



# Of American Furniture

**Eileen Dubrow**



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device master record dmr is the term used in the quality system qs regulation for all of the routine documentation required to manufacture devices that will consistently meet company requirements section 820 3 j of the qs regulation defines device master record as a compilation of records containing the procedures and specifications for a

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the mdr requires existing legacy medical devices to undergo conformity assessment to the mdr and to be ce marked anew even if they have been on the market previously under the mdd aimdd no grandfathering

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the device master record procedure prescribes the responsibilities for preparing device master records dmr and to ensure the completeness of dmr indexes indices a device master record should be prepared and maintained for all devices products manufactured or under development all equipment specifically including medical devices

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description medical device standard operating procedure template describes the organization content creation and use of the device master record employed in the production of all medical devices distributed by the company package consists of the procedure and a device master record index log

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what are dmrs what are mdfs how do they compare this white paper focuses on medical device compliance per 21 cfr 820 181 for dmr and iso 13485 2016 4 2 3 for mdf documentation the intent is to demonstrate how these compare as well as how a single system can fulfill the requirements of each what is a device master record dmr

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which is a

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sep 30 2011 section 820.3(j) of the federal code defines device master record dmr is a set of documents containing procedures and specifications for a finished medical device simply put device master record dmr is a collection of all the documents required to manufacture and test a medical device

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a device master record dmr is a compilation of all the instructions drawings and other records that must be used to produce a product the term is used in quality management systems that cover product design and production contents

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