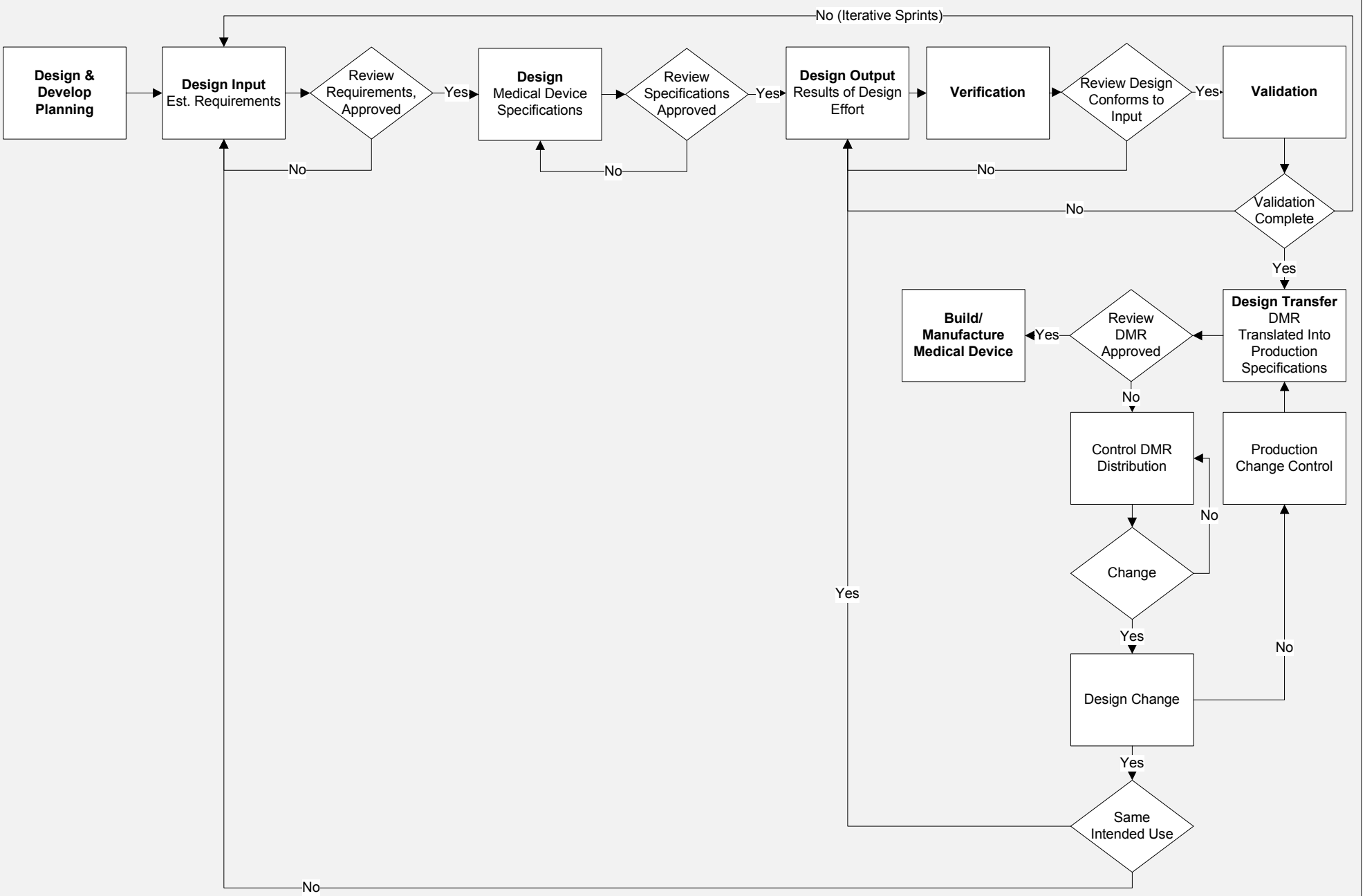
Design Control Process

INTEGRATED RISK MANAGEMENT



Design Control Input / Output Process Map

Design & Develop Planning	Design Input	Design	Design Output	Design Review	Verification	Validation	Design Transfer	Design Changes
Output - Approved Design & Dev Plan	**Output** -Approved Device Requirements	**Outputs** -Approved Design Specifications	**Outputs** -Basis for Medical Device Record (DMR), the device, packaging, labeling	**Outputs** -Follow Design Review Program -Evaluated design, resolve concerns, implemented corrective actions -Document results in DHF	**Outputs** -Approved, successful Verification -Document results in DHF	**Outputs** -Approved, Verified conformance of design output with designed input -Document results in DHF	**Outputs** -Approved, Validated devices conform to defined user needs & intended uses -Build/Manufacture Device -Document results in DHF	**Outputs** -Approved changes -Integrate changes -Document results in DHF
Inputs -Designed and developed goals & objectives -"what is to be developed" -Defined organizational R/R -Identified major tasks & owners and timelines, Critical Path, allocations, constraints -Identified major reviews & decision points -Selected/identified reviewers, team composition, review procedures -Defined controls for design documentation -Defined communication & notification activities	**Inputs** -Approved Design Plan -Identified physical, functional, performance, safety, interface requirements NOTE: Input requirements should specify what the design is intended to do not the solution -Developed rapid prototype to explore feasibility (if needed)	**Inputs** -Approved Device Requirements -Translated requirements into design	**Inputs** -Approved design specs -Developed production specifications as well as descriptive materials which define and characterize the design. For example: •assembly drawings •component and material specifications •production and process specifications •software machine code (e.g., diskette or master EPROM) •work instructions •quality assurance specifications and procedures •installation and servicing procedures •packaging and labeling specifications, including methods and processes used •the results of risk analysis •software source code •results of verification activities •biocompatibility test results •bioburden test results	**Inputs** -Conducted systematic assessment of design results, including the device design and the associated designs for production and support processes -Provided feedback to designers on existing or emerging problems -AssessEd project progress -Provided confirmation that the project is ready to move on to the next stage of development -Assessed **internal focus** - on the feasibility of the design and the produceability of the design with respect to manufacturing and support capabilities. -Assessed **external focus** - on the user requirements; that is, the device design is viewed from the perspective of the user	**Inputs** -Conducted Q/A check at each stage. Determined whether the output conforms to requirements for that stage. -Verified using 3-prong verification activity approach: tests, inspections, analyses. For example: •Worst case analysis of an assembly to verify that components are derated properly and not subject to overstress during handling and use. •Thermal analysis of an assembly to assure that internal or surface temperatures do not exceed specified limits. •Fault tree analysis of a process or design. •Failure modes and effects analysis. •Package integrity tests. •Biocompatibility testing of materials. •Bioburden testing of products to be sterilized. •Comparison of a design to a previous product having an established history of successful use.	**Inputs** -Validated design conforms with user needs and intended use(s), given expected variations in components, materials, manufacturing processes, and the use environment -Validated label and packaging -Conducted simulation tests of the expected environmental conditions -Validated device meets needs of all relevant parties/ users	**Inputs** -The design & development procedures should include a qualitative assessment of the completeness and adequacy of the production specifications. -The procedures should ensure that all documents and articles which constitute the production specifications are reviewed and approved. -The procedures should ensure that only approved specifications are used to manufacture production devices.	**Inputs** - Initiated change request -Assessed impact -Approved, or rejected change -Issued Change Order -Communicated changes -Updated change control log

Sample PMO Framework

FEASIBILITY /INITIATING	PLANNING	EXECUTING	CLOSING

MONITOR & CONTROL
Risk Management, Scope, Schedule, Cost, Resource Management, Communication & Stakeholder Management, Quality Control, Change Management

User Need	Design & Develop Planning (PG1)	Design Input (PG2)	Design Medical Device Specifications (PG3)	Design Output Results of Design Effort (PG4)	Design Transfer	Design Review	Verification	Validation	Design Changes	Closeout
PMO Artifacts -Business Case with financials -Project Charter _____ **FDA Guidance Documents for medical devices**	**PMO Artifacts** -Project (Design) Planning Document (PDPPD) includes management plans for: -Scope -Time -Human Resource -Quality -Cost -RAID/FMEA -Communication -Procurement -Change Control -Process Waiver Form -CSAT Survey -Project Schedule -Resource Demand Matrix -Roles and Responsibilities Matrix _____ **FDA Guidance Documents for medical devices** -DHF	**PMO Artifacts** -Requirements Traceability Matrix or Quality Function Deployment (QFD) -FDA Guidance Documents for medical devices -Design Procedures -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -Product Specifications -Design Input Document -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -Reference Design Control Review Program -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -Verification Traceability Matrix -FMEA -Structured Assessment Document for activities and results -DHF	**PMO Artifacts** -See Monitor & Control _____ **FDA Guidance Documents for medical devices** -Design Validation Results Document -DHF	**PMO Artifacts** -Change Request Template or SP form -Change Control Log to capture deficiencies and corrective actions _____ **-FDA Guidance Documents for medical devices** -DHF	**PMO Artifacts** -Product Delivery Acceptance -Post Project Document -Lessons Learned _____ **-FDA Guidance Documents for medical devices** -DHF