Kapstone medical

Kapstone Medical New Product Development (NPD) Roadmap

Kapstone Medical is a Single-Source Solution for Medical Device Companies

We take a fully integrated approach to new product development, weaving our expertise in design, engineering, manufacturing, regulatory affairs, intellectual property strategy, and quality assurance into an effective development process. Our medical device experts partner with your team to advance your product forward at any stage of the process and help you to navigate a cost-effective and expedited route to market.

Benefits of a Single-Source Solution:

- *Hire a single firm with expertise in every discipline needed for each stage of the new product development process from conceptualization through commercialization.*
- *Conserve costs and collect your project budget under one roof instead of outsourcing to multiple resources.*
- *Reduce the amount of management work required for your internal project team.*
- *Avoid costly and time-consuming mistakes that less experienced teams make.*

"If we're waiting on parts to be made or tests to be run, we can fill that time with downstream activities in a way that makes the best use of our project team. This keeps them fully engaged in the project."

Hayden Kapitan
Business Development Executive

The Kapstone Difference: Integrated Product Development in Action

Our approach to new product development organizes the complex journey to market into five distinct phases, integrating numerous disciplines into each part of the process. Below is a snapshot of some of the activities most commonly performed by Kapstone Medical.

	Concept	Development	Design V & V	Regulatory	Commercialization
Design and Engineering	• Concept Generation • Prototypes	• CAD Refinement Functional Prototypes • Bench Testing • Engineering Analysis • Finalize Specifications/ Drawings	• Verification Testing • Validation Testing	• Transfer to Production	• Transfer to Production
Quality Assurance and Control	• User Needs • Risk Plan	• Design Inputs • Design Outputs • Risk Analysis	• Quality Plans • Verification and Validation Reports	• Finalize Risk Plan • Traceability Matrix • DHF Closure	• Ongoing Quality Needs
Regulatory Affairs	• Initial Regulatory Assessment	• Testing Strategy • Predicate Device Selection	• V & V Rationalization or Reports	• Labelling • Regulatory Submission	• Ongoing Regulatory Needs
Intellectual Property	• IP Landscape Search	• Initial Patentability Assessment • Initial Freedom to Operate Assessment	• Provisional Patent Application	• Freedom to Operate Assessment refined	• File Non-Provisional Patent Applications
Manufacturing	• Design for Manufacturing	• Identification of Manufacturing Partners • More DFM • Pilot Production Build for Testing	• Sourcing Strategy for Launch • Manufacturing Cost Structure Optimization	• Production Planning • Manufacturing Validation	• Manufacturing Optimization

Advanced Human Factors Engineering

Human factors engineering (also called usability engineering) and testing are becoming increasingly important to global regulatory bodies—and increasingly central to the Kapstone offering. Our process forces the project team early on to account for human behaviors, plausible errors, and biological interactions to reduce clinical risk of the medical device. Our team is fully trained in the overlap between human factors engineering and device development and prepared to integrate our expertise from the get-go.

Benefits of Integrating Human Factors Engineering:

- **Early Assurance of Device Usability**
  Incorporate user research and testing into the early stages of device development to ensure that the device is actually designed to meet the needs of its ultimate users. We also take the diverse needs of those users into account, optimizing your product for all potential use cases to increase adoption rates.

- **Reduced Cost of Changes to Design**
  Proactive consideration and testing for human factors protects the project team from having to make costlier changes later down the line.

- **Risk Reduction**
  Product risks are difficult to anticipate—unless you actually use and test the device. By identifying the critical tasks with users early in the process, we leverage decades of experience to predict, assess, and design for product risk factors, safeguarding the project from unpredictable revision costs.

Regulatory Affairs

Our team has expertise in both US and EU regulatory governance, including FDA and Tech File (CE Mark) submission strategy and execution. We strategically integrate regulatory affairs into the early stages of the new product development process, ensuring that your product design and testing frameworks are set up to meet regulatory benchmarks.

Examples of Early Regulatory Affairs Integration:

- ✔ **Feasibility-Stage Regulatory Strategy**
  By performing an initial regulatory assessment at the project start, the team has greater confidence of the regulatory pathway, marketing and labelling claims, and testing needed, which allows for more accurate and efficient decisions on product design.

- ✔ **Strategic Predicate Device Selection (US-only)**
  Select a comparative device as early as possible so that specific substantial equivalence measures can inform product design and testing.

- ✔ **Proactive Verification and Validation Planning**
  Plan for regulatory adherence, designing the product and its testing to meet specific benchmarks.

Our Fully Integrated Regulatory Affairs Process:

1. Concept	Initial Regulatory Assessment
2. Development	Testing Strategy & Predicate Device Selection
3. Design V & V	V & V Rationalization or Reports
4. Regulatory	Labelling & Regulatory Submission
5. Commercialization	On-going Post-Market Surveillance

Intellectual Property (IP) Insights

Intellectual property is an essential component of the value we create for our clients. While we do not explicitly offer legal services, our registered patent agent and team of experts are able to maximize that value by incorporating IP insights throughout the product development process. We are able to holistically evaluate a monetization strategy and design strategy to make sure you have maximized your IP and protected your design. From a competitive landscape analysis to supporting a patent application, we ensure that your product is properly positioned, designed, and protected.

The Comprehensive Kapstone IP Approach:

- ✔ **Patentability Assessment:**
  Is the IP patentable?
- ✔ **Infringement Assessment:**
  Does the IP infringe on any existing prior art?
- ✔ **Monetization Strategy:**
  Are there multiple applications or patents available for the IP?
- ✔ **Design Strategy:**
  What does the design need to stay clear of? What must the design include?
- ✔ **Patent Application:**
  We can help prepare the work for a patent application to be completed by an attorney.

Why Work with Kapstone:

Capabilities	Kapstone	Traditional Design Firm	RA / QA Consultancy
ISO 13485:2016 certified QMS and processes	✓	✗	✗
Understanding of the latest regulatory guidance	✓	✗	✓
Knowledge of the latest verification and validation trends	✓	Maybe	✓
Qualified IP specialist (registered patent agent) on staff	✓	✗	✗
Expertise in human factors engineering	✓	Maybe	✗
Ability to provide a robust, all electronic-ready QMS with decades of rigor	✓	✗	✗
Prototyping capability and manufacturing expertise	✓	✓	✗

Let's Get Your Device to Market. Connect with Kapstone Medical Today!

Hayden Kapitan
Business Development Executive

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