PREVAS PRODUCTS

MEDICAL PROJECT START-UP

It is crucial for the success and compliance of your medical device development project to get a good start. This Template Package will get you going.

Ideal for new product development

- The document templates guides you through all the required steps
- The document templates creates a solid and compliant foundation for your project
- Risk management, user needs, usability and traceability are included
- The document templates are prepared for medical device development projects including mechanics, electronics and software

Regulatory compliance

Using this package of templates, you will be sure to start a project compliant with the requirements of:

- ISO 13485, EN ISO 14971
- IEC 62304, IEC 62366-1
- MDR, IVDR, FDA 21 CFR 820

Templates are easy to use

The templates come with an introduction MS PowerPoint presentation explaining the relations between and the use of each of the templates. Each template:

- is logically structured according to Good Documentation Practice, and will be usable for all future projects.
- contains explanations of each chapter and section,
- and examples of text to fill into most sections.
- is easy to convert to your preferred document layout.
- contains (in an appendix) relations to the standards covered.

The documentation package includes the following templates

START-UP PACKAGE	
User Requirements Specification	Specify your top requirements to be validated at the end of the project.
Regulatory Strategy	Define the markets to sell the product, the classification of the product, and determine the standards and regulations to comply with.
Master Quality and Project Plan	Define the project organization, phases, deliveries and milestones – in order to estimate the cost of the whole project.
Documentation Overview	Define the documents to produce, and when.
Risk Management Plan	Define how to comply with the risk management requirements.
Hazard Analysis	This is the basis for (and results of) the required risk analysis
System Requirements Specification	This document includes the top level technical system requirements of which the system are verified and validated.
Requirements Traceability Matrix	The complete MS Excel tool for traceability between various levels of requirements, risk, verification and validation.
System Architectural Design	The top-level design of the product. How to meet top-level system requirements?
Verification & Validation Plan	The plan for the required verification and validation activities to be completed during the project.
Verification Specification	A generic template for verification or test specifications.

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