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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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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 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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