

Good design practice for medical devices and equipment

The Cambridge Engineering Design Centre has just published the third workbook in their series 'Good Design Practice for Medical Devices and Equipment'.

The aim of the series, which has been developed through extensive consultation with device manufacturers and an analysis of regulatory requirements, is to help medical designers tackle some of the less well understood and arguably more difficult aspects of medical device design.



Fully illustrated, the workbooks describe a practical approach to 'design for validation' that can be used to enhance existing medical device design processes in any organisation.

Published by **University of Cambridge Institute for Manufacturing** based on research carried out at **Cambridge Engineering Design Centre**

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The first workbook provides designers with a method for **Requirements Capture**, arguably the most important aspect of the design process because it lays the foundation for the rest of the design. Three tools are provided to facilitate this key process: functional analysis, a comprehensive matrix checklist and regulatory guidelines. The workbook also includes a template for co-ordinating the output from these tools into a requirements specification document. Appendices contain further guidance on device classification and approval routes, and the main sources of standards and regulatory information. ISBN 1-902546-10-5

Whilst presenting a **framework and overview** of the development process, the second workbook provides real guidance on the good design practices that facilitate effective device validation. This is another key aspect of product development as success, in both technical and economic terms, is largely determined by using appropriate and effective validation methods. In general, regulations and quality standards lay out validation requirements, but it is left to each individual manufacturer to establish and maintain its own validation procedures. However, recently issued regulations and standards have been encouraging the integration of validation into the development

process, which poses particular challenges to the manufacturer since there is a distinct lack of guidance in this area - a problem which is also addressed. ISBN 1-902546-08-3

The third workbook focuses on **Design Verification**. Medical devices must be proven to be fit for purpose before they are placed on the market. Part of this proof is given by documenting evidence of design verification activities, which show that device design requirements have been met. This workbook presents an approach for identifying and selecting verification methods, determining when verification should occur in the design process and ensuring that it is carried out within a commercially viable framework, thereby improving the chances of developing a device that is fit for purpose within the bounds of commercial reality. Ideally, it should be used in conjunction with pre-existing working practices and, perhaps even more importantly, in addition to the array of regulations for medical device design. ISBN 1-902546-12-1



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