Phase Gate Controls Design & Development Process

0 Concept & Feasibility

- Feasibility Evaluations: Appropriate Technologies
- Proof of Principle Design & Test
- Market Studies
- Decision to Proceed: Product & Project Planning
- Preliminary Risk Control Mitigation: Business & Systems
- Preliminary Critical Requirements Evaluation

1 Planning & Requirements

- Design & Development Planning
- Product Development Quality Plan
- System Architecture Development
- Product Requirements Development
- Initial System Risk Analysis
- User Interface Development

2 Design

- Architectural Design Development
- Subsystem Design Development
- Industrial Design Model Development
- Prototype V&V Plan Development
- Detailed System Risk Analysis Development
- Initial Costed Bill of Materials Development

3 Prototype

- Prototype Component Procurement
- Complete Software Coding
- Engineering Prototypes & Subsystem Integration
- Module & System-Level Verification Tests
- Initial Agency Safety Testing
- Preliminary Verification Report Generation

4 Design Transfer & Mfg Process Validation

- Manufacturing Quality Plan Development
- Production Materials & Fixtures Procurement
- Production Line Set-Up & Assembly Procedures
- Design Transfer Finalization & Review
- Final V&V Testing & Reporting with System Risk Traceability
- Conduct IQ/OQ/PQ

5 Saleable Production

- Production Builds under Configuration Control
- Formal Change Controls for All Designs & Processes
- Mfg Process Optimization, Supply Chain Planning
- Lean Flow Manufacturing Method Application
- DHF Updates, with System Risk Analysis
- Mfg Quality Plan Update Adding Service Capability

6 Production Scale-Up

- Service Center & Delivery Spares Establishment
- Full Production Capability Scale-Up
- DHF Updates, with System Risk Analysis
- Continuous Process Improvement
- RMA & Service Authority Monitoring for Improvements
- Standard Cost Verification

creation TECHNOLOGIES