the importance of meeting customer, regulatory, and statutory requirements.
- establishing an appropriate quality policy and measurable objectives and ensuring these are communicated and understood throughout the company.
- providing a framework for review of quality objectives and processes, including regularly scheduled Management Reviews to ensure continuing suitability, adequacy, and effectiveness of the QMS.
- ensuring the integrity of the QMS as changes are planned and implemented.
- allocating sufficient resources and providing education and/or training as required.

9.1.2 Management is ultimately responsible for determining and satisfying customer/product requirements.

9.1.3 Roles, responsibilities, authorities, and their interrelationships are clearly defined, documented, and communicated within JPMC. Personnel who manage, perform, and/or verify work affecting quality have the authority and independence to perform these tasks effectively.

9.2 The QA Director serves as the **Management Representative** and, as such, is responsible and fully authorized to manage the QMS and related matters on an ongoing basis. Roles and responsibilities include the following.

- Interprets the ISO 13485:2003 standard and continually verifies QMS compliance.
- Ensures that required processes are established, implemented, and maintained.
- Advises the management team regarding operation and performance of the QMS and opportunities for improvement.
- Serves as liaison to external parties regarding matters relating to the QMS.
- Promotes awareness of customer and regulatory requirements throughout JPMC.

9.3 **Management Review**

9.3.1 Management Review Meetings are conducted regularly, at least once per year, more frequently if deemed necessary, to review the status of the QMS.

9.3.2 Input to management reviews may include, but is not limited to, the following.

- Quality Policy
- Quality Objectives

- Follow-Up Items From Previous Management Review
- Audit Results
- Customer Feedback
- Non-Conformances (NCRs)
- Delivery Performance Data
- Supplier Performance Data
- Corrective & Preventive Action Status
- Changes that could affect the QMS
- Changes in Regulatory Requirements
- Resource Issues/Requirements

9.3.3 Output of management reviews includes decisions and actions related to the following.

- Improvements needed to ensure continued effectiveness of the QMS and its processes
- Improvement of Product
- Resource Needs

9.4 **References**

PR-56-001 · Management Review

10. Resource Management

10.1 The JPMC management team is responsible for identifying, obtaining, allocating, and/or training appropriate resources to ensure effective implementation and management of the QMS and to satisfy customer and regulatory requirements.

10.2 **Human Resources** · Training & Competence

10.2.1 Personnel who manage, perform, and/or verify work affecting quality are fully competent on the basis of education, training, skills, and experience.

10.2.2 New employees are provided with the following essentials and are subsequently deemed fully qualified for a position or job function.

- Review of Company Policies & Best Practices
- Review of the Quality Manual, including Quality Policy & Objectives
- Review of Relevant Procedures and Work Instructions
- Familiarization with Equipment and/or Software
- Facility Tour & Introductions

10.2.3 All changes to the QMS are reviewed with appropriate personnel when they are put into place.

10.2.4 Competencies are re-evaluated, with respect to current and future requirements, on an ongoing basis to determine if/when/what additional training is necessary. Appropriate training is provided if a deficiency is identified.

10.3 The **Infrastructure**; including building/workspace, equipment/tools, and support services; is designed and maintained to enable conformity with product requirements and continuous improvement.

10.4 **References**

PR-62-001 · Personnel Qualifications & Training
PR-63-001 · Facility & Equipment Maintenance

11. Product Realization

11.1 Product Realization at JPMC encompasses the following process steps.

- Request for Quotation (RFQ) · from customer

- Initial Assessment · by JPMC Quote Team to determine if…
  - work is suitable and within JPMC capabilities,
  - customer delivery and price targets are realistic,
  - requirements, specifications, acceptance criteria are adequately defined.
- Quotation · based on material cost and labor estimates
- Order Processing · including review and confirmation of requirements
- Job Planning & Scheduling
- Purchasing
- Manufacturing
- Measurement/Inspection
- Documentation
- Delivery · to customer

11.2 **Risk Management**

11.2.1 Given that JPMC is a *contract manufacturer* and does not design, develop, or market its own products/brand(s), risk management is limited to the analysis of customer requirements/ specifications and control of manufacturing processes.

11.2.2 Risks associated with product realization are addressed within the procedures of the QMS and other documents that provide evidence of risk management.

11.2.3 Information/specifications provided by customers are reviewed, prior to manufacturing, to ensure product(s) can/will be produced to meet the requirements. Manufacturing plans are based on these risk assessments.

11.3 **References**

PR-71-001 · Risk Management
PR-72-001 · Quotation, Order Entry, Job Planning
PR-74-001 · Purchasing & Supplier Evaluation/Selection
PR-75-001 · Manufacturing
PR-75-003 · Shipping & Receiving
PR-75-006 · Product Identification & Traceability
PR-82-001 · Inspection
PR-83-001 · Control of Non-Conforming Material

12. Purchasing

12.1 Suppliers are evaluated and selected based on their ability to provide products and/or services in accordance with specified requirements; and supplier performance is reviewed regularly to ensure ongoing control over purchased products and outsourced services.
Evaluation/selection/review criteria and procedures have been established and documented.

12.2 Purchasing documents describe products/services clearly and completely.
(Information may include technical specifications, acceptance criteria, requirements for certification, traceability, etc.)

12.3 Incoming product is controlled in accordance with referenced procedures to ensure that:
- receipts are properly recorded and relevant information is retained,
- purchase requirements have been met,
- non-conformities are handled correctly, promptly and consistently.

12.4 **References**

PR-74-001 · Purchasing & Supplier Evaluation/Selection
PR-75-003 · Shipping & Receiving
PR-75-006 · Product Identification & Traceability

PR-82-001 · Inspection
PR-83-001 · Control of Non-Conforming Material

13. Production Control / Product Identification & Traceability

13.1 The manufacture of JPMC products is planned and carried out under the following controlled conditions.

- Requirements, procedures, work instructions, reference materials, etc. are available, as needed.
- Product is manufactured and verified using suitable tools and equipment.
- Material/product identity and status is clearly discernible at all times, throughout the manufacturing process.
- Product is adequately protected while in-process and packaged to prevent damage when shipped.

13.2 A record containing relevant manufacturing information is established and maintained for each lot of manufactured product. Records include the following information to enable product identification and traceability.

- Product Specifications/Requirements; including provisions for permanent identification.
- Raw Material Information; including specifications, certifications, heat numbers.
- Lot Size; i.e. quantity of product manufactured.
- Manufacturing Details; including sequence of operations, start and completion dates.
- Purchasing Information
- Inspection Reports
- Shipping Information

13.3 When the output of a manufacturing process cannot be verified by subsequent measurement or monitoring, the process is validated according to industry best practices that are acceptable to the customer.

13.4 **Customer Property**
Acquisition and control of customer-supplied materials is addressed in *PR-75-006 Product Identification & Traceability* and *WI-82-002 Receiving, Inspection, and Labeling of Raw Materials*. Such material that is lost, damaged, or otherwise deemed unsuitable for use, is handled in accordance with *PR-83-001 Control of Non-Conforming Material* and the customer is notified promptly.

13.5 **Preservation of Product**

13.5.1 Employees, contractors, and suppliers who come into contact with work-in-process or finished goods are provided with the proper instructions, tools, and supplies to protect the materials during production, handling, and while in transit.

13.5.2 Products manufactured by JPMC do not require special storage conditions and do not have limited shelf life.

13.6 **References**
PR-42-002 · Control of Records
PR-72-001 · Quotation, Order Entry, Job Planning
PR-74-001 · Purchasing & Supplier Evaluation/Selection
PR-75-001 · Manufacturing
PR-75-003 · Shipping & Receiving
PR-75-005 · Control of Electronic Data
PR-75-006 · Product Identification & Traceability
PR-76-001 · Calibration & Control of Inspection, Measuring, and Test Equipment
PR-82-001 · Inspection

PR-83-001 · Control of Non-Conforming Material
WI-75-006 · Purpose & Use of Parts Trays
WI-82-002 · Receiving, Inspection, and Labeling of Raw Materials

14. Control of Inspection, Measuring, and Test Equipment

14.1 Inspection, measuring, and test equipment (IMTE) is controlled, calibrated and/or verified in accordance with a documented procedure.

14.2 A Calibration Log (Record) has been established and is updated on an ongoing basis to track the calibration history, status, and schedule of all IMTE. Each piece of IMTE as well as the calibration standards are identified by a unique ID number and detailed description.

14.3 IMTE is further identified by a calibration label (corresponding to the log) and is handled and stored to maintain accuracy.

14.4 Calibrations are performed at predetermined intervals that are subject to annual review and adjustment.

14.5 If particular IMTE was not calibrated as prescribed and inadvertently used in production or inspection, then affected material is considered to be non-conforming, i.e. handled in accordance with *PR-83-001 Control of Non-Conforming Material*, until the validity of the measurements is determined.

14.6 Calibration laboratories and service providers contracted by JPMC are required to use standards traceable to the National Institute of Standards and Technology (NIST).

14.7 **References**

PR-76-001 · Calibration & Control of Inspection, Measuring, and Test Equipment
PR-83-001 · Control of Non-Conforming Material
RE-76-001 · Calibration Log

15. Measurement, Analysis, Improvement

15.1 **Customer Feedback & Communications**

15.1.1 Communications related to customer requirements, product quality, and process improvement may include:

- Customer Complaints & Feedback
- Recall Notices
- Supplier Non-Conformance Report & Corrective Action Request (SNCR)

15.1.2 A documented feedback system is in place (ref. *PR-82-002 Customer Relationship*). Customer complaints and feedback trigger Corrective or Preventive Action and records of complaint investigations are maintained.

15.1.3 Recall Notices are issued, as needed.

15.1.4 SNCRs are issued when purchased materials/products or outsourced services are found to be non-conforming.

15.2 **Internal Audits**

15.2.1 The purpose of internal audits is to verify that process activities and work practices are in compliance with QMS procedures. Audits are planned and conducted in accordance with a documented procedure.

15.2.2 Auditors are drawn from various functional areas and departments and qualified according to relevant QMS procedures. Because auditors must maintain independence, they do not audit their own work, functional area or department.

15.2.3 Audit results are reviewed with personnel working in audited areas. Findings and observations are addressed through corrective or preventive action.

15.3 **Process Monitoring & Evaluation**

QMS processes are monitored and evaluated by comparing planned results to actual outputs. Deficiencies are addressed through management review and subsequent corrective or preventive action.

15.4 **Product Monitoring & Measurement**

15.4.1 Raw materials and work-in-process are subject to Receiving, First Article, and In-Process Inspections as they progress through manufacturing operations; and finished goods must undergo Final Inspection before they are released for shipment to customers.

15.4.2 All inspections are performed in accordance with documented procedures and work instructions to ensure that evidence of conformity with requirements is recorded and maintained. Inspection data includes measurements, inspection methods, inspectors' identities.

15.5 **Control of Non-Conforming Product**

15.5.1 Product that does not conform to requirements is identified and controlled, to prevent its unintended use or delivery, in accordance with documented procedures.

15.5.2 JPMC employees have the responsibility and authority to report nonconformities promptly and take appropriate action.
Responsibility and authority for review, investigation, and dispositioning of non-conforming product is also defined.

15.5.3 The following steps are taken when a non-conformity is identified.
- Review · to determine the disposition of non-conforming product.
- Corrective Action · to investigate and eliminate the cause of the non-conformity.
- Recall Notice (if necessary).

15.6 **Data Analysis & Improvement**

15.6.1 To ensure continuing suitability, adequacy, and effectiveness of the QMS and demonstrate product conformity, JPMC has established, documented, and implemented procedures to monitor, measure, analyze, and improve its processes. Information collected and used for this purpose includes:
- Customer Feedback
- Audit Results
- Product Conformity/Inspection Data
- Other Measurable Process Outputs/Results (such as delivery performance, supplier evaluations, etc.)

15.6.2 Results of analyses are used to identify trends, determine causes of existing or potential problems, guide decisions pertaining to corrective/preventive actions, and assess process effectiveness and supplier performance.

15.7 **Corrective & Preventive Action**

15.7.1 The process for initiating, investigating, planning, implementing, verifying and closing corrective and preventive actions is described in *PR-85-001 Corrective & Preventive Action*.

15.7.2 Corrective/Preventive Action is required in the following situations.

Corrective Action	Preventive Action
• Process output is found to be unacceptable.	• The reliability or effectiveness of a process is called into question.
• Non-conforming material is identified.	• A potential cause of non-conformance(s) is identified.
• Customer complaints indicate a deficiency or negative trend.	• New or revised customer requirements call for re-evaluation of current methods.
• A non-conformity is identified through management review or quality system audit.	• An opportunity for improvement is identified.
• A resource shortage or surplus exists.	• A resource shortage or surplus is anticipated.
• An employee is injured.	• A safety concern is raised.

15.8 **References**

PR-56-001 · Management Review
PR-82-001 · Inspection
PR-82-002 · Customer Relationship
PR-82-003 · Internal Audits
PR-83-001 · Control of Non-Conforming Material
PR-84-001 · Data Collection & Analysis
PR-85-001 · Corrective & Preventive Action

16. Approval for Use

The undersigned have approved this Quality Manual for use in the business activities of

Jade Precision Medical Components LLC (JPMC).

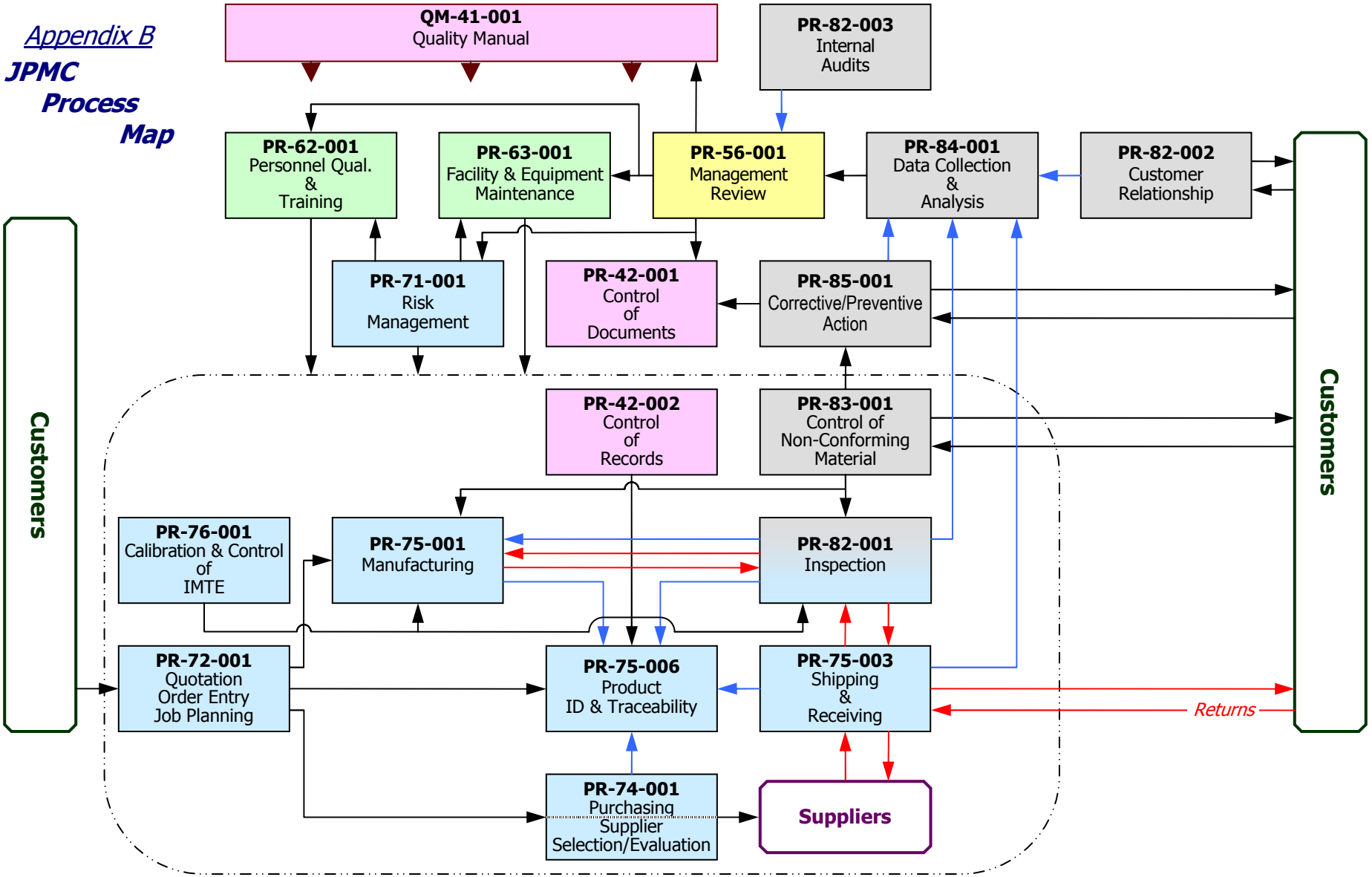
General Manager: _____ Date: 4/16/08
Signature

Quality Assurance Director: _____ Date: 4/16/08
Signature

Appendix A

ISO 13485:2003		QMS		Management Responsibility						Resource Management				Product Realization					Measurement Analysis & Improvement					
Sub-Clause:		4.1	4.2	5.1	5.2	5.3	5.4	5.5	5.6	6.1	6.2	6.3	6.4	7.1	7.2	7.4	7.5	7.6	8.1	8.2	8.3	8.4	8.5	
Document Map **JPMC Procedure** Doc. No. Title		General Requirements	Documentation Requirements	Management Commitment	Customer Focus	Quality Policy	Planning	Responsibility, Authority, Communication	Management Review	Provision of Resources	Human Resources	Infrastructure	Work Environment	Planning of Product Realization	Customer-Related Processes	Purchasing	Production & Service Provision	Control of Monitoring & Measuring Devices	General	Monitoring & Measurement	Control of Non-Conforming Product	Analysis of Data	Improvement	
QM-42-001	Quality Manual	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●
PR-42-001	Control of Documents		●																					
PR-42-002	Control of Records		●																					
PR-56-001	Management Review	●	●	●	●	●	●	●	●	●	●	●	●	●	●	●							●	
PR-62-001	Personnel Qualifications & Training	●													●			●						
PR-63-001	Facility & Equipment Maintenance	●														●		●			●			
PR-71-001	Risk Management	●	●															●						
PR-72-001	Quotation, Order Entry, Job Planning				●													●	●		●			
PR-74-001	Purchasing & Supplier Evaluation/Selection	●	●																	●				
PR-75-001	Manufacturing																				●			
PR-75-003	Shipping & Receiving																				●			
PR-75-006	Product ID & Traceability																				●			
PR-76-001	Calibration & Control of IMTE																				●	●		
PR-82-001	Inspection	●	●															●		●	●	●	●	●		●	
PR-82-002	Customer Relationship	●	●				●												●					●		●	●
PR-82-003	Internal Audits	●	●																					●			●
PR-83-001	Control of Non-Conforming Material																			●	●			●	●		
PR-84-001	Data Collection & Analysis	●	●																					●		●	●
PR-85-001	Corrective & Preventive Action	●	●																					●	●	●	●

Appendix B
JPMC Process Map



Revision History

Rev.	Description of Change	Reviewed by		Approved by	
		Signature	Date	Signature	Date
A	*Initial Release*		4/16/08		4/16/08