

New Product Design Control

Unneeded Bureaucracy Or Essential To Success

Key To Innovation And Business Success

By John E. (Jack) West, a Silver Fox Advisor

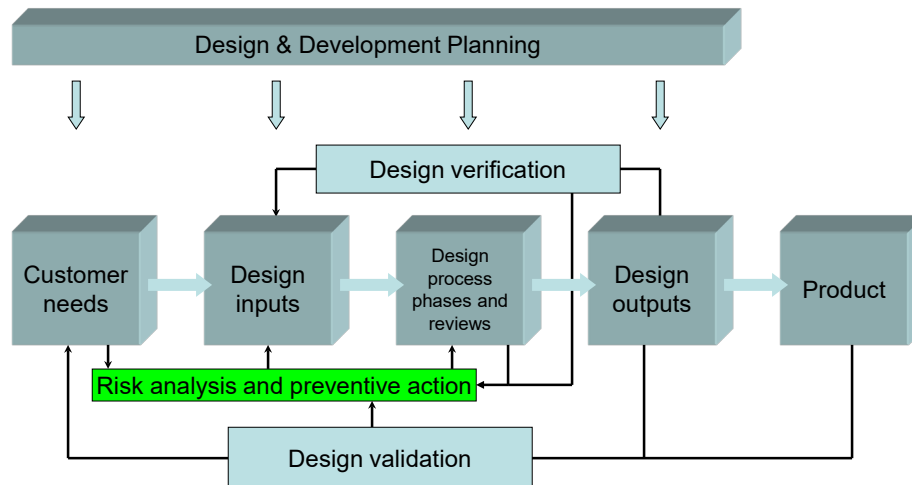
Organizations of all sizes have a tendency to resist formalizing their design controls. And there are some good reasons for this reluctance.

There is of course the real concern that applying the formal design review, verification, and validation requirements of formal standards like ISO 9001:2000 Clause 8.3 might cause over-control of development efforts and drive in unwarranted costs. But the issue has little to do with formal quality systems. There is also a concern about “folks looking over the designer’s shoulder.” (Could be a big problem if the designer is the owner of the business!) But perhaps most important, there may be a reluctance to analyze and understand the benefits of good design controls as a means to manage risk and take prudent actions very early in the development cycle using tools like failure modes and effects analysis (FMEA). In other words, in the mind of designers, the potential negatives of exercising controls tend to overshadow the potential benefits. On the other hand, most recognize that many (perhaps a majority of) manufacturing and service delivery problems have their roots in the design and development processes. We often see entrepreneurs who are unable to obtain funding for their developments because they lack an adequate development process or even development plans that can be demonstrated to be adequate. This also is a driver of failure to find an initial customer base so necessary to product rollout. For complex products, it may even prevent the developer from finding an initial partner to help perform essential validation steps. Perhaps the issue is to implement design and development in a manner that will contribute to designers’ creativity, reduce costs, and ensure customer needs are met!



One approach is to ensure there is a clear understanding of the design control process and how it relates to the issues such as achieving the organization’s design goals, maintaining creativity, and meeting cost objectives. Organizations need to start by explaining the required controls to the design team and get them to list the problems and issues they see in implementing those controls. Then address each issue during the design and development planning process. Focus on defining areas where creative thinking will be necessary to achieve design objectives and meet customer needs.

The overall product design and development process is shown in the figure. These prevention-based concepts are key to developing successful, robust designs.



It is important to determine how to use the tools of design review, verification and validation as input to risk analysis and development of preventive actions. It is also key to define what role customers will have in the process and how they will be engaged in the validation step. Let's look at the key steps:

For design reviews: Design review is normally conducted at various stages during the design process and is one way to address issues such as product dependability, service reliability, and all the other “abilities” related to the product. It is of course critical to consider the importance of producibility and service delivery capability as appropriate. Early identification of issues in these areas can enable the organization to avoid surprise capital needs and cut ultimate introduction costs dramatically.

For design verification: Verification is simply a comparison of design output to the input requirements to make certain the development project is on track. Consider how the design output will be used in the organization to produce the product or deliver the service. Be rigorous in determining whether the initial design inputs will be met. Be willing to consider changes to the initial criteria but not without making certain customer requirements won't be compromised.

For design validation: Validation is a confirmation that the product will meet actual application needs. This is best conducted directly with users and may involve having them use prototypes or development models of the product. For services it may involve test sites where the service is piloted with actual clients. Feedback from actual users or potential users can be critical in making the right final product design decisions. When users provide negative feedback, you may have the best opportunity for designers to use their innovative talents to develop customer friendly solutions. Design changes that deal with significant validation issues are potentially the most valuable preventive action opportunities an organization can have.

Perhaps most important of all, each design and development control is not just a potential opportunity to reduce the cost of the overall product development and introduction program it is also an opportunity to: hone product production and service delivery processes, and fine tune the design so that the product captures the market.

Properly planned and applied with a focus on prevention, the design and development control process can be powerful toolbox full of opportunities! And that is just if we apply the concepts to product design. There are additional benefits if we choose to use these concepts in developing the production and service delivery processes.

There needs to be clear delineation of the steps to be taken in a development plan with related phased funding needs and stated criteria for success at each step. The wise developer never forgets what the old song says: “you gotta know when to hold ‘em, know when to fold ‘em, know when to walk away, know when to run.” Without a clear plan with pass-fail criteria, success is unlikely and it is also very likely you may not recognize when it is time to cut losses and move on! ♦
