**Operating Procedure:** 4
**Reference 4/2013** (Approved January 2013)
**Review Date:** January 2015

## Mantra Medical Ltd

# Design Control Procedure

### Application of this Procedure

This Procedure applies to the process of product development, and defines an overall process to be followed by the organisation when developing any product intended ultimately to reach market. It should be read in conjunction with the Product Development Protocol (Reference 5/2013) that relates to the specific steps that must be taken when developing a device within the overall framework described herein.

This Procedure is engaged whenever it is proposed that development of a device is undertaken, during ongoing development of any device undertaken by the organisation, and after any product development process has been completed.

### Legislative and Standards Considerations

All products must be compliant with:

- The Medical Devices Directive 93/42/EEC
- ISO: 9001
- ISO: 13485

### Other Considerations

Beyond legislative and standards considerations, other factors to be considered before and during product development include:

- Evidence of a need for the proposed innovation
- Evidence of market
- Evidence to support likelihood of financial return
- Expected timeframe
- Compatibility with the organisation's overall strategic position
- Compatibility with existing routes to market
- Anticipated third-party or external requirements

**Initial Concept Presentation to Board**

- The initial concept presentation must be in the format as described in the Product Development Protocol Ref 5/2013.
- Market analysis must show a clear need for the innovation, with competitor analyses and IP searches undertaken as detailed in 5/2013.
- Expected financial projections must be detailed.
- A description must be given of how the proposed innovation will complement the existing range of products, and how it is expected that the brand will be strengthened as a result of the innovation.

**Decision to proceed following Initial Concept Presentation**

- If the proposed innovation receives Board approval the design may progress to next stage
- If rejected by the Board no further development will take place unless the proposal is amended and presented as fresh Initial Concept Presentation
- If voting is a tie the final decision as to whether to proceed falls to the Managing Director

**Draft Project Plan**

Following approval of the initial concept a Draft Project Plan must be completed. This must include:

- A Gantt chart detailing the stages of development and expected timeframe for each stage.
- Estimated costs for each stage
- A risk analysis, and a plan for risk mitigation
- A work plan and resource analysis, specifying which elements of the work can be undertaken within the organisation and which elements will require the input of third parties.
- A proposed project management plan structure detailing
    - Who has overall responsibility within the organisation for development of this innovation
    - Who is project manager (ie who co-ordinates the day-to-day development tasks)
    - The role of third parties in the project management plan
- Reporting lines for any problems

- A checklist constructed using the legislation listed herein, the Quality Assurance Manual, and this Procedure, to ensure that required standards are considered at every stage of development

**Third Parties**

Where a project plan requires the involvement of parties external to the organisation, the following procedure should be followed:

- A description of what is needed must be drawn up
- The selected external party must be able to demonstrate a capability to perform the work in accordance with the organisation's quality system and quality control standards. Evidence that may be considered includes:
    - Previous work
    - Quality standards
    - Proposed cost
- Work must be agreed in a formal contract, specification or purchase order.

**Progress Monitoring**

Development must be monitored to ensure that it is time and resource efficient, remaining commensurate with quality standards and still in keeping with the strategic position of the organisation.

- Progress must be discussed as an agenda point at every Board meeting
- Gantt charts and other timescale indicators must be kept up to date
- Any significant problems must be outlined
- Any important other developments (eg relevant changes in government policy, new competing solutions, etc...) must be summarized.

**Completion**

Development will be regarded as complete when all work detailed in the original project plan has been completed, when all additional elements identified during Progress Monitoring have been overcome, and when development is accepted at Board level as being complete.

**Abandonment**

It may be appropriate to abandon a project while still in development if:

- A competing product is developed or discovered that eliminates the innovation's market position
- It becomes known that to continue to develop the innovation would be likely to infringe external intellectual property, risking litigation
- A decision is made by the Board to reallocate resources to another project deemed more critical to the success of the organisation.
- It is not possible to mitigate the risks identified in the risk analysis and the innovation seems unlikely to pass a regulatory assessment

A decision to abandon development is subject to the usual voting procedure of the organisation.

**Management**

- Each innovation must have a dedicated project file
- Overall responsibility for maintaining the project file falls to the Director for Management Systems and QA.
- The Director for Management Systems and QA is responsible for scrutinising the work undertaken for compliance with the quality system, and if it is discovered that the work is failing to meet the required quality standard attention must be drawn initially to the project lead. If a solution cannot be found this way, it must be discussed at Board level.

**Distribution List**

- Board of Mantra Medical Limited
- Clerk to the Board

**Document Review Date**

January 2015

**Obsolete Documents to be Withdrawn**

N/A

**Arrangements for Regularly Contacting External Suppliers**

Project manager to co-ordinate with project lead and external supplier

**Initiator of this Operating Procedure**

Paul Hercock (Managing Director)