Implantable Medical Device Program Management

- Based on a referral, the organization needed critical Program Management help and brought me in.
- I came into an organization with no background in the product technology, no knowledge of the underlying therapy and no experience with systems/processes for this organization.

Requirements
- Electrical
- Test
- Mechanical
- SW
- Simulate
- Manufacturing
- Concept
- Design
- Validation
Medical Device Project
Situation

- Competitive, implantable medical device required a fast New Product Development turn around.

- A typical 18 month device project was requested in 10 months.
  - My management supported 12 months as a possible stretch if we leveraged an existing design.
  - Leverage assumption ended up not being true!
  - Included design, manufacturing, tooling and reliability testing functions
Medical Device Project Impact

- Because of a strong market share position, this competitive product could erode the present position.
- The competitor had some advantages that the company did not currently provide. We had to quickly match, and understand, what we could provide.
- A competitive assessment was also part of the overall project effort.
Medical Device Project Solution

- Requirements focus
- Carry parallel concepts
- Understand and develop regulatory approach
- Create resource gap contingencies
  - Full time, dedicated manufacturing resource was promised for this project, but never hired during the course of the project
  - Thus, I had to “borrow” already overworked resources to cover the tasks required for the new design
Medical Device Project Results

- Delivered project in 11 months, with a 3 week FDA approval.
  - Yes, three weeks with the FDA is unheard of.
  - Beat competition to approval

- The rationale for the potential schedule reduction to 12 months was inaccurate. The typical 18 month duration was more appropriate
  - Many design and manufacturing issues on previous design. Long lead tooling could not be reused.
  - We also fixed the previous design and tools in this period of time. That was how we were able to borrow the manufacturing resources.

Completed project in 60% of standard schedule
Program Management Case Study

Perry’s Solutions, LLC

- Consulting and Training services from DOE and SPC to project planning and management
  - Solving NPD design, execution and re-plan situations

- Phone: 651-230-3861
- Email: Perry@PerrysSolutions.com
- Website: www.PerrysSolutions.com