Arrotek

Six-Step Design Process

Whitepaper

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Introduction

At Arrotek, we offer a full range of medical device design and development services. This includes the development of advanced catheter technologies and other minimally invasive medical devices. We have created a Six-Step Design Process that we use for all our design and development projects.

Our Six-Step Design Process ensures there is a robust structure to projects, creating a solid foundation for the success of your new product. Ensuring the design process remains focused and stays on schedule are other key features of our structured approach.

It ensures the design and development process meets your expectations. This includes your expectations on the performance of the medical device product and its capabilities. Our Six-Step Design Process also ensures the manufacturability and scalability of your product to facilitate your move to the commercialisation stage.

While our Six-Step Design Process provides the framework for the development of your idea for a new medical device, we adapt the process for each project we work on. This flexibility enables us to take on a wide range of projects, and it ensures innovation and creativity can flourish, particularly when the new medical device includes challenging design or performance requirements.

We constantly push the boundaries of innovation here at Arrotek, and our Six-Step Design Process is crucial to that approach.

In this whitepaper, we will cover the key aspects of our Six-Step Medical Device Design Process. This includes the Quality Management System and design controls, as well as the methodologies we use and the key features of the process. We'll also discuss what is involved in each step, and we'll highlight the benefits of this approach.

Quality Management System

Quality is central to everything we do at Arrotek, not least because it is a key requirement for all the clients that we work with, and it is essential for compliance reasons. We are also acutely aware of our responsibilities as medical device product designers, as the products we design and develop on behalf of clients are used to treat and diagnose patients around the world. We are committed to ensuring everything we do has a positive impact on patient outcomes.

We have a well-established Quality Management System (QMS) that is ISO 13485:2016 & EN ISO 13485:2016 accredited. This is compatible with the requirements set out in FDA 21 CFR Part 820 for getting your new medical device product approved for the US market. Our certification covers the design, development, and manufacture of sterile and non-sterile medical devices.

We also have a Quality Manager who manages an experienced quality management team. As well as delivering on the specific requirements of customer projects, our quality management team also works continuously to improve and enhance our QMS.

That QMS includes design controls, risk management, document controls, and supplier management. The overall aim is to ensure the following:

- The newly designed product meets user needs and does what it is supposed to do.
- The product is suitable for the use it is intended for.
- That both of the above can be proven.

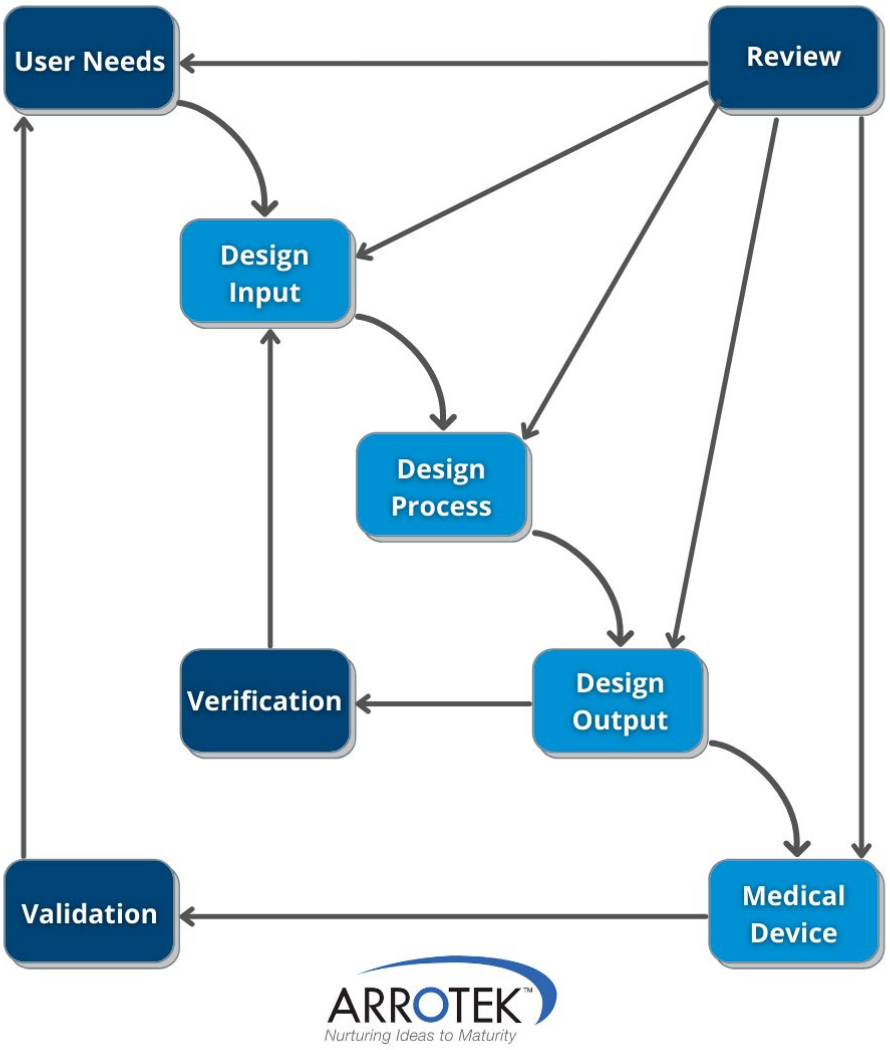
Design Controls

Looking at design controls specifically, the requirement from regulators is that you must have a process in place that describes all design and development activities. This aspect is included in our QMS, so it will form the basis of the Quality System that we will help develop for your new medical device product. This is a requirement you must meet to submit your product for regulatory approval.

In fact, design controls are essential throughout the entire product lifecycle, from the earliest stages of the design process to after the product has been introduced to the market. This is because the requirement for design controls exists whenever there is any change to the design of the medical device or its manufacturing process. Obviously, those changes are frequent when initially designing and developing the product, but they can happen at any time in a product's lifecycle.

> ***Knowledge Hub Extras:***
> *Read our blog for more information on design controls.*

The FDA created a waterfall diagram back in 1997 to provide guidance on design controls for new medical devices. It is as relevant today as it was then.



It is important to not only follow this process but also document each action you take so you can show traceability between each stage.

Everything starts with user needs as it sits at the top of the waterfall. You then go through the design steps, all of which are regularly reviewed. Design outputs are verified and go through as many iterations as required. At the end of this process, you will have a medical device that is validated against the previously documented user needs.

Knowledge Hub Extras:
You can read more about regulatory guidance on user needs, as well as the design controls waterfall diagram, on our blog. You can also read more about medical device design verification and validation.

Design Reviews

One of the lesser discussed aspects of the design process waterfall diagram, and the medical device design process in general, is design reviews. However, design reviews are one of the most important parts of the process.

They ensure there are structured procedures in place to assess each design decision. They also assess the progress of development and, when used effectively, will identify potential issues as early as possible.

We take a flexible approach to design reviews to make the overall design process as iterative as possible. This facilitates high levels of agility while remaining within the general waterfall guidance that is accepted as industry best practice standards.

The FDA recognises this need for agility and flexibility in the process, particularly in relation to design reviews. In the text that accompanies the Waterfall Design Process in the FDA's Design Control Guidance document, it says: "In practice, feedback paths would be required between each phase of the process and previous phases, representing the iterative nature of product development."

It goes on to say that this practical reality was left out of the waterfall diagram to highlight the importance of design controls.

Design History File

In summary, the design controls we put in place will produce a design history file (DHF) that will become part of the Quality System for your new medical device. A DHF includes:

- Design inputs
- Design outputs
- Design review processes and results
- Verification
- Validation
- Design changes and controls for design changes
- Design transfer

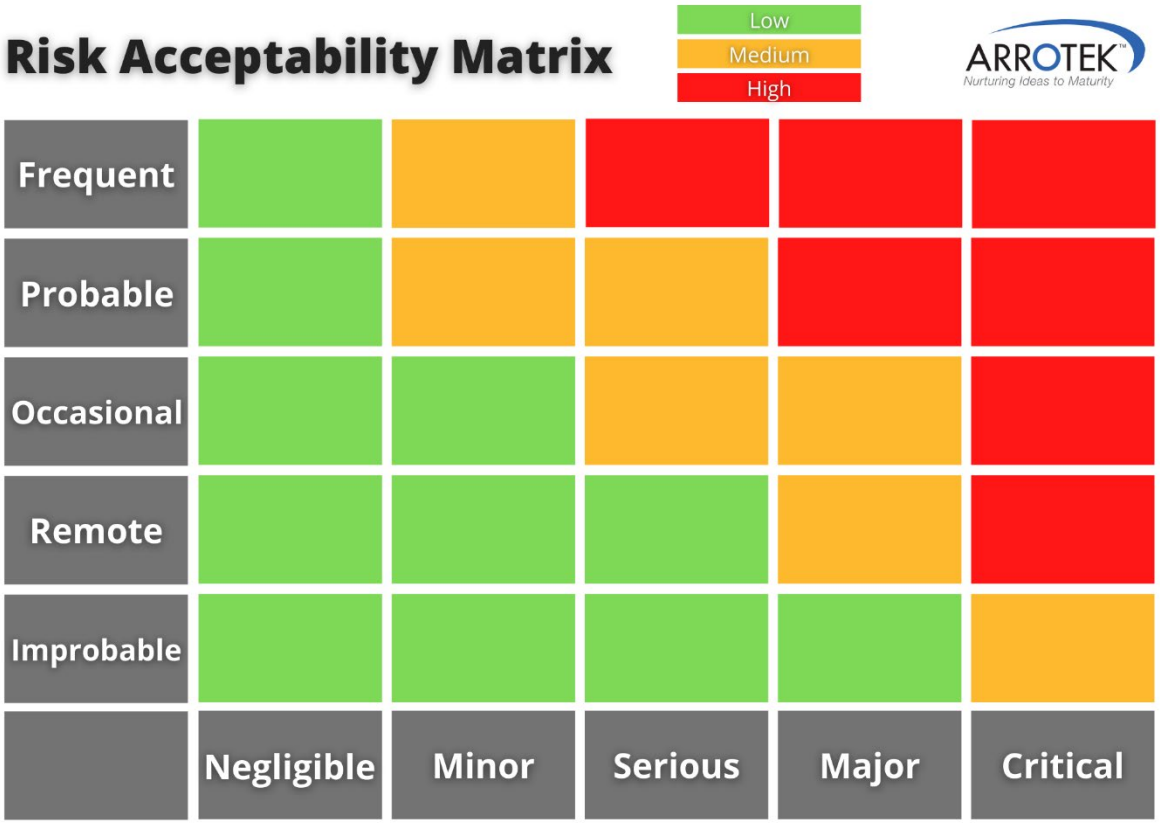
Knowledge Hub Extras:
Read more about Design History Files on our blog.

Risk Management

Risk management is another essential component of a QMS that is worth looking at further. Risk management involves identifying and mitigating risks to improve the safety of your medical device.

Risk management also establishes processes and procedures for the mitigation of risks, as well as defining the risk acceptability of your new medical device product, i.e., what are

deemed to be acceptable and unacceptable risks. This is likely to be visualised in a risk acceptability matrix.



So, design controls and risk management are distinct from each other, but there is a strong connection between the two, with one often impacting the other. For example, steps taken to mitigate an identified risk can change the design of the device, resulting in revisions to design inputs.

As part of the medical device design process, we will create a Risk Management File. This is a living document that remains essential after the design process has concluded. Some of the elements of that Risk Management File include:

- Risk management plan
- Individual risk analyses
- Risk evaluations
- Risk control measures
- Evaluation of risk acceptability
- Risk management reports

Knowledge Hub Extras:
Read our blog on risk management planning to learn more about the process.

Design Process Overview

The six steps in our design process are as follows:

- Defining client requirements and documenting user needs
- Concept generation
- Concept development
- Stage 1 prototype
- Concept refinement
- Stage 2 prototype

This process aligns with the design process waterfall diagram produced by the FDA.

Concurrent Engineering

It is important at this stage to mention a limitation of the FDA's design process waterfall. This limitation is recognised by the FDA and is covered in its Design Control Guidance document in a section that immediately follows the introduction of the Waterfall Design Process diagram.

In brief, the limitation is the process outlined by the waterfall diagram, when strictly applied, is only suitable for simple medical device products. This is because it envisions a scenario where the design process is fully concluded before a design transfer stage takes place, where everything is handed to the production team to develop processes for manufacturing.

For more complex devices (like those we design here at Arrotek), this would be a highly inefficient approach as the realities of the factory floor must be considered as part of the design process. If they are not, the disconnect between the designed product and the realities of manufacturing can result in various negative outcomes, significantly damaging the product's potential for success.

So, while our Six-Step Design Process aligns with the FDA's waterfall diagram, it doesn't strictly adhere to it. As we go into the detail of the process later in this whitepaper, you will see we use a concurrent engineering methodology.

Concurrent engineering involves the consideration of production and product servicing requirements during the design process. This ensures the product not only meets user needs (the objective of the design process waterfall), but can also be effectively, consistently, and profitably manufactured.

Concurrent engineering also offers other benefits:

- Reduces design and development costs
- Reduces the time it takes to commercialise a new medical device
- Improves the quality of the product

Design for Manufacture and Design for Assembly

Design for Manufacture (DFM) and Design for Assembly (DFA) are methodologies that are crucial to our Six-Step Design Process for new medical devices. They both tie in with our concurrent engineering approach as they are concerned with ensuring the product can be manufactured and assembled as easily as possible and within the target cost range.

DFM and DFA are considered at all stages of our Six-Step Design Process to fully optimise manufacturability. Both methodologies involve considering:

- The processes that would be needed to manufacture and assemble the product
- How well the design adheres to Good Manufacturing Principles (GMP)
- The materials included in the design
- The performance expectations of the product
- Any regulatory considerations

Knowledge Hub Extras:
You can read more about DFM on our blog. For more information on DFA, read this blog.

Human Factors Engineering

Ensuring that a new medical device product works properly in the controlled environment of an advanced engineering facility (like the one we have here at Arrotek) is not enough to ensure project success. To achieve that success, it is also necessary to consider the many different factors that will influence how the product is used in real-world conditions. Those factors include everything from environmental conditions to the capabilities and expertise of the person using the device.

The consideration of these factors is known as Human Factors Engineering. It is sometimes referred to as usability engineering, but both terms are interchangeable.

We use human factors engineering processes at Arrotek to ensure the medical devices we design are as effective and safe as possible in the real world. We do this by taking steps during the design and engineering process to minimise the possibility of the device being used incorrectly.

We achieve this through research, risk assessments, and usability testing to identify areas where the usability of the medical device can be improved. We also use our extensive experience from past projects and our detailed knowledge of the realities of clinical settings, user limitations, and more.

Knowledge Hub Extras:
On our blog, you can read more about human factors engineering and the process we use to optimise usability when designing a new medical device.

Project Management

Effective project management is another important part of ensuring the success of our Six-Step Design Process. The structure of the process creates a template that our project managers and wider engineering and quality teams then implement.

Our project management processes and capabilities ensure effective collaboration throughout the project with the setting of clear and measurable timelines, milestones, and objectives. It also ensures the sufficient allocation of resources, and it maintains effective communication and knowledge sharing.

Knowledge Hub Extras:
Read more about project management in medical device design projects on our blog.

Six-Step Design Process

Step 1 – Defining Client Requirements and Documenting User Needs

This step in the design process involves defining your requirements, including the functional requirements of the new medical device product. A document will be created with these functional requirements that can then be referred to later in the process.

We will also define the goals of the project, and we will set milestones and targets. The project scope will also be defined and agreed during this step, and we will establish the Quality Management System. We'll develop the Risk Management Plan, too, and we'll establish the Design History File and Device Master Record (DMR).

In collaboration with you, we will then move to documenting user needs for the new medical device. This process includes defining the following important points:

- The intended use of the product, i.e., describing what it does and its purpose.
- The indications for use of the product, i.e., describing the situations where the product will be used.

Knowledge Hub Extras:
You can read more about the process for documenting user needs and why it is important to do so on our blog. We also have a blog that outlines the essential questions that should be asked when documenting user needs.

Finally, we will also confirm the device classification for your new product. Medical device classifications are used by the FDA, and they are also part of the EU MDR. They outline the requirements that your product must comply with to be approved for sale in the applicable market. There are also different application processes you must go through depending on the classification of your device.

The classification process is based on risk. Under FDA regulations, there are three main classifications of medical device products:

- Class I
- Class II
- Class III

Class I is for the lowest risk devices, and Class III is for the highest risk.

Classifications in Europe are similar, with the main classifications being:

- Class I
- Class IIa
- Class IIb
- Class III

Again, Class III is for the highest risk devices, and Class I is for those with the lowest risk.

Knowledge Hub Extras:
You can read more about FDA medical device classifications and EU medical device classifications on our blog.

Step 2 – Ideation

When looking at the FDA's waterfall diagram, this step essentially involves moving down a level to the design input stage and then into the design process stage. In other words, we take the information produced so far, including the user needs document, to create design inputs and begin designing the device.

The crucial task in this step is group ideation, where the design team will develop multiple ideas, concepts, and solutions that have the potential to deliver on your requirements. Therefore, the product will start to take shape during this step in the process.

Step 3 – Concept Development

As part of the iterative review process, preferred designs will be selected from the ideas and concepts created in the previous step. We will review manufacturing methods and materials for the selected designs, and we'll complete any necessary further development of the concept. We'll also create 3D CAD models of the designs to help with the review and assessment process.

Step 4 – Stage 1 Prototype

This step involves the production of a physical model of the device. This is often the first time the device will have been represented physically. It is an important step in the process as it allows all stakeholders, including the engineering design team, to hold, visualise, and physically manipulate the newly designed device.

The Stage 1 prototype is also used for bench testing and evaluation, and it is reviewed, with the results of each review documented and fed back into the design process.

All potential aspects of the device are checked at this stage, from the functionality to the size to the ergonomics of the device and how easy it is to use. The prototype we produce helps to confirm the product can perform as it is intended to perform, and it ensures performance is up to standard.

Prototypes can also be assessed for regulatory compliance, and they help ensure the commercial viability of the product.

While all the key questions won't be fully resolved with the Stage 1 prototype, it is crucial to the overall process.

> ***Knowledge Hub Extras:***
> *You can find more information in our blog on the importance of prototyping in the medical device design process.*

As we have contract manufacturing capabilities at Arrotek, we have extensive in-house expertise in the production of prototypes. This means we can use a range of different methods to produce the most effective prototype possible, from 3D printing to injection moulding to laser welding and more.

Step 5 – Concept Refinement

While all the steps are important in our Six-Step Medical Device Design Process, this one is particularly significant. This is because it involves settling on a design for the new product and going through final design processes to refine and improve it. These refinements and improvements will be largely based on the tests, assessments, and reviews completed on the Stage 1 prototype.

DFM, DFA, and Human Factors Engineering will have been important parts of the process up to this point, but they also take on greater significance now as the product moves closer to completion.

Another important aspect of Step 5 is verification and validation of the design to prove the product is safe and does what it is intended to do.

This step also involves the creation, updating, and/or finalising of documentation that may be required for your new medical device. This includes (but is not limited to):

- Process Specification to ensure the manufacturing process is repeatable to a consistent quality standard.
- Equipment Installation Qualification (IQ), Operational Qualification (OQ), and Performance Qualification (PQ).
- Design verification report.
- Sterilisation plan.
- Packaging, shelf life, biocompatibility, and transit plans and specifications.
- Risk management report.
- Supplier qualification plan.
- Master validation plus process validation, test validation, and material validation.

Step 6 – Stage 2 Prototype

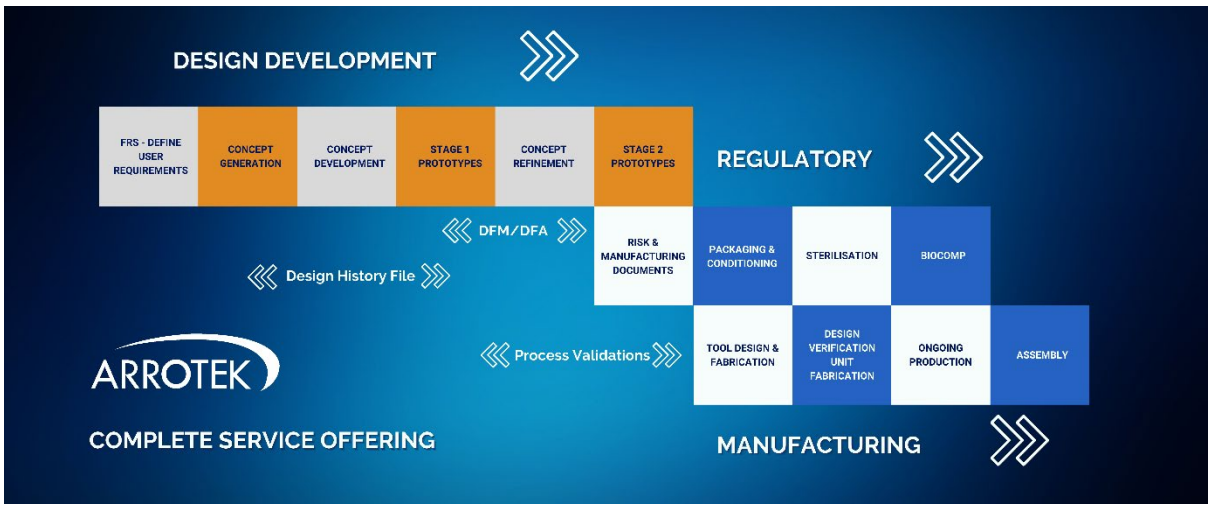
The sixth and final step in our medical device design and development process involves the production of a Stage 2 prototype. This prototype will be based on the refined design created in the previous step, and will be manufactured to a high standard, typically in a small batch. This ensures the Stage 2 prototype is ready for any testing that is required for regulatory reasons, and to help with any necessary commercialisation stages.

All documentation relevant to the design process will be updated at this stage, including any further design transfer requirements, as well as the Design History File. In other words, all compliance and design requirements will be completed as part of this stage.

While the design process is concluded at this point, our team can still provide support to help bring your new medical device product through the approval process with regulators and then into production. We offer both regulatory and contract manufacturing services, as well as expert consultancy services on all aspects of medical device product design and development.

Arrotek's Complete Service Offering

It is worthwhile pointing out that our Six-Step Design Process is only part of what we offer here at Arrotek. We also have capabilities that extend beyond the end of the initial design and development process. This includes regulatory and manufacturing capabilities.



The regulatory stages of bringing your product to market include:

- Developing and updating risk and manufacturing documents
- Packaging development, including conditioning the packaging for testing
- Sterilisation method development and validation
- Biocompatibility testing

The manufacturing stages of brining your product to market include:

- Tool design and fabrication
- Design verification unit fabrication to provide you with sufficient devices for testing purposes
- Ongoing production of your product to meet market demand
- Assembly of your product ready for distribution

Knowledge Hub Extras:
Read our blog to find out more about Arrotek's complete service offering, including our regulatory, manufacturing, and assembly capabilities.

Why Our Six-Step Design Process is Important

1. Improves Product Quality

Producing high-quality medical device products doesn't happen by accident. You need a structured process where there is a focus on quality at the start, where design challenges can be overcome, and innovation can play a central role. Our Six-Step Design Process creates the conditions where these things can happen, resulting in a higher quality product.

2. Maintains Focus

Product design projects can go off track without proper structures in place. After all, it's easy to add new things or change the focus, often without recognising the impact this can have. The result is usually a product that doesn't meet your expectations. It also probably won't meet user needs as they were originally defined at the start of the process. Our Six-Step Design Process ensures focus is maintained throughout, with everything documented and clearly communicated, so everyone is aware of the project's direction and progress.

3. More Efficient Design Process

All product design projects start with the intention of making progress as efficiently as possible. Those intentions are then superseded by the impact of many different factors, both avoidable and unavoidable. Our Six-Step Design Process helps to minimise the avoidable factors that can negatively impact and delay the design process. This includes taking steps to ensure design changes occur as early in the process as possible. You can read more about the importance of this on our blog.

4. Reduces Costs

Delays in the design process, missed deadlines, and pushed-out milestones can increase project costs. This is in addition to other factors that can also push up the cost of designing and developing a new medical device. Our Six-Step Design Process helps to control costs, keeping them in line with original estimates. Crucial to this cost-saving feature of our design process is the fact it makes the process as efficient as possible while also ensuring it remains focused.

5. Optimises the Regulatory Process and Ensures a Smooth Transition to the Manufacturing Phase

Our Six-Step Design Process ensures regulatory guidance and requirements are followed during the design process while also putting in place the proper documentation protocols, controls, and procedures. As manufacturing and assembly are both considered at the earliest possible stage in the design process, the transition to manufacturing is also much smoother.

Conclusion

The Arrotek Six-Step Design Process creates a framework for the development of new medical devices while also ensuring there is flexibility and space for innovation. Compliance considerations are also a crucial component, as it is the ultimate goal of the project in the first place – the commercialisation of your idea so it can be launched into your chosen markets to help improve patient outcomes.

For further information on our Six-Step Design Process or to discuss the design and development of your idea for a new medical device product, please get in touch with a member of the Arrotek team today.