|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| **Project Title** |  | | | | | |
| **Deliverables** | **Phase 1** | **Phase 2** | **Phase 3** | **Phase 4** | **Phase 5** | **Comments/Links** |
| **Feasibility**  **& Concept** | **Design Inputs**  **& Develop** | **Verification**  **& Validation** | **Transfer to Mfg** | **Post Market**  **Assessment** |
| NPD Project Plan/Schedule |  |  |  |  |  |  |
| Design Review Minutes |  |  |  |  |  |  |
| Customer Need Document |  |  |  |  |  |  |
| Business Case |  |  |  |  |  |  |
| Design Concept & Feasibility |  |  |  |  |  |  |
| Regulatory Strategy |  |  |  |  |  |  |
| Marketing Launch Plan |  |  |  |  |  |  |
| Manufacturing / Operations Plan |  |  |  |  |  |  |
| Design Inputs |  |  |  |  |  |  |
| Labeling Requirements |  |  |  |  |  |  |
| Quality Plan |  |  |  |  |  |  |
| Initial Risk Assessments |  |  |  |  |  |  |
| Initial Traceability Matrix |  |  |  |  |  |  |
| Design / Usability FMEA’s |  |  |  |  |  |  |
| Sterilization & Shelf-Life Testing |  |  |  |  |  |  |
| Biocompatibility Testing |  |  |  |  |  |  |
| Software Validation |  |  |  |  |  |  |
| Product Safety and EMC Testing |  |  |  |  |  |  |
| Product Performance Testing |  |  |  |  |  |  |
| Usability Validation |  |  |  |  |  |  |
| Packaging Validation |  |  |  |  |  |  |
| Clinical Validation |  |  |  |  |  |  |
| Regulatory Submission |  |  |  |  |  |  |

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| **Deliverables** | **Phase 1** | **Phase 2** | **Phase 3** | **Phase 4** | **Phase 5** | **Comments/Links** |
| **Feasibility**  **& Concept** | **Design**  **Planning** | **Verification**  **& Validation** | **Transfer to Mfg** | **Post Market**  **Assessment** |
| Training |  |  |  |  |  |  |
| Process FMEA |  |  |  |  |  |  |
| Process Validation |  |  |  |  |  |  |
| Traceability Matrix |  |  |  |  |  |  |
| DHR & DMR |  |  |  |  |  |  |
| Regulatory Approval |  |  |  |  |  |  |
| Design Transfer ECO |  |  |  |  |  |  |
| Technical File |  |  |  |  |  |  |
| Declaration of Conformity |  |  |  |  |  |  |
| Production Status Report |  |  |  |  |  |  |
| Customer Feedback |  |  |  |  |  |  |
| Risk Analysis Review |  |  |  |  |  |  |
| Clinical Evaluation Review |  |  |  |  |  |  |

**Before proceeding through to the next Design Review Phase, the following approvals are required:**

Approve  Disapprove

Reason for Disapproval:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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Project Leader (Chair) Date Operations Date

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Quality/Regulatory Date Sales / Marketing Date

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Research & Development Date Finance Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_

CEO/President Date