



Mantra Medical Ltd

Innovative Healthcare Products

Quality Assurance Manual

Registered in England and Wales. Company No. 07113788

Contents

Introduction	3
Policy and Objectives	4
Terms and Definitions	5
Compliance with ISO 13485	
Quality Management System	6
Level 1: The Quality Manual	
Level 2: Operating Procedures	
Level 3: Quality Planning	
Organisation	7
Organisational Chart	
Authority	
Responsibilities	
Training	
Reviews	11
Management Review and Audit	
Contract Review	
Control	13
Design Control	
Process Control	
Service and Maintenance	
Documentation and Change Control	
Records	
Purchasing	16
Inspection	17
Inspection of Goods Received	
Inspection and Testing	
Indication of Inspection Status	
Asset Management	18
Production and Measuring Equipment	
Customer Supplied Items	
Handling, Storage, Packaging, Preservation and Delivery	
Non-conforming items, Preventive and Corrective Action	

Introduction

Mantra Medical Limited was established in 2009 to develop and produce medical devices which aim to improve patient and staff safety, patient care and the patient experience.

The organisation's principal area of work is the development of a range of products for use by healthcare staff.

The organisation benefits from having the involvement of clinical expertise, information technology experience, successful business development acumen and senior public sector management experience.

The Company's principal strength is proving to be in the field of product development to meet identified clinical needs, the identification of appropriate design partners and the subsequent commissioning of producers with the requisite experience, expertise and quality procedures and standards which are commensurate with the provision of medical devices which are appropriate for use in a global clinical setting.

Policy and Objectives

The objective of the quality policy of Mantra Medical Limited is to achieve sustained profitable growth by designing and producing medical devices which consistently meet the demands, needs and expectations of healthcare staff and patients in their care.

The necessary level of quality is achieved through the adoption of a system of procedures and processes that demonstrate, on a regular and systematic basis, to customers, potential customers, auditors and regulatory bodies the competence of the organisation in producing devices of suitable quality.

The implementation and maintenance of this quality policy is achieved through the involvement of all Directors of the Board and the Board Members in the development, approval and supervision of the working of the policy. Each Board Director both jointly and severally is responsible for the quality of the Company's work and for the continuous improvement of the company's ways of working.

To achieve and maintain the required level of assurance, the Board has designated a Director to have specific responsibility for overseeing the Company's quality assurance systems and procedures.

The objectives of the Quality Management System are:

1. To maintain an effective Quality Assurance System compliant with BS EN ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes.
2. To achieve and maintain a level of quality which enhances the Organisation's reputation with its customers.
3. To ensure compliance with relevant statutory, regulatory, safety and audit requirements and to ensure that changes following audit are implemented.
4. To endeavour, at all times, to maximise clinician and patient satisfaction with the products and services provided and commissioned by Mantra Medical Limited.

Paul Martin Hercock

Managing Director, Mantra Medical Limited

Terms and Definitions

The terms and definitions used in this manual are those given in ISO 13485.

Mantra Medical Limited is the “organisation” as defined in ISO 13485 and any reference to “the company” is a reference to the “organisation” as so defined.

The term “supplier” refers to any design company or sub-contractor and to any other provider of goods and/or services to the organisation.

Where any actions, processes, systems or procedures are documented in the quality management system then all such actions, processes, systems and procedures will be implemented as an integral part of the quality management system.

Additional definitions may apply to any site or location, other than the organisation’s established premises, where work is undertaken as part of a formal contract. However, in all such circumstances Mantra Medical Limited will ensure that any contractor will have established quality systems which are appropriate to the production or supply of products or services for the development and production of medical devices.

Compliance with ISO 13485

The quality system is structured with specific policy statements relating to each medical device/area of activity being within the relevant Operating Procedure.

Quality Management System

The quality management system applies to all activities of the organisation, including products and services procured or commissioned by the organisation. The system has been developed in accordance with ISO 13485. The quality assurance system is fully documented and structured in 3 levels:

Level 1: The Quality Manual

This document details the corporate quality policy, the structure of the organisation and references appropriate operating procedures.

Level 2: Operating Procedures

These documents specify the procedures established and the processes and controls applied in relation to all activities concerned with the attainment of a quality assured service.

Level 3: Quality Planning

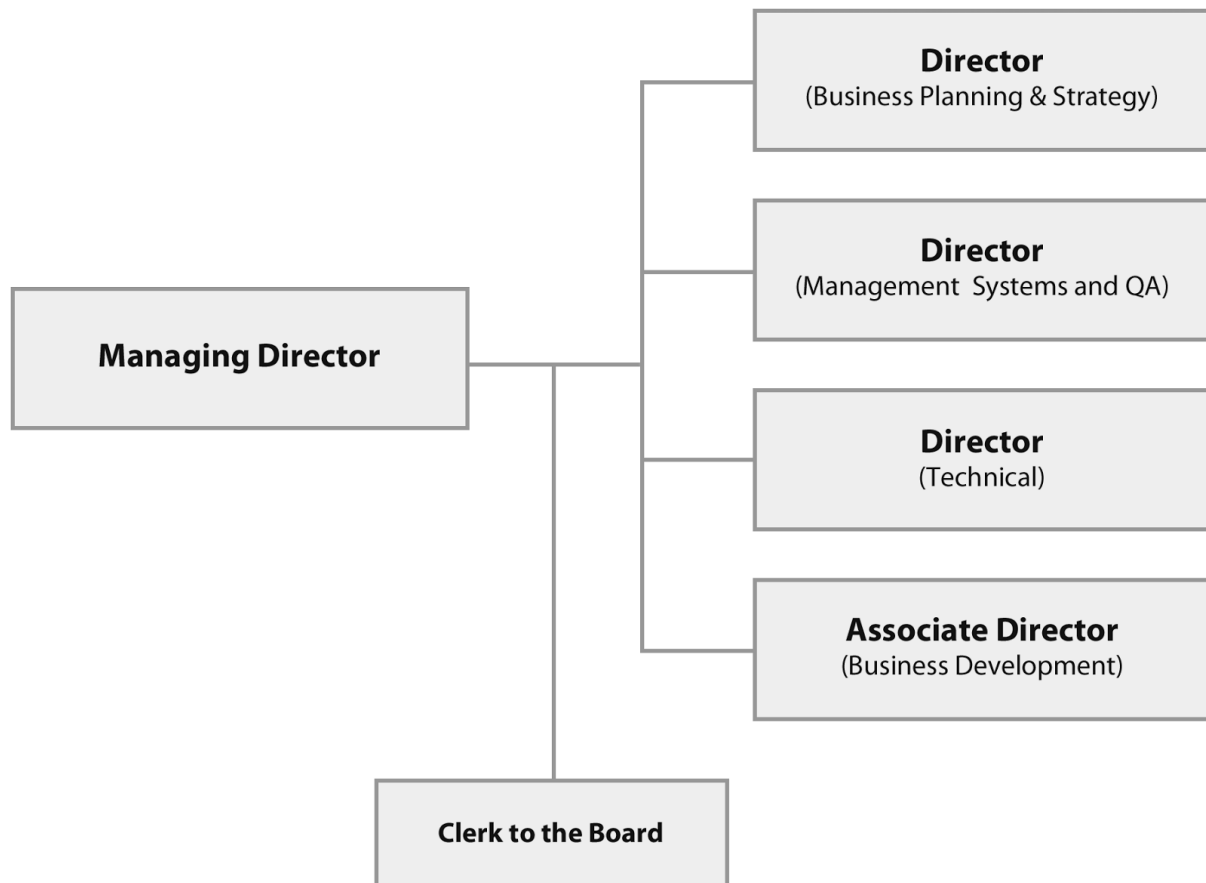
All systems and processes involved in the development of the organisation's medical devices are approved and supervised by the Board of Directors and in particular by the Designated Director. The interaction of the various components within the quality management system is monitored by the Board through a report by the Designated Director to every meeting of the Board.

The essential components of the quality management system include *inter alia*:

- The policy and objectives
- The operating procedures
- Documentation, recording systems and document controls
- Human resource deployment
- Financial resource deployment
- Contracting, procurement and commissioning
- Design control
- Inspection and testing
- Customer satisfaction
- Measurement, analysis, review and improvement

Organisation

Organisational Chart



Authority

The Board of Directors is committed to the development and implementation of the organisation's quality management system and demonstrates this commitment by considering a quality review report presented by the Designated Director at every meeting of the Board. Each Director, the Associate Director and the Clerk to the Board has designated responsibilities which are documented below and in the Operating Procedures.

Jointly and severally the Directors and Associate Director have the authority and responsibility to identify any non-compliance with the quality management system and to draw such non-compliance to the attention of the Designated Director in order that such instances can be recorded and corrective action taken both to rectify the immediate situation and to

prevent any recurrence.

The Managing Director continually reviews the organisation's resources to ensure that adequate staff, equipment and materials are available to meet requirements. In the event they are not, the Managing Director will consult with the Board in order to review the availability of resources.

Responsibilities

The responsibilities allocated are designed to minimize interdependencies so as to ensure, as far as possible, that there are specific accountabilities. Where there are potential interdependencies these are identified .

Managing Director

- Product innovation
- Design control – overall responsibility
- Contract/project management and control
- Supplier selection and purchasing
- Control of production
- Regulatory liaison including ensuring conformity with legislation and regulations and drawing new or revised regulatory requirements to the attention of the Board.
(Interdependency with the Director responsible for Management Systems and QA)
- Clinical trials and research
- Financial resource allocation, budgeting and accounts (in collaboration with the Member responsible for Business Planning and Strategy)
- Customer liaison. (Interdependency with the Director responsible for Management Systems and QA)

Director (Technical)

- IT systems design, procurement and maintenance
- Product user experience design – feedback reporting and collation
- Focus group workshop management
- Supervision of the processing of sales orders
- Data management and statistics
- Website design, development and maintenance
- Brand management
- Marketing

Director (Management Systems and QA)

- Identification of management requirements
- Management supervision

- Control and maintenance of the quality assurance system including risk assessment and risk management, reporting to the Board on the performance of the assurance system and ensuring the Board's awareness of regulatory and customer requirements. (Interdependency with the Managing Director)
- Documentation and document change control
- Internal audit (in collaboration with the Associate Director responsible for Business Planning and Strategy)
- Training
- Company administration

Director (Business Planning and Strategy)

- Business plan development.
- Financial strategy and resource allocation. (Interdependency with the Associate Director responsible for Business Development)
- Funding
- Accountancy
- External networking
- Audit

Associate Director (Business Development)

- Financial planning and strategy. (Interdependency with the Director responsible for Business Planning and Strategy)
- Contract adviser
- Contract and procurement negotiation
- Marketing
- Identification of and negotiation with strategic partners

Clerk to the Board

- Producing Board minutes and agenda and associated Board administrative matters
- Progress chasing
- Maintenance of the register of quality assurance system documentation and notification to the Board of review dates for all such documentation
- Maintenance of the Risk Management Strategy and Framework
- Sales database administration
- Checking of sales orders
- Allocation of Order Reference Numbers
- Inspection and testing database and administration

Training

The organisation ensures that all personnel are trained and experienced to undertake their duties and responsibilities effectively.

The organisation procures, recruits and contracts persons and organisations capable of meeting the technical, skill, experience and educational requirements of the company's activities.

The Director (Management Systems and QA) is responsible for identifying training needs, including staff awareness of the relevance and importance of their activities, and for ensuring that all those who are allocated specific tasks are suitably qualified and experienced.

Full records are maintained of all training undertaken.

Reviews

Management Review and Audit

In addition to the monthly reporting to the Board by the Designated Director, a Board review of the suitability and effectiveness of the Quality System takes place twice per year in June and December; that is at the end of the first and third quarters of the financial year. The Board identifies action to be taken and by whom. All actions are minuted/recorded by the Clerk to the Board in order to help ensure the ongoing development of the organisation's quality management system.

The objectives of the Board reviews are:

1. To ensure that the Quality System is achieving the expected results and is meeting the organisation's requirements; that it continues to conform with ISO 13485; that it continues to meet customers' needs and expectations and that it functions in accordance with the established Operating Procedures.
2. To expose any irregularities or defects in the system, to identify any weaknesses and evaluate possible improvements.
3. To review the effectiveness of any previous corrective actions and to review the adequacy and suitability of the Quality System for current and future operations of the organisation.
4. To review any complaints received, identify the cause and recommend any required corrective action.
5. To review the findings of internal/external audits and identify any areas requiring amendment / improvement.
6. To review reports on any non-conforming products, product elements, systems and processes and any trend information with a view to identifying possible improvements.

Internal audits of the Quality System are undertaken at least once per annum in order to confirm compliance with the organisation's agreed procedures. A comprehensive Audit Plan is compiled by the Board in advance of each financial year. However, in the event that particular needs are identified by the Board, the Plan may be amended to address such needs.

Audits are undertaken by appropriately qualified accountants who are independent of the organisation. The Board determines action to be taken arising from audit, by whom and within what timescale. The actions are recorded by the Clerk to the Board and those responsible for such actions are required to report progress to the Board via the Clerk.

Contract Review

The organisation provides a range of medical devices, each to a standard specification. The products and the general specification for each of them are documented in the organisation's catalogue.

Prior to accepting a customer's order, the organisation will discuss with the customer their specific requirements in the context of the clinical environment concerned. Once an order is placed, it is recorded and reviewed in order to ensure that customer requirements will be met by the product or products selected. Should the organisation feel that customer requirements might not be fully met, the organisation will initiate further discussions with the customer with a view to satisfying fully the customer's needs and requirements.

Where the customer requests an addition/variation to the original order, such change will be documented and agreed with the customer prior to processing the order in order to ensure that no ambiguity exists. Any changes agreed will be communicated to all relevant personnel in the organisation. No changes will be agreed by the organisation where this would compromise required quality standards.

Control

Design Control

In view of the fact that all substantive design activities are outsourced, such activities are overseen and controlled by the Board to ensure that all designs comply with requirements contracted by the organisation.

Initial design requirements and a project brief are specified and drawn up by or in consultation with the Managing Director, who is a clinician, and then approved by the Board for commissioning a supplier to develop the product to production stage. A product file is kept by the Clerk to the Board for each product which includes all design documentation. Contract procurement and negotiation will be led by the Managing Director but will also involve the Technical Director and the Associate Director (Business Development).

The work of the design company employed for the development of each product is supervised on an operational basis by the Managing Director and the Technical Director and they report to every Board meeting on progress. The Board ensures that the development work meets the design requirements brief, meets all relevant clinical, functional and regulatory requirements and identifies all elements which are critical for safe and effective operation.

All designs and design developments are reviewed by the Board and all necessary clinical testing /trailing is identified and approved by the Board following advice from the Managing Director.

The supplier commissioned to develop each design is required to specify any inspections or tests which may verify the effectiveness of the design from both a clinical and a regulatory perspective at the earliest stage of development and such a requirement is included in the contract specification.

All changes to the design criteria are subject to review by the Board and are documented by the Clerk to the Board in the Board minutes and the project file.

Process Control

All production by the organisation or by its suppliers is planned and undertaken in accordance with the organisation's procedures and any specific documents agreed for individual contracts.

Work instructions are provided by agreed contract specifications and by any documents referred to in such specifications and in all cases work will be performed in order to ensure the organisation's compliance with ISO 13485.

Service and Maintenance

Service and maintenance contracts are offered to all customers and these activities are controlled in the same manner as Process Control.

Documentation and Change Control

All documents used within the organisation related to the quality system itself or to the execution of individual contracts are controlled, reviewed and approved for adequacy prior to use in order to ensure that all such documents are issued to appropriate personnel, under the correct level of authority, are revised and reissued as necessary and that all obsolete versions are removed from the point of use. Such documentation includes:

- Product specifications
- Plans/drawings
- Customer orders
- Quality assurance manual
- Operating procedures
- National/international standards
- Codes of practice

The Quality Assurance Manual and Operating Procedures are maintained by the Director (Management Systems and QA) who ensures that the appropriate documents, revised as necessary, are issued to all who need them within the Organisation.

Product specifications, plans/drawings, standards and any Codes of Practice are maintained by the Managing Director who ensures that appropriate documents are available within the organisation and are issued at the correct revision levels. External suppliers of documentation are contacted regularly to ensure that the documents held by the organisation remain current. Following withdrawal, all obsolete documents will be retained on file for a minimum of 2 years or for the lifetime of the device (as defined by the Organisation) whichever is the longer period of time.

The distribution of documents is controlled and recorded by the Clerk to the Board. The Clerk holds a register of documents showing date produced, revision dates, responsible officer for production/maintenance, distribution lists and dates of distribution. The Clerk to the Board also ensures that all documents remain legible and easily identifiable.

All changes to documents are made by the person responsible for the original issue or by a person designated by the Board and/or Managing Director. Master copies of all original and revised documents are held by the Clerk to the Board. Each supplier and customer contract has

an individual file.

Some documents are held and shared within the organisation using Google Drive and Dropbox. This use is controlled by the Technical Director.

Records

All record storage facilities, whether electronic or paper, are such that all stored records are identifiable and retrievable and the storage facilities are secure and free from damp and other agents which could cause premature deterioration.

Where records are maintained electronically these are subject to back-up at regular intervals with the back-up information being stored in a protected location to ensure security from loss or damage.

All records are clearly identified as such and are retained for a minimum of 2 years but in the case of documents relating to medical devices and any associated items supplied by the organisation these will be retained for the lifetime of the device as defined by the organisation.

Purchasing

Suppliers of products, materials and services, where not specified by a customer contract, are selected on their ability to meet the organisation's requirements for quality, statutory and regulatory compliance, timescales and costs. The following factors will be taken into consideration in selecting suppliers:

- Previous performance in supplying to similar specifications and requirements
- Stocking of high volume standard items conforming to a relevant British or International Standard (as applicable) or supplied with a statement of conformity
- Compliance with an approved third party product/quality registration scheme
- Recommendation by other similar purchasers or manufacturers
- A trial order and evaluation of performance through implementation of the quality system

All supplies and sub-contracts are subject to an authorized purchase order specifying the type and extent of supply.

Purchases of up to £1,000 in value are made under the delegated authority of the Board by the Managing Director. Purchases over £1,000 in value require specific Board approval according to agreed standard procedure.

Inspection

Inspection of Goods Received

All stores areas are maintained as secure areas so far as is reasonably practicable. Items received by the organisation are identified and verified against the Delivery Note and the Purchase Order. All items or batches of items (as relevant) are inspected by the Clerk to the Board to verify correct identity and quantity and to identify any signs of damage.

All goods received are documented and in the event of non-conformance the items are placed in a reject area and labelled to ensure that such goods cannot be used to meet any customer orders. The extent of any non-conformance is documented by the person receiving the goods and the supplier is notified in order to secure a remedy.

Inspection and Testing

Inspection and testing are carried out on all products or, where appropriate, batches of products, before they are supplied to customers. Inspection and testing are also carried out on completion of any installation or maintenance performed or contracted by the organisation. Results of all inspections are documented and referenced to every specific product, each of which bears a unique reference/serial number.

Should any items supplied by the organisation prove not to be acceptable in accordance with the agreed contract criteria they will either be repaired, replaced or identified for a subsequent evaluation and decision. All repaired items are subject to re-inspection to ensure acceptability/compliance with regulatory requirements.

Indication of Inspection Status

As goods are inspected, the status is defined by location in stores with all non-conforming items being placed in a reject area and marked as reject for review.

The status of work in progress is established by marking and by associated documentation recording any inspections undertaken and their acceptability or otherwise.

Asset Management

Production and Measuring Equipment

Any production and measuring equipment held by or used on behalf of the organisation is maintained in good condition and is capable of safe and effective operation within a specified tolerance of accuracy. Any testing and measuring equipment is regularly inspected and/or calibrated in accordance with a schedule maintained by the company to ensure that such equipment is capable of accurate operation by reference to external sources traceable back to any appropriate national standards.

Customer Supplied Items

Goods received from customers, including free issue items and equipment being serviced, are inspected by the organisation on receipt, with any undeclared non-conformance being immediately reported to the customer and confirmed in writing.

Handling, Storage, Packaging, Preservation and Delivery

The identification of materials/equipment is confirmed by the presence of a manufacturer's or supplier's part number or description label or other marking for each item. The identification of the item may be on the packaging or on the item itself but in the case of all products supplied by the organisation such identification will be on the packaging and the item.

All products supplied by the organisation bear a unique reference/serial number and these are all recorded individually.

Materials and goods received will, as far as practicable, be protected and their quality preserved until such time as they are transferred to a customer or disposed of to a third party. The objective is to prevent deterioration and damage whilst in storage or in the process of transportation, installation, commissioning or maintenance.

Non-conforming items, Preventive and Corrective Action

Non-conforming items are identified by location, associated documents and/or specific markings to prevent their inadvertent use.

All non-conforming items and customer complaints are subject to review and rectification. The type and extent of non-conformity is documented in order to establish trends and identify possible areas for improvement.

The corrective action required to prevent recurrence is evaluated and documented and its effective implementation is monitored. All rectification is subsequently re-inspected to ensure complete customer satisfaction.

All Directors and employees of the organisation are encouraged to suggest improvements in design, methods, materials and suppliers. The organisation has established procedures for review of all activities in order to identify and evaluate improvements in methods, materials and procedures.