|  |  |  |
| --- | --- | --- |
| **DDP #:** | | ***<Enter DDP #>*** |
| **DEVICE/PROJECT IDENTIFICATION** | | |
| Device/Project Name: | *<Enter device name, device family or project name>* | |
| Model/Type/Config.: | *<Enter the model, type or configuration of the device, if applicable>* | |

1. **SCOPE**
   1. *<Define the scope of the design and development project>*
   2. *<Identify the applicable design stages required for the device>*
2. **PROJECT TEAM, MAJOR TASKS, RESPONSIBILITIES & MILESTONE DATES**
   1. *<Define responsibilities and authorities for design and development, identify and describe the interfacing requirements between different groups or activities that provide input to the design and development of a device, and identify major milestones: a RASIC matrix (example here below) or project Gantt chart may be referenced* *here.>*

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Project Team** | | | |
| **R** - responsible for delivery of task **A** - approves the course of action or task **S** - supports the task with time, material and resources **I** - informed of task, not critical contribution **C** - consults on an ad hoc basis | Project Leader/Development Engineer:  Name, Company | Design Engineer/Specification Developer:  Name, Company | Manufacturing Engineer:  Name, Company | Regulatory/Quality Support:  Name, Company |
| **Design & Development Planning** | | | | |
| D&D Plan | R | A | I | S |
| **Detailed Design** | | | | |
| Design Inputs | R | R/A | I | S |
| Risk Analysis – Initial and following updates | R | A | I | S |
| Design Outputs | R | R/A | R/S | S |
| **Design Verification & Validation** | | | | |
| Design Verification & Validation Plan | R | A | I | S |
| Design Traceability Matrix | R | A | S | S |
| Design Verification & Validation Testing (Protocols & Reports) | R/S | R/A | R | S |
| Submit and Receive Regulatory Clearance | R | A | I | R |
| **Production Readiness** | | | | |
| Process Validation | I | A | R | I |
| **Production Transfer** | | | | |
| DHF Release | R | A | I | S |
| DMR Release | I | A | R | I |

1. **DESIGN INPUTS**
   1. *<Describe the planned activities that are appropriate for the design inputs stage including risk management activities (i.e. how risks will be identified, assessed and controlled)>*

1. **DESIGN OUTPUTS**
   1. *<Describe the planned activities that are appropriate for the design outputs stage>*
2. **DESIGN VERIFICATION AND VALIDATION**
   1. *<Describe the planned V&V activities that are appropriate for the design verification and validation stage>*
3. **DESIGN REVIEWS**
   1. *<Identify when design reviews are required during the design of a device>*
4. **DESIGN HISTORY FILE**
   1. *<Describe the planned activities for creating and maintaining the DHF for the device>*
5. **DESIGN TRANSFER**
   1. *<Describe the planned activities for design transfer, including the review of the product’s DMR and Risk Management Documentation>*
6. **REGULATORY STRATEGY**
   1. *<If applicable, describe the regulatory strategy for the device>*

**RECORD HISTORY**

|  |  |  |
| --- | --- | --- |
| **APPROVALS** | | |
| Title | Name (Printed) | Signature & Date |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **REVISION HISTORY** | | | | |
| Rev. # | Released Date  (YYYY-MM-DD) | DR # / ECO #[[1]](#footnote-1) | Description of Change | Author |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |
|  |  |  |  |  |

1. Design Review (DR) # is to be used during the design process until transfer to production. Engineering Change Order (ECO) # is to be used after design is transferred to production. [↑](#footnote-ref-1)