1. Phase 1 – Proof of Concept

During this phase we will focus primarily on the product idea itself and the work of defining requirements, target markets and other key metrics for your product and business. The main tool for driving and recording this process is the Product Requirements Specification document.

1.1. Product Requirement Specification (PRS)

Product requirements can be anything from physical weight and size dimensions to electrical performance characteristics and safety standards and regulations you want your product to meet. At this stage, there are no bad ideas or questions, and everything should be evaluated and discussed to determine the best path forward.

Once the PRS is in place we can start to brainstorm different product concepts that meet your product requirements. This process can build off an existing prototype or patent you have or can be made from scratch.

Next, we will mock-up some 3D designs of the chosen concepts for visualization. In parallel, we will start research and testing of critical electronic modules and circuits needed to meet your product requirements and features. Following this period, we are ready to produce a Generation X1 Experimental Prototype.

1.2. Experimental Prototype

The purpose of the experimental prototype (or prototypes depending on how many concepts you are evaluating) is to gain confidence that the proposed design concept, consisting of its mechanisms, materials, components, modules and circuitry, can meet the defined product requirements. Depending on the simplicity of the product, this prototype could closely resemble your intended final product, but will be made from rapid prototyping processes such as 3D printing/additive manufacturing and machining.

More complex designs may include custom made electronics (i.e., circuit board assemblies) to test out the required electrical features and characteristics. This may also be evaluated on a breadboard to mitigate the cost and time required to manufacture quick turn, low volume, circuit board assemblies.

1.3. Prototype Evaluation and Design Modification

Experimental generation prototypes will very rarely 100% match their intended product requirements. This is an expected and useful result since it will identify where the design is lacking so we can formulate improvements and modifications to better the product. After testing and evaluation, we will determine if the scope of change is too significant to move forward to the next phase of design and development in which case, we will need to stay in Phase 1, tweak the design and make another batch of prototypes. In most cases, the necessary design modifications were either anticipated or are

so minimal in scope that we can safely proceed to Phase 1 Design Review and implement the changes in Design Refinement during Phase 2.

1.4. Software Firm Evaluation and Proposal

If your product will utilize a smartphone application, work on the cloud or requires a sophisticated algorithm or artificial intelligence, then now is the time where we will jointly identify software groups capable of meeting your product requirements. We will solicit bids from these sources and choose one to move forward with in establishing your products Software Requirements Specification (SRS).

1.5. Regulatory Pathway

Early on in the process we will work with third party test labs such as Underwriters Laboratory (UL) and Intertek, to outline your product safety and qualification testing requirements. For medical products, we will work with you and your regulatory team to identify your premarket regulatory pathway to ensure our design process mitigates all risk, to the furthest extent possible.

When realized too late, regulatory hurdles can result in significant re-designs and duplication of work. These issues can cost substantial sums of money and can wreak havoc on your go to market timeline.

1.6. Phase 1 Design Review

Design review is a process that will be repeated throughout the design and development of your product. The purpose is to compile all the deliverables of the phase and review them with the customer for adequacy. This process is a gate to the next phase and cannot proceed without the customer's written approval. This process will be documented in meeting minutes and will follow a Design Review Checklist which includes a summary of the phase deliverables.

Typical deliverables at this stage include; Product Requirement Specification (PRS), Risk Management Plan (RMP), Quality Management Plan (QMP), Design Failure Mode & Effects Analysis (DFMEA), Project Plan, Prototype Evaluation Report (including results of testing), Preliminary Bill-of-Materials (BOM), Regulatory Pathway Report, Software Requirement Specification (SRS), Software Proposal, Preliminary Electrical Computer Aided Design (ECAD) files, Preliminary Mechanical Computer Aided Design (MCAD) files, Preliminary Firmware files, physical Experimental Prototypes along with other raw materials, modules, parts and components relevant to the design.

2. Phase 2 – Prototype

2.1. Design Refinement

This critical step in the process will focus on finalizing your product design by building on the successes of the experimental prototype and addressing the weak points. This will ensure your product is ready for robust validation testing designed to simulate real world use and to verify we are achieving key performance metrics.

The outputs of this stage lay the foundation of your Design History File (DHF) and Device Master Record (DMR). These reservoirs of information are critical elements in passing third party qualification testing and regulatory approvals, along with ensuring each product is repeatable and reliable once we reach production.

2.2. Preliminary BOM Costing

With design modifications out of the way, we should start to have a clearer picture of your product Bill-of-Materials (BOM). With this, we can start sourcing for pricing based on anticipated production volumes as well as identifying alternate or equivalent components which can help to avoid inventory related delays in your product production launch.

It may also be a good idea to begin securing volatile components to ensure you can go to market when you are ready. The electronic component industry in particular, is extremely scarce at times and the lead-times can be several months to one year, for common chips and modules.

It is understood that any material purchased in volume at this stage is "at-risk" to becoming obsolete by design modification or a change in requirements. More often than not though, it is a safe bet to buy these parts early rather than wishing you had, when it comes time to launch production.

2.3. Design Verification Protocol & Report (DVP&R)

Every product requires a Validation Master Plan (VMP) which establishes the scope and timing of validation and verification (V&V) activities. Each internal V&V activity will require a Design Verification Protocol & Report (DVP&R) formulated around your product requirements and performance targets, which have been established throughout the design process. These protocols will require customer review and approval before commencement of testing and the results of will be summarized in a final report, which is also review and approved, in writing, by the customer.

2.4. Prototype Build and Design Verification Testing

This build should utilize production components, whenever possible, including circuit board assemblies, machined components, sheet metal components and final firmware and software (as needed). One exception to this rule is the use of components that require significant capital tooling investment, such as injection molded parts. In these instances, these parts will typically be made by an additive manufacturing process, such as 3D printing.

The assembly process should be recorded throughout (i.e., pictures, videos, notes, flow charts, etc.) to allow for future generation of work instructions and travelers or routing cards. Any critical processes should be identified as such on the Process Failure Mode & Effects Analysis (PFMEA) so risk appropriate mitigations can be planned.

Each prototype device will be subjected to the required design verification testing based on the VMP. All test results will be recorded in the appropriate DVP&R document(s) and each prototype will have its own Device History Record (DHR) upon completion of testing.

2.5. Prototype Evaluation and Design Modification

The prototype results will be evaluated on their performance and ability to meet product requirements. Satisfactory designs will go through another minor update to incorporate necessary improvements and modifications before moving on to Phase 3. Any product design found to be deficient, will require significant modifications and may need additional prototyping and design verification testing.

2.6. Product Manufacturing Quotation

At this point in the development process, we are far enough along to provide a Product Manufacturing Quotation. This Statement of Work (SOW) will outline our proposed selling price to you based on estimated production volume pricing of direct materials, labor, indirect labor and overhead and profit. The SOW will also include cost estimates for capital tooling and special equipment (as needed) for the production process.

2.7. Phase 2 Design Review

Successful completion of Phase 2 is a significant goal of the design and development process. This milestone signifies that we have a product which meets our internal product requirements and now we are ready to take it to the laboratory's product safety and performance qualification testing.

Typical deliverables at this stage include; updated Product Requirement Specification (PRS), updated Risk Management Plan (RMP), updated Quality Management Plan (QMP), updated Design Failure Mode & Effects Analysis (DFMEA), Process Failure Mode & Effects Analysis (PFMEA), updated Project Plan, Prototype Evaluation Report (including results of testing) document, updated Bill-of-Materials (BOM), updated Software Requirement Specification (SRS) document, Software Architecture, Software Verification Protocols (SVP), Updated Electrical Computer Aided Design (ECAD) files, Updated Mechanical Computer Aided Design (MCAD) files, Updated Firmware files, Validation Master Plan (VMP), Design Verification Protocol & Reports (DVP&R), physical Prototype(s), Product Safety & Qualification Testing Quote, and a Product Manufacturing Quotation (w/tooling estimate).

3. Phase 3 – Pilot/Design Freeze

3.1. Design Freeze

All design CAD files (electrical and mechanical), specification sheets, drawings, BOMs as well as all firmware and software should be in a state in which it is approved and appropriately validated as production ready. These files are part of your Device Master Record (DMR) which is the blueprint to produce your product.

3.2. Tooling Production

If your product utilizes injection molded plastics then now is when we would kick off production of the tooling. This typically starts with a Design for Manufacturing (DFM) phase in which the supplier thoroughly reviews production files for any weak points or deficiencies in the moldability of the part design. During this phase, we will also be approving and finalizing cosmetic features such as the finish and location of gate marks and parting lines.

Once DFM is out of the way, the supplier will begin production of the tool(s) and will submit a T1 sample for customer verification before proceeding. The T1 sample parts are typically molded in the intended final material but the color may be a simple black or white, depending on what the supplier has available. The T1 sample may also be lacking in the final production cosmetic finishing since this is applied at the end of the tooling process. The main point of the T1 sample is to check that the dimensions and overall part are within specification of your drawings and CAD data.

If the part requires changes then the supplier will implement accordingly and resample (T2, T3, etc.). Unless the issue is a defect or error from the supplier, there will be limitations to what changes can be achieved without incurring additional cost or having to restart the tool altogether.

The typical tooling process for an injection molded plastic takes 10 - 12 weeks or longer. For this reason, there are generally discussions about doing the tool "at-risk to design changes" before the end of Phase 2. This can save some months in the timeline since most Product and Safety Qualification testing will require your product to be in its intended production material. This testing is usually one of the final gates to launching production, so some companies opt to start the tool early, in order to try not delay their Pilot Build.

3.3. Supply Chain and Cost of Goods Sold (COGS) Review

Now that tooling is underway, we will begin to buy for the pilot build and to requote (as needed) and source for inventory of critical components and all other parts. If there are any major pricing changes, we will share them with you for review and approval and update the Product Manufacturing Quotation (as needed). It is also a good time to start buying inventory of critical or hard to find components to support your production launch.

3.4. Design Verification Protocol & Report (DVP&R)

More testing means more paperwork! The good news here is this batch of protocols will help to verify that your product design meets its requirements and is safe and suitable for market. These DVP&R documents must be reviewed and approved before commencement of testing.

3.5. Pilot Build

This pilot production batch should be made from suppliers and components which are equal to the ones we intended to use in production. This build should also follow written assembly procedures and

utilize production routers and test data sheets. Each device produced in the Pilot Build should have its own Device History Record (DHR).

3.6. Design Verification & Validation Testing

This process is typically the last major internal testing required for your product. All the results should be recorded on the appropriate DVP&R and a final report should be written and submitted to the customer for review and approval.

The different steps and criteria of this testing will form the baseline of your production testing requirements. There are many features and dimensions that we will verify in design that are not required for inspection in production. Going through all this testing helps us to identify the critical to quality (CTQ) characteristics of your product so we can create appropriate production test requirements and procedures that find a balance between quality and cost.

3.7. Packaging & Labeling Design

Depending on your intended markets and distribution channels, your product may need different forms of packaging. From primary and retail packaging to secondary containers and palletized goods, we will make sure your product looks great and reaches its destination intact.

No product is complete without a serial nameplate label. We can provide solutions to meet every need and environment and we'll work with you to establish the content of your labeling, including safety and warning symbols required by law. We will also work with you on your instructions for use (IFU) content and the look and feel of your labeling and marketing inserts.

3.8. Product Safety Testing (outside laboratory)

The majority of electronic products will require some form of basic safety and electrical performance testing along with some more narrowly scoped standards for the specific technologies utilized in your product. This testing is conducted by Nationally Recognized Test Laboratories (NRTLs) and should be done using production or production equivalent devices.

Completion of this major milestone tells your customers that your product is safe and effective and you should now be ready to begin selling your product through various distribution channels and countries.

3.9. Clinical Evaluation

For medical devices, now is the time that you can begin your clinical evaluation in order to show your product is safe, effective and meets its intended purpose. Typically, we will build another batch of devices for the study and distribute them to your sites according to your guidance. Square 1 can provide guidance and support on this matter, but you will have to engage a third party early in the development process to assist in your clinical trial.

3.10. Design Review

It's been a long, difficult and rewarding road and your product is now ready for production. One more phase to solidify the launch and you will be ready to shift into auto-pilot.

Typical deliverables at this stage include; updated Product Requirement Specification (PRS), updated Risk Management Plan (RMP), updated Quality Management Plan (QMP), updated Design Failure Mode & Effects Analysis (DFMEA), updated Process Failure Mode & Effects Analysis (PFMEA), updated Project Plan, updated Bill-of-Materials (BOM), updated Software Requirement Specification (SRS), updated Software Architecture, updated Software Verification Protocols (SVP), Updated Electrical Computer Aided Design (ECAD) files, Updated Mechanical Computer Aided Design (MCAD) files, Updated Firmware files, updated Validation Master Plan (VMP), updated Design Verification Protocol & Reports (DVP&R), physical Pilot Prototype(s), Product Safety & Qualification Test results and final report, updated Product Manufacturing Quotation and Clinical Evaluation documentation.

4. Phase 4 – Manufacturing Transfer

4.1. Production Planning and Buy

Your product will have a Manufacturing Plan that will guide us in setting up your production line, determining resources needed and recording important information such as cycle times and critical processes, among others. This living document survives the entire life cycle of your product.

Any materials not already secured in phase 3 (or earlier) will be procured at this time. This initial buy will establish our standard costs for materials moving forward.

4.2. Special Tools and Equipment Qualification

Special Tools, such as test fixtures and jigs, must be designed and manufactured according to their purpose. These Special Tools, along with other equipment as needed for production, will be added to the Calibration Database to ensure they remain in good working condition.

4.3. Finalize Work Instructions and Other DMR Documentation

Building off the preliminary work instructions established before the Pilot Build, we will create detailed work instructions and production documents such as; work routers, test data sheets, inspection plans, etc. When appropriate, assembly and test procedures should include detailed pictures for ease of use.

4.4. Release DHF & DMR Documentation

All Device Master Record (DMR) documentation must be released and controlled before transfer to manufacturing. This process requires customer review and approval, and future changes must be initiated through an Engineering Change Order (ECO) request from either party (Square 1 or customer).

4.5. Manufacturing Process Verification Protocol

The Manufacturing Process Verification (MPV) will follow the Manufacturing Flowchart established in the Manufacturing Plan. All steps and documentation used during this process should be accounted for in the MPV. This protocol will require customer review and approval prior to commencement of the build.

4.6. Manufacturing Process Verification Build & Test

This initial production build will be in batch sizes intended to mimic typical production. This work should be performed by production personnel who have been previously trained to the work instructions and test procedures. Successful completion of this build and test lets us know we have a stable process which is repeatable and reliable.

4.7. Regulatory Submission and Notified Body Certification

For medical devices, we can begin the regulatory submission process, which is different depending on your device and markets. With successful completion of internal verification testing, lab testing and a completed clinical evaluation, we should have the required data to clear any regulatory hurdles. Square 1 can provide guidance and support on this matter, but you will have to engage a third party early in the development process to assist in your regulatory submissions and notified body certification.

4.8. Design Review

All the hard work has paid off and your product is officially ready to enter production! In this new phase, the challenges will be different, but the knowledge gained from the market and your customers will be critical in improving your existing product and launching you next one.

Typical deliverables at this stage include; Released Product Requirement Specification (PRS), Released Risk Management Plan (RMP), Released Quality Management Plan (QMP), Released Design Failure Mode & Effects Analysis (DFMEA), Released Process Failure Mode & Effects Analysis (PFMEA), Released Bill-of-Materials (BOM), Released Software Requirement Specification (SRS), Released Software Architecture, Released Software Verification Protocols (SVP), Final Electrical Computer Aided Design (ECAD) files, Final Mechanical Computer Aided Design (MCAD) files, Final Firmware files, Released Validation Master Plan (VMP), Released Design Verification Protocol & Reports (DVP&R), Released Manufacturing Plan, Released DMR Documentation, physical Special Tools/equipment and physical production units.

5. Document History Tracking (DHT)

Revision	Description of Changes	CN#	Date
A	Initial release	N/A	01/14/2023