Six Costly Mistakes to Avoid When Launching Medical Devices in Europe: Practical and Timely Advice for Start-Up CEOs

Representing one-third of the global medical device market, the European Union provides a significant opportunity for start-up, medical device companies. But, it can also present costly challenges for the unprepared. Following are a half-dozen cautions drawn from real-world experience that could help you avoid some common commercial pitfalls.

1. Chasing conflicting commercialization objectives. What are the strategic reasons for launching your product in Europe? Our experience has validated more than 10 unique objectives ranging from driving rapid revenue growth to providing product free of charge. Expecting rapid revenue growth, premium pricing and deep account penetration simultaneously leads to frustration and disappointment. Analyze your strategic options, understand financial implications and stay laser-focused on what's most important.

2. Believing that CE Mark approval proves product viability. CE Mark approval requires limited clinical data – often less than 50 procedures done by a handful of highly experienced physicians. The true test of commercial viability actually comes after CE Mark, when many more physicians test your product's capabilities and uncover limitations. So focus energies post-CE Mark building your clinical data set (through post-marketing registries) and listening closely to customers' feedback.

3. Going broad before understanding how to go deep. CE Mark approval, with its access to 27 countries, makes it tempting to expand rapidly across Europe. But strategic acquirers care most about what is happening at the individual account level. So, select 20-30 accounts, test and refine your sales strategies and focus on driving deep product adoption. Do this with your nascent sales team and potential acquirers will quickly calculate the future potential.

4. Underestimating what it takes to increase product supply tenfold. Nothing destroys product launch momentum like product shortages and quality issues. Establishing a robust supply chain takes significant time, expertise and effort. Selling in Europe means new, multi-language labeling and documentation, local logistical support and a thorough review of your quality system. Select the best partners for long-term growth, expect delays and act decisively to protect patient safety.

5. Relying on distributors to develop new markets/technologies. Distributors bring local market knowledge and relationships with the added benefit of being capital-efficient. But they also carry a bag full of products and are motivated to sell products with the greatest return and least amount of effort. If your product requires changing clinical practice or developing a new market, hire direct sales professionals. Distributors do not have the incentive or patience to build for the long term.

6. European talent equally motivated by "The Big Payout." Top talent from industry-leading companies are well paid, value stability and enjoy rich benefit packages. Cultural and tax law differences make the equity upside pitch a tougher sell. All aspects of the employer-employee relationship are governed by lengthy employment contracts. The most critical hire is your top sales leader – choose wisely. Engage an experienced recruiter and expect new hires onboard 3-6 months after offers are accepted.

+1.919.619.7581 | greg@medcelerate.com | medcelerate.com