Design Control Toolkit

The Design Control Toolkit offering is a suite of documents that comprehensively establishes an all-inclusive Product Development Program (PDP). The Design Control Toolkit document suite is comprised of a set of 21 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, a step-by-step guide for customizing and utilizing these procedures to implement a design control program and 8 hours of Quality Compliance Consulting (QCC) to help you implement your design control.

The documents contained in the Design Control Toolkit suite have been specifically created to meet the FDA design control regulations outlined in 21 CFR 820.30. The toolkit has been successfully customized and implemented by a variety of companies, both start-ups and larger organizations. The Design Control Toolkit 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 Toolkit documentation set includes the following:

• SOP: Product Development Plan SOP-0001
• SOP: Design Control SOP-0002
• SOP: Change Control SOP-0003
• SOP: Risk Management SOP-0004
• SOP: Design Review SOP-0005
• SOP: Verification and Validation SOP-0006
• SOP: DHF SOP-0007
• SOP: DMR SOP-0008
• FORM: Change Control FRM-0003
• FORM: Phase I Design Review FRM-0005A
• FORM: Phase II Design Review FRM-0005B
• FORM: Phase III Design Review FRM-0005C
• FORM: Phase IV Design Review FRM-0005D
• FORM: Phase V Design Review FRM-0005E
• FORM: Risk Assessment FRM-0004
• FORM: Traceability Matrix FRM-0002
• FORM: DFMEA
• TEMPLATE: Project Charter
• TEMPLATE: Risk Management Plan
• TEMPLATE: Design Transfer PLN-0001
• TEMPLATE: Project Design Plan

About MasterControl

MasterControl Inc. creates software solutions that enable life science and other regulated companies to deliver life-improving products to more people sooner. MasterControl’s integrated solutions accelerate ROI and increase efficiencies by automating and securely managing critical business processes throughout the entire product lifecycle. More than 1,000 companies worldwide, ranging in size from five employees to tens of thousands, rely on MasterControl cloud solutions to automate processes for new product development, clinical, regulatory, quality management, supplier management, manufacturing and postmarket surveillance. MasterControl solutions are well-known for being scalable, easy to implement, easy to validate and easy to use. For more information, visit www.mastercontrol.com.