



Superior Scientific

Global Medical Device Experts



Medical Device Business Review

- Regulatory
What is an appropriate regulatory strategy and required steps?
- Intellectual property
i) Technology & Product Review ii) IP Review (e.g. Does the patent cover the product? Does the holder have the freedom to do business with its technology & Products?)
- Clinical impact
Will the product impact clinical adoption and commercialization, lead to improvements in healthcare, or influence clinical guidelines? If so, how?
- Execution risk
What are the difficulties and risks of putting the business plans into action?
- Business model viability
Is the business model realistic?
- Predicate devices
Are there other devices that can be used as predicates for regulatory or reimbursement purposes?
- Business financial requirements
What financial support (e.g. amounts, sources, uses, timing) is required for the business?
- Sales and Distribution
How does the business plan to sell its product?
- Reimbursement
What are requirements for reimbursement of purchasers of the technology?
- Market need and opportunity
What is the market opportunity that the product seeks to address? How big is the market? How does the product address the needs of the market for the product?
- Competition
What other businesses or devices will compete with the business or its device?
- Go To Market Strategy
What action plan will the business use to reach its unique target market?