Design Control Templates

The Design Control Templates offering is a suite of documents that comprehensively establishes an all-inclusive Product Development Program (PDP). The Design Control Templates document suite is comprised of a set of 25 interrelated standard operating procedures, templates, and forms ready for customization. The included forms are provided in Microsoft Word® and Microsoft Excel® formats. Other materials provided include a 20 page overview of design controls and a step-by-step guide for customizing and utilizing these procedures to implement a design control program.
The documents contained in the Design Control Templates suite have been specifically created to meet the FDA design control regulations outlined in 21 CFR 820.30. This Medical Device Design Control program has been successfully customized and implemented by a variety of companies, both start-ups and larger organizations. The Design Control Templates offering is the most comprehensive set of off-the-shelf medical device design control documents currently on the market. Furthermore, it is ready to be uploaded into your MasterControl system to provide a fully automated design control program to help bring high quality medical products to market faster.

The Design Control Templates documentation set includes the following:

- SOP: Product Development Program (Top Level SOP that establishes the overall product development process and the application of design controls.)
- SOP: Product Development Program - Glossary of Terms
- SOP: Phase 0 - Feasibility
- SOP: Phase 1 - Design Requirements and Planning
- SOP: Phase 2 - Design Development
- SOP: Phase 3 - Design Verification
- SOP: Phase 4 - Design Transfer
- SOP: Phase 5 - Design Validation
- SOP: Prototype Management
- SOP: Lab Notebook Maintenance
- SOP: Design Risk Analysis for Medical Devices
- SOP: Verification and Validation Protocol Development and Maintenance
- SOP: Design History Files
- SOP: Design Review
- Template: Design FMEA
- Template: Design Review Meeting Minutes
- Template: Design Requirements and Traceability Matrix
- Template: Feasibility Summary and Project Charter
- Template: Design Transfer Plan
- Form: Engineering Work Order
- Form: Engineering Work Order Log
- Form: Laboratory Notebook Traceability Log
- Form: Action Item Tracking Log
- Form: Commercial Release Checklist
- Form: Design Review

About MasterControl Inc.

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit www.mastercontrol.com, or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan)

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