**Medical Device Design Project Plan**

Refer to *QP703: Design Control*

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| PROJECT |  | | New Device ❒ | Design change ❒ ECR No.: | Project Manager |
|  | | Device/part name, model: | | | |
|  | | Project description:  The Project Description block is for a short description of the project, reference of conceptual designs etc. For design changes, reference the specific drawings and specifications that need to be changed | | | |

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| Project schedule | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e | w/e |
| 010 Design input |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 020 Preliminary |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 030 Calculations |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 040 Drawings and Specifications |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 050 Design verification |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 060 Design validation |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 070 Design transfer |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |
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| 901 through 903 Design Reviews |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |  |

The above is just a summary. Your schedule should be more detailed, breaking down 030 and 040 into individual activities. It would be preferable to build the schedule using a specialised project management program, and attached to this plan as a separate page/document

Add as many phases/activity block as you need to plan the whole design project, including all design reviews (three in this example). These would usually be the same as used in the project schedule. It is normal for this form to be several pages long.

Replace ‘w/e’ with the weekending dates proposed for the project. Each Project Schedule table displays 24 weeks. Copy and paste the table below it to add further week ending dates. Shade to indicate the duration of each task.

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| --- | --- | --- | --- |
| 010 Design input | | Start date: | End date: |
| If the input is very simple, you can use this space directly to specify the design input. Otherwise, identify relevant activities and refer to other documents where the design input should be documented. (In this document, it is the first design review meeting that reviews and approves the design input.) | | | |
| Approved (name, title, sign) | | | Date |
| 020 Preliminary | | Start date: | End date: |
| Design team/participants | Purpose of review | | |
| Names or titles of the design team responsible for this phase and activity (can also be consultants or sub-contractors) | Use this space to provide pre-formatted fields, tables, checklists etc to describe the activity, list of planned output documents, references to records (e.g. minutes of meetings) | | |
| Approved (name, title, sign) | | | Date |
| 030 Calculations and analysis | | Start date: | End date: |
| If the input is very simple, you can use this space directly to specify the design input. Otherwise, identify relevant activities and refer to other documents where the design input should be documented. | | | |
| Approved (name, title, sign) | | | Date |
| 040 Drawings and specifications | | Start date: | End date: |
| If the input is very simple, you can use this space directly to specify the design input. Otherwise, identify relevant activities and refer to other documents where the design input should be documented. | | | |
| Approved (name, title, sign) | | | Date |

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| --- | --- | --- | --- |
| 050 Design verification | | Start date: | End date: |
| If the input is very simple, you can use this space directly to specify the design input. Otherwise, identify relevant activities and refer to other documents where the design input should be documented. | | | |
| Approved (name, title, sign) | | | Date |
| 070 Design transfer | | Start date: | End date: |
| If the input is very simple, you can use this space directly to specify the design input. Otherwise, identify relevant activities and refer to other documents where the design input should be documented. | | | |
| Approved (name, title, sign) | | | Date |
| 901 Design review #1 | |  | Date: |
| Participants | Purpose of review | | |
| Names or titles of personnel, managers, and consultants who must perform this review | Use this space to briefly define the general purpose of the design review (this first one is usually to review and approve conceptual designs and to define / approve the design input) | | |
| Approved (name, title, sign) | | | Date |
| 902 Design review #2 | |  | Date: |
| Participants | Purpose of review | | |
| Names or titles of personnel, managers, and consultants who must perform this review | Use this space to briefly define the general purpose of the design review (if required)) | | |
| Approved (name, title, sign) | | | Date |
| 903 Design review #3 (Final) | |  | Date: |
| Participants | Purpose of review | | |
| Names or titles of personnel, managers, and consultants who must perform this review | Use this space to briefly define the general purpose of the final design review (this final review is usually to approve and release the design) | | |
| Approved (name, title, sign) | | | Date |

Amend spacing etc once all instructional text has been removed and to meet your company requirements.

Document Information

| Revision History | | | |
| --- | --- | --- | --- |
| Revision | Modified by | Change Control No. | Description of Change |
| 01 |  |  |  |
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|  |  |  |  |

Complete the above fields for each revision of this document. Ensure that there is sufficient description of changes so that the change history of this document can be followed. Additional columns can be added to include document/change tracking numbers generated by your company’s systems if required (eg. change control).

| Associated forms and procedures | |
| --- | --- |
| Doc. No. | Document Title |
| QP703 | Design Control |

List all controlled procedural documents referenced in this document (for example, policies, procedures, forms, lists, work/operator instructions

| Associated records | |
| --- | --- |
| Doc. No. | Document Title |
|  |  |

List all other referenced records in this document. For example, regulatory documents, in-house controlled documents (such as batch record forms, reports, methods, protocols), compliance standards etc.

DOCUMENT END