

THE INTEGRATION OF LEGAL REVIEWS INTO FORMAL PRODUCT DEVELOPMENT PROCESSES

I. Introduction

Most larger companies utilize a formal product development process. Historically, these processes evolved out of informal product development activities that grew in complexity as the company itself grew. As a result, these processes tended to be fairly different from one company to another. Over time, particularly for regulated industries such as defense contractors, aerospace and pharmaceutical and medical device manufacturers, a standardized set of manufacturing guidelines evolved and became formalized. These Good Manufacturing Practices (GMP's) became recognized standards and were incorporated into regulations governing the practices of many regulated industries. They also became a de facto standard for all manufacturers as part of various quality improvement systems over the years.

As the quality improvement systems evolved, they began to look at improvement in functions beyond just the manufacturing process itself. They began to include all corporate functions that impact product safety and reliability and all aspects of the customer's relationship with the company. As a result, these systems grew to include customer service, finance, supply chain management, delivery and product development. The "father" of this movement is W. Edwards Deming who originally applied the concept of statistical process control to manufacturing processes. Various systems incorporating these principles have evolved over time, such as Total Quality Management (TQM), Six Sigma, EFQM Excellence Model and Toyota Production System.

One common source of a standardized quality system is the ISO 9000 system and related quality systems (such as ISO 13485, which is specific to medical device manufacturers). The FDA has its own requirements, which are very similar to the ISO paradigm, in what is known as the Quality System Regulation (QSR). Also, many of the features of these systems are measured for awards such as the Malcolm Baldrige award.

II. Quality Management Systems and Product Development

As quality management systems developed and expanded in scope, the product development process came under scrutiny since proper product design plays a huge role in the final product quality, safety and usefulness. As we know from products liability law, there are design defects and manufacturing defects; it doesn't matter if a manufacturing process is 100% reliable if there is a design defect, you are just reliably making a defective product.

To simplify the discussion, I am going to focus on a particular product development process management tool known as Design Control that is a feature of many quality systems such as ISO 9000/9001 and related ISO standards, the Quality System Regulation and many other quality management systems. Fortunately, there has been a great deal of harmonization among various regulations and systems, so that the primary attributes of most product development process management systems are common in Design Control. Also, if your client

is ISO certified, which is very common for businesses with any significant international business, they likely use the ISO version of Design Control.

Regardless of the specific quality assurance systems to which your clients might be certified and/or the specific implementation of those systems your client may have created, there are a number of phases of Design Control that are common features of most such systems. Plugging legal review into the appropriate phase of these systems will allow your clients to more routinely obtain appropriate legal reviews at various stages of the design process, do so more efficiently and avoid unnecessary “surprise” costs and delays associated with unanticipated legal problems with new product designs.

III. The Typical Design Control Process

The following stages are typical of most Design Control processes and are specifically referenced by most of the major standards and regulatory bodies: 1) Initial Planning and Project Management Development, 2) Design Input, 3) Design Output, 4) Design Verification, 5) Design Validation and 6) Transfer to Manufacturing. Each of these phases will be described briefly as to their function in the Design Control process.

- A. Initial Planning and Project Management Development** – This phase primarily is related to the initiation of a design project, identifying the participants and their roles in the process and development of an initial project timeline for the project. While little substantive design work takes place in this phase, a great deal of important resource identification and scheduling takes place and often, an initial project budget is developed.
- B. Design Input** – This is a very critical component of the Design Control Process since it begins to shape the specific criteria relating to the ultimate goals of the development project. This phase typically involves quite a bit of conceptual planning with input from many different constituencies: marketing, engineering, R&D, regulatory, manufacturing, finance, quality assurance, etc. The ultimate “output” of this phase of a design project is to create a set of product characteristics and features that ultimately will evolve into an actual product specification.
- C. Design Output** – Typically, the result from this phase of the project starts with one or more conceptual designs that typically evolve into concept prototypes, functional prototypes and, eventually, production prototypes. In most instances, the Design Input and Design Output stages are closely linked in an iterative process in which the product features and specifications evolve in light of the practicalities of what is reasonably possible and the associated costs.
- D. Design Verification** – This phase represents a formal comparison of the results of Design Output to the Design Input criteria. In the initial stages, the verification stage may simply be a comparison of a conceptual design on paper with the input criteria. As the product proceeds to the prototype stage, actual testing and trials

may be incorporated. Once the product reaches a design freeze, a formal comparison of the detailed product specification and the actual design will be performed and documented as part of the verification process.

- E. Design Validation** – This stage is essentially a repeat of the verification process, but using production samples in statistically significant quantities. In addition to validation of the design itself, this phase may also incorporate manufacturing process validation – that is, can the engineered manufacturing process reliably result in a product that meets its specification at acceptable quality levels. Usually, formal validation protocols specifying multiple production lots, sample sizes having statistical significance and test procedures are created. The use of outside test laboratories to assure that any relevant standards or regulatory requirements are met often occurs at this stage. Part of this process may include field trials of the product.
- F. Design Transfer** – This stage represents the formal end of the Design Control process and is designed to facilitate the transition from tightly controlled prototype construction, limited batch size production and tightly controlled manufacturing runs to routine, day-to-day manufacture of the product.

In most design control processes, all of the above-described activities are conducted in regularly scheduled meetings and are documented with various reports and forms as prescribed in a formal, written procedure. In addition, these are not all necessarily sequential and independent steps, but may be conducted multiple times and in different sequences as additional facts are learned. For example, the Design Input and Output processes are likely to be iterative and multiple reviews are likely to be conducted as the design evolves. Validations may turn up unexpected problems in the transfer from “artisan” production to “shop floor” production that could necessitate revisions to the product design and re-opening of Input, Output and Verification stages. Also, post-Transfer issues that appear on a longer time frame as more field experience is incurred might also result in re-opening of the design control process for further modifications to the design.

IV. IP Legal Integration Into The Design Control Process

As can be seen from the quick review of the design control process presented above, there are numerous points where appropriate legal reviews can be scheduled and implemented. The critical path is to ensure that the Intellectual Property review (and other necessary legal and regulatory reviews) is integrated into the standard procedures and forms that control the design control process. Of course, in-house legal departments typically have an advantage in driving such integration, but it is the small and medium-sized companies, usually without in-house legal departments, that might stand to benefit more from such integration. The key here is communication and client development. Perhaps some free consulting on integration of key IP reviews into the design control process would be welcomed by the client and can be attributed to client development activities.

- A. Initial Planning And Project Management Development** – The key element here is to make sure that IP reviews are integrated into the procedures and forms used by the client so that such reviews are an integral part of the project management plan and are populated into timelines and critical path activities. Typically, in this phase of design control, all of the necessary resources are identified, their functions and deliverables defined and initial project timelines, Gantt charts, etc. are developed.

In working with clients to integrate IP reviews into this phase of design control, it is important to assist clients in identifying the appropriate types of IP reviews, what phase of design control is most likely appropriate for those reviews and a timeline of when those reviews can most likely be completed. These assessments will become part of the regularly scheduled activities for all design control processes. It is important to note that not all activities will be commenced and completed within a single phase of design control. For example, while it might be necessary for a “State of the Art” search to both be initiated and completed during the Design Input stage, it might be appropriate for an initial “Clearance” opinion to be initiated in the Design Output stage and completed during Design Verification, Design Validation or Design Transfer, depending upon the nature of the project. It is also possible to modify the standard procedure for a given project, but at this initial stage, reference is usually to a standard procedure that will evolve as the project progresses.

For this stage of Design Control, the primary points of integration include identifying the typical IP reviews and integrating them into the planning and scheduling process. Considerable client education may be required to identify the purpose and appropriate timing of such reviews. Also, most clients will seek some realistic advanced budgeting in order to properly budget the entire design project.

Key IP reviews that should be scheduled in advance would include: State of the Art Searches, Patentability Searches/Opinions, Patent Drafting and Filing, Clearance Searches, Non-infringement Opinions, IP related contracting (acquisition of rights, licenses, etc.), Trademark Searches and Opinions, Trademark Registration Filings, and Copyright reviews. Most of these items can be handled with a simple form that is completed by the appropriate legal advisor. For example, at DeRoyal, we have a simple one-page form that addresses IP protection and infringement avoidance. Often, that form will refer to supplemental memos and other documents to be completed. That form is then routinely updated if subsequent tasks are completed or additional information needs to be provided. Typically, attorney-client privileged information is not attached to the form, since the design control documentation is not necessarily limited to sufficiently maintain the privilege, but the fact that the review was made and the determination that the project could proceed was made is documented in the form.

- B. Design Input** – At this stage of the process, the key elements of the scope of the project and the desired project output are defined. Often, this includes the beginnings of development of the output specification, features, functions and characteristics. Typically, the R&D (or Engineering) and Marketing groups work closely to develop the deliverables of this phase of the project. If used properly, this stage provides critical input for IP reviews such as identifying key product characteristics and functions, competitive products and companies, likely target markets, and possible trademarks. This stage often provides the jumping off point for education of IP counsel regarding the project, information useful for initiating preliminary State of the Art searches, identification of key proprietary positions of competitors (to aid in design-around or need for licensing) and necessary contracting activities (if, for example, key elements of the project are to be developed by outside contractors, joint venture parties or research entities).

For review and sign-off, typically the IP counsel would identify those activities that were completed during this design phase and would also identify key activities that have been determined are to be completed at other stages of the process. As previously described, the Design Input/Design Output phases are often iterative and the forms are updated with new information as the project progresses.

- C. Design Output** – Ultimately, the output of this phase of design control is a set of product specifications and plans developed in response to the information generated as part of the Design Input stage. In the iterative process, initial design outputs may progress from feasibility determinations to preliminary designs, to various prototypes and, ultimately to a pre-production prototype and design freeze.

Obviously, depending upon the complexity of the process and the specificity of the information generated during the Design Output phase of the project, considerable IP review and activity is likely to be generated during this phase. Once some concrete project/product parameters are set, more definitive State of the Art searching, design around guidance, preliminary patentability searching/opinions, patent application drafting/filing and initial right to practice research and opinions can be initiated.

Often, the Design Output phase is the appropriate forum for generating invention disclosure documents. It is important that the generation of this type of documentation be an integral part of the Design Output process. If appropriate procedures and forms are properly crafted, the documentation of the Design Output process will automatically result in a useful invention disclosure (whether the form bears that title or not). Again, because of the iterative nature of the Design Input/Design Output process, the level of activities that the IP counsel will be involved in will vary, but ideally, important input from IP counsel will be integrated into the process so that the ultimate project/product specified in the Design Output phase will stand a good chance of passing IP muster.

- D. Design Verification** – This is a review phase that takes the final output from the Design Input phase and compares it to the output from the Design Output phase. At early stages of the iterative process, it might be a discussion of the practical implications of what is achievable and what isn't (for example, to meet the input criteria, the product might have to be made of hand worked titanium (or “unobtainium”), but that the marketable price point might require that the product be injection molded commodity plastic). At later stages of the iterative process, the gaps between input and output should be narrowed by appropriate revisions to each and, ultimately, the Design Output product should be able to be tested by objective criteria to verify correspondence with the Design Input criteria. Frequently, the design “freeze” will occur at this stage of the process.

For the IP counsel, this may well be a critical point that enables the finalization of some of the IP review work. Hopefully, any necessary State of the Art information has been integrated into the design work carried out by R&D and/or Engineering and major IP hurdles have been cleared. Having more concrete final product information and, hopefully, sufficient test data to verify the major specifications of the project/product will enable the IP counselor to move fully into appropriate IP drafting and filing and clearance work. It is important to note that in the transition from Verification to Validation, the team may want to create some trigger points for capital intensive projects that delay certain capital expenditures until the IP clearance work is completed. For example, if the move to the validation stage is going to require significant investment in capital equipment or tooling, then all interested constituencies need to be in agreement that those expenditures will be delayed until final clearance approval is given. If implemented properly, the time for this sign-off has been budgeted in the original design plan and has been routinely updated as the scope of the project has become more defined in the prior stages of the design project.

In addition, the transition from the Design Verification stage to the Design Validation stage is a common point for the development of the new product's marketing program and is a good point to trigger marketing related IP considerations such as trademarks, trade dress, copyright considerations in packaging and labeling, comparison advertising (to competitive products), etc.

- E. Design Validation** – To a great extent, the Design Validation phase will duplicate the Design Verification stage, with more statistically significant sample sizes and, possibly additional field/market testing. Usually, validation will require that the objective measurement of the product performance as compared to product specifications and desired features/functions will be conducted on items that result from actual production processes as opposed to hand-fabricated prototypes.

Frequently, the product manufactured for the design validation stage will be field tested in some form or fashion to get actual intended user feedback in addition to actual experience regarding “real world” performance of the product. This might

be as limited as a field trial or test market or could be as complex as clinical testing for a medical product. The test market/field trial stage may raise implications regarding contracting with the test customers to preserve confidentiality, particularly if the input from this stage is critical for preparation of IP filings, in order to avoid Section 102 concerns.

Other considerations of IP counsel at this stage include a review of the information generated by any field experience, since issues might necessitate revisions to the product design and could trigger possible revised opinion work or updated patent filings. In addition, to the extent necessary for patentability issues, the validation data may provide necessary best mode information for patent applications or can be used to overcome obviousness rejections in a crowded field of art.

- F. **Design Transfer** – This stage is essentially the hand-off to the manufacturing function and doesn't necessarily implicate IP counsel significantly in most cases. However, to the extent that this transition might also signal the public launch of the market and/or other significant commercial activity, it may represent a good target date for the completion of certain filings and reviews.

V. Other Types of Legal Reviews

For attorneys with practices that extend beyond the Intellectual Property sphere, or who interface with those attorneys, the above discussion likely triggers thought of the integration of other necessary legal reviews into the design control process. For example, since DeRoyal is in the FDA regulated field of medical devices, additional regulatory and legal reviews are a necessity in order to comply with FDA regulations.

A number of important legal reviews can be integrated into this process. In the FDA arena, all of the labeling, packaging, marketing materials, instructions for use, warnings, claims, indications and contra-indications (collectively referred to as "labeling") have to be reviewed for compliance with FDA requirements. This review is integrated into design control.

Also, regardless of regulatory requirements, there is the concern with products liability and, obviously, product safety and reliability should be integrated into the design control reviews as well. Most standard Design Control processes require a sub-task related to Risk Management that involves identifying potential areas of risk from the project and minimization/mitigation analysis related to those risks. This would be a key process for involvement of counsel from a products liability perspective.

Other legal related reviews could involve import/export questions, foreign market regulatory issues, and contract issues with suppliers, contract manufacturers, distributors and customers. Each of these reviews, to the extent they are relevant to a particular client or project, can easily be integrated in the same manner as discussed for the IP reviews. Again, by including these reviews in the overall design plan and budget, unnecessary delays and unexpected costs can be avoided by the client.

VI. Summary

Familiarity with the design control process and integration of legal reviews into the process is a value added service that has benefit for both clients and legal practitioners. For the client, it institutionalizes necessary legal reviews into a familiar and accepted process. By doing so, it allows for predictability in legal costs and for appropriate timing of legal reviews, which are often elements that are not budgeted and planned for. Although many clients might initially be suspicious that this integration might be a way to increase fees, proper education should be able to demonstrate that earlier and consistent involvement in the process by counsel will actually serve to keep projects on budget and on plan.

For counsel, integration into the design control process provided innumerable benefits. It provides an important and continuously open window into the client's business and allows for the identification of issues at a much earlier stage of the process – potentially avoiding costly landmines down the road. In addition, it weds the attorney to the client in a manner that merely serving as a periodic service employee cannot. Finally, when managed properly, it results in an orderly flow of work having more predictable costs and time budgets, which mutually benefit both attorney and client.