



International Business Development
Strategy and Implementation

US STRATEGY & IMPLEMENTATION FOR A GERMAN MEDICAL DEVICES COMPANY

Commercial pathway for an innovative German audiology product

Background

- A successful German company had a market leading software/hardware system for optimizing the performance of hearing prosthesis devices. Having maximized the commercial value in Europe, they wished to develop the business in North America.

Challenges

- How to optimize the product to meet the unique needs of North America.
- Gain FDA approval in a low risk way while preserving necessary marketing claims.
- Educate customers about the innovative product benefits to gain wide adoption in a market that had never used similar products.

TCG Approach

- Conduct market research into the market dynamics and customer requirements
- Interview experts to understand the best regulatory and reimbursement pathway for the US product, to meet the required claims for the new application
- Meet with the German development engineers to determine the status of German product development and technical feasibility of the US product.
- Engage experts in developing FDA submissions in diagnostics and software systems
- Engage leading US practitioners and clinicians to use the product, publish peer reviewed research papers, and present at selected medical congresses

Results

- Identified a low risk and cost effective pathway to market for the company.

Value to Client

- The company executed a successful market development program after gaining valuable fact-based information that outlined a promising launch strategy.