

COBEAL

Design, Engineering,
Manufacturing Guide



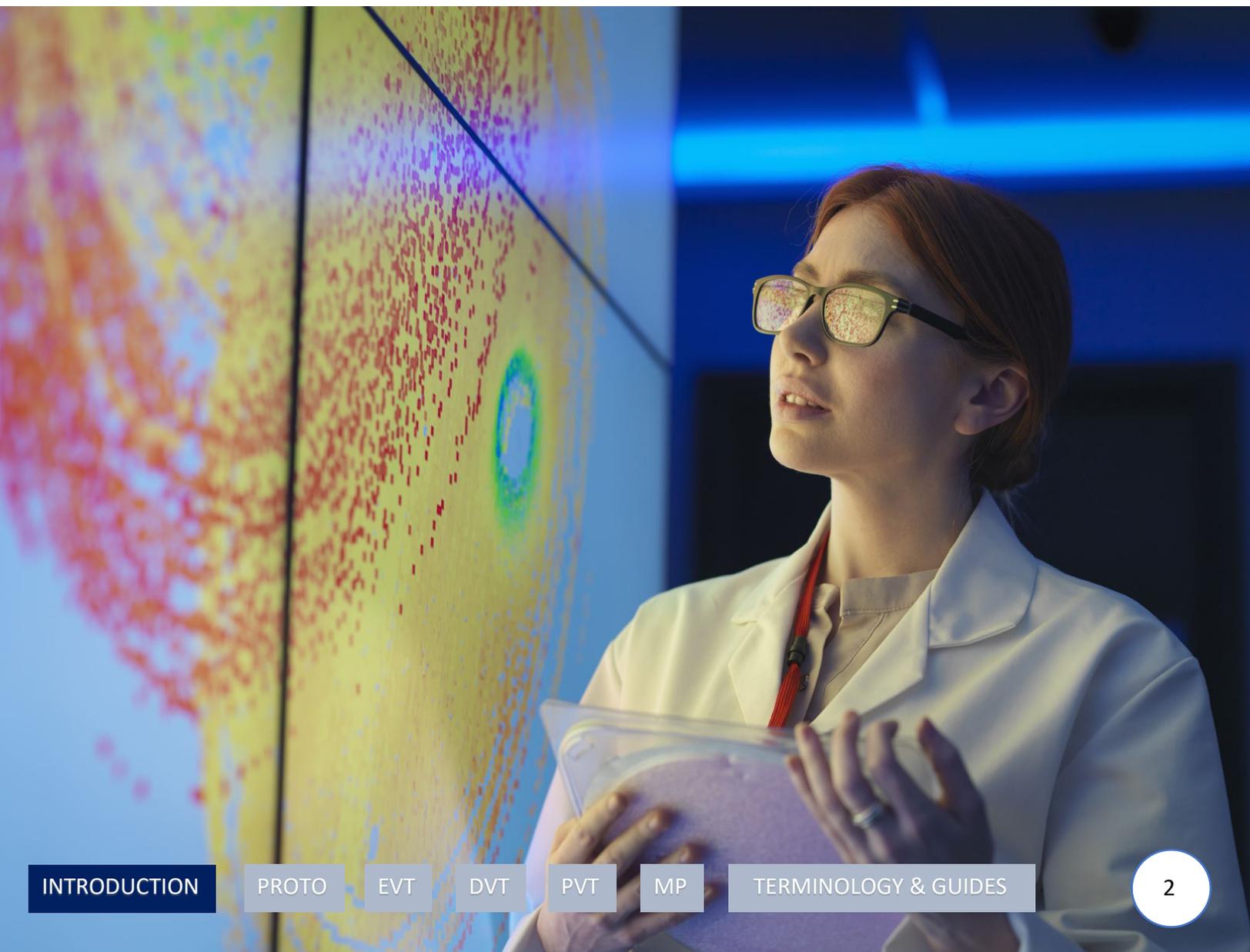
Cobeal's software engineers write code, but our hardware engineers speak it. EVT, DVT, PVT, MP; OK, NG, FA, CA; PD, EPM, OPM; PRD, DRP, BOM. Different companies may use slightly different nomenclature, but the basic concepts are the same: a manufacturer builds prototypes of the design multiple times to finalize the mass production ready design.

Nevertheless, there are differences in understanding across industries on what EVT and DVT product maturity means.

This Guide Features:

- **Definitions** of common acronyms
- **Workflows** and example processes
- **Terminology** for key concepts
- **Guides** that provide perspective

Cobeal has put together this guide to explain the builds, timelines, and common problem areas that engineers work through to bring your product to mass production.



This is the first prototype build where a small test run of key product concepts are built to gain confidence that they work. Form factors include looks-like and works-like.

Purpose: to examine any risks in the design prior to release to EVT phase. This could include things as simple as which adhesives or seals work best.

- Fragility of cover-glass in drop test with different adhesives, done on dummy housing bucks
- Waterproofness of five different seal designs

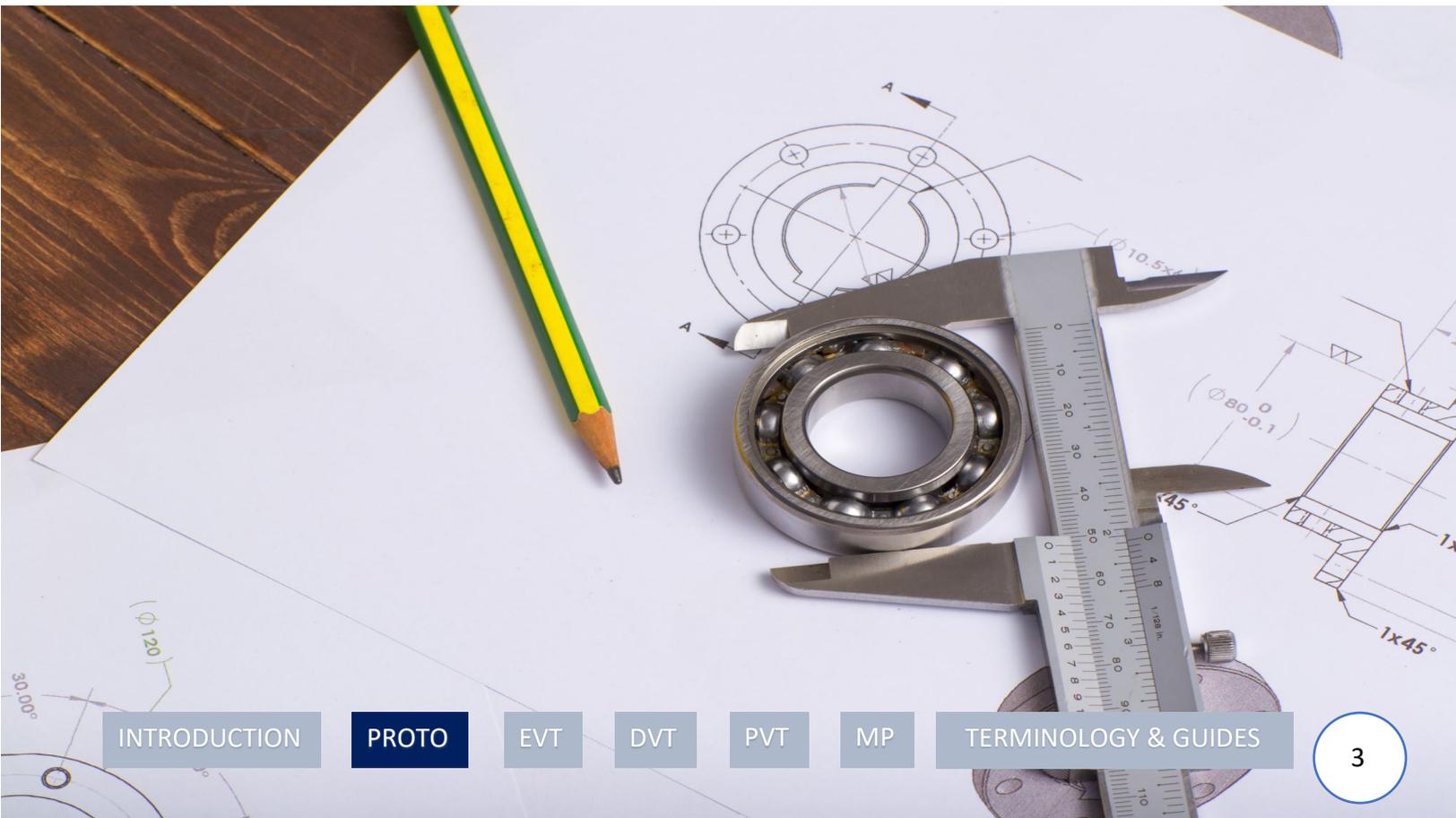
Typical Quantities: 10 or fewer, sometimes no “full systems” are built

Typical Challenges:

- Parts may be “stand-ins” or rapidly prototyped parts that function for the test.
- Opportunity to correct dimensions that do not correctly interface from design to build.
- If necessary, new CAD (3D models) are built so that parts are not modified by hand.

Exit Criteria:

- Design concept for the product that the team has reasonable confidence is three major iterations or less from a mass-production worthy design.



THE EVT build is when special technical parameters and criteria to combine looks-like and works-like are brought into one form, with production intent materials and defined manufacturing processes. A build matrix of options is completed to select desired production intent design.

Purpose: to identify any issues that need to be fixed in the design.

- Units must be fully functional, testable, and made from intended materials and with the intended manufacturing process but may be constructed from soft tools. No rapid prototype or 3D parts allowed.
- Refined controls are built for production.

Typical Quantities: It is common to produce 100 to 1000 samples during this phase.

Typical Challenges:

- If during this phase a new revision of the intended design does not meet rigid reliability testing, tighter than expected (or capable) tolerances may be needed to meet performance specifications.
- Fine tuning to get processes, hand-soldering, environmental seals, and other complex steps are engineered.

Exit Criteria:

- 3rd party verified, production-worthy configuration that meets all product requirements for functionality, performance, and reliability.

THE DVT build results in the approved production-worthy configuration, made from production components and hard tools (processes) and on a line that follows production procedures identified in EVT.

Purpose: to evaluate the production-worthy design in relation to cost, to ensure the design can be fully mass-produced. This is the real test for whether DVT has been achieved.

- If there are running side configurations of 20 units or more, this is not a DVT phase. It is an EVT2.
- Verify mass production yields with one production worthy design (one configuration for each SKU).
- Qualifies the first hard tool for each part in the assembly. The parts are formed from hard tools or mass production capable processes.
- All functional test stations are present with limited identified to understand true yields.

Typical Quantities: It is common to produce 300 to 2000 samples during this phase.

Typical Challenges:

- This is a phase of fast failure analysis (if applicable) with associated corrective actions.
- Cosmetic yields are low to 0% - cosmetic part suppliers may be shipping scratched parts, which must be rejected or returned, or utilized and modified according to pre-specified allowances while the supplier issue is corrected for the next build.
- Generally, there are one or two key processes that are still not fully automated or under tight control.
- Project management team works intensely with vendors for support, provides relevant updates to hardware team, and notifies Project Leaders for input.

Exit Criteria:

- High level of confidence that all corrective actions have been taken on pre-production issues that are defined as unacceptable, yields that do not meet production goals, or new defects in production parts caused by the implementation of new mass production (hard) tools.

THE PVT build is the last build prior to mass production. These units are sold to customers. These units are the first delivery units. They must PASS all test stations. PVT is the last step prior to Ramp Up and Mass production.

Purpose: to identify mass production yields at mass production speeds.

- Any additional tools needed to support quantities are validated.
- No parallel experimental units are allowed.
- The build phase is three-fold:
 - **RED:** New production process, operator observations for training, line speed and line yield defined.
 - **YELLOW:** Semi-mature production process, operator training, line speed and line yield in accordance with controls prepared for implementation.
 - **GREEN:** Mature production process, operator training ongoing, line speed, line yield in accordance with tight controls.

Typical Quantities: It is common to produce 1k to 20k units during this phase.

Typical Challenges:

- “There’s always one in the bunch,” as the saying goes. Meaning, there’s always one vendor whose yields are lower than expected, and because of this reason, delivery dates, quantities promised, or quantities that do not meet strict QA in-take approvals during the receiving/inspection stage may cause delays. These fall outside the scope of Cobeal’s control and are treated as issues to be solved. Policies governing corrective actions are followed.
- Commercial/Residential dehumidifiers have a higher cosmetic standard than industrial units. The process of getting the cosmetic yield to 0% can take weeks and hundreds or thousands of units. Cobeal uses instrumental systems to streamline and significantly accelerate solving any such typical new product production challenge.

Exit Criteria:

- Mass production yields at mass production speeds on at least one line. Replication to other lines is occurring simultaneously.

The Ramp Up and MP phases is when parallel assembly lines are brought up to mass production speeds to increase daily output volume. MP is a superset of Ramp Up. This phase continues to improve ongoing yield.

Purpose: to identify mass production yields at mass production speeds.

- Additional tools and vendors are identified and implemented.
- Design changes may be made depending on product returns, early field failure analysis (EFFA), or cost down efforts.
- Quality assurance parameters and training increases during this phase.
- Engineering has already finished work on the line.

Typical Quantities: It is common to produce 1k to 20k units during this phase.

Typical Challenges:

- At any time, vendors can change processing parameters or take down tools for maintenance, resulting in dimensional or quality shifts that can cause line failures. Parts from unqualified tools can cause failures. For these reasons a single-sourced part is the supply gate, and critical to managing and improving ongoing yield goals and issues.
- All phases in the design/build process are driven by the need to iterate hardware to get the design right. This need can come into conflicts with the market, i.e., the need to ship additional inventory by Christmas. The tension between the iteration process and the market-driven schedule can affect the development process.

Exit Criteria:

- This phase is ongoing supervision and controls.

- **CCB (Change Control Board):** In software development, a Change Control Board is a committee that consists of Subject Matter Experts (SME, e.g., software engineers, testing experts) and Managers (e.g., QA Manager, Project Manager), who decide whether to implement proposed changes to a project. The main objective of a CCB is to ensure the client accepts the project. Factors affecting a CCB's decision can include the project's phase of development, budget, schedule, and quality goals. The CCB will review any proposed changes from the original baseline requirements that were agreed upon with the client. If any change is agreed upon by the committee, the change is communicated to the project team and the client, and the requirement is baselined with the change. Decisions reached by the CCB are often accepted as final and binding.
- **Component:** A product which requires integration with other components or products such that integrated tests are required to ensure compatibility and conformance to system specifications.
- **Design Review:** A documented, comprehensive, and systematic examination of a design to evaluate its capacity to fulfil the requirements for quality, identify problems, if any, and propose solutions.
- **Design Verification Test:** A test performed to ensure the design stage output meets the design stage input requirements.
- **Design Validation Test:** A test that confirms the final manufactured product and/or service is capable of meeting particular requirements, under defined operating conditions, expected by the intended customer. It is preceded by a successful design verification.
- **General Sale Product:** A product that satisfies one or more of the following: 1) capable of being ordered by many customers through a catalog or data sheets without the assistance of a sales engineer; 2) offered in a limited number of predetermined configurations; 3) offered to a broad customer base as opposed to a single customer.
- **OEM Product:** An OEM product is an Engineering Change Order (ECO) released and is developed for either a specific market, application, or customer requirement. These products are typically designed to meet performance specifications for a particular use pattern.
- **Pass-Through Product:** Products either designed in-house or through a selected vendor.
- **Sales Release:** An authorization by management that allows the sale of a new product.
- **Ship Release:** The authorization to deliver product purchased by a customer.
- **System:** A product requiring integration of general sale products, purchased items, software, components and/or custom manufactured parts. Verification through a defined system test protocol of integrated components or products is required to ensure satisfactory compatibility and conformance to specifications.
- **Special Item:** A custom end item product, not ECO released, developed for a specific customer in limited quantities.
- **Value Engineering:** A process of modifying an existing product or service to provide cost savings, increase features, or better customer value through improved product performance.



PLANNING PHASE GUIDE

Product Title	
Product Description	
Project Manager	

Objective: To develop an initial project plan
 Inputs: A draft product plan
 Outputs: A complete product plan, initial quality plan, initial project plan, initial manufacturing plan

Design

✓ To	✓ Done	
		Create detailed performance specifications
		Assess technology risks
		Determine regulatory/standards impact on design
		Define user interface requirements
		Define needed accessories
		Assess patent position
		Other:

Operations

✓ To	✓ Done	
		Write a manufacturing plan draft
		Write a materials plan draft
		Identify manufacturing resources, e.g. manpower, equipment, budget, facilities
		Identify testing requirements
		Identify packaging, storage, shipping requirements
		Identify special processes and associated risks
		Create a manufacturing pilot build schedule
		Other:

Marketing/Sales

✓ To	✓ Done	
		Update draft product plan
		Other:



PLANNING PHASE GUIDE, cont.

Product Title		
Product Description		
Project Manager		
Quality		
<input type="checkbox"/>	To	<input type="checkbox"/> Done
		Write quality plan draft
		Define which standards apply and interpret requirements, e.g. safety, emissions,
		Identify reliability tests to be done
		Determine any calibration requirements
		Identify need for inspection capability studies
		Identify production or receiving inspection QC needs
		Other:
Finance		
<input type="checkbox"/>	To	<input type="checkbox"/> Done
		Do a financial analysis
		Determine return on investment/Net present value
		Project cash flow
		Perform a sensitivity analysis
		Other:
Service		
<input type="checkbox"/>	To	<input type="checkbox"/> Done
		Plan post sales support both in-house and field
		Identify special inventory plans
		Identify service resources, e.g. manpower, equipment, budget, facilities
		Identify obsolete product spares inventory
		Provide testability requirements into design
		Other:
Project Manager		
<input type="checkbox"/>	To	<input type="checkbox"/> Done
		Review draft product plan
		Establish key project measures, e.g. project budget, ROI/NPV, development time
		Develop an overall project plan
		Review draft quality plan
		Review draft manufacturing plan
		Other:



DESIGN PHASE GUIDE

Product Title		
Product Description		
Project Manager		
Objective: To design a product that meets product plan specifications		
Inputs: A complete product plan		
Outputs: Pilot released ECO, design review minutes, test report		
Design		
✓ To	✓ Done	
		Design the product
		Build engineering prototypes
		Prepare engineering documentation
		Confirm prototype performance meets product plan requirements
		Assist in supplier development
		Other:
Operations		
✓ To	✓ Done	
		Refine manufacturing plan
		Provide inputs to the design regarding manufacturability and testability requirements
		Identify critical parts and processes, e.g. single source parts, advanced materials
		Schedule pilot run
		Assist with supplier selection and qualification
		Assist with initial product structure
		Order long lead items considering associated risks
		Other:
Marketing/Sales		
✓ To	✓ Done	
		Outline sales and distribution plan
		Manage products out for beta site testing
		Initiate writing user's manual
		Other:



DESIGN PHASE GUIDE, cont.

Product Title		
Product Description		
Project Manager		
Quality		
✓ <u>To</u>	✓ <u>Done</u>	
		Refine quality plan and identify resources
		Participate in critical supplier qualification
		Perform reliability tests on critical components
		Input to the design standards requirements, e.g. safety, emission, immunity, CDRH
		Other:
Finance		
✓ <u>To</u>	✓ <u>Done</u>	
		Collect elements for cost roll-up
		Other:
Service		
✓ <u>To</u>	✓ <u>Done</u>	
		Develop service strategy
		Other:
Project Manager		
✓ <u>To</u>	✓ <u>Done</u>	
		Disseminate beta site customer feedback
		Review preliminary manufacturing plan
		Conduct Design Reviews
		Allocate pilot units
		Provide impacts as a result of product plan changes
		Other:



GUIDES



PILOT PHASE GUIDE

Product Title		
Product Description		
Project Manager		
Objective: To prove the product can be manufactured to product plan specifications		
Inputs: Pilot released ECO, design review minutes, test report		
Outputs: Production assembly and test procedures, 1 st article inspection reports, marketing and sales aides as needed, product costs entered into Database.		
Design		
✓ To	✓ Done	
		Incorporate hardware changes generated by operations, quality, suppliers, etc.
		Incorporate software/firmware changes generated by operations, quality, etc.
		Support operations in assembly, testing, purchasing
		Assist quality in completion of regulatory documentation
		Review and approve user manual
		Other:
Operations		
✓ To	✓ Done	
		Build pilot run
		Finalize tooling, test fixtures and processes
		Complete MRP
		Finalize PAPs and PTPs
		Perform statistical Process Capability Study
		Provide manufacturing feedback issues to design engineering
		Establish product lead times
		Record 1st product shipment for patent/trademark protection
		Hold un-allocated pilot-built product till sales release sign off and disposition
		Other:
Marketing/Sales		
✓ To	✓ Done	
		Perform training for sales
		Perform training for application engineers
		Coordinate production of advertising sales literature
		Review and approve user manual
		Other:



PILOT PHASE GUIDE, cont.

Product Title		
Product Description		
Project Manager		
Quality		
<input type="checkbox"/> <u>To</u>	<input type="checkbox"/> <u>Done</u>	
		Coordinate the completion of the Design Verification Testing portion of the quality plan
		Begin Design Validation Testing
		Coordinate the implementation of corrective and preventive actions from problems found
		Complete Receiving Inspection tooling needs
		Complete preliminary Receiving Inspection procedures
		Complete First Article Inspections
		Review and approve PAP and PTP
		Complete transportation and storage environment tests
		Complete reliability tests on product
		Review and approve user manual
		Complete regulatory tests, e.g. CE, EPA, FDA
		Submit product and test reports to regulatory agencies
		Other:
Finance		
<input type="checkbox"/> <u>To</u>	<input type="checkbox"/> <u>Done</u>	
		Review project budget
		Other:
Service		
<input type="checkbox"/> <u>To</u>	<input type="checkbox"/> <u>Done</u>	
		Generate spare parts list and forecast
		Train service personnel
		Create documentation for telephone service
		Build test equipment for servicing functions
		Other:
Project Manager		
<input type="checkbox"/> <u>To</u>	<input type="checkbox"/> <u>Done</u>	
		Assess product test and analysis results
		Implement corrective actions if any
		Update project plan as needed
		Control requirement changes
		Verify hardware orders are placed
		Review shipping container design
		Review and approve PAP and PTP
		Setup and conduct Sales Release sign off meeting
		Other:

TYPICAL PRODUCT DEVELOPMENT ROADMAP

Planning Phase:

- Assign Project manager
- Provide Draft Product Plan or product requirements to Project Manager
- Form project team
- Review and complete Product Plan
- Generate and sign initial Quality Plan
- Generate initial Manufacturing Plan
- Develop initial Project Plan

Design Phase:

- Preliminary Design
 - Generate preliminary drawings or concept models
 - Generate preliminary software or firmware code
 - Perform preliminary design reviews
- Design Iteration(s)
 - Incorporate changes from critical design review
 - Repeat applicable portions of Detail Design
- ECO Release
 - Incorporate changes into detail drawings
 - Update Product Plan
 - Update Quality Plan
 - Generate ECO release package & submit to CCB (Change Control Board).
 - Enter data into Database (Item Master, BOM, etc.)

Pilot Phase:

- Create data sheet
- Set up database and order hardware
- Design tooling and/or test fixtures
- Write test, assembly and quality procedures as required
- Manufacturing builds designated number of pilot units
- Validate operator instructions (manual, sheet, etc.)
- Complete Quality Plan DVT
- Approve for Sales Release
- Incorporate into pilot units: mandatory corrections
- Disposition Pilot units
- Approve for Ship Release
- Archive relevant project records

Note: All steps and actions identified within this guide may not be appropriate for a given project.