The Medical Device Development Path: Taking Your Product to Market

The purpose of this text is to provide a guide to the steps of development for a medical device from concept through to production. It is not intended as a comprehensive list for all devices, but it outlines some of the critical areas for attention and potential pitfalls.

For further information or clarification of the information contained in this document please contact Medical Device Development by email **info@medvice.co.uk** or **call 0845 201 14 15**. For a full list of services offered by Medical Device Development please visit the website **www.medvice.co.uk**

Return on Investment

The primary question is whether the development and productions cost of the product are clearly understood and are the market predictions correct? The returns can look very attractive but if the launch is delayed and markets change what will be the resulting return on investment? Remember that competitor's prices may not be fixed and they could offer large discounts by bundling their product free with other products in order to price you out the market.

Viability Study

Is the product technically viable including manufacture? Are the technical boundaries clearly defined in order to prevent false assumptions further along the product development cycle? Simulations of performance are only accurate if the inputs and assumptions are correct. Building and testing prototypes can reveal hidden variables that would not otherwise be apparent.

Project Proposal

The project proposal must encapsulate the intended purpose of the product for both the user and manufacturer including technical and revenue limitations. It should be constantly updated as new information that may affect the products success becomes apparent.

Select Regulatory Route to Market e.g. 510k for American market

The cost of meeting regulatory requirements can make a product financially non-viable for example class III devices require a clinical trial involving a large number of patients before any revenue can be gained from the product.

User Requirements

These are designed to capture all of the intended uses and requirements of the end user e.g. Surgeon. They should be assigned a weighting in order to optimise the design, but the list should be as comprehensive as possible.

Design Specification

The design specification captures the User Requirements in a form that may be verified through testing i.e. assign a numerical value such as mass in kg. Care must be taken to capture the true spirit of the User Requirements.

Search for Intellectual Property i.e. Patents

No product development should be started without a good understanding of the Intellectual Property (I.P.) barriers to entry. At the start people can be so keen for a successful project

The Medical Device Development Path: Taking Your Product to Market

that they overlook a patent that will eventually kill the project dead. It does not hurt to be paranoid about protecting your own I.P.

Project Plan

The project plan must be submitted at the Phase Review stages. Experience and a good understanding of all the technical issues surrounding the product lifecycle are essential for creating an accurate plan.

Prototyping

Prototyping is often the best method to get feedback on product performance and highlight hidden issues. It can save a great deal of time, money and help to crystallise the vision for a product early in the development cycle.

Prototype Testing and Iterative Design Changes

Don't under estimate the number of twists and turns in the development cycle. Iterative design and test loops early in the development cycle can avoid great cost further on.

Design for Production

Experienced designers that work closely with suppliers and end users will produce far more cost effect products. Including the supplier early in the development cycle is extremely valuable.

Sterilisation Protocol

A sterilisation protocol is required to demonstrate that the parameters affecting the level of sterility are controlled. These may include bio-burden issues e.g. whether the manufacturer is in an area that is affected by seasonal change such as pollen count.

Risk Analysis

The risk analysis must identify all the potential medical risks and weigh these against the potential benefits.

Packaging Design

The packaging design must be considered relatively early in the development cycle as there can be some non-obvious technical issues e.g. shelf-life and interaction of materials, sterility barriers etc.

Transportation Testing

The final testing may be completed later in the cycle, but initial testing should be conducted as early as possible in order to give confidence in shelf-life testing sterility barriers.

Cost Analysis

If the market for the product changes the new forecast should be used to identify potentially low returns as early as possible.

Test development

All parameters affecting safety and efficacy must be verified through testing. Test method development and validation may take longer than initially thought. There may be some

The Medical Device Development Path: Taking Your Product to Market

parameters that cannot be bench tested and must be validated through use e.g. surgical efficacy on specific living human tissue. This could require very expensive clinical trials.

Material Selection

The manufacturer may use any materials that pass biocompatibility, but medical grade materials are always preferable as the manufacturing process is controlled and traceable.

Biocompatibility Testing

The manufacturer is required to demonstrate that all patient contacting parts of a device are biocompatible via testing. Even if the material supplier can provide test data, the manufacturer must still perform independent testing. The test types are dictated by the device application and in the case of implantable devices can be high in number and cost.

Accelerated Ageing Study

A product can be released with six months justification on shelf-life, however this may not be enough for some markets. Accelerated ageing is the best method to increase shelf-life prior to product release.

Manufacturing Plan

This should be in place once the design is finalised to allow the design of jigs and fixtures and cost predictions.

Part Inspection Plan

This needs to be considered at the design stage in order to avoid unnecessary lengthy inspections.

Design and Commission Inspection Jigs and Fixtures

These may be developed later in the cycle, but watch out for long lead-times.

Commission Production Tooling

Remember that your suppliers may also need to make tooling and their lead-times may not match your requirements.

Design Failure Mode Effect Analysis

This is a process that scores the severity, likelihood of occurrence and detect-ability of a device failure. It highlights areas of design that require further justification or testing. It is a living document and requires the input of experienced people.

Process Failure Mode Effect Analysis

This is conducted in the same manner as the Design Failure Mode Analysis but only scores the processes used to manufacture the device not design issues.

Select Route to Market i.e. Clinical Trial or Evaluation Report

This should be known at the project proposal stage, as the variation in cost between various routes is very significant. Most products can use a written document i.e. clinical evaluation to justify safety, however this route requires a predicate device.

The Medical Device Development Path: Taking Your Product to Market

Verification/Validation Plan

This is required relatively early in the development cycle to allow reasonable cost forecasts and to allow time for test method development and validation. Leaving the detail in the plan till the last minute can create a logjam in the development cycle.

Verification Testing

Whenever possible test method validation should be conducted to demonstrate that the verification test method selected is fit for purpose. If tissue testing is required for verification, test methods can be very difficult to validate.

Validation Testing

The purpose of this testing is to demonstrate that the product meets the User Requirements. Consequently creating validation test methods and testing early in the development cycle will help the design input to meet the User Requirements. The final validation testing can be relatively costly requiring cadaver labs performed in the country of the proposed market.

Creation of Instructions for Use (IFU)

When planning the IFU build in long lead-times for translation into foreign languages, proof reading and print lead-times.

Source Suppliers

Remember to include inspection costs and the affect of poor quality into your costing. A reliable supplier may appear expensive on the surface but could prevent huge costs incurred due to quality issues e.g. contaminated parts. Unless the volumes are very high or specialist processes are not available it is much easier and cheaper to use suppliers within the country of origin due to auditing and quality management issues.