



Considerations in early stage device development: A Medical device consultant's perspective

Pediatric Medical Devices Workshop
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THE MARKET

- US Medical Device Market
 - Approximately 105.8 Billion (2011)¹
 - Projected growth of approximately 6.6% per year for the next five years¹

- US Diagnostics Market
 - Approximately 44 Billion (2011)¹
 - Growth of approximately 7.8% over the next five years
 - Molecular Diagnostics segment projected to grow 11% per year²

1: <http://www.espicom.com/usa-medical-device-market>

2: <http://www.genengnews.com/gen-articles/infectious-disease-molecular-diagnostics/3918/>

FDA

FDA is responsible for:

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled; human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health

Source: <http://www.fda.gov/AboutFDA/>

FDA

- Collaborative
 - Pre-IDE process
 - Get to know your key contacts at FDA
 - Join trade associations (AMDM, ADVAMED)
 - Attend workshops like this one

Think of the FDA as a partner in the process rather than a barrier to be overcome.

EARLY STAGE CONSIDERATIONS (NOISE – LOTS OF NOISE)

- Why are you doing what you are planning to do?
- Do you have a strategy (not just a business plan)?
 - What are you trying to achieve?
 - Why?
 - What is your plan?
 - What are your FDA & related regulatory requirements?
 - How will you accomplish this? How long will this take?
 - What will it cost?
 - Who is going to do the work? How will you pay them?
 - What are your goals? How will you know you have achieved success/failure?

EARLY STAGE CONSIDERATIONS

- Intellectual Property Protection (i.e., Patents)
- Design Control – Freeze
- Funding
- Knowledge of what is involved – cost, timing, steps for success
- Indications for use in X patient population for Y conditions

GET TO “NO” FAST

- Your Time / Money
- FDA’s Time / Budget
- Family’s Time
- Investor’s Time / Money

60 SECONDS

The Plan / Strategy will drive everything,
while providing a road map, ETA, and budget.



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