STABLE ORTHOPAEDICS PTY LTD

QUALITY MANUAL

0 Introduction

Stable Orthopaedics Pty Ltd is a national distributor for orthopaedic implants. A rigorous evaluation process is in place to ensure that only high quality products are registered with the aim of sourcing products with a six sigma fault rate. To complement the product offering, Stable Orthopaedics Pty Ltd provides a need-based service management which leverages new communication technologies.

Stable Orthopaedics applies a customer-centric quality control which builds on a listen, learn and act feedback loop process.

1. Policy Statement and Objectives

Quality Policy Statement

"We are committed to consistently exceeding customer expectations by providing products and information of the highest quality in terms of safety, reliability, compliance, accuracy and timeliness. Our success is based on continuously improving our product offering, distribution processes, and service provision to meet the needs of our customers."

The objectives of our quality policy statement are:

1. To meet the high quality standards of our customers
2. To ensure compliance with relevant regulatory, statutory and safety requirements
3. To endeavour, at all times, to maximize customer satisfaction with the services provided

2. References

ISO 9001: 2015 - Quality Management Systems – Requirements
ISO 13485: 2016 Medical Devices Quality Management System – Requirements for Regulatory Purposes

3. Definitions

Company
Refers to Stable Orthopaedics Pty Ltd

Quality
Quality in Stable Orthopaedics means meeting customer's expectations in regards to costs and service. The objectives are supported by the Quality Policy Statement.

Regulatory
Regulatory in Stable Orthopaedics means that the company has met all legal, regulatory and compliance requirements to be able to sell and distribute the products within that country.

Non-conformance
A non-conformance is an unlikely failure on the part of a goods or services to meet Stable Orthopaedics Quality Policies or Customer specifications.

4. Context of the Organisation

4.1. Understanding the Organisation and its context

The focus of Stable Orthopaedics is to provide high-quality implants and service. A rigorous evaluation process is in place to ensure that only high quality products are registered with the aim of sourcing products with a six sigma fault rate. To complement the product offering, Stable Orthopaedics Pty Ltd provides a need-based service management which leverages new communication technologies.

4.2. Needs and expectations

Stable Orthopaedics works closely with suppliers, logistic companies and customers to provide efficient and tailored distribution models. Aim is to maximise benefits for customers by reducing unneeded steps along the value chain of manufacturing and distributing sport medicine implants.

Stable Orthopaedics requests the same high quality standards from all suppliers and manufacturers.

4.3. Scope

This Quality Manual covers the Quality Management System for Stable Orthopaedics Pty Ltd. Stable Orthopaedics Pty Ltd runs a self managed Quality Management System which meets the key elements of ISO 9001 certified company.

Stable Orthopaedics Pty Ltd will ensure it procures orthopaedic implants and instruments which have been designed and developed according to all requirements outlined in ISO 13485, thus will only purchase orthopaedic devices from ISO 13485 certified companies.

4.4. Exclusions

Stable Orthopaedics is not a manufacturer of orthopaedic implants.

4.5. Quality Management System

Stable Orthopaedics Quality Management System is built around three pillars. As well as a rigorous evaluation of products, a data-driven inventory management and a strong feedback loop to listen to, learn from and action upon customer feedback. The interaction of the processes may be described by the Process Interaction model (below) which shows how the various processes interact as a result of customer requirements and customer satisfaction analysis, so as to achieve product realization of products with a six sigma fault rate and to continually improve the Quality Management System.

5. Leadership

5.1. Leadership and Commitment

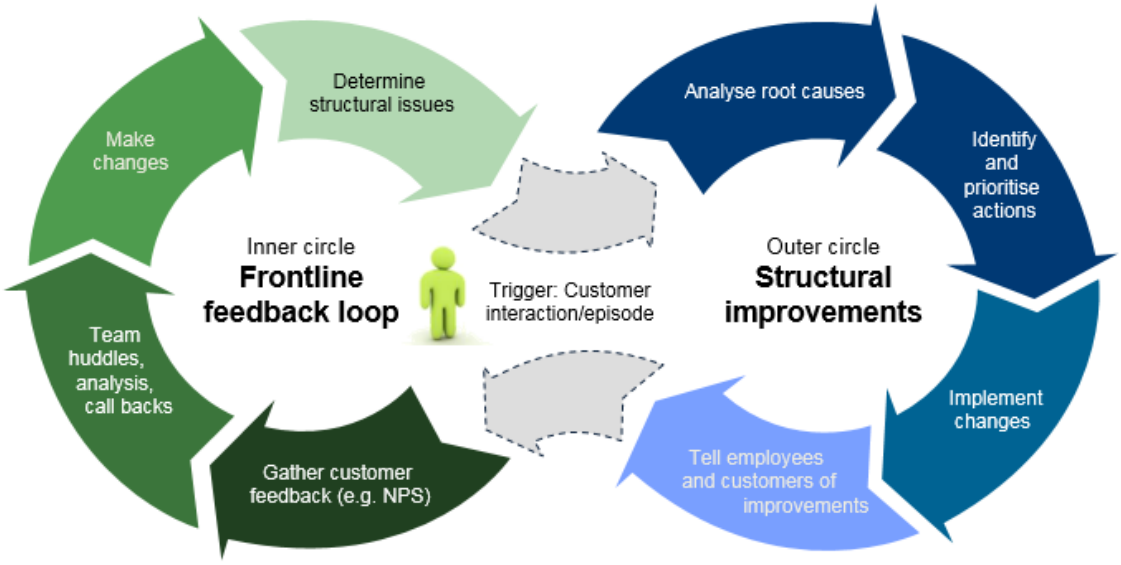
5.1.1. Leadership and Commitment to Quality Management System

The Board provides evidence of its commitment to the development, implementation and improvement of the Quality Management System by:

1. Having established a Quality Policy Statement and Objectives
2. Role-modelling quality management by meeting suppliers and conducting customer call backs
3. Communicating to staff the importance of meeting statutory and regulatory requirements
4. Annually reviewing the Quality Manual
5. Ensuring availability of resources to meet company objectives

5.1.2. Customer Focus

The Board and Director, Regulatory and Quality ensures that customer needs and expectations are determined, converted into requirements and fulfilled with the aim of enhancing customer satisfaction, so that we listen to, learn from and action upon customer feedback.



This is achieved by:

1. Gathering sufficient customer feedback – especially across the holistic experience of customers (i.e. from ordering to using implants in operations)
2. Discussing feedback as a team
3. Determining and adhering to legal and regulatory requirements
4. Making changes to test impact
5. Determining if any feedback is related to structural issues
6. Dealing with structural issues on a strategic level (incl. root cause analysis, prioritising actions, implementing change)
7. Regular interactions with customers to keep them in the loop on improvements/ changes

Customers will provide input by using the email account feedback@stableortho.com. In addition, Net Promoter Score surveys will be deployed.

5.2. Roles, Responsibility and Authority

All staff is allocated with authority to perform their allocated responsibilities in order to ensure high quality. The following provides a summary of the principal responsibilities of quality related job roles.

All staff shares the authority and responsibility of identifying non compliances or possible improvements, and recording these instances such that corrective action can be taken, both to rectify the immediate situation and to prevent recurrence.

The Board continually reviews the company's resources to ensure that adequate staff, equipment and materials are available to meet customer requirements.

Managing Director
To build customer relationships and to meet the high quality requirements of customers. Strong product understanding and ability to train surgeons as required. Responsible for management of business as well as maintenance of high-quality product lists.
Will ensure all business aspects of the company are reviewed and modified to ensure high quality standards. Focus on product evaluation and logistics.
Email: shaun@stableortho.com

Director, Regulatory and Quality
Will ensure all regulatory and quality requirements aspects of the company are reviewed and maintained to allow us to sell and support required products to appropriate customers. As well as ensure all aspects of this Quality Manual are maintained.
Email: dario@stableortho.com

Visitors/business partners are made aware of the Quality Management System and Quality Manual. During their time on site, all visitors are to conduct their business with due consideration to create a minimum impact on the environment and observe the requirements of the Quality Manual.

6. Planning cycles

The Board ensures that the planning of the Quality Management System is carried out in order to meet the requirements given in the quality manual, and that the integrity of the Quality Management System is maintained when changes to the Quality Management System are planned and implemented.

6.1. Actions to address risks and opportunities

The Board and Director, Regulatory and Quality takes action, as appropriate, to eliminate the causes of potential non-conformities in order to prevent their future occurrence. Preventative actions are appropriate to the probable effects of the potential non-conformities.
The methods for preventative action are as follows:

1. Determine the potential for a non conformity and its possible root cause through risk identification and assessment;
2. Evaluate the need for action;
3. Plan and implement specific preventative actions as determined necessary;
4. Record the results of any investigation and actions taken; and
5. Monitor and review any preventative action taken and its effectiveness.

6.2. Objectives and plans to achieve them

The Board and Director, Regulatory and Quality ensure quality objectives, including those needed to meet requirements for the product and services are established for relevant functions and levels within the organisation. The quality objectives and its effectiveness are continually evaluated and communicated through:

1. Company Meetings
2. Discussions with customers
3. Discussions with manufacturer's
4. Board meetings

6.3. Planning of Changes

The Board and Director, Regulatory and Quality ensure that changes required to Quality Objectives maintain the integrity of the Quality Management System. The Board and Director, Regulatory and Quality also ensure that such changes are approved at the Board Meetings and resources are available to implement the changes.

7. Purchasing and Inventory

Stable Orthopaedics ensures an uninterrupted supply of products is available to its customers, by ensuring we have a rigorous approach to evaluating products and hence only listing high quality products which are sources from reliable manufacturer's/suppliers with the aim of sourcing products with a six sigma fault rate. Stable Orthopaedics also maintains a list of manufacturer's/suppliers that meet the requirements for the product to be purchased and supplied to the requirements of our customers.
Stable Orthopaedics strives to purchase high quality product at a reasonable cost and without bias, by evaluating all manufacturers/suppliers and ensuring a supply/distribution agreement is implemented along with a Quality Agreement.

7.1. Product management

Stable Orthopaedics ensures that the process for the purchase, receipt and storage of all products guarantee that the quality of the products is not compromised.

Environmental conditions for the storage of all products will be agreed with the manufacturers/suppliers and conditions maintained.

7.2. Selection and evaluation of manufacturer's/suppliers

Stable Orthopaedics evaluates the manufacturers/suppliers for the products.

The evaluation should be conducted against defined criteria which may include:

1. Product quality
2. Value for money
3. Availability
4. Post-delivery support
5. In-country registration requirements
6. Registration of the manufacturer's/suppliers

All the evaluations are recorded and a list of the manufacturer's/suppliers is established through the quality agreement.

7.3. Stock management and inventory

Stable Orthopaedics will ensure products are stored under correct environmental conditions and are used prior to their expiration dates.

This is achieved by ensuring a regular review of all inventory is conducted throughout the year. We will leverage state-of-the-art statistical models to ensure optimised stock management.

8. Support

8.1. Resources

The Board and Director, Regulatory and Quality determines and provides the resources needed to implement and maintain the Quality Management System and continually improve its effectiveness, and to enhance customer satisfaction by meeting customer and regulatory requirements.

8.1.1. General

The quality system identifies the requirements for the performance of work and verification, and assigns these activities to trained personnel.

8.1.2. People

Personnel who are assigned responsibilities as defined in the Quality Management System are competent on the basis of applicable education, training, skills and experience.

8.2. Competence

The Board and Director, Regulatory and Quality define the competencies required for each position. The Board and Director, Regulatory and Quality ensure that all personnel are competent and qualified to the task they are performing.

The training needs of employees are identified through:

1. Performance evaluation,
2. Legislative requirements,
3. Technological improvements,
4. Customer Feedback,
5. Regulatory requirements.

8.3. Awareness

All new staff including casual and contract personnel shall participate in training and understanding of this Quality Manual as well as any other applicable documents deemed necessary by The Board and Director, Regulatory and Quality to ensure regulatory and customer needs are met.

8.4. Communication

Communication will be maintained either at company meetings or by direct one on one conversation between the Board and Director, Regulatory and Quality. Thus ensuring we can act on the strong feedback loop in place to listen to, learn from and action upon customer feedback.

Customers will communicate feedback using the email account feedback@stableortho.com

9. Documented Information

9.1. General

The Quality Management System documentation includes:

1. Quality Manual
2. Documents as deemed necessary by The Board and Director, Regulatory and Quality to ensure regulatory and customer requirements are met
3. Records providing evidence of conformity to requirements and effective operation of the Quality Management System
4. Survey data

9.2. Creating and Updating

Documented information are established and maintained to provide evidence of conformity to requirements and to the effective operation of the Quality Management System.

9.3. Control of Documented Information

Documented information are established and maintained to provide evidence of conformity to requirements and of the effective operation of the Quality Management System. Documented information may be in the form of hard copy or electronic media.

10. Operations (NOT APPLICABLE)

11. Performance Evaluation

11.1. Monitoring, measurement, analysis and evaluation

11.1.1. General

The Board and Director, Regulatory and Quality apply suitable methods for monitoring and, where applicable, measurement of the Quality Management System processes. These methods demonstrate the ability of the processes to achieve planned results. Corrective and preventative action shall be taken as appropriate, when planned results are not achieved, to ensure conformity of the product or services.

Company meetings are the process used to assess the Quality Management System process effectiveness. So that we can ensure we have an effective management model which focuses on visionary leadership, high performance management, close relationship management with customers and suppliers and business expertise to enable sustainable growth.

11.1.2. Customer Satisfaction

Customer perception is monitored indirectly through feedback from employees and non conformance reports. Customer complaints and feedback are documented and addressed for corrective and preventative actions. Customer satisfaction, customer complaints and customer feedback is reviewed and reported at the annual Board Meetings.

Directly through the customers providing feedback by using the email account feedback@stableortho.com

11.1.3. Analysis and Evaluation

Director, Regulatory and Quality, collects and analyses appropriate data to demonstrate the suitability and effectiveness of the Quality Management System, and to evaluate where improvement of the Quality Management System can be made.

Results of data analysis along with related conclusions/recommendations are presented to the Board for review and action during the annual Board meeting

11.1.4. Internal Audit

The Director, Regulatory and Quality conducts regular Internal Audits to verify that systems comply with this manual and any other documents and records created to maintain regulatory and customer requirements.

11.2. Management Review

11.2.1. General

The Board and Director, Regulatory and Quality review the Quality Management System annually at the annual Board meeting to ensure regulatory and customer requirements are met and improved upon as required.

11.2.2. Review Input

The input to the management review includes information on

1. Follow up actions from previous Board meeting
2. Adequacy of Quality Manual
3. Audit results
4. Corrective Action Reports
5. Customer feedback
6. Process Performance and Product Conformity
7. Survey Feedback
8. Changes affecting the Quality Management System
9. New or revised regulatory requirements
10. Training needs
11. Supplier concerns
12. Equipment needs, working environment and maintenance
13. Data Analysis and Trending
14. Resources

11.2.3. Review Output

As a result of the management review, adverse occurrence, variations, non-conformance or opportunity for improvement reports may be raised and the responsibility for determining and implementing corrective action may be allocated to appropriate members of the organisation to improve the effectiveness and suitability of the quality system.

12. Improvement

12.1. General

The Board and Director, Regulatory and Quality identifies and implements changes necessary to ensure and maintain the continued suitability and effectiveness of the Quality Management System to the requirements of regulatory and customer needs. So that we ensure we have an effective management model which focuses on visionary leadership, high performance management, close relationship management with customers and suppliers and business expertise to enable sustainable growth

Customer complaints are recorded and, as necessary, subjected to corrective action processes. If corrective action is determined not to be required, the justification and authorisation is recorded and maintained.

12.2. Nonconformity and Corrective Actions

The Board and Director, Regulatory and Quality take action where necessary to eliminate the cause of non-conformities in order to prevent reoccurrence. Corrective actions are appropriate to the effects of the non-conformities encountered.

The method for preventative action as follows:

1. Determine the potential for a non conformity and its possible cause through risk identification and assessment;
2. Evaluate the need for action;
3. Plan and implement specific preventative actions as determined necessary;
4. Record the results of any investigation and actions taken; and
5. Monitor and review any preventative action taken and its effectiveness.

12.3. Continual Improvement

Data relating to customer satisfaction, product conformance, and process conformance and supplier performance are analysed during the annual board meetings to evaluate suitability and adequacy of Quality Management System.

Document history and change record

Issue	Issue date	Description of change
1.0	May 2016	Initial Issue
2.0	April 2018	Reviewed with minor changes; Title change for quality and introduction focus
3.0	Nov 2020	Reviewed with no changes
4.0	Mar 2023	Reviewed with no changes

SIGNATURES OF AGREEMENT:

Managing Director

Name **Shaun Van Wyk** **Date** **Mar 2023**

Director, Regulatory and Quality

Name **Dario Pedulla** **Date** **Mar 2023**