



## Donawa Consulting Medical Device CEO Clinical Primer

Your company is working hard to develop a breakthrough medical device, pushing to get your product to market in the U.S. and Europe. How can you manage your company's clinical work to reach this goal with minimum resources and maximum benefit?

The Medical Device CEO Clinical Primer will give you some critical fundamentals to help you ensure that your company's clinical program and implementation meet the demands you face from regulators and investors.

The Primer covers questions such as:

- How do we build the clinical evidence to support our claims for regulatory approval and reimbursement?
- Do we need a clinical study for regulatory approval? To support marketing activities?
- If we need study, how do we plan to get the most mileage from the data? How do we budget time and funds?
- What kind of staff do we need to handle our clinical work?
- How do we build quality assurance into our plan?
- How does clinical study activity fit into design controls?

**The right product at the right time is not enough, so learn how the right clinical planning can boost your bottom line and set you on the path to success.**

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