

Case Study 6: Regulatory Management

Situation (Discuss)

The client was interested in obtaining U.S. regulatory approval for human use of a medical device that had already been successfully commercialized in the veterinary market. They were in the process of preparing to submit a PMA application to FDA as a Class III device, but having had no previous experience as a medical device company the client recognized that they could benefit from some assistance with the regulatory approval process.

Business Recommendation (Design)

The Magellan team proposed a thorough business review and a full analysis of the possible regulatory pathways. The team recommended a comparison of the pros and cons of continuing with the PMA submission versus requesting that the device be reclassified as a Class II device through the FDA “De Novo” process, which would allow the client to seek approval for the product as a 510(k) device instead. Magellan also proposed the development of a new internal quality documentation system; evaluation of potential reimbursement opportunities; creation of new clinical and regulatory organizations; and training of both the new clinical and regulatory organizations and the existing outsourced manufacturing organization on the procedures, processes, and methods necessary to manage this new technology.

Magellan Team (Deploy)

A Regulatory Manager and Clinical Research Manager were brought in to explore the available regulatory options. Once the client chose a regulatory approach Magellan developed and presented the 510(k) submission documents. A Regulatory Advisory Board was also established to provide counsel throughout the submission process. A Reimbursement Manager outlined potential reimbursement strategies, while a Quality Engineer evaluated client procedures and developed a plan for integrating quality requirements into the existing manufacturing facility. The project was supported by a Project Manager and Project Coordinator who handled day-to-day planning and administrative functions, as well as an Executive Sponsor who ensured consistent quality throughout the process.

Results (Deliver)

The project produced the following key outcomes for the client:

- Completion of an FDA “De Novo” reclassification request and 510(k) regulatory submission
- Creation of procedures, processes, and management tools necessary to manufacture and support an FDA approved device for human use
- Initial implementation of the infrastructure for quality and manufacturing processes
- A reimbursement assessment

Business Impact

The project supported the expansion of a new business for the client, extending their veterinary technology to human use. The project shortened the time to submit and receive approval for the product, reducing the time and cost of entry into this new market. Equally importantly, Magellan helped the client establish the processes, procedures, and manufacturing quality infrastructure necessary for the successful management of a medical device company.

Competencies Demonstrated

Strategic Planning (New Product Development, New Business Development) • **Product Development** (Design Validation) • **Regulatory Management** (Regulatory Pathway Design, Submission Support, Labeling, Standard Operating Procedure Development) • **Reimbursement Management** (Reimbursement Strategy, Coding Analysis, Payor Market and Policy Analysis) • **Professional Education** (Business Literacy Training) • **Business Development** (Due Diligence)

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