



# Rhone 20vintage Report

**JE Gale**



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the device master record dmr is one of the holy trinity of files that developers need to collate and maintain in order to prove compliance with fda medical device regulations these files specified in fda 21 cfr part 820 181 are the design history file dhf the device history record dhr and the device master record dmr itself

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feb 10 2023 the terms dhf dmr and dhr which stand for design history file device master record and device history record respectively have had associations with design controls for some time now but the similarity of letters in each respective name is enough to cause ongoing confusion among medical device professionals

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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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device master record index template upon compilation of all documents to be included in the master record a device master record index template should be prepared to identify all items in the record and locations of these records eng104 2 device master record index includes descriptions such as product specification and product literature

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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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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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