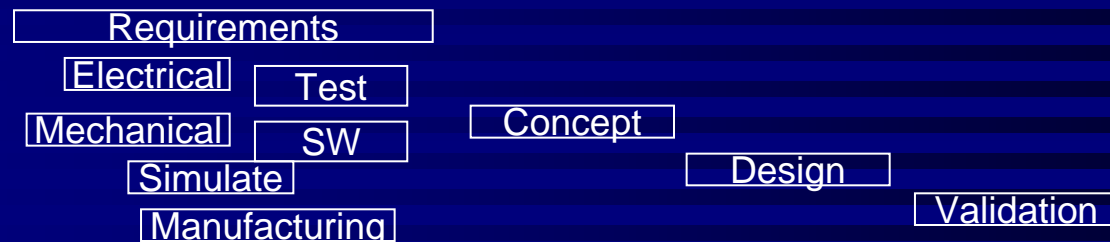


Implantable Medical Device Program Management

- 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.



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

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
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