INNOVATION AND CONTROL IN MEDICAL DEVICE DESIGN

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The need for medical innovation is driven by the infinite variety of unsolved or poorly-solved therapeutic and diagnostic problems. Such innovation is supported by the rigorous pace of medical and biotechnological research, by evolutions in clinical practice, and by the strong economic incentives at play: the emergence of new geographic markets and the fierce competition for existing consumers.

At the same time, an increasing awareness of the role that medical devices play in patient safety has led to a rise of regulations, all aimed at reducing risk and defining responsibility.

These needs have had a polarizing effect on the industry. Within large organizations, R&D departments struggle to innovate under the stifling influence of their own quality systems. Start-ups and spin-offs have taken on an increasingly important role as the source of innovation, while Fortune 500 multinationals provide the sheer bureaucratic horsepower to drive products through the regulatory quagmire and out onto the market.

Based on our experience supporting innovation processes in this environment, we believe a more enlightened approach to harmonizing innovation and control can reduce this polarization and provide significant benefits to any organization developing new medical devices.

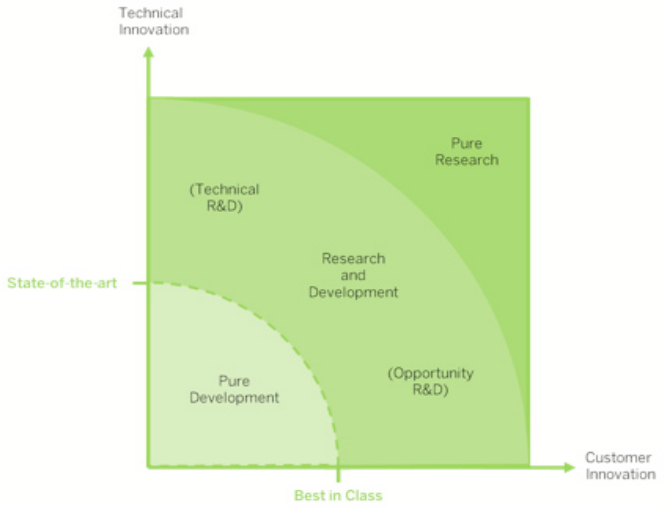
Innovation

"If we knew what it was we were doing, it would not be called research, would it?"
- Albert Einstein

Innovation is one of the most over-used words in business. Its true meaning is surprisingly simple: "the act or process of introducing new methods, ideas, or products." In common use, however, we expect an innovation to be not just new, but new and better – or at least, in our culture of ubiquitous reinvention, newer than usual. We can clarify this fuzzy definition by distinguishing between two categories of innovation: technical innovation (introduction of new technical enablers for a given customer benefit) and customer innovation (delivery of new customer benefits). Both are continuous variables that can be mapped to a matrix. (Diagram 1)

A project that uses less than state-of-the-art technology to deliver less than best-in-class customer benefit can be

DIAGRAM 1



considered a pure development project and does not represent an innovation – though that doesn't mean it's always easy. But more often than not, design projects mix elements of pure development with hardcore R&D. Managing this mix is a key challenge of innovation processes.

If we define an innovation as a product or service that delivers new customer benefits and/or improved technical solutions, we can define innovation processes as the set of activities that augment mainstream product development in order to deliver these innovations to the market. There are three main elements of innovation processes:

1. TECHNICAL R&D
Applied scientific research and advanced engineering help companies explore and extend the technologies that underlie their product portfolios. This is the core expertise of many medical device companies.

2. OPPORTUNITY R&D
Deliberate and structured R&D activities help companies identify and evaluate potential customer benefits. This level of research is often fragmented or altogether missing from R&D groups, as many companies look to market research alone to provide consumer insights. In fact, market research usually reveals only good and bad features of existing

solutions, yielding limited opportunity definitions such as "increase performance of function X" or "eliminate feature Y." To search for new opportunities requires opportunity research and development – a true mix of generative and evaluative activities.

3. CROSS-FERTILIZATION
One of the most powerful enablers of innovation is cross-fertilization between the different arms of R&D, mainstream product development, and marketing. This includes:

- Using opportunity R&D results to guide technical R&D; and vice versa
- Leveraging R&D output in running projects (and managing the risks of doing so)
- Identifying which aspects of a project require R&D activity, and applying the appropriate R&D resources in parallel to the mainstream development.

All of these processes can be stifled by excess rigor – good ideas are often weak in their earliest manifestations, and it's all too easy to kill them off before they reach maturity. Serendipity, inspiration, guesswork, vision, genius, passion, curiosity, intuition, instinct, and reflective contemplation: all these are essential ingredients of innovation that cannot be codified or completely controlled.

Control

Control is in many ways subtler and less easily defined than innovation. Its use in the case of medical devices is multifaceted and includes the following concepts:

- Mastery (to dominate, direct, or regulate; e.g. the brain controls the body)
- Verification (checking outcomes)
- Order, traceability, and rationality (being "in control")

The need for control in the medical device industry is self-evident. Patients put their lives in the hands of medical professionals, who in turn put their trust in the suppliers of devices. This chain of trust requires a corresponding chain of evidence that devices are safe and effective.

Over the years, the means for producing this evidence have become increasingly sophisticated. In the early days of product safety, a few units would be tested and, if found to be safe and effective, the medical device was approved. With the emergence of Total Quality Management (TQM) came an increased awareness of manufacturing variability, and Quality Systems were developed to prove that the devices produced over time were identical to those initially tested and approved. But in the late 1980s an analysis of product recalls showed that up to half were caused by design, rather than production. A new quality system requirement was codified in the Federal Register in 1996 (CFR title 21, part 820.30), establishing a mandatory Quality System covering the design process by which new medical devices are developed. This new requirement was called Design Control.

This is the point where control and innovation meet. A startling inferential leap has been made that by implementing more rigorous controls into the design process, device quality would be improved.

The regulation defines nine mandatory components of a Quality System for medical device design:

1. Design and Development Planning
2. Design Input
3. Design Output
4. Design Review
5. Design Verification
6. Design Validation
7. Design Transfer
8. Design Changes
9. Design History File

Some of these items are macroscopic activities (planning, verification, validation, transfer); others are work products (inputs, outputs, design history file) or transversal processes (design changes). As a whole, they are intended to constitute a toolkit for controlling design activities from conception to manufacturing.

Unfortunately, this set of control tools is often interpreted as a description of the design process itself, perhaps because of parallels with the waterfall model of design.

Design Control and the Waterfall Model

The idea of rigorously controlling the design process is not new. Since the 1970s, theorists from the camps of Systems Theory, Software Engineering, and Quality Assurance have proposed dozens of process diagrams, methodologies, and general theories of the design process. One process that has gained widespread traction, in spite of well-documented flaws, is the so-called "waterfall model."

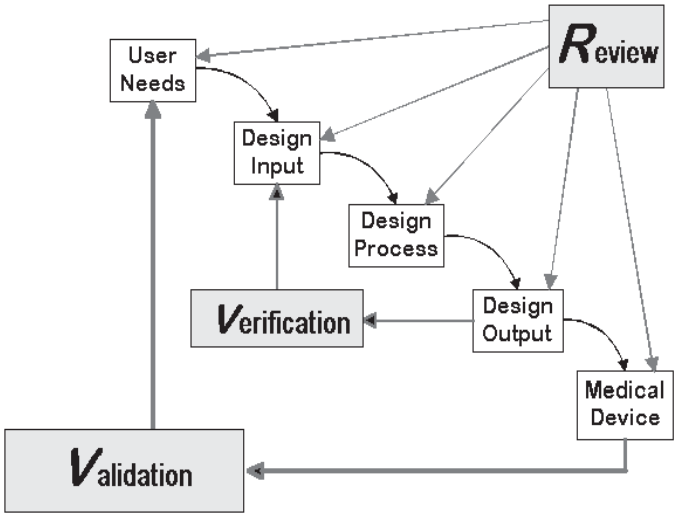
The waterfall model describes design in terms of a linear sequence of activities, in which each "output" is 100% determined by rational transformations of that phase's "input." A sequence of such phases forms an uninterrupted chain of cause and effect from the design problem to its solution. Most designers and engineers with experience of real-life projects consider the waterfall model to be, at best, a gross oversimplification – and, at worst, a dangerous misrepresentation.

The waterfall model is particularly weak for projects with high

innovation potential, because it requires formal approval of requirements which are complete and consistent before starting a given design activity. This is really possible only for incremental improvement projects. Systems that introduce new features need to be conceptualized, simulated, and tested – often before requirements can be defined. In the most innovative design process, basic assumptions are consistently reexamined, early decisions reversed. An innovative, effective design process must be one that allows for this change.

However, in spite of this weakness, the waterfall model remains highly attractive to management, promising as it does to transform design into a determinate activity, with clear progress checks and reliable outcomes. Perhaps for the same reasons, the waterfall model is explicitly referenced by the FDA when providing guidance for the application of design control, as shown in Diagram 2.

DIAGRAM 2



The supporting text goes on to advocate a strict and rigid application of the waterfall model, as typified here:

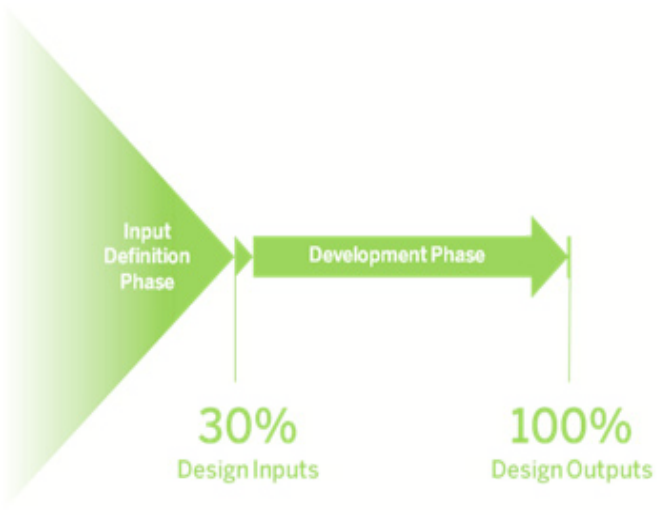
"A documented device specification or set of specifications derived from the input requirements should exist at the beginning of the physical design project. . . . The device specification will undergo changes and reviews as the device design evolves. However, one goal of market research and initial design reviews is to establish complete device requirements and specifications that will minimize subsequent changes."

Innovation and Control

Here is the crux of the problem: device companies must innovate to survive, but they are constrained to follow linear design processes that have been demonstrated to be unsuited for innovation. How can this be resolved?

Some important clues are evident in the structure of the FDA guidelines themselves. The guidelines place great emphasis on design inputs, recommending that up to 30% of the project duration be spent on input generation – yet the process for defining these inputs and the form they should take is left open to interpretation. Once these inputs have been defined, the FDA guidelines become highly detailed and prescriptive, in order to ensure that the design falls in line with these early discoveries. Thus, a simplified breakdown of this design process falls into two macro-phases, separated by the pivotal moment of design input definition, as visualized in Diagram 3. The name "design input" is somewhat misleading, occurring as it does midway through the design process.

DIAGRAM 3



INPUT DEFINITION PHASE

This phase may start with a single individual's visionary concept, with a deliberate investigation of new market or customer opportunities, or with the discovery of new technological solutions. Regardless, a new product idea emerges, and is immediately massaged, shadow-boxed, quantified, and qualified. This is the phase in which the iterative, non-linear, exploratory activities essential to innovation can be readily integrated without conflict with design control. It is important to understand that the goal of this phase is to select and define a solution, not merely to characterize a problem. Key principles for the input definition phase include:

Design, build, test

Although this phase may end with a set of documents, it should not be considered a "paperwork" phase. The sooner

ideas are put into the world through rapid prototyping, the better. This is especially important for all the experiential and behavioral aspects of a design, such as ergonomics, appearance, and interactive behavior.

Create a vision (not a shopping list)
The famous maxim "a camel is a horse designed by a committee" exemplifies the dangers of an overly granular, requirements-based approach (although this is somewhat unfair to the camel). A holistic vision of the final product is usually more valuable than a list of its characteristics.

Give it time
Many organizations try to rush the inputs phase by forcing decisions prematurely – an acceleration that inevitably drives forward only the most conservative choices. This tendency may stem from the perception that design inputs are the starting point for design – whereas we have seen that they are, in fact, a midpoint. The inputs definition phase should be used to build confidence in innovative solutions and to explore multiple (and sometimes contradictory) scenarios – before making final decisions about product requirements.

Multi-lens view
No single way of looking at a device is the right one. Top-down, bottom-up, outside-in, inside-out; user scenarios, task analyses, block diagrams, drawings, models, and simulations; each provides a unique and valuable perspective on the problems and solutions under investigation.

Trust your gut
There are dozens of techniques which claim to "objectively" build requirements by establishing priorities of individual product attributes. These can be useful for incremental improvement projects, but will never lead to real innovation. An expert designer, engineer, or product manager can often instinctively sense the right solution without being able to fully justify it right off the bat – and while instinct is not infallible, it is often a more reliable early guide than evaluation matrices and QFD tables.

Use your A-team
The input definition phase requires a team that is small, focused, expert, experienced, multidisciplinary, passionate, creative, and empowered to make decisions. If a team meeting these characteristics cannot be assembled internally, external resources should be brought in to help.

DESIGN INPUT DOCUMENTATION
The design inputs are defined when the threads of R&D activity converge into a clear vision of the product. This is often the point of entry for additional internal and external teams into the project, so the form that these design inputs take is critical for successful transfer of the design intent. The objective is to share, in the clearest possible way, the end-goal of the development process – without being over-prescriptive.

Share the vision
A brief high-level description of the product (purpose, user, context, key value proposition, market and technology drivers) should always accompany product requirements, at every level. Everyone who works on a piece of the development needs to understand the big picture to which they are contributing. This seems obvious – but we often read 100-page requirements specs that don't explain how a product is used or why it's needed.

Pictures are better than words
Design inputs inform the developers what they are building. This can often be achieved more effectively and efficiently with a single annotated diagram, picture, or photograph than with tens of pages of written requirements. The software engineering and systems engineering communities have begun to recognize this, as evidenced by the UML and SysML initiatives, which aim to provide a standardized graphical modeling language for system design. Although some written requirements are needed, connecting them to a visual representation can remove much ambiguity from the process. Think of the diagrams in an instruction manual – the simpler, the better. (The objection is sometimes raised that written requirements define criteria for acceptance or success, while diagrams and pictures define solutions. This is nonsense – all requirements are based on assumptions about the solution or category of solutions under consideration. It is usually more useful to specify exactly the preferred solution than to hint at it obliquely through artificially abstracted requirements.)

Just enough
The FDA requires that design inputs be complete and consistent – this does not mean long, repetitive, and minutely detailed. Inputs should be sufficient to convey design intent: no more, no less. This simplicity helps to ensure that they are read and understood, reduces the likelihood of internal inconsistencies, and provides opportunity for alternative design implementations and updates.

Explain why
The premises on which design inputs are based may change or be proved false during later phases of development. Documenting these premises together with the design inputs will help ensure the inputs are updated appropriately.

DEVELOPMENT PHASE
According to the waterfall model, this phase is a cascade of logical consequences from input to output. If that were true, there would be no room for innovation in this phase. In

reality, a single set of design inputs could lead to an infinite range of final solutions (of varying quality), depending on decisions made during this later phase. The FDA establishes the design review as a guidance mechanism, together with verification and validation of the final device. A number of additional strategies can help promote excellence and guide the project between these formal milestones:

Keep the vision alive
As the product evolves in its detailed implementation, it is easy to lose sight of the big picture. The team should always have some physical artifact – a diagram, picture, model, or simulation – that they can glance at and say, "That's what we're designing."

Pre-Validate
Validation means checking if the product actually meets the real-world need for which it was created (as opposed to verification, which checks if design outputs correspond to design inputs). Full validation is only possible when production-equivalent prototypes are available – but pre-validation of individual design aspects can be performed earlier and help guide the project direction. For example, the need for a readable display may be codified in a certain text size and contrast level in design input documentation – but pre-validation of the selected display with end-users in the use environment may reveal that although the codified requirement is met, the real-world need is not.

Be agile
Each day spent developing the device according to misguided inputs is a day thrown away – and it is impossible to define perfect design inputs. It is therefore essential to have frequent participation from decision-makers throughout the development process, a mental readiness to challenge starting assumptions, and the ability to rapidly update design inputs and disseminate them to the entire team.

Summary

This paper proposes a number of organizational strategies aimed at encouraging innovation within the context of a regulated design process, focused on:

- Germination and growth of innovative ideas in the inputs definition phase
- Effective transfer of innovation through design input documentation
- Continuous innovation throughout the development phase

It is our hope that the adoption of these best practices can improve the success rate with which medical device innovations make it to market. Over time, we believe that Quality Assurance departments and regulatory bodies will become more sensitive to the need for innovation. Perhaps it is not too much to ask that future releases of FDA and ISO guidelines for device developers will temper their zeal for a state-of-control with a recognition that the disruptive power of human creativity is essential to manage the complexity of our age.