The top ten changes in MEDDEV 2.7.1 Rev 4

Clinical Evaluation:
A guide for manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC.

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MEDDEV 2.7.1 Revision 4 has been released

Revision 4 of Clinical Evaluation guidance document MEDDEV 2.7.1 was released by the European Commission on 1 July 2016. A copy of the latest revision can be downloaded from our website.

How does this affect manufacturers of medical devices?

Although the new revision is longer and more detailed, in practise most of the differences are to provide helpful guidance and examples, and to clarify existing requirements, rather than to introduce new requirements. Much more explicit guidance is provided to manufacturers on how to undertake a robust and systematic clinical evaluation, and how to demonstrate the scientific validity of their data and conclusions. The new revision is also beginning to align with the European Medical Devices Regulation, and we believe this will be helpful in transitioning from the requirements of the Directives to those of the Regulation.

BSI will assess all new applications (e.g. new certificates, renewals, changes that affect the clinical evaluation) against Revision 4. We understand that some manufacturers may require a transition period to ensure that their documentation is fully compliant. Meeting MEDDEV 2.7.1 Rev 4 will support your transition to the Medical Device Regulation.

MEDDEV 2.7.1 Rev 4: Key changes and clarifications

1

Clarification: Frequency of updates to the Clinical Evaluation Report (CER).

Clause 6.2.3 requires the CER to be updated at least annually for high risk or new devices, and every 2 to 5 years for lower risk, well-established devices. A justification for the frequency of updates will be required. For all risk classifications of devices, the CER will need to be updated whenever new information from the Post Market Surveillance (PMS) affects the evaluation or its conclusions.

2

New requirement: Qualifications of report authors and evaluators.

Clause 6.4 introduces specific requirements for the expertise and experience of CER authors and evaluators, including a relevant higher education degree and five years' related professional experience, or ten years' professional experience if a degree is not considered a prerequisite for the task. Deviations from these requirements should be documented and duly justified. All evaluators must now make a declaration of interest.

3

Clarification: Specific and measurable objectives for the CER.

Revision 3 of MEDDEV 2.7.1 required the manufacturer to document the objectives and scope of the CER, and to define these in terms of safety, performance and risk endpoints related to the Essential Requirements – but the link between scope and endpoints was perhaps somewhat buried in Appendix F, the Clinical Evaluation Checklist for Notified Bodies. Revision 4 makes the requirement for the objectives of the CER to be linked to specific safety, performance and risk-benefit endpoints clearer; detailed guidance is provided in Section 7 and Appendix 5.

4 Clarification: Establishing the state of the art.

Clause 8.2 provides more detail with respect to establishing and documenting the state of the art and available treatment options. This includes establishing the safety and performance of the device, its claimed equivalent(s), and any benchmark or other similar devices, as well as the risks and benefits of other available treatment options.

5 Clarification: Scientific validity of data.

The new revision places much greater emphasis on demonstrating the scientific validity of data, including statistical considerations. Section 9.3.1 ("How to evaluate methodological quality and scientific validity") addresses factors which can affect the scientific validity of different types of datasets. In addition, clarifying and explanatory detail is provided throughout the guidance document for each stage of the clinical evaluation process: factors which could affect the completeness, objectivity or weight of data are described, including literature search and retrieval methods (Section 8 and Appendix 5), data appraisal and weighting (Section 9 and Appendix 6), and the analysis of data and demonstration of conformity (Section 10 and Appendix 7).

6 Clarification: Equivalence.

What was just a footnote in Appendix F of Revision 3 of the guidance document has been expanded considerably in Revision 4, and the requirements for demonstration of equivalence are described in detail in Appendix 1. The criteria (clinical, technological, biological) are unchanged, but more information on how this should be documented and factors which could affect the demonstration of equivalence are provided. In particular, Revision 4 requires that design differences and their impacts on clinical safety and performance be described in detail, that comparative drawings and diagrams should be provided, and that each individual device with which equivalence is claimed must meet all three equivalence criteria.

7 New requirement: Access to data for equivalent devices.

Revision 4 also requires that the Notified Body challenge the manufacturer's access to data on the equivalent device(s) (Appendix A12.2.3); this is considered a transition point for the Regulation, which will require a manufacturer to have a contract in place allowing access to data for competitor devices with which equivalence is claimed.

8 Clarification: When is a clinical investigation required?

Appendix 2 describes key considerations relating to device risk and how manufacturers should determine if they have sufficient clinical evidence.

9 Clarification: Risk-benefit.

Appendix 7 provides detailed guidance on the analysis of data to demonstrate device safety and performance. Appendix 7.2 discusses the risk-benefit profile in particular, including the evaluation and quantification of benefits and risks, and the evaluation of the overall risk-benefit profile. The value of post-market data, and factors which could affect the statistical validity of the evaluation of this data, are addressed in some detail.

10 Clarification: Post Market Surveillance (PMS) and Post Market Clinical Follow-up (PMCF).

Throughout Revision 4 of the guidance document, the links between clinical evaluations, PMS and PMCF are reinforced. Appendix 12 highlights the requirement for Notified Bodies to ensure that PMCF is planned and appropriately justified in light of the data retrieved and conclusions documented in the CER.

Additional resources

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Informative white papers – Our white paper series provides regular updates on key topics to keep you informed about changes in the industry.

Informational webinars – We offer webinars on a range of topics, delivered by our regulatory and product experts to provide information about the requirements for medical devices.

Medical device e-update service – Keep updated on what's happening in the industry and changes in the regulatory and quality requirements.

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bsigroup.com/en-au

BSI Group ANZ Pty Ltd
Suite 2, Level 7,
15 Talavera Road,
Macquarie Park NSW 2113
Australia

T: 1300 730 134
F: 1300 730 135
E: info.aus@bsigroup.com

BSI/AU/034/MD/0317/en/BLD