OCCAM DESIGN

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The Development Step Process for Your New Products

How OCCAM DESIGN Can Help You: Occam Design, a contract medical device developer, takes experience in ideation, prototyping, design engineering, regulatory guidance, and manufacturing to develop and deploy your product to the marketplace. This brochure summarizes how *OCCAM DESIGN* can integrate with your marketing and financial resources to develop a product in an orderly set of steps.

Occam Design deliverable Values:

- *Quality*
- *Accountability*
- *Innovation*

The Step Process: The development of new products requires the medical device developer to follow an orderly and coordinated set of steps to avoid costly mistakes. Industry experience has demonstrated that it can cost three to ten times more to correct oversights than should have been accomplished in a preceding step. This document summarizes these steps, which have become accepted as an efficient development process and part of our quality processes. Their descriptions emphasize each step's engineering, regulatory, and manufacturing roles. Remember that your marketing and financial divisions require similar parallel efforts.

Your Product's Documentation Record: To pass regulatory approval and be manufacturable, your product's documentation record must be complete. *OCCAM DESIGN* follows industry good manufacturing practices (i.e., FDA GMP Guidelines) and the delivered documentation package (what we call the "bible") includes a Design History File and Master Device Record listing all documents and their revision identity. Unless specified otherwise by the client, *OCCAM DESIGN* employs its industry-compliant manufacturing number and configuration control procedures for your Medical Device design. Documentation is married to your product development, and we take care of it for you.

Step One: ***IT IS ALL ABOUT THE SCOPE***

Development Steps:

1. Scope
    - A. Initial Meeting
    - B. Feasibility/ concept
    - C. Specification
2. Lab Prototype
3. Production Prototype
4. Pilot Production
5. Production

Step One-A: INITIAL MEETING:
A preliminary step with a new client accesses the capabilities we can provide and establishes responsibility lines. OCCAM DESIGN can often draw upon its years of experience to offer the client novel approaches to your idea that substantially bolster the original product concepts. A meeting is held, and general product marketing and engineering issues are reviewed. A preliminary study (consultation) of available components and techniques is usually done to establish the magnitude of effort required for the new project.

Step Deliverable: An email consultation report of findings, recommendations, and an invitation for Occam to hold the next step meeting.

Step One-B: CONCEPT & FEASIBILITY STEP:
A meeting to discuss the overall concept and if the concept is feasible concerning the market and product purpose. Once a concept is defined, the client and Occam Design jointly determine the market and technical feasibility of that concept. The new client may interview potential customers, and Occam Design may model-specific high-risk subsystems to assure technical feasibility. Sometimes, an "alpha" prototype may be detailed to verify cost, size, and technical feasibility. The scope of the project is well understood.

Step Deliverable: A preliminary study report is created and presented to the client, which typically includes product sketches and vital preliminary specifications**. An estimate for the work is also provided at this step**. If the new client agrees, the next step meeting is scheduled.

Step One-C: **SPECIFICATIONS DEFINED** Once the concept and technical feasibility are defined, a detailed working specification is created. Clients should consider regulatory and manufacturing strategies in more detail. If work requires the prototype from this stage, the agreed pricing includes the cost or can be separate.

Step deliverable: A functional device specification lists applicable regulatory standards, controls/firmware personality behavior, and required environmental, electrical, electronic, and mechanical parameters.

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Step Two: LAB PROTOTYPE STEP:
A project team meeting is held with *OCCAM DESIGN* and the client to refine product specifications and define regulatory requirements (IEC, FCC, FDA, U/L, etc.) Design of all subsystems, computer code, or software begins. A preliminary Risk Analysis for your medical product may also occur. Specific subsystems are modeled, and, in some cases, a working crude prototype or "brass-board" may be made, which, to the extent practical, duplicates the intended product (minimal valuable product MVP). Usually, there is minimal or no expenditure for tooling (PWBs, cabinet molds, labeling), but it occurs later in the development. The project documentation record may entail greater detail to lend to the Design History File (DHF), and regulatory control parameters may be set.

Step Two Deliverable: Preliminary documentation for circuit schematics, computer source code, and a crude working model are usually presented. A more detailed product specification is provided, along with a summary report and an estimate for the following work step.

REASSESSMENT IS KEY!
Sometimes after the "Lab Prototype", the Feasibility/ Concept and the Specification steps (Step One-B and Step One-C) are necessary to repeat to secure funding and proceed to producing the complete Prototype.

Step Three: PRODUCTION PROTOTYPE STEP: (up to five tooled prototypes)
The project team is expanded to include a manufacturing associate. A more detailed product specification is created. Funding is typically acquired and specified for a short product run (2 to 5). Tooling costs include PWBs, metal CNC machine setups, molds, or artwork. Design review meetings are held to review all designs before funding commitments. Except for some items (e.g., labels, packaging), full product documentation is created, such as bills-of-materials (BOM), Risk Analysis, mechanical drawings, PWB artworks, metal and mold drawings, panel graphics, and the like. The User Manual or Instructions For Use (IFU) document parameters are discussed. Materials are procured under the design team's control, and a small quantity of products is built with the manufacturing associate. These "production prototypes" are used for regulatory testing, sales photographs, early customer evaluation, and engineering debugging. If regulatory agency testing determines that changes are required, *OCCAM DESIGN* will support these requests as compliance testing progresses.

Step Three Deliverable: A preliminary manufacturing document including BOM, drawings, and the working (DHF), a small number of working demonstration products, and initiation of regulatory testing reports. An estimate for completion of the next step is also provided.

Step Four: PILOT PRODUCTION STEP: (Begin sellable products)
The project becomes a production with a meeting where specifications are updated, final vendors are selected, and engineering completes design tasks (labels, shipping cartons, test procedures, assembly guidelines, tooling, test sets). It cooperates with manufacturing to train personnel and assist in assembling and testing the first products to be sold. Engineering and manufacturing debug the processes and complete the detailed document package. At the end of this step, engineering signs off to release DHR documents for traditional manufacturing. After such a point, it only provides incidental support to the manufacturing for design modifications known as Engineering Change Notices (ECNs), and engineering expenses essentially stop at this step.

Step Four Deliverable: In addition to the complete DHR, a defined quantity of products suitable for early sales. The Device Master Record (DMR) is finalized, which tabulates all documents defining the product and their revision numbers.

Step Five: PRODUCTION STEP: (batches of the product are scheduled)
Manufacturing personnel is fully trained. All product documentation (hardware, embedded code, application software, manuals, etc.) is under rigid change control procedures (DCO, ECN, ECO, and allotted). Products can be released for quantity build as defined by the client's marketing forecasts. Manufacturing is typically done on a batch basis. *OCCAM DESIGN* engineering personnel are available as needed to manufacturers as component substitution issues arise. Often, a manufacturing agreement is reached with Occam Design to continue the client's manufacturing needs.