Why It's Important to Partner with an Expert for Medical Device Design & Development

Mi3 Limited, Shadsworth Business Park, Nuttalls Way, Blackburn, Lancashire BB1 2QJ, United Kingdom.
phone 01254 678398 email info@mi-3.co.uk visit www.mi-3.co.uk

GB Registered Company No. 5778266

Why It's Important to Partner with an Expert for Medical Device Design & Development

Design and development (D&D) of a medical device is the most crucial phase of the product's route to market for its success. A loosely defined and designed product cannot comply with regulatory needs and it will fail to deliver the user defined functionality and benefits.

Many designers and manufacturers have different processes to achieve the same thing. Partnering with Mi3 on the journey to design & develop your device, or assist in this process will ensure that every consideration is made from Regulatory Strategy and D&D planning, to meeting end-user needs compliantly, cost effectively and ensuring patient safety.

The idea for a new medical device typically comes from the discovery of an unmet need. Identification of need is only the first step in a multi-functional and series of complex processes required to bring a medical device to the market. Mi3's MDSAP and ISO 13485 compliant QMS is designed to bring together technical and business processes for successful product delivery, and beyond the D&D phases, while incorporating our customers' unique and differing needs.

We discuss below seven key steps in the D&D process and the critical outputs an experienced contract manufacturing partner can bring to the process.

1. Identification of need

Identifying the user need is the first step for creating a medical device, if there is no or little need for the product then it is unlikely to succeed in the market. The more understanding of the need the more inputs can be created and enhance the product definition at this stage.

The Engineering team at Mi3 are experts in understanding plastic materials, geometrics and manufacturing technologies that allow for concept refinement and are able to advise further in this area.

2. Business case and commercialisation

Typically the things a designer / manufacturer should think about before commercialising a device are, product attributes / technical specification, value proposition, strategic fit, market (size, growth), sales channels, competition, Intellectual Property position (patent protection, freedom to sell), development and project plan costs, manufacturing plan, launch plan and costs, regulatory pathway, clinical evaluation or human factors, reimbursement, countries of sale, risk analysis, product value/financials, supply chain (in and out) and distribution models, product training requirements, budgets, branding and marketing. All these feed into the regulatory requirements for the regions of sale and the initial business case for realising the product.

When you partner with a contract manufacturer you want to be confident your business requirements for the product are factored into the design, development and manufacturing processes every step of the way. The team at Mi3 can support you to develop a robust business case to securing the vital funding required for commercialisation.

3. Device classification

Medical device classification is based on the risk associated with the use and enforced by law. It is important to get the classification determined early in the process in order to understand the regulatory pathway and requirements. Typically device classification is agreed with your Notified Body.

With Mi3's Quality Management Systems certified and audited to ISO 13485:2016 via the Medical Device Single Audit Programme (MDSAP) our experienced regulatory team can support you in every step of this process including providing assistance around intended use, associated risks and proposed classification.

4. Discovery

This phase is for refining concepts and initial designing, prototyping, and iteration driven redesign. Developing working prototypes is a crucial part of the development process and depending on what the prototype is for, Mi3 can advise on the most suitable prototyping method and generate prototypes to support all stages of the D&D process

5. Regulatory requirements and strategy

Medical devices are subject to regional and international standards. These regulatory requirements should be identified early on in the development process and reviewed periodically to ensure that any changes in the regulatory environment as well as any new scientific technologies are taken are considered.

Regulatory compliance is critical so ensure you partner with a team that can provide comprehensive medical device consulting services to help remove the complexity that often arises across the regulatory landscape.

Mi3's regulatory systems are constantly evolving alongside the ever changing medical device regulations to ensure compliance to the most stringent standards within the industry. We regularly celebrate zero non-conformance audits from Notified Bodies and successfully achieved MDSAP accreditation in July 2018. Mi3 can help you develop a regulatory strategy incorporating the specific regulatory requirements as well as the possible pathway(s) to take that is balanced, realistic and achievable to support your organisation's mission and vision.

6. *Testing, verification and validation*

Verification and validation (V&V) of medical devices aims to ensure that the device is aligned with the voice of the customer and delivers the intended purpose. It also demonstrates whether all the requirements are being satisfied or not and are compliant with regulations.

Standardised V&V activities can streamline the manufacturing process as well as enhance the approval processes. Additionally, tests used for V&V activities also need to be validated (and often are transferred to QC for release of the product in routine manufacture).

This includes clinical and product safety testing, sterilisation considerations and primary packaging as well as overlapping with the manufacturing process development and process validations for manufacturing the product.

Mi3 can advise and perform all your V&V testing requirements, including the development and validation of new methods or adaptation of State of the Art Standards.

7. *Risk management and PMS*

Every medical device manufacturer must have established risk management procedures in place, and those processes must be in compliance with ISO 14971. These requirements apply to all stages of medical device design and development, as well as the entire lifecycle of the device. Risk management activities should be aligned with all phases of D&D and post-market requirements.

Mi3 can support, advise and provide a comprehensive range of services in support of risk management and post market surveillance requirements.

Table 1: Design & Development Steps – Business Processes and Considerations

Step or Action	Considerations
Identification of need	Identifying the user need is the first step for creating a medical device. The more understanding of the need the more inputs can be created and enhance the product definition at an early stage.
Business case and commercialisation	Product attributes / technical specification, value proposition, strategic fit, market (size, growth), sales channels, competition, Intellectual Property position (patent protection, freedom to sell), development and project plan costs, manufacturing plan, launch plan and costs, regulatory pathway, clinical evaluation or human factors, reimbursement, countries of sale, risk analysis, product value/financials, supply chain (in and out) and distribution models, product training requirements, budgets, branding and marketing
Device classification	Medical device classification is based on the risk associated with the use and enforced by law. Typically agreed with your Notified Body
Discovery	Refining concepts and initial designing, prototyping, and iteration driven redesign. Developing working prototypes
Regulatory requirements and strategy	Medical devices are subject to regional and international standards. To be identified early on in the development process and should be reviewed periodically to ensure that any changes in the regulatory environment as well as any new scientific technologies are taken are considered.
Testing, verification and validation	Verification and validation (V&V) ensures the device is aligned with the voice of the customer and delivers the intended purpose. Also demonstrates whether all the requirements are being satisfied and are compliant with regulations. Additionally, tests used for V&V activities also need to be validated. This includes clinical and product safety testing, sterilisation considerations and primary packaging as well as overlapping with the manufacturing process development and process validations for manufacturing the product.
Risk management and PMS	Every medical device manufacturer must have established risk management procedures in place, and those processes must be in compliance with ISO 14971. Risk management activities should be aligned with all phases of D&D and post-market requirements

There is so much more to consider when designing and developing a medical device than having an innovative idea and then 'simply' manufacturing a product. Designers and developers must carefully evaluate needs, functional requirements, specifications, and more, all while assuring quality and managing risk. Safety of the device is a priority in medical device design as it is a requirement to ensure that devices meet functionality, reliability and safety features.

To conclude, medical device design and development is a complex process encompassing regulations, specifications, application requirements and end user needs. If a device lacks usability, market share will suffer, and if a device doesn't meet regulatory guidelines, it won't be approved for market at all.

Look out for other articles in the Mi3 Design & Development series.

About the Author:

Kelly Jackson is the Senior Technical Manager at Mi3, subject matter expert in Validation and Regulatory Affairs and oversees the Quality and Engineering & Product Development teams. Kelly has over 30 years of experience in medical devices up to and including Class III and implantable devices, sold globally including in the United States.

Kelly's experience spans Project Management, Quality, Technical and Operations functions and she has honed her expertise in validation, process development, specifications and design control.

About Mi3:

Mi3 are the experts in designing, developing and manufacturing end-to-end advanced medical and surgical solutions – providing specialist knowledge in thermoplastic engineering, tubing systems, and regulatory compliance.

We take your product ideas from consultation to concept to production, and work alongside you to bring medical innovations to life. Visit our website at www.mi-3.co.uk to learn more about our services design, development and manufacturing services or contact us directly by clicking here to discuss your requirements.