

This paper addresses only the efforts that go into design and development from an engineering standpoint. The other important factors of marketing and finance will be left for experts in those fields.

Many “startup” companies begin with a person or group with an idea and a vision. This may be a process, a toy, a medical device, or anything of value to some portion of the population. As a new company, the goal is to develop and produce the product to sell to a willing market. The first step is the product definition:

- Product requirements (what will the product do?)
 - Product function
 - Interface with the process, patient, system, ...
 - Interface with the user
 - Visual
 - Audible
 - Physical
- System requirements
 - Logic of operation
 - Physical constraints
 - Size
 - Operating environment
 - Electrical requirements
 - EMI/EMC requirements
- Costs
 - Target COGS (Cost of Goods Sold)
 - Retail cost
- Testing and validation

The second step in the process is to develop the concepts. Necessary disciplines may include Industrial Design, Electrical/Electronic Engineering, Mechanical Engineering, and Software Development (embedded and/or PC). All disciplines must work together to insure that the product developed actually meets the requirements.

During the design process, concepts will be developed and prototyped for testing. During this time relationships are developed with the vendors that produce components for the product. In many cases, the startup company has a minimal staff and has not hired engineers or an engineering firm to provide all of the required design functions. The vendors may step in to help with the effort as a favor, or with the intent of obtaining production quantities of components. These relationships are invaluable to the startup company as many vendors have engineers on staff or are otherwise competent to provide design services. While these companies have helped with the development, where does documentation control lie?

Engineering Documentation Control A Necessary Commitment

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Engineering documentation is the media that conveys the design intent and necessary information to successfully produce a product over time. These documents can be maintained in many formats, which may include but is not limited to:

- Technical drawings, paper or electronic data
- Assembly drawings with Bills of Material, paper or electronic data
- Three dimensional solid models, electronic data
 - STEP files
 - IGES files
 - Files native to the software used to produce the design such as Pro/E and SolidWorks
- Gerber files (PCB design)
- Purchased component specifications

Each of the above documents must be complete and accurate. The caveat here and the main point of this paper are the completeness and control of the design documents. Issues of concern are:

- Who owns the design?
 - Did the company pay for the design services?
 - Does the vendor recognize that the company owns the design data and documentation?
 - Is the vendor willing to turn over the design data on request?
- Is the design documentation complete?
 - Are drawings technically correct so that another vendor can produce the components?
 - Are materials and processes specified adequately?
 - Should the vendor go out of business or the relationship dissolve can another vendor be brought online immediately?
- In the event of litigation by a customer:
 - Who is responsible for the engineering in the product?
 - Who is to answer questions about the validity of the design work involved?
- How is the product maintained over time?
 - Who is in charge of revision control?
 - Are changes tracked and history of design preserved?
 - Can replacement parts be manufactured for existing product?

It is extremely important for a company with a production product to be in control of that product. All contracts with vendors and engineers should include provisions for intellectual property rights. Deliverables should include complete and accurate documentation along with the design data.

To conclude, truly own your product!