Operating Procedure: 5
Reference 5/2013 (Approved January 2013)
Review Date: January 2015

Mantra Medical Ltd

Product Development Protocol

Application of this Procedure

While the Design Control Procedure ref 4/2013 describes an administrative and Board-room level process to oversee product development, this Procedure describes a technical process that must be followed by the design team working on each project.

It applies to each individual development project performed by or within the organisation.

It is to be read in conjunction with the Design Control Procedure ref 4/2013.

Project File

Each innovation to be developed within the organisation must have a project file. This must be both electronic and on paper. The project file must be maintained throughout development and for a period afterwards as described in the Quality Assurance Manual.

Initial Concept Presentation

Following the generation of the initial concept, an Initial Concept Presentation must be prepared for presentation to the Board. This must outline:

- The problem that is being addressed by the innovation
- In broad terms, how it is proposed the innovation will work
- An outline of the intellectual property position
- A summary of important regulatory standards and other legislative factors that are likely to relate to the proposed innovation
- A competitor analysis
- A SWAT and PEST analysis

Design Specification

This important document forms the basis of any contract with third parties contracted to provide services in relation to development of the innovation. It must detail:

- A list of overall objectives
- A list of exclusions – ie features, elements or factors that must be avoided in the final product
- The essential features that must be present in the finished design
- A list of unknowns that must be solved during the development process
- A product development plan
- Delineation of the product development plan into work blocks, with specific and clearly defined deliverables for each work block
- A clear list of overall deliverables, clearly defined to avoid ambiguity.

There must be evidence of clear agreement of the design specification within the Board, and between the organisation and any relevant third party.

Guiding Principles during Development

Throughout development, alongside factors listed in the Initial Concept Presentation and Design Specification, consideration should be given to the following factors:

- Likely cost of final product
- Will it work?
- Environmental aspects – concept to production analysis
- Production and disposal of waste
- Required manufacturing methods
- Any barriers to adoption of the innovation, and how to overcome them
- Any associated or side benefits/spin off products
- Comparison to existing solutions
- Cosmetics
- Useability

Useability Testing and Feedback

At regular and appropriate stages during development, prototypes of the innovation must be presented to appropriate focus groups. This will form part of a cycle of development, feedback, and design refinement intended to lead to design optimisation. The number of cycles required will vary between innovations. Factors to be considered during prototype testing include:

- Does the innovation solve the problem it is intended to solve
- Is there a better way of solving the problem?
- How should the design be changed?
- Are there any important factors in relation to the innovation that have not been considered?

Intellectual Property

An outline of the intellectual property position forms part of the Initial Concept Presentation. Following a decision to develop the innovation, advice must be sought from a Patent Attorney on the best means of applying for protection of the innovation. The Managing Director has overall responsibility for co-ordinating the application for intellectual property rights, with advice from the Board on financial matters and other factors relating to the intellectual property position.

If there is doubt about possible infringement of external intellectual property, a form of freedom to operate search must be conducted.

Regulatory Assessment

Once the cycle of development, feedback and refinement has been satisfactorily completed, the innovation must be presented, along with the project file, to a Notified Body for regulatory assessment. If any further refinements of design are required following this assessment, the Board must be informed and resources must be allocated, unless the Abandonment procedure is to be followed.

Project Completion

Product Development will be deemed to be complete when:

- All deliverables listed in the Design Specification have been completed
- The cycle of user feedback and design refinement has been completed to a satisfactory extent

- The Board is confident that the design is optimal
- Regulatory assessment has been passed and certification is obtained
- The innovation is adequately protected by its intellectual property position.

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

N/A

Initiator of this Operating Procedure

Paul Hercock (Managing Director)