DESIGN FOR MEDICAL DEVICES

1.1 The Design Process for Medical Devices

The design process for medical devices is highly regulated to ensure the safety of patients and healthcare workers. In Europe, the Medical Device Directive was developed to regulate medical devices. It is a document that is legally binding, enforceable in law and with penalties for non-compliance. Regulations outside Europe vary. For example, in the United States of America, the Food and Drug Administration (FDA) is responsible for the safety of medical devices. In order to comply with the regulations, companies are required to have a quality management system in place to ensure that the whole design process is managed and planned in a systematic and repeatable manner. To show compliance with the regulatory aspects it is necessary to maintain a Design History File (which can also be known as a Technical File or Design Dossier) which describes the design history of a product and is maintained post-product release to include subsequent changes to the product and relevant post-market surveillance data.

1.2 THE DESIGN PROCESS

1.2.1 Overview

The medical device design process can be broadly divided into six areas:

1. Market
2. Design specification
3. Concept design
4. Detail design
5. Manufacture
6. Sell

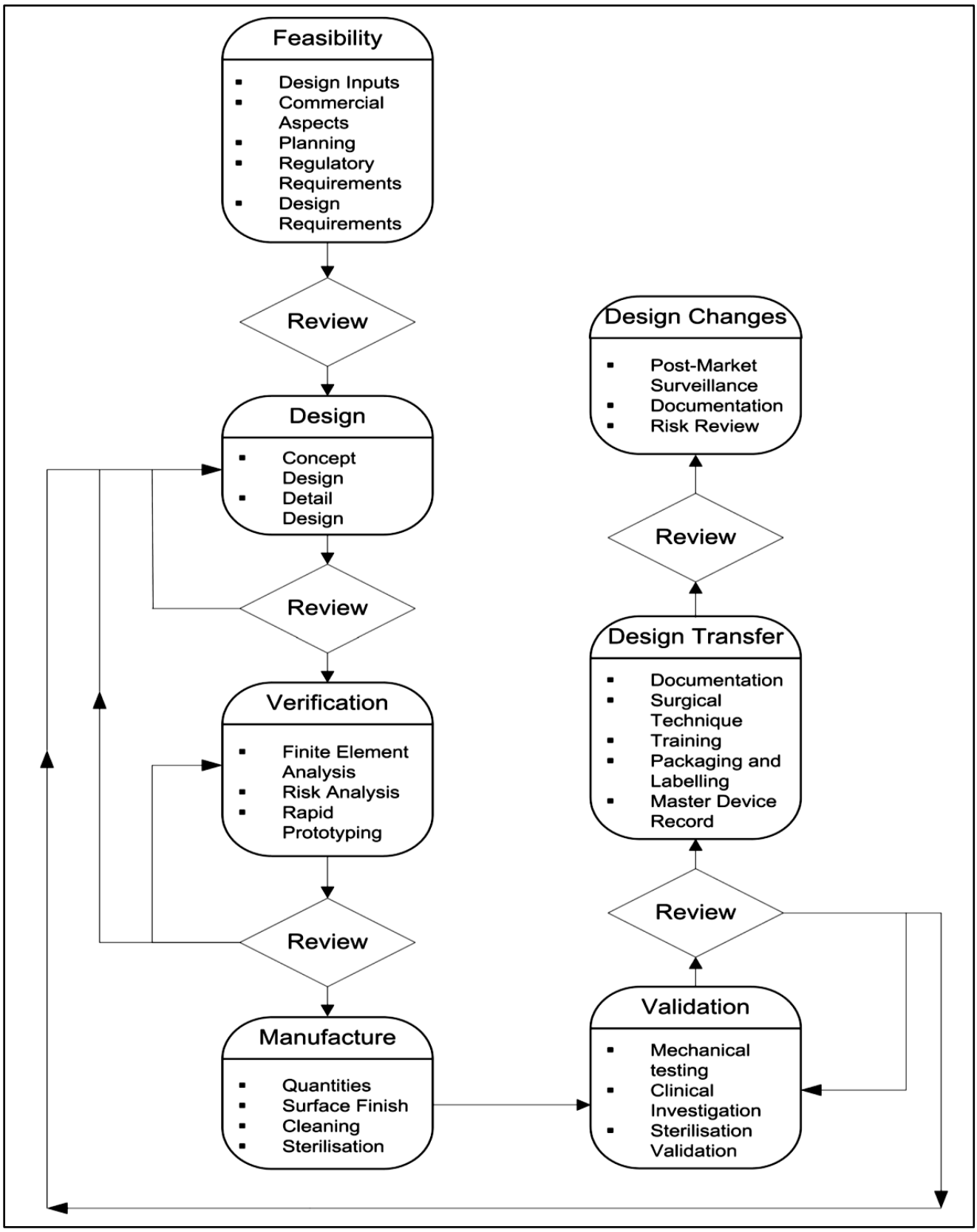

Fig. (1). The medical device design process.

1.2.2 Commercial Aspects

There has to be a market or customer need for a medical device to be designed and produced. A feasibility study for a new idea for a device needs to be undertaken to identify the potential market share, similar devices produced by competitor companies and the potential market value of devices. A review of the intellectual property is also required to determine whether the design can be protected and does not infringe other patents.

1.2.3. Planning

It is important that each aspect of the design process is project managed with achievable milestones set and defined throughout the project life cycle. The setting of milestones should enable the project manager to assess the progress of the project to ensure that it is completed on time and within budget. For example completing the market feasibility report and the project objectives. The project plan should include:

- regular milestones and project meetings to assist with the identification of problems and allow early action to be taken to counteract delays to a project.
- risk management plan, which should highlight the relevant strategies that will be employed to reduce and manage the risks that are associated with a project.
- identify the human and financial resources required to be in place to successfully realize a design.

1.2.4. Regulatory Requirements

All medical devices must have regulatory approval before they can be released to market. There are a number of internationally and nationally agreed requirements to which medical devices must conform. Currently these

standards are not harmonized, and there are differences between those that regulate Europe and the United States. Medical devices must also be classified according to the level of risk associated with their use upon a patient and to the user.

By identifying these standards complications in the latter stages of the design process can be avoided. Whilst not all of the standards are mandatory, compliance will often help to accelerate the approval process.

1.2.5. Design Requirements

The design requirements (or product design specification) are essential before a medical device can be designed. It sets out exactly what is required of the design against which each stage of the design can be verified. A general standard exists to help determine the design requirements.

Any design changes to the implant will have a knock-on effect for the design of the instrument. In many cases the complexity and design time of the surgical instruments are greater than the actual implant itself.

The design requirements for the device will include:

- intended performance
- design attributes
- materials
- design evaluation
- manufacture
- testing
- instruments required
- sterilization
- packaging
- information to be supplied by the manufacturer

1.3. Design Reviews

A design review is required, at each stage of the design process, to formally document comprehensive, systematic examination of a design to:

- evaluate design requirements
- assess capability of the design
- identify problems

1.4. The Design Process

1.4.1. Concept Design

The concept, or conceptual, design stage is where solutions are generated to meet the design requirements. The aim is to generate as many ideas as possible. At this stage ideas should not be judged. Concept design may involve:

- simple sketches of ideas;
- computer aided design models;
- analytical calculations;
- initial manufacturer consultation.

Once a range of concept designs have been developed it is worth assessing each of the concept designs for patentable technology to ensure that the final design has been fully protected.

1.4.2. Detail Design

At the detail design stage the flesh is put onto the bones of the chosen conceptual idea. A concept design is worked through until a detail design has been produced. This will include:

- generation of solid computer aided design models
- specification of materials
- drafting of engineering drawings

- analysis of tolerance stacks within associated assemblies to ensure correct operation
- detailing with the inspection requirements to ensure that the part/assembly operates correctly
- liaison with manufacturers to ensure that the device is designed for manufacture (DFM), designed for assembly (DFA) or designed for manufacture and assembly (DFMA)

1.5. Design Verification

1.5.1. Introduction

Design verification involves confirmation by examination that a medical device meets the design requirements and is essentially asking the question "are we building the thing right?". Design verification methods can include:

- finite element analysis
- risk analysis
- rapid prototyping

1.5.2. Finite Element Analysis

Finite element analysis is a widely used technique in medical device design and can be used to verify if a design will have sufficient strength to withstand the loading conditions in the human body. Finite element analysis is a proven cost saving tool and can reduce design cycle time.

1.5.3. Risk Analysis

A key part of the medical device design process is to undertake a risk analysis. Any medical device should be designed and manufactured so that it does not compromise the safety of patients or healthcare workers. Manufacturers must eliminate or reduce risks as far as possible; any risks that exist must be weighed against the benefits to the patient.

The way to show risks have been eliminated or reduced is to undertake a risk analysis.

An international standard for medical device risk analysis has been published. Risk analysis helps to realize a design if it is undertaken at an early stage and should be undertaken at stages during the design process, including a final risk analysis.

1.5.4. Rapid Prototyping

Rapid prototyping is a very effect technique for verifying the design of medical devices as it aids communication between engineers and end users. Models can be produced by a variety of methods such as Selective Laser Sintering (SLS), Fused Deposition Modeling (FDM) or three-dimensional printing.

Multi-component systems can also benefit from the use of rapid prototyping as they allow designers to evaluate the interaction between components, thus minimizing the opportunity for component incompatibility.

1.6. Manufacture

Before the design is transferred to production it is essential to ensure that the chosen manufacturing processes are repeatable and reliable. The choice of manufacturing technique depends on many factors:

- number to be produced
- surface finish required
- post machining cleaning processes
- sterilization process (if necessary)

As well as the manufacture of the devices, packaging for the device and instruments, sterilization techniques, operation instructions and labeling printing requirements also need to be finalized.

1.7. Design Validation

Validation of the device is performed under actual or simulated conditions for use. While verification is answering the question “are we building the thing right”, validation is asking “have we built the right thing”. Validation is to ensure that the medical device meets the user requirements and the intended use. Validation can include:

- mechanical testing of prototypes
- evidence that similar medical devices are clinically safe
- a clinical investigation
- sterilization validation

There are a large number of standards available to guide the pre-clinical mechanical testing of medical devices.

In some cases of mechanical testing it is beneficial to use human cadaveric material.

The investigation will need Ethics Committee approval and the manufacturer will be required to decide on the length of the investigation, the number of patients to be involved and the type of data to be collected.

1.8. Design Transfer

Before a design is transferred to production it is necessary to ensure that all documents and training associated with the device are in place. Design transfer can include:

- generation of instructions for use
- finalization of the surgical technique
- plan the training of surgeons
- finalization of the labeling and packaging

- completed vendor requirements such as audits, first article inspection or surveys
- Total cost bill of materials
- completed inspection plans and process worksheets
- creation of the master device record

1.9. Design Changes

After a medical device is on the market it is necessary for the manufacturer to have a post-market surveillance process in place to ensure the safety of patients and healthcare workers after the device is on the market. Feedback from surgeons may lead to design changes being made to the device or the surgical instruments. The changes that arise from this feedback must be fully documented and the effects upon the device fully investigated. This latter process may involve repeating much of the verification and validation processes, depending upon the magnitude of the change. All design changes must be accompanied by an updated risk assessment to ensure that the full impact of the change has been understood.