Innovating Inside the Box

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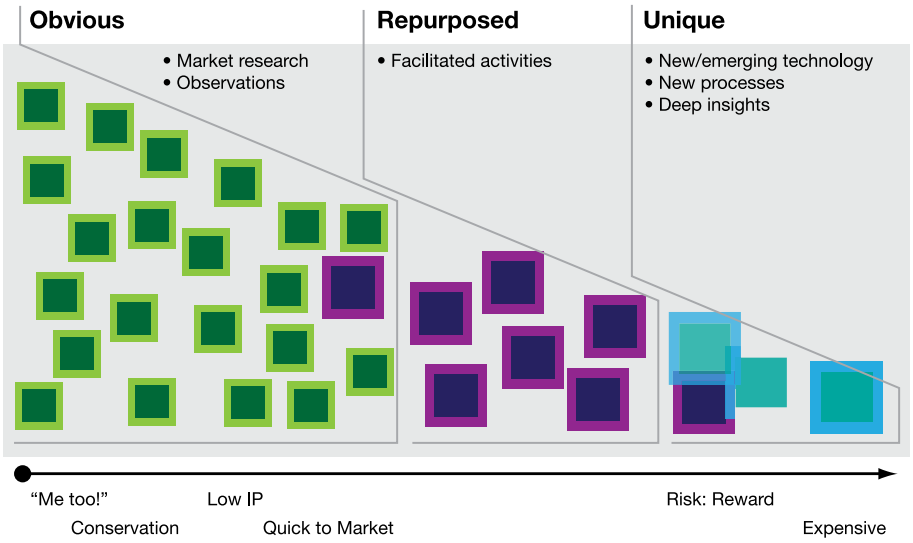
The shift away from incremental innovation is leading manufacturers to look toward more focused and targeted approaches to developing their next generation of devices.

Technical innovation is a core process to ensure rapid exploration and identification of solutions to complex innovation requirements. A departure from brainstorming, (notorious for being amusing but often fruitless), highly prescriptive methods like TRIZ, (which tend to be narrow, time-consuming, and open to misinterpretation), technical innovation, which is employed by Ximedica, ensures the creation of truly differentiated products.

Successful product development starts with shifting the construct around concept generation: moving from trying to capture everything outside the box to focusing on the core ideas inside the box. Technical innovation is the heart of product development and product success. What many device innovators want, but often fall short of, is to reach innovation and design goals at the very earliest point in product development; to be able to conceive, evaluate, and pick technical solutions very early allows much of the remaining development process to be executional and streamlined.

Defining the box is a tool to support technical innovation. Trying to be all things to all people will no longer work in today's product development environment. While it will always be critical to come up with new and fresh ideas that extend beyond the obvious, a more refined approach is taking hold. This more focused strategy that involves thinking inside the box requires a very early collaboration—at the beginning of the thought.



Effective brainstorming requires a large number of concepts to move beyond the obvious (list of 100).

The overarching value to Ximedica's technical innovation is that it brings process and direction to innovation, ensuring the creation of truly differentiated products, not me-too products. It also mitigates the risk of use error and prevents development program timelines from being derailed. This is key in today's product development landscape as large device manufacturers such as Johnson & Johnson have recently shifted more toward disruptive innovation and away from incremental design and development.[1] In general, companies are looking toward diversifying their innovation portfolio, and thus hitting the mark early on is critical. But this process is not solely designed for early ideation—there is utility to this process in the post launch phases as a means of remedying user concerns, addressing issues that may arise on the assembly line, and for securing intellectual property.

Not only does technical innovation bring a product's evolution along swiftly but it also has tremendous value to stakeholders both internally for the design firm and externally on the client side. Internally, it accelerates the immersion process, and thus quickly develops a deep "bullpen" of concept seeds for the team to draw from. It prevents any tendency to spend time on ideas that simply are not viable. At the same time, it focuses not only the core team, but enables the team to draw upon unique insights and expertise from individuals outside the core team by involving them in this initial ideation step.

Externally, the benefits are equally rewarding. With the client involved at this very early idea formation, the clients become champions for concepts in which they have ownership. Not only does it draw the clients into the process at the earliest stage of the program, it also exposes them to team members outside the core team as they all participate in brainstorming, refining, and cross-fertilizing of the ideas that arise from the session.

Predefining the Box

Technical innovation provides context, parameters, and stimulus. Up-front research and activity enables the team to dive in with relevant ideas right at the start. A critical element to having a meaningful innovation, or ideation, session is having done thorough preparation to identify, research, and define the correct topics for the product being developed. Doing so will enable the team to create concepts that are appropriate and unique. This is an exercise in generating ideas—not giving answers—and allowing those ideas to be creatively followed through by the group. The box is defined by the prior research going into the session. Research analysis and assessment of potential ideas is conducted before any activities among cohorts. Predefining the box allows development to be more precise, leading to viable ideas that are ready for prototyping.

As a design team, it is essential to know not just what you're doing but also why you're doing it, and to start from the seeds of innovation. It is the application of these tools that is ultimately critical to transforming healthcare.

An often-used example of the difference between *out of the box* and *inside the box* thinking is a little exercise that goes as follows: Ask someone to write down all the objects that they can think of that are white in a minute. Then ask them to write as many objects than they can that are in a refrigerator, the box. The outcome is that the constrained brainstorm produces more ideas. Further when the constraints are tight to the specific technical issue or innovation need the results are more relevant to the final solution. Pick the constraints well, build the stimulus well, and the outputs will be much stronger. With a focused approach, the process takes on much more relevance as the ideas are the stimulus provided and the ideas are thus in context. What it means to think inside the box is to have done the kind of thorough prep work required to allow for this targeted thinking to occur. Providing context increases productivity.

Why do we need to rethink innovation in this way? Not because we are trying to distill it, but rather to ensure that innovation is quickly followed by implementation. Early technical ideation is a huge differentiator among development firms; it is important to find a partner that does go beyond being great at ideation. There must be a credible path to implementation, and we know that the road is littered with innovations that either were irrelevant to the market need or unrealistic to implement. A partner needs to innovate with a mind toward developing a product that is commercially successful.

Chances are your first concept is not original. Shifting the paradigm requires dedication and a robust process.

The Sum of Its Parts

It has been said that a whole equals the sum of its parts. This philosophy can be applied to ideation; that is, a design team can come up with those critical features that will be compiled into systems solutions. There are four stages of ideation that bring the final product into focus:

- Define the problem. Hit the hard stuff first and understand the client's objectives.
- Establish parameters that provide the context.
- Convey evaluation criteria to all team members—both core and noncore.
- State the desired output so that the team has direction and focus.

Team leaders can provide tools to ensure that innovation sessions are as effective as possible. As mentioned earlier, it is essential that the team leader build in enough planning and preparation time. The more complex the product, the more research needs to be done to ensure that the resulting idea leads to a successful product and doesn't become just a me-too product. After collecting sufficient information, the team leader needs to review these primer materials with the team.

Even with lots of research, though, without the right stimulus, the exercise could fall flat. This is where it is incumbent on the team leader to bring in appropriate items to jump start the team's creative juices. These might include analogous products, new objects, magazines and catalogs, sample materials, or other items discovered during research.

Team composition is also critical. It should be a no-brainer, but be sure to have a mix of both men and women from across a variety of disciplines—research, human factors and industrial design, regulatory, engineering and manufacturing, marketing, and others who can bring some unique perspective. And you want to have a good contingency from the client because they are closest to the vision of their company and hold much embedded knowledge. You want a core team that will see the product through the entire development process, but you also want others on the team who come in for just this step. It may be useful to have a particular expert on hand, whether it is a physician or a nurse or someone with a specialty such as robotics.

The environment should be comfortable, with a mix of types of seating—soft couches, tables and chairs, and so on—so that depending on the type of discussion, the team has an appropriate work space. Multiple areas are essential so that the team can break up into smaller, more intimate groups. To ensure that the team stays focused, it is equally important to have all of the supplies and tools that they might need. You don't want to have one team member have to leave for supplies or equipment and then miss out on a critical debate or discussion. The right supplies can include markers, pads, post-it notes, white boards, bulletin boards, or other supplies and equipment to foster creativity. Depending on the product under development, be sure to have enough anatomical references to be accurate with any drawings and proposals.

And never underestimate the need for food, snacks, and drinks. You want the team to feel energized at all times, and this will keep them from having to stop the innovative process or to leave the room mid idea for food or drink. However, you do want to build in breaks to avoid brain drain, and you don't want anyone to feel "stuck" in the room. Deciding how much time to devote to the exercise can depend on the product and its complexity. However, a day and a half is generally sufficient to accomplish your goal.

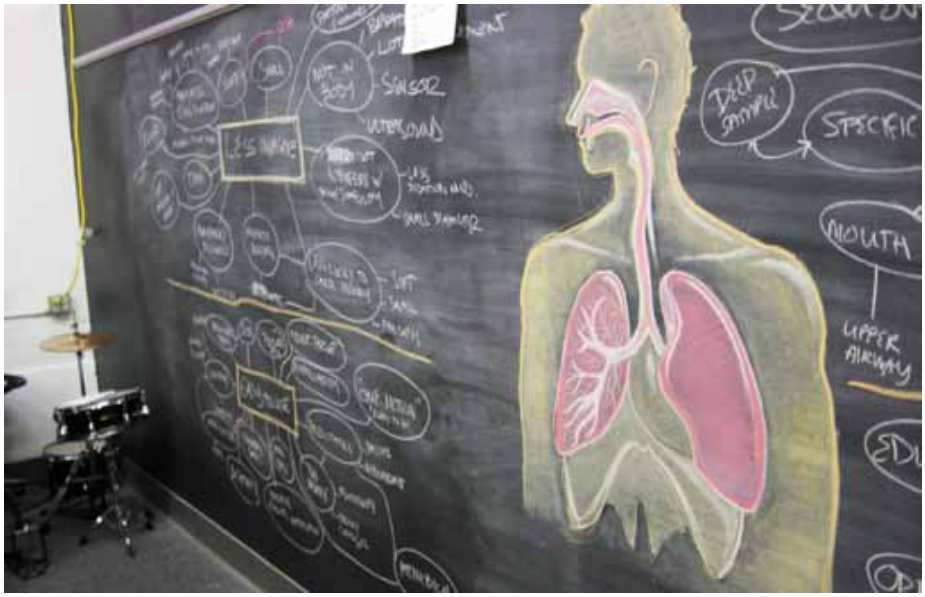
To achieve such innovation, it is important to resist the urge to grab everything that sticks to the wall "just in case."

Inputs are the key to an effective process; prior research work whether primary or secondary will uncover core findings that can then be used to fuel the individual sessions. These can include competitive analysis, technology scouting, patent analysis, analogous products, biomimicry, and many more. Considering how an insect would execute a similar task may sound strange initially, but the results are often surprising and valuable. The inputs are intended to ensure that a great question has been asked such that a great answer is generated.

Innovation sessions themselves have several key components that must be totally separated; the creation of numerous ideas, the consolidation of concepts into nascent solutions, and the evaluation of those solutions against agreed criteria. Once again, picking criteria thoughtfully is a critical part of the activity as the commercialization activity needs to be initiated even at this early stage. It is also important to understand that a 'winner' in the evaluation process does not indicate a binary decision but rather the weighing of priorities.

The biggest bang of such a strategy is that it puts the company in control of when and how innovation happens and enables the innovation to take hold early. When using an innovation partner, this strategy relies on collaboration and thrives on involvement from the client at every step. It is essential to focus resources in such a way that the company maximizes potential gain: it is a balance of time, money, and risk. It is designed to produce an ideal prototype that is as close to finished device as possible in those early phases.

All of these activities around technical innovation set the stage for multifaceted development. With the resulting concepts, the team can hand it off to prototyping. The key to maximizing innovation at these very early stages is to explore a wide range of potential solutions and measure them against business risk, development risk, and user risk very early on.



Ximedica's concept generation sessions take place in a purpose built environment packed with stimulus and structered activities.

The Prototype

In technical innovation, the prototype is a representation of a product, functional subassembly, or element. Once the design team is focused on the elements critical to the product, the design process begins, and it is here that the prototype allows the designer to mitigate use error, facilitate use testing, and calibrate expectations, and more. But it also promotes great questions from the team and provides an avenue for identifying issues early. The prototype is the perfect time for robust feedback. The result? Generating excitement among the team, saving development costs, reducing time to market, and thus ensuring market success. All of this is possible because prototyping aligns expectations with engineering's vision.

Prototyping must be accomplished in the first three phases—phase 0, phase 1, and phase 2—of a typical phase gate product development process (see Figure 1). Phase 0 addresses research, product strategy, and concept generation. Phase 1 focuses on concept development, requirements, and development. Phase 2 is dedicated to design development. It is during these three phases that the team brings in all of its research, begins to innovate, refines the concept, and executes the detailed development into a prototype.

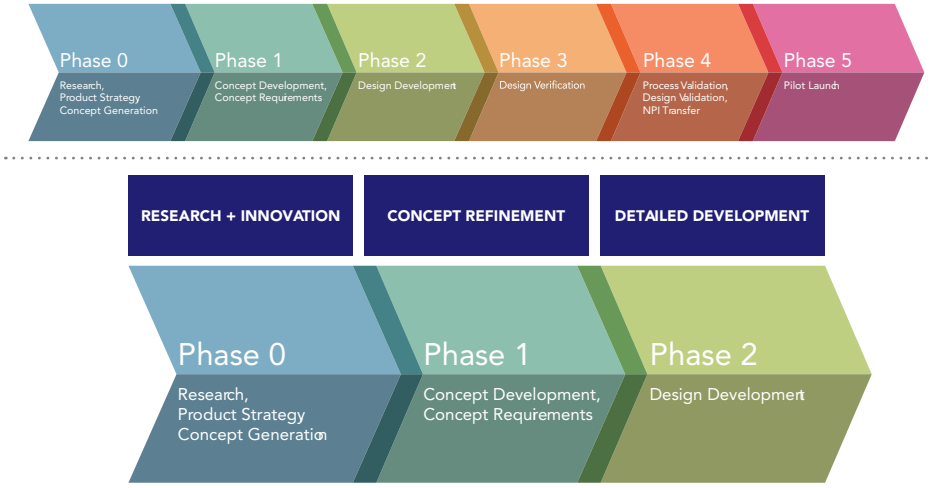


Figure 1. Phase gate product development process.

The first step is to break down the problem. This process requires isolating systems and features into manageable problem sizes. And, as unlikely as it seems, it is important to hit the hard stuff early. By doing so, it enables you to identify the highest risk items and minimize the chance that these issues will come up later in the product development process when the only option is to scrap it and start over.

Once the problem is fully understood, then it is time to begin putting concepts into reality. This is where you sketch and build concepts for the team to review—to touch and feel and analyze as they compare them with the ideas generated earlier.

Multifaceted development enables the team to get as much feedback as possible. Execute activities in parallel to establish a solid foundation for the product. Such activities include architectural layout, breadboard experiments, anthropometric studies, and form studies. It is essential to remember not to try to solve too much at once. Isolate the technical challenges and address them according to their importance to the design, manufacturability, cost, and risk to the end user.

An architectural layout enables you to explore the layout and orientation of major components and assemblies. With this activity, you can minimize failure modes (separate electrical and fluidic systems), select the user interface, inform form study, identify cabling needs, minimize electromagnetic interference issues, address the center of gravity, examine airflow, and hone in on costs. Limit your variables, and freeze as much as you can with this exercise.

The breadboard experiment is the moment of truth. Never underestimate the value of making something work. Get into the shop and use the device. Sketch models allow the team and client to provide early feedback at a stage in the program where it is much more efficient to support changes.

Keep the team focused on the desired end results. Some items to consider include the following:

- Speed should take precedence over appearance.
- Focus on core functionality while considering long-term embodiments.
- Leverage existing designs and technologies.

Anthropometric studies measure man and woman. Prototypes and/ or measurement instruments should be developed to quantify size, fit, or configuration of a product within the intended demographic. Throughout the process, ask yourself: Have you designed for the user? More importantly, can you prove it?

Compress timelines by executing technical and form development activities in parallel. This "divide and conquer" approach gives you one model that provides what the product works like and another that provides a fairly good facsimile of what it will look like. The prototype-driven specifications evolve into specification-driven prototypes. The "works-like" model offers the opportunity to examine functional prototypes to demonstrate feasibility. Valuable information comes out of every build. The "looks-like" model, on the other hand, demonstrates the form factor and branding of the intended product without the function(s) of the final product.

Innovative solutions are often discovered through questions that no one has asked. Voice-of-the-customer data allow you to develop product specs based on your understanding of needs and environments. These data provide decisive identification of relevant insights that lead to unique innovation. This is also the stage at which technological opportunities are guided by both the user and market requirements. Testing performance is critical, because without data, any information you present is just an opinion. During the testing phase, you will determine operational ranges. It is imperative to document all testing. Remember: if it isn't documented, then it didn't happen. This is particularly true when it comes to submitting data for regulatory approval.

Again the essential part of the process is to evaluate your success criteria. At this point, you want to ensure that you have a defensible, analytical approach to concept 'down selection'. Review form, structure, performance, cost, development risk, etc and make sure that you can justify your decisions.

Don't settle for one idea—yet. Multiple concept configurations help avoid serial iterations that can wreak havoc on schedules and budgets. Multiple concepts pursued in parallel provide for contingency and offer an opportunity for identifying and securing intellectual property (IP) protection.

With all of this completed, the prototype demonstrates to the greatest practical extent the materials and functionality of the final design. Human-use prototypes focus on what they do more than what they say. Now it's time for some studies to put the prototype to the test. Whatever the key requirements are would then be tested against prior to bringing it under a formal development process. In other words, "wring out" the concepts so that development is largely executional. The costliest and most disruptive activity that you can take in device development is still being in research when your timeline says you are in development.

Time, Money, Risk

Focused technical innovation ensures the creation of truly differentiated products. Medical device OEMs are looking for a more refined approach to getting relevant innovation more quickly and efficiently to market and to revenue. Success requires a strategy of thinking inside the box, very early collaboration, and providing the right context, parameters, and stimulus to get to those new and fresh solutions.

References

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Providence | Minneapolis / St. Paul | Hong Kong

55 Dupont Drive, Providence, RI 02907 | T: 401.330.3163 | F: 401.626.3356 | www.ximedica.com